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DEPUY INTRODUCES THE CI™ SYSTEM FOR COMPUTER-ASSISTED SURGERY

In March of 2004, DePuy, a Johnson & Johnson company, launched iOrthopaedics™ (“Intelligent Orthopaedics™”). This groundbreaking business initiative explores and develops breakthrough technologies, products and services designed to enhance and extend the orthopaedic surgeon’s existing skills and experience.

iOrthopaedics initiatives are selected based on their potential to improve products in three distinct areas: implant functionality, implant survivorship as well as the surgeon’s ability to perform less invasive procedures more accurately for patients.

DePuy’s landmark iOrthopaedics offering is the Ci™ System, the first totally integrated, customizable, computer-assisted surgical package for total knee replacement. It provides proprietary hardware, software and instruments designed to work together for more accurate minimally invasive procedures.

The Ci System provides an unobstructed view of the patient’s knee joint on screen to give the surgeon a 3D rendering of each step of the surgery, which assists in providing proper alignment of the implants. reduces the potential for knee joint malalignment—the most common cause of implant failure.1 This is especially critical technology as more patients opt for minimal incision surgery—a surgery which, by its nature, restricts the surgeon’s ability to see the operative area.

Born of a unique collaboration between DePuy and BrainLAB, the world leader in computer-guided surgery operating room information technologies, the Ci System harnesses the power of information technology to provide accuracy, precision, customization, flexibility, and control and reproducibility to the orthopaedic surgeon during total knee replacement surgery.

For example, the Ci System allows surgeons to view the consequences of surgical decisions before they are made - not later, when a post-operative X-ray can only provide a retrospective assessment. This increased level of informed, intra-operative decision-making can assist in providing successful implant alignment. lessens the potential of joint malalignment and imbalance after surgery.

The Ci System supports DePuy’s industry-recognized line of knee implants, including P.F.C.® Sigma™, P.F.C. Sigma RP, Preservation® Uni and LCS® Complete™ systems.

DePuy designed the Ci System to address the issue of potential risks of knee malalignment in joint replacement surgery. The system also helps surgeons employ the most minimally invasive techniques in total knee reconstruction, potentially allowing for reduced incision size, and associated scarring and soft tissue disruption.

ABOUT DEPUY ORTHOPAEDICS, INC.

DePuy Orthopaedics, Inc., a Johnson & Johnson company, is a driver of transformational change in orthopaedic care, with a focused commitment to help surgeons achieve excellence in surgical practice. Thousands of surgeons worldwide rely upon DePuy every day. DePuy designs, manufactures and distributes orthopaedic devices and supplies including hip, knee, extremity, trauma, orthobiologics, and operating room products.
WE WOULD LIKE TO EXTEND
OUR SINCERE GRATITUDE
TO THE FOLLOWING ORGANIZATIONS
FOR PLEDGING THEIR SUPPORT
AND FOR HELPING TO MAKE THE
4TH ANNUAL MEETING OF THE INTERNATIONAL
SOCIETY FOR CAOS A SUCCESS:

Aesculap
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Medtronic Surgical
Navigation Technologies
ORTHOsoft, Inc.
PI Precision Implants AG
Praxim Medivision
Smith & Nephew
Stryker Orthopaedics
Zimmer

Thank you!
Special appreciation is extended to the following parties for their assistance in making the 4th Annual Meeting of the International Society for CAOS a success:

- Brian Davies, Frank Langloltz and the CAOS Program Committee
- Karin Nolte – Administrator, CAOS International
- David Kahler, President and the Executive Committee of CAOS
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- Lilli Kornblum
- Brian Weiss
- Celeste Carlin
- Juli Corcoran
- S. Joseph Austin
- Victoria Brander, MD
- Nancy Schwanz, George Duda, Rob Davis and the Staff of General Learning Communications
- The Westin Chicago River North
Dear CAOS International 2004 Participant:

It is my great pleasure to welcome you to Chicago and to the Fourth Annual International Meeting for Computer Assisted Orthopaedic Surgery. CAOS is one of the fastest growing new technologies in our field. Its emergence as an important technology in Orthopaedics is being further stimulated by the vigorous introduction of a number of minimally invasive surgical (MIS) procedures, many of which can be facilitated by various CAOS techniques.

A substantial amount of new activity has taken place in this field within the last year. A large number of surgeons have recently begun using this technology in their practices. Consequently, I believe this year’s meeting presents a momentous opportunity for attendees to learn from the experiences of a substantial number of new clinical and technological investigators, as well as to be updated on the experiences of those who have been working in this area for many years.

This program is the culmination of the extraordinary effort put forth by a surprisingly small number of people, which include: the CAOS Program Committee; Katharine Cline, Shirley Galloway and the talented staff of Preferred Meeting Management, Inc.; and members of the Northwestern Orthopaedic Institute including Brian Weiss, Celeste Carlin, Lilli Kornblum, S. Joseph Austin, and Dr. Victoria Brander. I am exceedingly grateful for their efforts.

We are pleased and honored that the International CAOS organization entrusted us with this important symposium, and we hope that you enjoy the convention and your stay in Chicago.

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THE USE OF COMPUTER NAVIGATION IN PREVENTING MALALIGNMENT IN UNICOMPARTMENTAL KNEE ARTHROPLASTY

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Introduction: Unicompartmental knee arthroplasty (U.K.A.) for the treatment of localised medial compartmental osteoarthritis has been advocated since the 1970’s.

The recent orthopaedic literature reports excellent results in numerous mid to long term survivorship of both fixed and meniscal bearing U.K.A’s. An important predictor of success in U.K.A. surgery is the accuracy with which the components are implanted. Accurate alignment in the coronal plain is important in relation to the survivorship of the prosthesis. Over correcting a varus deformity at the time of surgery leads to excessive loads on the unresurfaced compartments of the knee contributing to disease progression, anterior cruciate ligament dysfunction, and ultimately early failure (1-4). Many U.K.A. systems offer limited and potentially inaccurate instrumentation that relies on a substantial amount of surgical judgement for prosthetic placement. We hypothesise that due to the minimally invasive nature of U.K.A. surgery and the less well developed instrumentation that even the above rates are difficult to achieve in single compartment arthroplasty. Computer assisted surgery has been developed to allow accurate implantation of prosthesis. The aim of our study was to assess intra-operative computer navigation and its ability to produce a safe, reliable and reproducible way of obtaining correct leg alignment in U.K.A. surgery.

Patients and Methods: Between May 2001 and August 2003 thirty consecutive primary medial compartment unicompartmental knee arthroplasties were performed by the senior author (A J S). Of this group fifteen had an un-navigated Allegretto (Sulzer) unicompartmental knee arthroplasty whilst fifteen had a navigated EIUS (Stryker-Howmedica) unicompartmental knee replacement. All of the unicompartmental knee arthroplasties were assessed clinically using the Oxford knee score. Radiological assessment took two forms. All the knees were assessed post-operatively using long leg weight bearing AP radiographs as well as a CT alignment films. Both sets of imagery were assessed in a blinded fashion by a single radiologist using methods popularised by Kennedy et al (5).

Statistical analysis was performed using the Fisher exact test for two group comparison and analysis of variance for comparisons of greater than two groups with continuous outcome variables.
Results: Allegretto group: Their mean age at the time of surgery was 57 years. The mean follow-up was 17 months. The mean Oxford knee score was 18. The mechanical axis on both long leg weight bearing films and non-weight bearing C.T.scanograms passed through zone 3 in 4 cases indicating overcorrection. In the remaining 11 knees the mechanical axis passed through the central zone in 4 knees and zone 2 in 7 knees. EIUS group: Their mean age at the time of surgery was 55 years. The mean follow-up was 8 months. The mean Oxford knee score was 17. The mechanical axis on both long leg weight bearing films and non-weight bearing C.T.scanograms passed through the central zone in 5 knees and zone 2 in 10 knees.

Conclusions: Our study showed that the CAOS system allowed a higher rate of knees to be in the desired range of leg alignment. This was supported statistically using a Fishers exact test with p<0.05. All of the navigated knees were either in Zone 2 or Zone C, four of the non-navigated knees were in Zone 3. We have demonstrated that the navigated U.K.A, when compared to a non-navigated system, improves the accuracy of radiological leg alignment. This occurs without significant inconvenience and little change to conventional operating techniques. C.A.O.S. systems have the potential to have a significant impact on the everyday working practice of orthopaedic surgeons. In terms of U.K.A. surgery, the accurate and reproducible leg alignment this system achieves will improve biomechanical forces within the compartment with the prosthesis in situ as well as the unresurfaced compartment. This will lead to less disease progression and hopefully an improved environment for the implant to function in. At present our follow-up both clinically and radiologically is too short to be able to assess survivorship but ultimately this system has the potential to improve long term survivorship and therefore reduced revision rates. This has significant benefits in terms of cost as well as the obvious benefits to the patient.

References:

Background: We have been refining the ‘acrobot’ system. Our philosophy has been to keep the surgeon entirely in control, while giving him full 3-d preoperative planning, and robotic levels of precision in the operating theatre. Our current challenge is to implement these ideals within the constraints of the minimally invasive approach to arthroplasty.

Materials and Methods:

Preoperative CT based planning:

Pre and postoperative CT scans are performed with slices taken of the hip, knee and ankle joints, but with sparing of the shafts of the bones. The dicom data files are exported to the planner. Semi automatic segmentation of the bones is performed, followed by detailed planning of the implant positioning, with the precise location and orientation of each implant optimised in true 3d space. The surgeon can choose where to put each component, and can track back and forth to ensure that his choice of size and site is correct.

Active Constraint Boundaries:

Software boundaries are then set, which limit the surgeon in his bone preparation. He will only be able to mill the bone to accept the implant shape he selected. The shape of bone resected is defined by the shape of the implant and the space needed for a mantle of cement, if necessary. The preoperative plan is then saved, and sent to the acrobot device.

Bone clamping and soft tissue approach:

Bone clamps are placed through stab wounds onto both femur and tibia. They are tightened on, and the hip centre is then obtained by acquiring points using hip motion. Both bones are then immobilised onto a frame with the knee at 90degrees, and the acrobot is brought to the table. The incision for unicondylar knee arthroplasty (UKA) is then made in standard fashion, from the side of the patella to just below the
joint line. Typically this is 3 inches (8cm) long. The capsule is opened and retracted in standard fashion, and the joint inspected, confirming that it is appropriate for this operation.

Registration:

Points are taken using a small ball pointed probe attached to the cutting head in two stages: 4 preliminary points are acquired from preset areas, followed by about 20 points in total taken from 4 separate zones for each bone. An interative closest point(ICP) method is used to confirm the goodness of fit.

Bone preparation:

The registration tip is then exchanged for an 8mm ball ended cutter, which is used at 75,000 rpm. A foot pedal controls the speed of the cutter while the surgeon looks both at the bone and on screen to determine where is to be cut. The software boundaries stop him from milling away too much bone, and from straying out of the sides of the area to be prepared, allowing him to fashion a complex shape of convex and concave surfaces, together with a flat plane. A 2mm router is then used to finish the edges, and cut the slot for the keel of the tibial component and the post for the femorall component.

Implantation:

Trial implantation is still performed to confirm the sizing and orientation of the components and that the flexion and extension gaps match as planned, before the definitive implants are cemented in place in standard fashion, and the operation completely conventionally.

Postoperative care, CT scans and knee scores:

Patients are discharged home full weight bearing on the third postoperative day. The ct scans are repeated in the first 48 hours following surgery. These allow the position of the implants to be compared precisely with the preoperative plan. Knees scores are performed at six weeks postoperatively.

**Results:** 6 robot assisted minimally invasive unicompartmental knee arthroplasties have been performed, with the last 2 as the first two cases who have drawn the robot arm of a prospective controlled trial. The operating time of the cases has continued to reduce steadily. Time spent on registration and bone milling has now reduced to less than 20 minutes in total. Every case has had postoperative ct scans performed, and all are within the envelope of 2degrees and 2mm.

**Discussion and Conclusions:** CAOS systems have been developed to improved outcome and abolish outliers in routine arthroplasty. Two problems have been encountered: lack of user-friendliness of the devices, and lack of objective evidence of superior outcome. The user friendliness is addressed with ‘acrobot’ by it’s back-driveability. The surgeon does all the operating. Only a few authors have been able to show substantial improvement in outcome (Mielke, Clemens et al. 2001). This lack
of objective evidence may in part be due to the inaccuracies of navigation systems, and in part owing to the lack of precision of measuring the position obtained. We have found that without ct based systems, the accuracy of a system cannot be seriously scrutinised. Many previous authors may therefore have failed to demonstrate a difference that was there, but not detected by plain radiography. Unicompartmental knee arthroplasty is a technique with a learning curve that has superior results in the right hands (Murray, Goodfellow et al. 1998). For others, it has a higher failure rate, reflecting the technical difficulty of the procedure (Robertsson, Knutson et al. 2001). The Acrobot® system has been described in total knee arthroplasty (Jakopec, Harris et al. 2001). We have now used it in minimally invasive unicompartmental knee arthroplasty. It is more reliable and more accurate than most experienced surgeons. This is being proved at present in a randomised controlled trial. Work still needs to be done to make the operation take less time, for while patients are universally eager to have their operation performed precisely, surgeons will only use this technology if it is quicker too.

References:


figure 1: pre and post operative images of a case showing the difference between the planned and achieved position. the preop plan is in white, co-registered with the postoperative position of the implant in gold.
EVALUATION OF THE USE OF THE PRAXIM NAVIGATION SYSTEM WITH THE ROTATING PLATFORM TRI CCC TKR PROSTHESIS

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Introduction: To investigate the reliability and validity of a computer-assisted surgical navigation system [SURGETIC® (Sociéte PRAXIM Grenoble France)] for implantation of the TRI CCC® Total Knee Replacement (Société SME Mauguio France). To evaluate the results on the final postoperative mechanical axis and the posterior tibial slope during normal usage.

Methods: We started using the SME prosthesis in May 2002. This prosthesis uses the SURGETIC Navigation system, based on peroperative bone morphing of the bony extremities. To date, we have used computer navigation for more than 250 Tri CCC prostheses. We collected the navigation data peroperatively on CD-ROM, and compared this to the standard pre- and post-operative radiographs. We studied 73 cases, comprising of 57 in varus, 14 in valgus and 2 with normal axes. The angulations ranged from 1-18° for the varus knees (median 7°) and 1-13° for the valgus group (median 4°). There was preoperative fixed flexion in 33 cases, ranging from 1-15°. The posterior tibial slope was between 2 and 8°, with a median of 5°.

Results: The operative time (tourniquet time) was between 63 and 110 mins, with a mean of 77 mins. The navigation was abandoned in 8 cases: 5 times due to movement of the sensors, 2 times due to inexperience and 1 time due to a computer bug. We have had no complications with the use of the navigation system. On the femoral side, we compared digital data on the navigated mechanical axis with the axis resulting from the bony cuts. 50 times the navigated alignment was registered as a normal axis, 12 times in valgus of 1-2° and 11 times in varus of 1-2°. The analysis of the bony cuts showed a normal axis in 17 cases, 15 cases with a valgus of 1-2° and 41 cases with a varus of 1-3°. On the tibial side, during the alignment navigation, the axis was normal in 45 cases, in valgus of 1-2° in 4 cases and in varus of 1-2° in 14 cases. The analysis of the tibial cut was only normal in 19 cases, 37 in valgus and 17 in varus of 0-3°. The final navigated axis was normal 16 times (21.9% of cases), in valgus of 0-3° in 25 cases and in varus of 0-3° in 32 cases. In over 86% of patients, the difference between navigated mechanical axis and postoperative radiographic axis was within 2°. The postoperative radiographic axis was normal in 9 cases, in valgus of 0-3° in 22 cases (30%) and in varus of 0-4° in 42 cases (57.5%). Only 3 patients in the series exceeded 3° of deviation from the normal axis, two at 4° and one at 5°, representing 4% of patients. The posterior tibial slope in 68% of cases was between 3 and 7° with a median of 5°.
Discussion: In a series of similar, but non-navigated TKRs the mean tourniquet time was 54 mins (44-72 mins). The additional time of 23 mins seems acceptable to us. If one eliminates the effect of the learning curve, the extra time taken is reduced to a mean of 18 mins. In Saragaglia’s series [1] the extra time was 32 mins, but the software was more complex. The observed differences between the digitally-guided and analysed bony cuts, either tibial or femoral, reveal inaccuracy which may come from the use of other instruments, or from the surgeon. We consider that 2° is within the error limits of radiographic goniometry due to the significant effect of limb rotation on perceived axis. In this case the value given on the screen by the navigation reliably reflects the true axis and can be considered accurate. This accuracy has also been found by the majority of other authors [2] [3] [1]. The findings of the frontal plane mechanical axis were very satisfactory. Only 5% of patients had an axis greater than 3°. In a previous study conducted in 2001 under our care on a series of 226 prostheses of the same type implanted using the same instrumentation, but non-navigated, we had 17% of patients with a varus or valgus axis greater than 3°. The differences between navigated and non-navigated groups was significant for Saragaglia [1], Hart [4] Jenny [3], Mielke [5] and Sparmann [6]. Bathis [7] showed that navigation systems not using preoperative imaging perform as well as those using preoperative CT scanning.

Conclusion: The PRAXIM ® navigation system for the Tri CCC ® prosthesis (SME) is shown to be reliable and reproducible. The numbers allocated by the computer during the surgery were virtually the same as those obtained from the post-operative radiographs. This technique has therefore become indispensable to us, and we practice it routinely on all our patients.

References:

A NON IMAGE BASED KNEE NAVIGATION SYSTEM WITH INCLUSION OF GAP AND SOFT TISSUE BALANCING USING A MOBILE BEARING TOTAL KNEE SYSTEM

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Objective: A consecutive series of the first 125 implantations of a new mobile bearing knee design (e.motion FP knee) was clinically and radiographically followed. The OrthoPilot system allows navigation of the resection planes and extension and flexion gaps. This enables the surgeon to include ligament balancing. The aim of the study was to determine whether the results would equal those described in literature with the use of conventional knee designs.

Results: The follow-up period was 13.4 months +/- 4.1 with a maximum of 24 and a minimum of 7 months. Age at surgery was 65.3 +/-10.5 years, 75% females and 25% males were followed. 54% of the patients had previous surgeries. Diagnoses were 63% primary osteoarthritis, 3% posttraumatic osteoarthritis (OA), 27% rheumatoid arthritis, 2% psoriatic arthritis, 2% HLA B27 related oligoarthritis and 1% ankylosing spondylitis, juvenile chronic arthritis and other inflammatory joint diseases 1% each (IJD).

The mechanical axis was corrected to an average of 0° with a maximum of valgus deformity of 6° in OA and 8° in IJD and a maximum of varus deviation of 6° in both groups. The KSS score was 99 points preoperatively and 156 points postoperatively with no statistical difference between OA and IJD. ROM ranged from 40° to 140° and resulted in a range from 60° in a case of juvenile chronic arthritis to 135° postoperatively. 69% of the cases had a postoperative ROM of more than 120°. The average postoperative range of motion was 117°. There was no statistical difference in ROM between OA and IJD.

In 59 of the 125 cases navigation was used for the implantation of the prosthetic components.

The results with respect to radiographically established alignment were rated excellent at 0° +/- 3° with respect to the mechanical axis and 90° +/- 2° for the single
femoral and tibial axes. The results were classified as outliers from 5° of deviation from the optimum with respect to the mechanical axis and more than 4° off the optimum in respect to the femoral and tibial axes.

Over-all alignment represented by the mechanical axis was excellent in 89.8% and only 3.4% of the results were unacceptable (outliers). With manual instrumentation an excellent result was achieved in only 71.2% and 6.1% outliers were registered.

The femoral axis in the coronal plane was corrected to an excellent result in 89.8%, no outlier had to be observed. With respect to the femoral axis in the sagittal plane an excellent alignment was achieved in 57.6% and 28.8% were in the intermediate group up to 4° of deviation. The tibial axis in the coronal plane was corrected to an excellent result in 98.3% and no outlier was recorded. The tibial axis in the sagittal plane showed excellent results in 91.5%, outliers were observed in only 1.7%.

**Conclusion:** The short term results using the e.motion knee system are absolutely promising. A majority of patients show excellent function with more than two thirds of the patients flexing their knees beyond 120°. Knee navigation clearly facilitated proper alignment of the prosthetic components and only few outliers had to be observed. Therefore, the over-all results of the e.motion knee system, also including the use of a navigation system, favourably compare to the data of earlier publications.
COMPUTER NAVIGATION OF THE TIBIA CUT FIRST TECHNIQUE IN MOBILE BEARING TOTAL KNEE ARTHROPLASTY

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Introduction: An important consideration of mobile bearing total knee arthroplasty technique has been flexion gap determination using a spacer block or tensor. This contrasts with methods that use a distal measured resection such as the transepicondylar axis or the posterior condylar reference to determine femoral component rotation. Boldt, et.al. has shown that arthrofibrosis after total knee arthroplasty may be related to exaggerated femoral component internal rotation in certain cases after the LCS mobile TKA.[1] This study assessed various parameters of alignment before and after ligament release and after component insertion using an imageless referencing computer navigation protocol with mobile bearing total knee arthroplasties.

Methods: Mobile bearing total knee arthroplasty was done in 35 patients using the LCS (Depuy) or LPS High Flex Mobile (Zimmer) prosthesis. Computer assisted navigation was done in all using imageless referencing protocol (Medtronic Universal Knee Imageless software, Stealth Station). Alignment was determined by referencing the mechanical axis and the transepicondylar axis (TEA). The femoral center was defined as the intersection point of the TEA and Whiteside’s line. The tibial center was the intersection of the medial-lateral and anterior-posterior midpoints. The ankle center was the center of the talus on both views. The transepicondylar axis was referenced from the depression of the medial epicondyle to the most lateral point of the lateral epicondyle. At 90° flexion, alignment was determined to be in varus of valgus with relation of the tibial shaft axis to the TEA. Surgical technique was the tibia cut first method which uses either a spacer or flexion tensor to determine femoral component rotation related to flexion space tension and not to a fixed reference point. In all cases, the knee was balanced in extension to the mechanical axis neutral position or slightly overcorrected before flexion spacing was attempted. Measurements included prerelease mechanical axis and 90° flexion alignment. Post-implantation measurements included mechanical axis alignment, femoral component rotation, and final 90° flexion alignment related to the TEA.

Results: Pre-release alignment was 2.9° varus average (CI: 4.4°; range 10° valgus to 16° varus). Post-implantation alignment was 0.9° varus average (CI: 0.6°, range 1° valgus to 2.5° varus). F ratio was 2.8 comparing the two groups. At 90° Flexion, prerelease alignment averaged 2° varus (range: 7° valgus to 12° varus); post-implantation averaged 0.2° varus (range: 10°valgus to 10° varus). Femoral component rotation
was outside of +/- 2° the TEA in 75%. For most cases, the femoral rotation measured with the flexion space cuts closely matched the final implant flexion alignment within 2°. In general, a varus knee typically presented with a varus flexion space alignment that remained unchanged after component placement. For example, a preoperative mechanical axis alignment of 10° varus had a preoperative flexion space alignment of 10° varus. While the postoperative mechanical axis reduced to 0°, the flexion space alignment remained at 9° or 10° varus and the femoral component rotation measured to the TEA, approximated a corresponding position of 9° or 10° external rotation. Similiarly, valgus knees usually had a valgus flexion space alignment and the final femoral component rotation tended to be internally rotated to the TEA. One noteable exception was the patient with 16° varus that required an extensive medial ligament release which resulted in considerable widening of the medial flexion space. In this patient, the final femoral component rotation measured 12° of internal rotation.

**Discussion:** This study confirmed that the mechanical axis and component position were within 2° of the projected position in most cases. However, in only a minority of cases did the femoral component rotation compare to the transepicondylar axis. There was a trend for the preoperative position in flexion to match the postoperative position and the corresponding amount of femoral rotation. In general flexion space varus of the tibial shaft axis as compared to the TEA, resulted in femoral component external rotation. Conversely, a valgus deformity resulted in valgus flexion alignment and femoral component internal rotation. The findings of this study are logical when one considers that ligament balancing is done primarily in extension releasing structures such as the collateral ligaments and the tensor fascia lata, that have only minimal effect on the flexion space. Contracted flexion space structures may require only minimal release to obtain extension space neutral alignment. Flexion spacing is done after the knee has been fully balanced in extension, and therefore it is presumed that additional release will not be needed unless the posterior capsule needs to be released for flexion contracture. Boldt, et.al. has shown a similar dispersion of femoral component rotation after satisfactorily done total knee arthroplasties when measured with computed tomography. In another study, where the LCS mobile bearing prosthesis was utilized, cases that resulted in late arthofibrosis were compared with cases that had an excellent postoperative outcome. The authors observed that femoral component internal rotation was significantly greater and more prevalent in the cases with poor outcome.[1] From our experience with computer navigation, we could predict that cases resulting with femoral component internal rotation after a flexion spacing technique were either a preoperative valgus deformity, or a severe medial varus-flexion deformity that required excessive medial release. Either problem could pose technical challenges, and therefore the poor outcome may be logically explained. We have begun to assess ligamentous balance in flexion after final component placement of mobile bearing TKA, and note the gaps to be small and near results of published data for satisfactory kinematic performance. Stiehl, et.al have shown that the greatest amount of condylar liftoff at 90° flexion was 3.2 mm (or degrees) after evaluating total knees that had excellent postoperative outcome.[2] Our current goal is to make the flexion space gap no more than three degrees of liftoff. For the measured distal femoral resection method, it would seem nearly impossible to change the flexion space gap, once extension balance had been achieved, without subsequently changing the extension space. It would appear that making these changes after the knee implants have been finally inserted present insolvable prob-
lems. Therefore, in the tibial cut first technique, if one ignores the distal femoral reference point, it follows that there may be a dispersion of femoral component placement compared to a fixed femoral reference point. The question to answer then would be what is the ligamentous stability in flexion after the distal femoral reference has been utilized, and can it be consistently created using that method. Computer navigation offers an exciting new tool to investigate these issues and provide a meaningful explanation of outcome. In the past, radiography and even postoperative computed tomography could only offer the position of the implants in regards to anatomical points and established references. Navigation allows the observation of the surgical procedure and enables the surgeon to quantitate the effects of ligament balancing on the eventual outcome. This would appear to be an important goal as many of the ultimate failures after total knee arthroplasty result from chronic ligamentous instability.

**Conclusion:** Computer assisted navigation has been used to assess alignment in extension and flexion before and after placement of a mobile bearing total knee arthroplasty using the tibial cut first technique in total knee arthroplasty. Our results are consistent with postoperative computed tomography studies regarding the femoral component rotation after this method, and suggest that component rotation functions primarily on the flexion space gap and balancing done to that gap, and remains independent on a fixed reference point such as the transepicondylar axis.

**References:**

CT-BASED PLANNING OF A SINGLE-RADIUS FEMORAL COMPONENT IN TOTAL KNEE ARTHROPLASTY USING THE ROBODOC SYSTEM

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Introduction: Recently, robot assisted surgery in total knee arthroplasty (TKA) has been reported to be able to prepare bony beds for implants precisely according to three dimensional preoperative planning [4]. It has been generally accepted that the mechanical axis through the femoral head center and the ankle center should pass through the knee center in the coronal plane [3]. And it has been suggested that the axial rotation of the femoral component should coincide with the transepicondylar axis (TEA) [1,2]. Sagittal alignment, however, has not been well discussed and the relationship of these three plane alignments has not been reported. Therefore, to clarify the relationship of these three plane alignments and their effects on the optimization of planning for the femoral component in TKA, we performed virtual implantation of a femoral component with a single-radius design using the preoperative planning workstation of the ROBODOC system (ORTHODOC).

Material and Methods: The CT data of 34 knees of 4 men and 25 women who had no symptoms and no radiological abnormalities of the knee were used. Their mean age was 69 years. The ORTHODOC provides multiple planar reconstructed images from CT data in three orthogonal planes and it has a function to measure the angle between any lines and the distances between any points in each reconstructed plane. Scorpio posterior stabilized femoral components (Stryker Howmedica Osteonics) were used. The condyle has a single radius of curvature in the sagittal plane. Virtual implantation was performed as follows. The femoral mechanical axis (FMA) was defined as a line through the center of femoral head and the midpoint of the TEA. The TEA was determined by connecting the most prominent point of both the medial and lateral epicondyle. Then, the femoral component was virtually placed where the center of curvature of each prosthetic condyle was placed coincident with the TEA. The size of the femoral component was selected according to the radius which was closest to the distance between the TEA and the joint line in the lateral condyle. When the antero-superior apex of the femoral component dug into the anterior cortex of the femur, the femoral component was flexed around the TEA to avoid creation of a notch. If a gap between the apex and the anterior cortex occurred, the
Implant was rotated into extension until contact was obtained between the anterior cortex and the matching surface of the prosthesis. Following virtual implantation, digitally reconstructed radiographs were generated by projecting the femur and the implanted prosthesis onto a plane parallel to the FMA and perpendicular to TEA. Using these images, the sagittal alignment of the femoral component was measured using the following parameters: (i) the angle between the anterior cortex line of the distal femur (ACLDF) and the FMA, and (ii) the angle between the distal femoral shaft axis (DFSA) and the FMA. We also measured the distance from TEA to both the posterior condyle and the distal joint line in the sagittal planes of the medial and lateral condyles in order to evaluate the flexion-extension balance. The distal to posterior distance (DPD) ratio was defined as the distance from TEA to the distal joint line divided by the distance from TEA to the posterior condyle.

Results: In all but two cases, rotation of the femoral component around the TEA was needed to avoid notching the femur. In the 2 cases, the sagittal alignment of the femoral component coincided with the FMA. On average, the ideal position of the femoral component was 6.5 degrees of flexion (SD 4.5; range: 0 to 15). The average angle between the ACLDF and the FMA was 0.7° (SD 1.6°). The average angle between the DFSA and the FMA was 0.9° (SD 0.9°). In the lateral condyle, the average distance from the TEA to the joint line was 22.0 mm distally (SD 2.1 mm); and 20.8 mm posteriorly (SD 1.7 mm). Medially, the distance from the TEA to the joint line averaged 25.4 mm distally (SD 2.6 mm), and 26.0 mm posteriorly (SD 2.8 mm). The average DPD ratio in the lateral condyle was 1.06 (SD 0.12). The average DPD ratio in the medial condyle was 0.99 (SD 0.20).

Discussion: In this virtual implantation study, it was possible to maintain coincidence between the radial axis of the condylar surfaces of the femoral component and the TEA, although the prosthesis had to be implanted in a small amount of flexion to avoid anterior notching in most cases. Moreover, the average DPD ratio was approximately one in each condyle. This means that even after the implantation of single-radius femoral component, the distance from the articulating surface of the femoral component to the posterior condyle, and the distance from the implant surface to the distal joint line are equal in normal knees. Therefore, this method of femoral component placement will maintain the flexion gap and extension gap balance. In conclusion, this method of defining the femoral coordinates and placing the femoral component with its radial axis coinciding with TEA seems to be effective for the sizing of the femoral component, the balancing of the flexion-extension gaps, and avoiding the creation of an anterior notch. This image-based TEA-oriented method of planning is expected to work even for severely deformed cases and revision cases.

References:
NAVIGATION ASSISTED MINIMALLY INVASIVE TOTAL KNEE ARTHROPLASTY

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Introduction: The success of minimally invasive unicompartmental knee arthroplasty encouraged surgeons to recognize the differences between unicompartmental knee arthroplasty and total knee arthroplasty[1,2,3]. Navigation is known to be helpful in reproduction of accurate alignment of lower extremity in total knee arthroplasty[4,5]. The purpose of this study is to evaluate early results of navigation assisted minimally invasive total knee arthroplasty by comparing them with regular total knee arthroplasty with manual technique.

Materials and Methods: We compared 49 navigation assisted minimally invasive total knee arthroplasties using Orthopilot® navigation system (Group A) to 53 regular total knee arthroplasties with manual technique (Group B). Thirteen patients underwent bilateral procedures (one side with minimally invasive technique and the other side with regular manual technique). The minimally invasive total knee arthroplasty means smaller skin incision around 10 cm long and limited mid-vastus approach that minimally invade extensor mechanism without eversion of patella. The early clinical results with regard to the length of skin incision, operation time, blood loss, pain score with 10-point visual analogue scale, time to recovery of 90° flexion and straight-leg raise after operation and radiological results with regards to mean value and outlier (over optimum ±3°) in anatomical axis of the lower extremity were evaluated and compared.

Results: There were no significant differences in age, pain score, ROM and anatomical axis of the lower extremity before operation between two groups. The average length of skin incision was 11.9 cm (range, 9-13 cm) in group A, compared to 17.8 cm (range, 14-23 cm) in group B (p < 0.001). The mean blood loss in group A was less than in group B by 230 cc. But this difference was statistically significant (P<0.05). There was no significant difference in operation time (p>0.05). The straight-leg raise was achieved on average of 29 hours in group A and 42 hours in group B (p=0.034). The 90° flexion was achieved on average of 33 hours in minimally invasive TKA compared to 51 hours in regular manual TKA (p=0.046). The statistically significant difference also existed in mean lag in active extension at 7 days after operation (2.5° for group A and 7.7° for group B, p=0.020). Using a 10-point visual analogue scale, minimally invasive total knee arthroplasty had less pain by one point than regular manual total knee arthroplasty at 7 day postoperatively. The overall valgus between two groups (6.9° and 7.6°) was not significantly different. But outlier over optimum ±3° was 3 knees in group B but no outlier in group A. In 13 bilateral procedures,
minimally invasive total knee arthroplasty had smaller skin incision (mean, 11.7 versus 16.9 cm), less blood loss (996 versus 1163 ml), less lag in active extension (3.2 versus 8.2°) and lower pain score (3.5 versus 4.3 point) at 7 days postoperatively.

**Conclusions:** Navigation assisted minimally invasive total knee arthroplasty is believed to help not only reducing pain, earlier and easier recovery from total knee arthroplasty but also producing more accurate anatomical axis than regular manual total knee arthroplasty.

**References:**

PELVIC LOCALIZATION ERRORS IN VIRTUAL FLUOROSCOPY AND THEIR IMPACT ON CUP PLACEMENT

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Background: The alignment of the acetabular implant plays a large role in the success of total hip arthroplasty. Malposition of the implant can create hip instability, joint dislocations, and increased implant wear [2]. Surgical navigation can improve the surgeon’s ability to place implants in precisely planned orientations. However, joint replacement planning is based on the reference system established by defining a set of anatomic landmarks, and the ability to correctly define these landmarks directly affects the final accuracy of the navigation system. The purpose of the present study is to evaluate landmark localization accuracy in fluoroscopic navigation for total hip arthroplasty. The study uses FluoroSim, a custom software program, to simulate virtual fluoroscopy images. FluoroSim generates pairs of synthetic fluoroscopy images by projecting through a CT image of patient anatomy. In simulating navigated fluoroscopy, FluoroSim allows for 3D measurements of selected landmarks from the image pairs. The true locations of the same anatomical landmark points are determined automatically by processing the CT dataset. The errors of fluoroscopic localization are then computed and analyzed.

Methods: Ten preoperative pelvic CT scans of patients that underwent total hip arthroplasty, with an in-plane resolution of 0.78 mm/pixel and an interslice distance of 3.0mm or less, were selected for use in this study. Scans with low resolution in the landmark regions and scans with metal artifacts were excluded from this study. The HipNav Planner [1] was used to automatically determine the location of the two iliac spine points and the two pubic tubercle points on each patient’s CT scan by locating the anteroposterior plane (APP) tangent to these anatomic prominences. These four points were then used to establish the ground truth pelvic coordinate system for each patient. Using the FluoroSim software, four pairs of fluoroscopic images were generated for each patient. Each pair consisted of one AP view of the pelvis and one oblique lateral view. The lateral views were posed such that the pelvic anatomical landmark points were clearly defined. These lateral views were shot obliquely with a slight posterior-anterior source-to-image slant to enhance the protrusion of the anatomical reference points. The lateral views were taken with the source located on the side of the patient where the points to be registered were located. For example, the two lateral views for acquiring the left pubic tubercle and the left iliac crest were taken with the source located to the patient’s left and positioned slightly posterior while the imager was positioned slightly anterior and to the patient’s right. FluoroSim was set to reflect the geometry of a common C-arm fluoroscope. For
this experiment, an image size of 12 inches by 12 inches (30 cm by 30 cm) was used. The source-image distance was chosen to be a realistic 3 feet (90 cm). The pelvic anatomy was centered between the source and the image. A group of ten users volunteered to perform fluoroscopic pelvic registration. The group consisted of an orthopaedic surgeon and nine CAOS engineers. Using FluoroSim, every user specified the anteroposterior plane landmarks on each of the ten patient pelvises, thereby localizing a total of forty landmarks. Although it was possible for each user to customize the fluoroscopic images they used by adjusting the fluoroscopy system’s rotation and translation parameters, for this study the users were instructed not to change these settings and every user performed registration on identical image sets. For each pair of images, the user selected a single landmark point by placing a blue cross in each of the two views. A red line was drawn in each of the two views to provide feedback to the user. In each view, the red line corresponded to the set of possible solutions given the location of the blue cross marker in the opposing view. The user would then iterate to refine the landmark selection, until the cross hair and the line intersected in both images. In the CT-scan 3D space this corresponds to selecting two lines. The intersection of these two lines defines the landmark point. Since these two lines may not intersect exactly, the landmark point was defined to be the midpoint of the shortest line segment between the two user defined lines. For each of the 100 pelvic registrations performed, the impact on cup orientation was measured. A nominal cup pose of 45° abduction and 25° version was used in the calculation of cup orientation errors.

**Results:** The mean pelvic flexion error (+/- standard deviation) was –0.256° +/- 0.913°. The mean pelvic superior-inferior angle error was –0.039° +/- 0.283°. The mean pelvic version error was 0.183° +/- 0.939°. The mean acetabular implant abduction error was –0.267° +/- 0.945° with a range of –2.969° to 2.363° and a median value of –0.254°. The mean acetabular implant version error was –0.196° +/- 0.980° with a range of –3.155° to 1.942° and a median value of –0.231°.

**Conclusions:** Building a pelvic reference system via the fluoroscopic localization of APP landmarks yields good results. However, it should be noted that the set of image pairs used in this study represents an idealized protocol. This study used four pairs of fluoroscopic images for each pelvis, and the acquisition of these images would require a rotation of the C-arm over a range exceeding 180°. These views may be unattainable in the operating room given the physical constraints of the C-arm, the operating table, the patient’s orientation, and other factors. Also, fewer images are acquired to identify the pelvic landmarks in a typical fluoroscopic navigation procedure. Using fluoroscopic images in which the anatomical protrusions are less clearly defined will increase the difficulty in localizing the landmarks and make the process more error prone. The human pelvis is well suited to this form of reference system generation, as the APP landmarks cover a wide baseline and are easily detectable in fluoroscopic views.

**References:**

Introduction: The purpose of this study was to assess the accuracy and efficiency of guide wire placement in a structured targeting task, using three different navigation systems employed by three different orthopaedic trauma surgeons. Standard freehand fluoroscopic technique was compared with each surgical navigation system. The hypothesis was that navigation would allow guide wire placement with improved accuracy, while decreasing both operative time and radiation exposure.

Methods: Three experienced orthopaedic surgeons having varying degrees of familiarity with navigation systems were recruited for this study. Test specimens were created from foam blocks with a density of 20 lb/cu ft to simulate the consistency of cancellous bone. Ten radio-opaque 1mm stainless steel spheres were implanted into each block to provide ten targets for drilling; an entry zone was identified for each sphere on the opposite side of the block to provide for an oblique drilling path measuring approximately 130mm in length. The blocks were mounted onto a wooden fixture that allowed fluoroscopic imaging in two planes: one image orthogonal to the drilling path, and another in line with the drilling trajectory, as might be done during placement of an iliosacral screw, or distal freehand locking of an intramedullary nail.

An OEC 9800 C-arm unit with a 9-inch field of view was used for all trials. The experimental task was to drill a 3.2mm guide wire from the entry zone to the target. For each surgeon, data was collected during passage of ten guide wires for each of four test conditions: 1) control group (standard fluoroscopy alone); 2) navigation using Medtronic/Surgical Navigation Technologies iOn Virtual Fluoroscopy system (optical tracking); 3) navigation using BrainLAB VectorVision (optical tracking); and 4) navigation using the GE Medical Systems Insta Trak 3500 (electromagnetic radiofrequency tracking). Each surgeon first performed a control trial using standard fluoroscopy alone to pass ten guide wires into the first block; the technique for passage of the guide wires was left to surgeon preference. Participants then used the navigation systems to pass guide wires in additional blocks, using two stored images for each pin. Data were collected regarding task accuracy, drilling and total task time, and radiation exposure.
Results:

Accuracy: Using aggregate data for all three surgeons, the mean distance from the pin exit site to the target was 7.2 mm in the control group. The mean error for the navigation systems in aggregate was significantly less, at 2.1 mm (p<.003). There was no significant difference in performance between the individual navigation systems. In the control group, at a drilling depth of 130 mm, 14 of 30 guide wires (47%) were within 5mm of the target. Conversely, 89 of 90 guide wires (99%) inserted using navigation were within 5mm of the target.

Radiation Exposure: In aggregate, the total radiation exposure measured in Rad/cm² was approximately three times less with each of the navigated systems (MSNT=28.4, BrainLAB=21.5, GE=23.2) than for the control group (control=84.1). The number of seconds of fluoroscopic exposure for ten pins was 132.8 seconds in the control group, vs. 47.8, 31.8, and 37.8 seconds for the MSNT, BrainLAB, and GE systems, respectively. The average number of fluoroscopic exposures per pin was 11.9 in the control group vs. 2.2 for the navigation systems.

Procedural Time: There was a strong trend toward lower procedural time using navigation for pin placement (control=142 sec/pin, navigation=75 sec/pin). Similarly, there was a trend toward lower total procedural time using navigation (control=57:12 min, navigation=39:40 min), despite the additional set up time associated with use of the navigation systems.

Discussion: The participants in this study had varying levels of experience in using surgical navigation; despite this, all had improved accuracy when using navigation over conventional technique. A previous clinical study showed that accuracy within 5 mm of target could be achieved in 95% of screw insertions at a normalized drilling depth of 100mm. [1]. In the current study, 99% of guide wires inserted using navigation were within this arbitrary 5mm safe zone, while only 47% of pins placed using standard technique met this goal. First-pass accuracy was clearly enhanced by using surgical navigation. Surgeon-by-surgeon analysis of the data in this study revealed that the careful surgeon using standard freehand technique can obtain good accuracy, or can use very little fluoroscopy time during screw insertion, but cannot attain both goals without using surgical navigation. Surgical navigation offers the potential for surgeons at all levels of experience and expertise to obtain excellent accuracy in guide wire placement, while decreasing radiation exposure to the patient, and without significantly increasing surgical time.

References:

ACCURACY OF NAVIGATION ON 3DRX DATA ACQUIRED WITH A MOBILE PROPELLER C-ARM

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Introduction: Image guidance of therapy requires the registration of image data to the patient. In case of navigation on 2D fluoroscopic images, this registration is implicitly obtained by tracking both the patient and the C-arm at the moment of imaging. For 3D imaging, the solution is less simple, as the imaging is often performed before therapy, and not at the operating room. Registration in this case is conventionally done either using markers which are rigidly attached to the patient and which are visible in the 3D images, or by performing a feature match, e.g. by matching the surface of (exposed) patient anatomy to the corresponding surface in the image. Both methods can be invasive and laborious.

A relatively new approach is to use 3D Rotational X-Ray (3DRX) data for image guidance of therapy. 3DRX is a 3D imaging modality that can reconstruct volumetric data at the operating room by rotating a C-arm around the patient and acquiring a sequence of X-ray images. This setup provides a direct registration between patient and image [1,3]. As 3DRX data can also be accurately registered to other 3D imaging modalities such as MRI data [2], intra operative acquisition of 3DRX data can also be used as a replacement of the invasive and laborious conventional registration in image guided surgery on CT and MR data. The purpose of this study is to evaluate the accuracy of navigation that can be obtained when using a mobile C-arm with propeller motion for the acquisition of the 3DRX data.

Materials and Methods: A prototype mobile C-arm (Pulsera with motorized propeller facility, Philips Medical Systems, Best, The Netherlands) was used to generate the 3DRX images. For navigation, we use a Treon StealthStation navigation system (Medtronic SNT, Louisville CO, USA) with special software that permits navigation on 3DRX images. For the coupling between the C-arm and the navigation system, a setup similar to the one used to evaluate the navigation accuracy of a fixed C-arm system was used [1].

The phantom used for the navigation accuracy measurements consists of vertical Perspex rods with a divot on top. Radiopaque spheres can be put at the rods ends such that the center of the sphere coincides with the divot at the rods top. After the calibration procedures, this phantom is imaged, with the spheres on top of the rods. The 3DRX data is loaded into the navigation software and the spheres are removed from
the phantom to get access to the divots. Subsequently, the navigation system is used to touch the divots on top of the rods of the phantom with a probe, and the positions of the divots touched are stored in the navigation system. This is done five times for two different probes. A total of eleven divots are in the field of view of the image, so per set of touched points, eleven points can be used in the evaluation. The touching of the points has been performed by three different operators for both probes.

Special purpose image processing software is used to extract the centers of the spheres from the 3DRX data. The set of sphere centers found is registered to a set of exact divot locations, as known from the phantom manufacturing process. Golden standard divot locations are now defined by the set of exact divot locations that best matches the set of sphere centers found in the 3DRX data. The golden standard divot locations are then compared to the positions touched with the probe. The total Root Mean Square Error (RMSE) and the error ranges are determined, both for the complete set of points, and for each of the probes separately.

Results and Discussion: The final RMSE for the 110 touched points (eleven per set, two probes, five times per probe) is 1.2 mm (errors in the range [0.47,2.4]). For the first probe, the RMSE is 0.71 (errors in the range [0.47,1.1]), for the second probe, the RMSE is 1.6 (errors in the range [1.2,2.4]), which suggests that the second probe requires recalibration. Similar numbers have been reported for the SIREMOBIL Iso-C³D [4]; the average errors range from 1.0 to 1.6 mm, depending on the experimental setup.

As compared to the fixed C-arm solution [1], the mobile version has the advantage that it can be applied in the operation room. The final navigation accuracy for both probes is only slightly larger than the accuracy of the fixed C-arm (RMSE 0.75 mm, errors in the range [0.38-1.2]), which shows that the mobility of the C-arm compared to the fixed solution does not really compromise the accuracy.

The overall accuracy is sufficient for many clinical applications. The depth of the Pulsera C-arm limits its application to the extremities and the head/neck region.

Conclusions: Navigation on 3DRX data acquired with a mobile propeller C-arm has potential for image guidance of therapy. The accuracy of approximately 1 mm obtained with our experimental setup is sufficient for many image-guided interventions.

References:
ULTRASOUND-BASED RECONSTRUCTION AND REGISTRATION OF 3D BONE ANATOMY USING STATISTICAL SHAPE MODELS

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Introduction: The aim of this work is to provide accurate image-guided total hip replacement without the need for an expensive preoperative CT scan. The method demonstrated here extends the previously developed method that used statistical shape models (SSM) built purely on surface points[2] to complete 3-dimensional (3D) vector fields of free-form deformations (FFDs) to establish voxel correspondence in the training set. This allowed a complete reconstruction of the 3D volume including, for example, estimates of bone density changes and internal structure that is represented in the training data. This paper illustrates this method using a left femur model and ultrasound (US) of a dry bone immersed in water.

Methods: In this work, we used a point distribution model (PDM), which is an example of a SSM[3], and is a deformable model based on corresponding point positions. This model was built by calculating the principal components of shape variation in 16 CT images of femurs. One image from this training database was selected as a template and aligned to the other images in the database using a non-rigid registration algorithm. This algorithm uses a combination of global motion (modelled by rigid and affine transformations) and local transformations (modelled by a FFD model based on B-splines)[5]. The result of the non-rigid registration of each training image and the template image was a set of approximating B-splines that define the FFD. The node points of these B-splines were then used to build the PDM. A similar method has been used on brain MRI images with encouraging results[4]. The instantiation process generates a high-resolution, grey-level 3D image, which has the appearance of a CT scan. In this study, surface points extracted manually from free-hand 3D US images were used as input data for instantiating a 3D surface model of a femur, represented by a densely tetrangulated mesh. The 3D shape of the model was described by 5 parameters (the first 5 modes of shape variation and 3 standard deviations). During each iteration of the instantiation algorithm, bone surface points from the US scans were aligned with the instantiated surface using the iterative closest point (ICP) algorithm[1]. The centre of rotation of the femoral head was also
included in the ICP optimisation to constrain the deformation. In practice, this point can be obtained intraoperatively by pivoting the (tracked) femur around the hip joint. The resulting root–mean-squared (RMS) point-to-surface distance was optimised over the modes of variation of the model after providing 20 different starting positions, obtained by adding random values with a standard deviation of 10° and 10mm to a manually-defined starting position. The approximate length of the femur was also provided at the start so that the first mode of variation could be set to roughly the correct value. The US-based SSM instantiation was investigated using data obtained from a dry, cadaveric femur immersed in water bath. US scans were acquired in regions that would be accessible in vivo.

Results: Fifteen out of 20 instantiations returned an RMS distance of 1.8mm between the US points and the instantiated model surface. The RMS distance between all points on the instantiated surface and the nearest points on the CT-extracted surface was 2.7mm. Since the application area of this study is hip replacement surgery, the RMS distance should be measured around where it matters most. When only the section near the femoral head was measured, the instantiated-model-to-CT RMS distance was 3.3mm.

Conclusion: This work presents the novel use of US to instantiate and register an SSM constructed using FFDs from non-rigid registration of relevant structures. The left femur PDM instantiation results have shown an RMS distance of under 2mm between US derived surfaces and the model. The combination of a B-spline-based PDM and the incorporation of the rotation centre of the femoral head was found to improve the accuracy of the model as well as the instantiation, especially in regions that are inaccessible to percutaneous US in vivo. The use of the models produced using FFDs generated by non-rigid registration also provided much higher resolution and potentially allows more information to be included in the model.

References:

EVALUATION OF REGISTRATION TECHNIQUES IN A ROBOTIC APPROACH TO PELVIC OSTEOLYSIS

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Introduction: Pelvic Osteolysis has a variety of etiologies, typically a consequence of metastatic disease, infection, or instrumentation debris secondary to joint replacement. The complexity and deep anatomic location of malignant and infectious lesions have limited the availability of surgical options to date. Repair of an osteolytic lesion behind a well-placed artificial acetabular component often warrants disruption of the arthroplasty with compromised post-operative recovery.\cite{1} The primary objective of surgical interventions for pelvic osteolysis is to evacuate and fill the lytic pelvic lesion. Traditional surgical approaches have required large skin incisions with wide exposure and large cortical defects. Pelvic Osteolysis is an ideal setting for the invocation of minimally invasive technologies. By enabling surgeons to adequately evacuate and fill these lesions through small bony defects we hope to substantially improve patient outcome and decrease post-operative recovery time. This work evaluates registration techniques and system-level analyses of a robotic, image-guided approach to these lesions.

Materials and Methods: Fluoroscopy-based pelvis registration methods offer several advantages over other registration strategies \cite{2,3}. The principal benefit is non-invasiveness. 3D-3D registration methods require establishing a cloud of points common to both CT space and pelvis rigid body (PRB) space (as defined in the operating room by an Optotrak rigid body on the pelvis). This requires balancing accuracy with non-invasiveness: fiducials may be invasively attached to skeletal anatomy where they are immobile, or they may be applied non-invasively to the skin surface where their mobility limits registration accuracy. Fluoro-based pelvis registration methods allow the transformation from CT to PRB space to be computed by estimating 3D pelvis position and orientation from 2D fluoro images of the pelvis. We have developed a fluoroscopy-based pelvis registration method that registers the pelvis to PRB by imaging the pelvis in known PRB poses with respect to a rigid body on the fluoroscopic apparatus, FRB. By taking images of the pelvis in two relative poses, we can compute the position and orientation of the pelvis using stereo correspondences. Two cadaveric pelvises were pre-operatively scanned and trajectories were planned for each. Intra-operatively, after system-wide co-registration, titanium bone screws were implanted along robot-guided trajectories. The primary axes and point of cortical contact of these bone screws were calculated from post-operative scans. These data were compared to pre-operative parameters. We ran four 3D-3D based experiments and two 2D-3D experiments on Pelvis 1. We ran four 2D-3D based experiments and two 3D-3D experiments on Pelvis 2.
Results and Discussion: It was found that the 2D-3D image-guided approach (2.68 ± 0.244mm) introduced approximately 1mm of residual error in position over the 3D-3D method (1.74 ± 0.97mm). Orientational results were comparable with 3.89 ± .37° and 3.03 ± 2.77° for 3D-3D and 2D-3D methods respectively. The results from Pelvis 2 show a dramatic positional and orientational accuracy difference between the ground truth (0.96 ± 0.21° and 1.86 ± 1.24mm) and the 2D-3D (1.99 ± 0.53° and 4.56 ± 0.24mm) methods. We sacrificed an average of 2.7mm by using the image-guided system. To investigate this discrepancy, we informally repeated the 2D-3D experiments with Pelvis 2 and confirmed a consistent 3mm deviation from their respective previous centers. These findings reveal a critical systematic error associated with the 2D-3D trials for Pelvis 2. The low standard deviation (0.26mm) of the positional errors indicates that the executed trajectories were very precise, indicating the rigid body may have moved after registration. Other confounds include the distance from rigid body to target site and the assumption of the articulated pelvis as a rigid body. Random error from imprecise drilling and screw-driving contributed to the propagated errors discussed above. From Pelvis 1, we see that the positional errors are quite low (2.67mm on average), indicating that the 2D-3D method merits well and has the potential to represent a viable clinical solution to pelvic osteolysis.

Conclusion: Our 2D-3D Registration technique improves on single-pose fiducial-based methods by incorporating multiple non-colinear fluoro projections. This has the benefit of reducing depth-inaccuracy that limits the accuracy of single-pose fiducial-based methods. It is clear that two-pose methods are more sensitive to fluoro calibration, but our results are still promising enough to support clinical viability for such a system. The clinical utility of our Minimally Invasive System will no doubt increase with imminent advances in imaging systems, pelvis registration methods, tracking systems, display environments and robotics. By aggregating existing technologies into a single clinical application we hope to expand the immediate orthopedic armamentarium and catalyze research that will drive Computer-Integrated Surgery forward.

References:

Introduction: Traditionally, intra-operative registration is facilitated by two external devices – X-ray imaging device (usually C-arm fluoroscope) and optical tracking device and is performed in following steps. First robotic system and imaging head of C-arm are instrumented with the passive optical trackers. Then X-ray images of operation region are taken from two or more directions, provided that in each “shooting position” optical tracker performs localization of both units – fitting clamp and C-arm – with respect to its own reference system. Knowing respective location of C-arm within robot coordinates in each shooting position, and fitting the 2D X-ray images to pre-acquired three dimensional CT data, the desired registration of vertebra to the robot coordinates is derived. The widely admitted drawback of this method is the usage of the external optical tracker that requires: (a) clear optical path, (b) attachment of the cumbersome optical targets with high precision and repeatability, (c) additional stands and wiring on the floor of operating room. Here we propose the novel method of registration [2] making the usage of the optical tracker obsolete. Instead, C-arm registration with respect to the fitting clamp is facilitated by the compact X-ray opaque targets attached directly to the clamp, and visible within the field of view of every X-ray image together with the operating object.

Materials and Methods: Direct registration of the C-arm to the robot became possible due to invention [2] made by authors, that position and orientation of three-dimensional X-ray opaque structures of certain types can be reconstructed with high accuracy (better than +/- 0.3 mm) through analysis of the shape of the shadow that said structure casts on single X-ray image. This invention is easily understood on example of several grid-arrays of metal balls, each array attached to facet of the X-ray translucent cube. Then the individual X-ray shadows are also arranged in arrays so that the pitch of some arrays is mostly sensitive to the height of the cube over X-ray detector while the shift between other two arrays is mostly sensitive to orientation of the cube in respect to detector’s plane. Said arrangement allows breakdown of the relevant mathematical model into separable variables and facilitates iterative solution for the unknown cube position and orientation from the known locations of the individual balls shadows in detector coordinates.

We utilized that approach through following workflow. First, the fitting clamp is attached to the spinous process of vertebra through the small cut and equipped with
the similar to the described one. C-arm is brought to nearly AP position and the image containing both - vertebra and the structure - is taken. Then one or more similar images are taken in nearly-LT and, possibly, intermediate positions of the C-arm. Special algorithm is then applied to derive substantially exact location and orientation of C-arm in each of shooting positions in respect to the same fitting clamp with the accuracy better than that delivered by the optical tracker. Then special 2D to 3D registration algorithm delivers the coordinates of CT model with respect to AP shooting position. Then, knowing location and orientation of AP shooting position in respect to the fitting clamp, registration of the CT model relative to the fittings clamp is achieved. Finally the robot is attached to the same fitting clamp and is guided to desired drilling position.

**Discussion:** Accuracy of C-arm to clamp registration was validated on the special mechanical test-bench. The typical accuracy of registration was better than +/- 0.3 mm in lateral direction and +/- 0.6 mm in height. Accuracy of the intra-operative registration was assessed by another sophisticated test-bench consisted of the dry bone spine segment instrumented with metrological gear. The registration accuracy was found to be better than +/- 0.9 mm, while the overall procedure accuracy, including the pre-planning stage and accounting for mechanical tolerances in fitting clamp was found better than +/- 1.2 mm [3].

**Conclusion:** We presented a method of intra-operative registration of the guiding tools, utilizing spatial X-ray opaque targets attached to the guiding system. We demonstrated that its accuracy achieved in controlled environment, is higher than the accuracy achieved by more complex systems utilizing the external tracking devices, in similar conditions. Currently we proceed with testing this method on cadaver studies of the pedicle screw guiding system [1]. We have gained positive indications that it assures robust and friendly intra-operative registration with higher performance and less drawbacks than other systems equipped with external optical trackers.

**References:**

ESTIMATING CUP ALIGNMENT ERRORS CAUSED BY ANATOMICAL LANDMARKS LOCALIZATION DURING TOTAL HIP ARTHROPLASTY

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Introduction: The anterior pelvic plane (APP) is commonly used as an anatomic reference for cup alignment in THR procedures. Practically, all computer assisted orthopaedic surgery systems which are used today rely on the anterior pelvic plane definition, derived from two pairs of pelvic bony landmarks: the anterior superior iliac spines and the pubic tubercles. While these systems strive to achieve accurate cup alignment on the order of 1”, failure to correctly identify the anatomical landmarks can lead to much higher inaccuracies in the final cup alignment. This work presents a complete mathematical formulation for the analysis of the inaccuracies related to the anterior pelvic plane axes (APPA) definition and their effect on final cup orientation. We also demonstrate a computational method which provides corrected version and abduction angles to achieve the desired cup orientation, given that the actual measurement errors are known.

Methods: As was suggested in [1], in order to define the APP, one needs to locate the anterior superior iliac spines and the pubic tubercles. When identifying these anatomic landmarks, one can introduce errors which affect the definition of the APPA orientations. There are three dominant errors in anatomic landmark localization which can result in APPA rotational errors. In the presented method, a kinematic skeleton model of the described system is given as a serial kinematic chain of six revolute joints. This set of joints relates the world coordinate reference frame, which is defined as the operating table, to the cup coordinate system. The first three joints represent three rotational errors of the pelvic location, i.e. anterior-posterior error (version) (0_1), flexion error (0_2), and superior-inferior (ab/adduction) error (0_3). The last two joints represent the nominal version and abduction of the cup, i.e. the intended cup orientations. By presenting cup alignment and resulting measurements errors as a set of three pure rotation aligned in a kinematic skeleton, we are able to apply methods taken from robotics and the kinematics of mechanisms in order to quantify the total error and the effect of each of the kinematic parameters on the total resulting error.

The opposite problem, determining what orientation to place the implant in the perturbed reference frame to achieve a desired orientation is known as the inverse kinematics solution. This approach assumes a predetermined final cup orientation (e.g. 45° and 20° abduction and version, respectively [2]) and solves for version and abduction angles (which are unknown a priori) that would result in that cup orienta-
tion, taking into account the three rotational errors in APPA localization. In order to use the inverse kinematics approach in the OR, one has to be able to define the measurement errors, which is not always feasible. Yet, if we are able to determine these errors, then the following method would be a very powerful one, as the resulting actual cup orientation would be as planned. One may think that knowing the errors is enough in order to correct the error directly or to correct cup orientation parameters; yet this is not an easy task, as the error usually results from two independent rotations, which is hard to imagine even for a skilled person. Furthermore, in some cases, a systematic error is committed (patient positioning on the operating room table) or can be estimated (landmark correction in obese patients), yet its direct correction may not be clear. Finally, the three rotational errors, affect cup orientation by a set of non-linear equations composed of sine and cosine functions, hence having even two unknown parameters would complicate the inverse kinematic solution.

Discussion and Conclusion: In this study we applied a closed-form mathematical solution for the analysis of the effect of inaccuracies related to the determination of the location of the anterior pelvic plane (APP) landmarks and their effect on the final cup alignment during total hip arthroplasty. We also preformed a sensitivity analysis of the results by introducing differential changes between sequential coordinate frames that simulates the errors in the APPA, and their effect on cup orientation. Next, we applied these methods on estimated error sampling models. The results indicate that when orienting the cup in version angle of 20° and an abduction angle of 45° using erroneous landmark data, the resulting mean cup orientation would be 49.8° of abduction, and 34.3° of version, an error of about 5° in abduction and 15° in version. The abduction range of error is ±15°, and the version range of error is ±20°. These results, indicate the magnitude of potential errors which are introduced when performing total hip arthroplasty procedures. These errors can result from anatomy sampling errors or simply by variation in pelvis orientation on the operating table. We also present a method to calculate new version and abduction angles that would result in proper cup orientation. These angles are determined by solving the inverse kinematic problem with the version and abduction angles as unknowns. For examples in case of extreme errors and the resulting abduction and version that would result in an actual cup orientation of 45° and 20°. Four examples, (assuming 2mm error in anatomical landmark localization) in case of an anterior-posterior error version angle of -7 degrees, a flexion error angle of -1.5 degrees, and superior-inferior error of 7 degrees the abduction and version angles needed to achieve the desired cup orientation should be 41.8 degree in version and 42.3 degrees in abduction. In case of anterior-posterior error version angle of -7 degrees, no flexion error angle, and superior-inferior error angle of -7 degrees the abduction and version angles needed to achieve the desired cup orientation should be 30.8 degree in version and 51.2 degrees in abduction. This is a powerful technique when each of the three rotational or measurement errors are known or are able to defined.

References:

ROBOT-ASSISTED DISTAL LOCKING OF LONG BONE INTRAMEDULLARY NAILS: LOCALIZATION, REGISTRATION, AND IN-VITRO EXPERIMENTS

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Introduction: Distal locking is recognized as the most challenging step of long bone closed medullary nailing. Complications include inadequate fixation, malrotation, bone cracking, cortical wall penetration, and bone weakening due to multiple or enlarged screw holes. The surgeon’s direct exposure to radiation is 3–30 minutes per procedure with 31–51% spent on distal locking alone. Many devices have been developed for distal locking, including proximally mounted targeting devices, mechanical guides, stereo fluoroscopy, and computer assisted navigation systems. However, all have drawbacks: they are difficult to use, are not accurate enough, do not provide mechanical support during drilling, or are not always applicable.

Materials and Methods: We are developing a new image-guided robot-based system to assist surgeons in performing distal locking of long bone intramedullary nails [1]. The system includes a miniature robot, MARS [2], which is mounted directly on the bone or on the nail head and fitted with a drill guide that provides rigid mechanical guidance for hand-held drilling. The system automatically aligns the axes of the drill guide and of the nail’s distal locking holes using a single fluoroscopic X-ray image. Mounting the robot directly on the nail or on the patient’s bone is minimally invasive, and eliminates the need for leg immobilization or real-time tracking during surgery.

The system consists of a robotically controlled targeting device, an image calibration ring for the fluoroscopic X-ray unit, and a PC computer with a video frame grabber. The sterilizable targeting device consists of the MARS robot, a base to attach it to the intramedullary nail head or to bone, and a targeting drill guide mounted on the robot top. A prototype of the system is currently operational.

Automatic alignment of the drill guide axes and the distal locking nail hole axes is performed using a single fronto-parallel fluoroscopic X-ray image. The targeting drill guide and the distal nail holes are identified in the image, and their spatial location is derived based on the characteristics of the C-arm. Finally, the rigid transformation that minimizes the distance between the axes is computed. The method consists of four steps: 1) C-arm distortion correction and calibration [1]; 2) Targeting drill guide
identification and localization; 3) Distal locking nail holes identification, and; 4) axis registration. The targeting drill guide is located by finding a pattern of two orthogonal pairs of parallel lines formed by the circle centers of the imaged fiducials. The distal locking nail holes are located by first identifying the longitudinal contour of the nail, then looking for the two hole circles, and finally computing the circle centers by fitting ellipses to them. The axis registration is performed by computing the poses of the drill guide and nail holes in the C-arm coordinate system.

The method assumes a fronto-parallel imaging setup in which the C-arm imaging plane is perpendicular to the distal hole axes. In this setup, the holes appear as circles in the image. To achieve this setup, the X-ray technician adjusts the orientation of the C-arm guided by our software. By analyzing the fitted ellipses the software indicates both the angular deviation from the fronto-parallel setup and the degree of hole circularity, thus guiding the operator to the correct orientation.

**Experimental Results And Future Work:** To quantify the accuracy of our system we conducted the following experiment. The robot was first manually placed in a pose in which two rods pass through the drill guide and nail holes, which guarantees successful locking. This constitutes the robot’s reference pose. Next, we placed the robot in 17 random poses, acquired fronto-parallel fluoroscopic X-ray images and computed the registration for each pose. To estimate the error, we compared the angle between computed and reference axes and the distance between the computed and reference entry and exit points. This distance is defined as the in-plane distance between the intersection points of the axes and two planes located at 100mm and 120mm from the robot base (the nail is located between these planes). Observed deviations in the robot’s reference pose are 0-0.9° and 0-3.9mm.

Our results show a mean angular error of 1.3° ($\sigma = 0.4^\circ$) between the computed drill guide axes and the reference axes, and a mean 3.0mm error ($\sigma = 1.1mm$) in the entry and exit drill point, which is adequate for successfully locking the nail with a 5mm screw.

We are currently working on mechanical and algorithmic improvements that will increase the accuracy results, and will then proceed with a cadaver and in-vivo evaluation.

**References:**

EXPANDING THE INTRAOPERATIVE FIELD-OF-VIEW OF OPTICAL TRACKING SYSTEMS

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Introduction: Optical tracking of surgical instruments is the method of choice in each computer assisted orthopaedic surgery system. The successful intraoperative application of this technology requires a number of inherent constraints to be respected. Tracking based on infrared light requires an uninterrupted line-of-sight between the camera system and the objects of interest. Moreover, the site of action, i.e., the operative situs has to lie within the field-of-view of the tracking device and at an optimal distance from the tracker. These constraints require certain intraoperative discipline regarding camera positioning and acting of the surgical staff. Nevertheless, experience has demonstrated that certain CAOS procedures require intraoperative re-adjustment of the camera position and/or orientation in order to keep the camera’s field-of-view focused on the location of interest. For example, in total knee arthroplasty (TKA) points from the hip center, femoral knee, tibial knee, and ankle must be tracked [1].

Guiding aids have been suggested to facilitate optimal camera adjustment. Most of today’s CAOS systems provide an on-screen feedback of the scene “seen” by the tracking camera in order to facilitate optimal camera alignment. Another approach has been suggested utilizing laser beams to highlight the camera’s focus [2]. However, any of these solutions requires the cumbersome and interactive manual correction the camera orientation, which usually interrupts the surgical procedure and may thus prolong the entire intervention. This paper presents an alternative technological approach that aims at overcoming these difficulties by actively controlling camera orientation.

In order to ascertain to what extent, and in which context camera related problems occur during the application of CAOS technology, a survey was conducted. A questionnaire was distributed to the CAOS-International mailing list, asking surgeons to describe difficulties they have encountered during intraoperative tracking of surgical instruments. More specifically, surgeons were asked to categorically identify problems from a list of choices:

- camera setup
- field-of-view
line-of-sight

instrument failure

other

It was possible for a surgeon to answer more than once, if he/she had experience in multiple disciplines. A total of 53 responses were received, 6 of which did not meet the requirements of the study. The results indicated that 129 out of a total number of 309 reported intraoperative problems could be contributed to difficulties related to the optimal setup of camera system or its limited field-of-view, which therefore can be considered most problematic during intraoperative tracking of surgical instruments.

**Materials and Methods:** In order to mitigate the aforementioned problems – camera setup and field-of-view – the Volume Expansion Toolkit (VET) was designed. The VET is a combined hardware-software solution that actively controls the camera’s orientation, allowing it to follow tools as they are about to leave the field-of-view. For the setup of a prototype configuration, the Polaris optical tracking system (Northern Digital, Waterloo, Canada) was utilized. It was mounted onto a TV8320 motorized pan-tilt assembly (Security-Center, Augsburg, Germany). This device allows for rotations of ±180° around the vertical axis ±35° around the horizontal axis with a maximum speed of 6°/sec. A Fischertechnik Intelligent Interface (Createc, Worb, Switzerland) enabled a Linux PC to control the TV8320. The figure shows a photograph of the experimental setup of the VET.

In order to automatically control the camera’s orientation and to allow it follow tracked tools in an active manner, software was developed in C++. This software reads current position data of instruments from the camera and issues commands to the pan-tilt assembly via a serial connection with the Intelligent Interface. The control algorithm utilizes several concepts in order to follow instruments. Firstly, a bounding space is defined, which represents a subspace of the actual volume in which the camera is able to track instruments. The bounding space provides a sensitive border area, allowing the system time to react as instruments approach the periphery of the field-of-view. Whenever an observed instrument enters this space, it is considered an object that is about to leave the camera’s field-of-view, and associated care is taken not to lose it (see below). Varying the width of the bounding space effects the sensitivity of the procedure. Widening it makes the algorithm react quicker, while a more narrow bounding space leads to a later detection of leaving instruments corresponding to a less sensitive control mechanism.

When an instrument intersects the surface of this bounding space, the future position of each tool is predicted; the camera is then moved to center the average predicted position of the tracked instruments. The prediction mechanism assumes linearity of tool movement, and thus requires only two sets of tool coordinates (present and past) to make a prediction. Special care needed to be taken to cope with multiple diverging instruments. If one object (e.g., a tracked surgical instrument) moves away from another one (e.g., the patient’s reference frame), an instrument priority list enables the control algorithm to decide which tool to drop once their distance has become large enough not to fit the camera’s field-of-view any more.
To prove the benefit offered by the VET a comparison study was performed. The principle of this study was to measure the viewing volume of the Polaris camera both with, and without augmentation using the VET. The difference in volume between the two cases provided the basis for comparison. In order to measure the camera’s volume a mechanical arm was used to place a rigid body with four LEDs at surface points on the volume, which was centered over a second rigid body representing a reference frame. A total of ninety-six surface points were collected from both the standard and augmented volumes. Every effort was made to collect a uniform distribution of points across each surface.

In order to calculate the camera’s volume from measured surface points, a Delaunay tessellation was performed, breaking the volume into tetrahedrons [3]. The volume of individual tetrahedrons was then calculated and summed.

**Results:** The implemented control loop as well as the realized hardware setup led to the expected behavior. During the comparison study, the camera’s viewing volume was found to be 0.89m³ for the standard case. When the volume was augmented by the VET, this value increased to 3.58m³ corresponding to a growth of 280%. However, the angular speed that was offered by the TV8320 pan-tilt assembly turned out to be slightly insufficient during the simulation of normal surgical steps, because the camera could be made loose instruments easily.

**Discussion:** The proposed setup offers an elegant way to relieve surgical staff from a cumbersome, time-consuming, but non-critical task – the perfect initial and constant re-alignment of the intraoperative tracking system. Although the VET was designed, set up, and tested with the Polaris camera (configured to track active LED markers), the toolkit could be integrated and used with other optical tracking systems as well.

The described setup, even though fully working, would need a small improvement to be capable of assisting during surgery. The pan-and-tilt speed should be increased. The device that serves in the presented prototype setup is a low-cost solution and much faster units are available off-the-shelf.

A considerable increase in tracking volume could be observed. It is obvious that the physical field-of-view of an optoelectronic camera is limited by the design of the tracker itself and that it cannot be improved by the VET. However, it is anticipated that even the provided dynamic volume increase will be beneficial, e.g., during navigated TKA, when the camera’s focus is supposed to be on the complete femur, on the complete tibia, or on the area around the knee, but never on the entire leg at one point in time.

**Conclusion:** The survey presented in this paper showed that there are still many problems associated with intraoperative optical tracking systems. The VET is a first step to improve upon issues of camera set-up and limited field-of-view. With the first version of this toolkit, a significant improvement has been measured.

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References:


ECHOMORPHING: INTRODUCING AN INTRA-OPERATIVE IMAGING MODALITY TO RECONSTRUCT 3D BONE SURFACES FOR MINIMALLY INVASIVE SURGERY

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Introduction: Different image modalities have been proposed and integrated into CAOS navigation systems, including pre-operative CT and MR, and intra-operative 2D and 3D fluoroscopy. In addition, there are several ‘image-free’ systems that rely solely on kinematic data and anatomical points digitized by the surgeon. In 2000, Praxim Medivision introduced BoneMorphing®, allowing the surgeon to build 3D bone surfaces intra-operatively using deformable models [1]. Each modality has its pros and cons for a given protocol and thus none of them provide the universal solution. It is now clear that different applications require a specific solution, and a trade-off must be found on ease-of-use, accuracy, additional time, instrumentation and costs, patient and staff radiation, intra- and pre-operative complexity, size of operative volume, access and approach, surgical invasiveness, etc. Nevertheless, an ultimate goal in CAOS is to have an acquisition means that has the following capabilities: no pre-operative imaging, no radiation, 3D reconstruction, unlimited volume, minimally invasive surgery (MIS) compatible, easy-to-use. In this paper, we introduce the Echo Morphing® imaging solution which has the potential to meet all of these requirements.

Material and Methods: EchoMorphing uses an ultrasound (US) system in which the probe is equipped with a localized rigid body. This well known principle of 2.5D acquisition and was introduced for CAOS in 1993 [2]. The basic idea is that US acts as a transcutaneous digitizing probe. A major technical issue is to obtain a very accurate calibration matrix between the US image plane coordinates and the external rigid body. Many solutions exist now and all of them rely on the use of a dedicated calibration phantom using wires, planes, etc. Another important issue is to have the US system embedded in the navigation system in order to access the image parameters (depth, focus, etc.) and to prevent any change of those parameters between calibration and acquisition. From a technical point of view, US images of bone surfaces provide complex information which requires special care in pre-processing. The
result is a set of potential contours that require further global processing to eliminate artefacts. Such a standard reconstruction process has been proposed [3]. Since only partial information is obtained, however, it is necessary to employ a sophisticated interpolation and extrapolation procedure. Here we use the deformation of statistical models contained in our Bone Morphing algorithms [1]. To reconstruct a bone, the surgeon simply scans with the probe until a reasonably clear interface is seen on the screen, and then presses the footswitch to save the image. The computer then automatically detects and segments the bone surface interface, if any, on the saved US images. This process is repeated at least 6 times before the morphing method is applied on the interface points. The intersection of the US plane with the 3D model is computed and overlaid both on the US image and on the 3D model. This provides immediate feedback on the robustness and accuracy of the system. The process is iterative with no limitation on the number of US images acquired. To overcome the problem of draping, we developed the HipLoc® system, which permits the surgeon to remove and reinstall a rigid body over and under the surgical drapes with a high degree of repeatability.

**Results and Discussion:** EchoMorphing has been successfully tested on plastic bones where soft tissues were simulated by an anechoic gel. In the areas where US images were acquired, the maximum surface error was 1.5mm. EchoMorphing has also been successfully tested on volunteers and has proven to be a very flexible and powerful means to acquire 3D data very easily and quickly. Accuracy on patients is dependent on 2 factors: (1) The number of image acquisitions selected by the surgeon. There is no limit in the iterative process we propose. (2) The distance between the transducer on the skin and the bone surface. Because of variations of the speed of sound, a maximal error of 3% is possible (e.g. 1.5mm error at 50mm) [3]. However, distances between the transducer and the bone surface are usually small even for obese patients since the probe is pressed against the soft tissue to get a good image. Furthermore, it has been published in [4] that the use of 2.5D US images for registration to CT leads to accurate clinical results. Other authors have also demonstrated that the use of 2.5D US images in clinical routine is possible, precise, and robust [5].

**Conclusions:** This paper has introduced a technology that has many CAOS applications. It is particularly suited to MIS applications, the exact acquisition protocol thus depending on the application. We believe it to be a breakthrough since: there are no pre-op imaging requirements, no patient or staff radiation, it offers complete 3D reconstruction in an unlimited volume, it is MIS compatible, and it is easy-to-use.

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A PRE-CALIBRATED MOBILE LASER GUIDANCE SYSTEM FOR SURGICAL NAVIGATION

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Introduction: Most commercial surgical navigation systems display images on a computer monitor positioned adjacent to the surgical scene and operative procedures are performed using a hand-held pointer and instruments with tracking markers. These systems require that the surgeon performs the mental task of combining two sources of spatial information, because the surgeon has to look away from the surgical scene to obtain navigational information from the computer monitor. To solve this problem, we developed a laser guidance system that uses two or more laser beam emitters fixed to a stand1. This system was combined with a CT-based navigation system using an optical sensor. The laser emitter oscillated within a range of 30 degrees at 50 Hz, producing a beam tract shaped like a fan. Two or more fan-shaped beam tracts intersected in a line that can be controlled in any direction by changing the angle and direction of the beam oscillation. This laser guidance system drew cross hairs on a target, and the intersection of the cross hairs was the entry point for a linear surgical tool such as a drill or steel wire. After stabilization of the entry point, the system drew two or more lines along the guide sleeve. When the lines drawn on the sleeve were parallel, the direction of the linear tool coincided with the line formed by the intersection of the laser beam tracts. We have further developed a pre-calibrated mobile laser guidance system to adapt to more procedures easily. The new system consists of two laser emitters fixed onto an optical sensor (Polaris, NDI). In this study, we report simulation analyses of the optimal laser emitter position in the sensor camera construct and preliminary clinical experience of the laser guidance system.

Methods: For design optimization of the monolithic laser emitter and Polaris camera construct, the following simulation analyses were performed. We defined the available range of alignment procedure as the range of angles and positions of linear tools where one-degree and one-millimeter accuracy of the procedures was guaranteed. According to our previous study, the accuracy of linear tool alignment depends on the angle theta between the intersecting two laser planes. Surgeons could align to within one-degree and one-millimeter of errors when the intersection angle theta was between 30 and 100 degrees2. Therefore, the available range was set to fulfill the condition that the intersection angle theta would be between 30 and 100 degrees. Based on these simulations, a monolithic laser emitter and Polaris camera construct was made and laser beam calibration was carried out in the laboratory. We used this
system clinically in 5 cases for guiding cup placement in total hip arthroplasty through a posterior mini-incision approach (8 cm). The diagnosis was osteoarthritis secondary to hip dysplasia in all cases. Preoperative planning was based on CT images. A cementless hip system (CentPillar, Stryker-Howmedica-Osteonics) was used. A shape-based surface registration of previously constructed bone models of the pelvis was performed. After registration, the laser guidance system was used to insert a K-wire of 3mm diameter. Then, a cannulated hemi-spherical reamer was introduced over the K-wire and was directed according to the laser beams. Final acetabular cup impaction was also guided. To evaluate the clinical efficacy of the laser guidance, the following matters were investigated in each case. First, the visibility of the laser beam cross-hairs in the bottom of the acetabulum through the 8cm skin incision. Second, the accuracy of the laser beam as measured by probing the beam lines. Third, the working space of the laser emitter and sensor camera construct, which should not limit either laser beam guiding space or bone-tool tracking space.

**Results:** Based on the above simulation analyses and the expected weight and positioning of the monolithic integration of the laser emitters with the Polaris camera, a new system was designed with a base length of 650 mm and a convergence angle alpha of 36 degrees. The new pre-calibrated laser guidance system worked well introperatively, although shadeless lights had to be turned off so that the green laser beams could be seen in the acetabulum through a mini-incision and on the surgical tools. The laser beam position was accurate and the maximum error was 1mm when the cross hairs were probed and measured with the navigation system in all cases. There were no line of sight problems. For the THA procedures, acetabular reaming was performed using a guide wire inserted under laser guidance. Acetabular cup placement was easy using the laser guidance, while tracking of the pelvis and cup inserter with infrared markers was possible in the same work space.

**Discussion:** Based on the available range simulation analyses of alignment procedures of linear surgical tools using the intersection of two laser planes, this monolithic system integrating a laser system with a Polaris camera was designed and developed. Due to the rigid connection of the Polaris camera, and the laser emitters, user calibration was unnecessary. The available range guaranteed that the alignment accuracy was within one millimeter and one degree. However, it should be noted that slight deviation from the available range did not mean the system was completely unusable. It meant that the accuracy decreased and that the system would alert the user in such cases. Our preliminary clinical experience shows that this pre-calibrated mobile laser guidance system works well in the operating room. It was able to draw laser beam cross hairs in the acetabulum even through a mini-skin incision.

**References:**

A GENERIC CT-FREE INTRAOPERATIVE PLANNING AND NAVIGATION SYSTEM FOR HIGH TIBIAL OSTEOTOMY

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Objectives To design and evaluate a generic CT-free intraoperative planning and navigation system for high tibial osteotomy (HTO).

Introduction: HTO is a widely accepted but technically demanding procedure. Failure may occur if operative experience and/or surgical techniques are inadequate. Retrospective clinical studies (e.g., [1]) have shown that the biggest problem is the postoperative axial malalignment, which can be either under- or over-correction. Moreover, an inaccurate osteotomy may result in tibial plateau fracture, damage to tibial dorsal neurovascular structures, or penetration of the hinge cortical bone. The latter can result in fixation failure or loss of correction in opening or closing wedge osteotomies.

All these common problems can be addressed with the use of surgical navigation system. In this paper, a generic intraoperative planning and navigation system is proposed based on our previous work [2], which has led us to the use of fluoroscopic images, since they are already routinely used in operating rooms. The system aims to support all the common surgical techniques, including opening wedge, closing wedge, and focal dome osteotomies, because each of them has its unique clinical advantages and cannot be substituted by others.

Materials and Methods: Surgical instruments are tracked optically using the SurgiGATE® navigation system (PRAXIM/Medivision, La Tronche, France). Following exposure, dynamical reference bases are attached to the femur, tibia, and proximal fragment of the tibia. The anatomical landmarks are registered intraoperatively for the representation of surgical objects and calculation of clinical parameters. The methods for registering landmarks include kinematic pivoting movement, percutaneous digitization using a pointer, and fluoroscopic image based bi-planar three-dimensional point reconstruction.

Once the landmarks are registered, a patient specific coordinate system is established. The surgeon then checks the soft tissue balance and measures the deformity intraoperatively. The osteotomy is then planned interactively with the aid of fluoroscopic
images. Different surgical techniques can be planned before the surgeon makes a final decision.

The bone cut is performed under navigational guidance. This is very important because an inaccurate osteotomy may cause problems such as tibial plateau fractures or damage to the tibial neurovascular structures. Different graphical user interfaces are provided in order to accommodate specific technical requirements of each osteotomy technique. With on-the-fly visualization, the surgeon is able to continuously monitor the position and direction of instruments in multiple fluoroscopic images during osteotomy. Moreover, with real-time feedback of the distance from the instrument tip to the planned cutting plane, a safe and accurate osteotomy can be achieved.

Despite the differences of these surgical techniques, they all aim to correct the deformity by realigning the mechanical axis of the affected limb. Clinically relevant parameters, including wedge angle, wedge orientation, joint line orientation, tibial plateau slope, and lower limb axial alignment, are navigated. These parameters provide the surgeon with a comprehensive view of the clinical outcome, thus enabling him/her to perform the planned procedure accurately.

Results: Between January 2003 and February 2004, 32 cases of opening wedge osteotomy have been successfully supported by the system in 5 clinics. None of the above-mentioned complications were found so far in any patient. No other complications were found regarding the use of the navigation systems. In each of the 32 cases, the deformity was accurately corrected after the operation. For example, the evaluation of the postoperative full-leg X-ray images at Luzern Kantonsspital, Switzerland, (13 cases: 10 men and 3 women; follow-up time: 2 to 10 months; range of age at operation: 23 to 68 years; range of preoperative deformity: 0º to 10º varus) showed that the mean error was 0.9º, and the maximum error was 2.0º, compared to the anticipated mechanical axial alignment. A clinical study of focal dome and closing wedge osteotomies is currently in progress.

Conclusions: A generic CT-free intraoperative planning and navigation system for high tibial osteotomy has been developed and successfully introduced into operating rooms. The system allows surgeons to accurately measure the deformity, interactively plan the surgical procedure, and precisely perform the osteotomy under navigational guidance. The system thus holds the promise to improve the accuracy, safety, and clinical outcome of this surgical procedure.

References:

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Introduction: The high tibial osteotomy (HTO) became a standard procedure for varus deformities of the proximal tibia in younger patients. To achieve optimal results the new axis must be planned and executed accurate. However intraoperative control of axis and osteotomy is limited as the complete leg axis is controlled usually using a cable method. The accuracy of this method has not been evaluated and irregular measurements might occur. Alternatively in other indications fluoroscopy based navigation could reveal an increased accuracy and reduced radiation compared to conventional techniques. The purpose of this study was to evaluate the accuracy of navigated HTO in comparison to conventional technique and if the achieved result matched the planned osteotomy and axis.

Material and Methods: A total of 10 specimen (20 legs) were randomised about conventional (n=10) or navigated (n=10) high tibial osteotomie surgical procedures. The complete approval by the local ethic commission was given. A blind radomised procedure was choosen directly before the operations started. All specimen were placed supine on the table. Randomizeds following operation steps were done: conventional HTO: Under fluoroscopic control the conventional series was done and results checked by cable method. The osteotomie and further opening wedge procedure was done with a conventional saw and chisels. Instruments of an angle stable HTO fixation system (Tomofix, Mathys) were used for the opening procedure. Final control was done with cable and fluoroscopic method. navigated HTO: Three reference bases were placed. Two in the tibia, proximal and distal to the planned osteotomy and one in the femoral shaft. All navigation tools including the c-arm were placed contralateral to the surgeon, the camera oblique. Goal was a alignment of the mechanical axis to pass through 80% of the tibial plateau (80% Fujisawa line) [1] not depending on pre-existing alignment. The introperative mechanical axis was measured with a fluoroscopy based navigated HTO module. Under permanent control on the screen a navigated saw and chisel the HTO was done in the navigated cases without further radiation control. All axis deviations were recorded by the navigation system (Medivision). An angle fixed implant was used to stabilize the osteotomie in all cases. Both techniques were measured with cable and fluoroscopic methods. Post operative CT scans were done and measurements of the Fujisawa-line and medial proximal tibia angle (MPTA) done with computer software (Medicad, Hectec).
Radiation time was measured by the dose area product, the operation time in minutes. For statistic analysis standard deviation (S.D.) and paired t-test were used.

**Results:** After conventional HTO the mechanical axis intersected the Fujisawa line at an average of 72.1 % (range 60.4% - 82.4%; S.D. 7.2 %). After navigated HTO the plateau was intersected at an average of 79.7 % (range range 75.5- 85.8 %; SD 3.3%), reflecting significant higher accuracy with navigation (p=0.020). Also the S.D. of the corrections were significant lower in the navigated cases (p=0.012). The MPTA increased 7.9° (range: 4.7-12.1°) after conventional HTO and 9.1 (range:4.6-12.6°) after navigated HTO. The average dose area products of conventional cases was 49.5 cGy/cm², navigated cases 42.8 cGy/cm². At navigation 89 % of x-ray imaging was used for registration. There was no significant different in post operative slope measurements. The total operation time was prolonged significantly (navigated HTO: 82 min, range 55-98 min; conventional HTO: 59 min, range 47-73 min) (p<0.001). During both procedures no tibia plateau fractures, loss of correction or implant breaks were found.

**Discussion:** HTO are common procedure for axis correction, however HTO must be planned thoroughly based on weight bearing long leg radiographs. Intraoperative imaging of mechanical axis is so far technical not possible. The accuracy of deformity correction is main factor influencing the outcome of this procedure. The current study revealed that fluoroscopy navigation leads to an increased accuracy as the executed matched the planned osteotomy in all cases. Furthermore the navigation system provided additional information as fixation stability recorded online by the actual axis. However set-up times and operating time with navigation takes longer and additional personnel is required to operate the navigation system.

**References:**

COMPUTER ASSISTANCE IN TRIPLE PELVIC OSTEOTOMY: NO INTRA AND DIRECT POST OPERATIVE BENEFITS

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Introduction: In the November 2002 issue of the Acta Orthopaedica Scandinavica, a critical editorial was published concerning the use of computer and robotic assisted surgery. “The new techniques should result in a more accurate and hopefully, less invasive surgery with a shorter operating time and fewer complications.” In pelvic osteotomy surgery due to the complex anatomy, the required accuracy and precision a computer navigation system was developed. Langlotz et al1-3 described the development and introduction of a computer assistance system (CAS) and gives a review on the results of 12 patients who were treated for hip dysplasia using CAS. The first step in assessing the potential of CAS for triple pelvic osteotomies (TPO) was an in vitro study in which the accuracy and functionality of CAS in pelvic orthopedic surgery was tested 1. The aim of this study was to compare the results of the CAS system during TPO with those without the CAS system regarding the intra and early post operative results.

Patients and Methods: During the period June 1998 until February 2002 61 TPO where performed for hip dysplasia in 52 patients by one of the authors (MK). From these patients two study groups were defined. Group A was composed out of 20 patients on who 21 operations with CAS were performed. During the same timeframe 40 operations where performed on 32 patients without CAS, they constituted Group B. The average postoperative follow up was 30 months. Group A consisted of 4 male and 16 female patients with an average age of 27 years. In group B 40 operations were performed on 32 patients, 4 males and 28 females with an average age of 32 years. Out of the in total 52 patients 8 patients where operated bilaterally during this study period. Research data were retrospectively obtained. The CAS used consists out of the SurgiGATE® hardware computer graphic workstation (Sun Microsystems Inc, Mountain View Ca) and an OPTOTRAK 3020 optoelectronic localizer (Northern Digital Inc, Waterloo, Ontario, Canada). Statistical measurements where made using the SPSS software.

Results: The study group showed no significant difference between the preoperative CE angles, HHS, BMI and the age of the patients (p>0.05) In 9 patients it was decided to discontinue the use of CAS. Technical failure was the reason to abandon the use of the CAS in 5 cases (cable dysfunction, software failure, LED failure), in 3
cases preoperative errors from the CT data made it difficult to ascertain a three-dimensional image of the pelvis. In the case of the last patient the decision was made not to use CAS because a previously performed TPO on the contra lateral side disturbed the CT data that was acquired before the first TPO. These 9 patients where grouped as group C during the data analysis. Group A consisted of 3 male and 9 female patients with an average age of 26 years. In group B 40 operations were performed on 32 patients, 4 male and 28 females with an average age of 32 years. Group C was formed out of 1 male and 7 female patients with an average age of 29 years. One of the 7 females was successfully operated on using the CAS system on the contra lateral side. An one way ANOVA showed that the operation duration and the average operative blood loss is significantly different for the three study groups (p=0.001, p=0.014). A bonferroni comparison showed that the operation duration and the operative blood loss for group A was significantly longer and more compared to group B (p=0.001, p=0.019); group C was only significantly different compared to group A for the operative blood loss (p=0.044). The post operative measured CE angles showed no statistical difference (p>0.05) between the three study groups.

**Discussion:** CAS gives information concerning the anatomy, the osteotomies and the acetabular reorientation, so it should not be necessary to interrupt the procedure for intraoperative radiographs. Langlotz et al \(^2\) published the clinical results on 12 patients who have been operated on using CAS during periacetabular osteotomies. One of his conclusions was that there will be little benefits when using this system if the surgeon is experienced in performing the operation. The major advantage of CAS is that an inexperienced surgeon can use it as a learning tool to master a technically demanding procedure. In almost 50% there were problems with CAS which made us to discontinue the use of the system during the operation. During those procedures in which CAS was used, the operating time and blood loss were significantly higher compared to the procedures without CAS. This increase of blood loss can be attributed to the prolonged operation time which is necessary to get acquainted using and positioning CAS. When the experience grows the operation time may go down and the amount of blood loss may decline. The main advantage of the CAS system is the possibility of pre-operatively planning and provide the surgeon with information which can be used during the operation. However, in our clinic with a large experience in pelvic osteotomy, the use of CAS increased operation time and intra operative blood loss and did not lead to better intra operative and short term postoperative results.

**References:**

ULTRASOUND FOR MEASURING THE MECHANICAL LEG AXIS IN TOTAL KNEE ARTHROPLASTY

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Aim: To assess a new navigated ultrasound method to measure the mechanical leg axis after total knee arthroplasty (TKA).

Materials and Methods: Long standing x-rays to determine the mechanical axis of the lower limb have shown to be inaccurate especially in severe deformities. Possible reasons for that are projection errors. Therefore we developed a new navigated ultrasound method to measure the mechanical axis after TKA. The system (US) is a combination of a 2D ultrasound device with a 3D navigation system. In the first step we compared the US with 15 3D CT scans, then we calculated the intraobserver variation in 50 patients and we compared the US method with long standing x-rays in 96 patients.

Results: The mean difference between 15 CT scans and US measurements was 0.2° with a maximum of 2 degrees. The mean intraobserver error in 50 patients was 0.3° with a maximum of 2°. The mean mechanical axis of the 96 long standing x-rays was 178.8° (range 172-185°) the mean of the US measurements in these patients 178.1° (range 172-184°). The mean difference between US and the long standing x-rays was 0.7° with a maximum of 7° (sd 2°). In 80% the difference between these two methods were less or equal than 3 degrees.

Conclusion: The navigated ultrasound method is more precise to measure the mechanical leg axis after TKA than long standing x-rays. The main advantage of this method is that there are no projection errors, which are mainly responsible for the differences. In exact a.p. long standing x-rays there is no significant difference between the two methods.
IMAGELESS COMPUTER NAVIGATED TOTAL HIP REPLACEMENT WITH A LIMITED POSTERIOR APPROACH

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Introduction: Total hip arthroplasty through a posterior approach has been used extensively due to its wide exposure of the femur and acetabulum, extensibility and limited damage to the musculature. A high dislocation rate, the morbidity and blood loss associated with a wide exposure and variations in ability to control component position have led to an interest in less invasive procedures [1]. Dislocations associated with the posterior approach have been reduced by closure of the posterior capsule and external rotators [3]. DiGoia [2] described improved results using the limited posterior approach along with computer-assisted hip navigation based on pre-operative computed axial tomography (CT) imaging. Computer-assisted hip navigation without imaging can be done based on palpation of anatomic landmarks to determine the anterior frontal plane of the pelvis [5].

Method: The limited posterior surgical approach and use of computer-assisted navigation was used on all sequential patients presenting for a primary total hip replacement. Using the Stryker Leibinger Hip Navigation system, the anterior frontal plane of the pelvis was determined by palpation and registration of the bony landmarks (right and left anterior iliac spines and pubis) with subsequent determination of the hip center through motion analysis. Navigated reaming and cup placement was used with a goal of 40° - 45° abduction and 17° - 23° of forward flexion. The technique has been used in 60 patients with 89.7% OA, mean age of 64, mean BMI of 30 with a 43%: 57% male to female ratio. The technique was compared to a retrospective cohort of similar total hip patients done with the manual technique. There were no significant differences in mean age, gender or diagnosis. Post-operative cup abduction (Abd) and flexion (Flx) were determined from radiographs taken one month after surgery using the method described by Pradhan [4]. There were 60 hips in the navigated group (CAS) and 48 in the manual group.

Results: The navigated values registered at surgery were Abd 42° ± 2 and Flx 21° ± 3. The radiographic measurements for the CAS group were Abd 43° ± 4 and Flx 21° ± 4 while the values for the manual group were Abd 46° ± 5 and Flx 22° ± 6. Radiographically, the navigated group showed a higher percentage (70% with navigation and 30% without) for cup abduction between 40° - 45° (p = .015) and cup flexion between 17° - 23° (p = .005). There have been no cases of post-operative dislocation with all components appearing to have stable fixation.
Discussion: The results of this study indicate that a limited posterior incision can be used routinely on patients for a primary total hip. The use of computer-assisted navigation improves the accuracy of component placement without the need for pre-operative imaging with CT scans or the intra-operative use of fluoroscopy. Since the post-operative radiographic technique and positioning can affect the measured values, studies comparing groups with CT scans would be expected to show any differences between the two groups more accurately. The limited incision preserves the benefits of the posterior-lateral approach with extensibility and adequate access to the femur and acetabulum with direct vision. Combining this with computer assisted hip navigation techniques allows the surgeon to accurately place the total hip components with minimal post-operative complications.

References:

Introduction: Minimally invasive total hip replacement surgery not only decreases the number of visual cues necessary for proper acetabular component position, the small incision makes it technically more difficult to use traditional mechanical alignment guides. Furthermore, traditional mechanical guides have been shown to be unable to accurately predict component position as determined by intraoperative computer measurements. [1,3] Computer assisted intraoperative navigation can enable minimally invasive surgery by giving the surgeon immediate intraoperative feedback of actual component position. We wished to compare the intraoperative computer determined measurement of acetabular inclination with the postoperative radiographic measurement of inclination in order to validate the results of the computer assisted measurements in the clinical setting.

Objectives: To determine whether computer assisted navigation of the acetabular component allows the surgeon to accurately place the prosthesis in minimally invasive hip replacement and to compare the results of intraoperative navigation with the postoperative radiograph.

Materials and Methods: 42 consecutive patients underwent a minimally invasive posterior approach for total hip arthroplasty with the assistance of CT based intraoperative navigation with the BrainLAB VectorVision software. Preoperative surgical planning was performed after acquisition of a CT scan. All components were templated to be placed in 45 degrees of inclination and 25 degrees of anteversion. Intraoperatively, cementless acetabular components were aligned with the computer navigation at these values prior to implant impaction. Because of the press fit nature and limited soft tissue exposure, many components would shift during impaction. Final component position was then verified and values recorded by detecting points on the acetabular surface. If the prosthesis was felt to be in an acceptable position, no attempt was made to modify component position to the predetermined values in order to avoid potentially compromising component fixation. Postoperative supine AP pelvis radiography was then used to determine final inclination. Measurements were made by drawing a line perpendicular to the acetabular teardrop and parallel to the acetabular component and measured with a standard goniometer. These data were then placed in an SPSS database and analyzed by an independent statistician.
**Results:** 3 patients experienced fixation failure of the reference array during surgery, leaving 39 patients for analysis. Regarding the size of the acetabular prosthesis, 74% of components implanted were exactly the same, 92% were within one size and 96% of components were within two sizes of the templated size based on the preoperative CT scan. Statistically there was no difference between the planned acetabular component and the actual acetabular component size (p=0.352, paired t test). The average inclination value determined by the computer was 44+/-6.5 and the average inclination on the postoperative radiograph was 43 +/- 5.8. The average intraoperative anteversion was 24+/-12 degrees. Overall the mean values were not statistically different in the computer measurements or the radiographic measurements. However, when the individual differences were evaluated comparing the intraoperative CT navigated results with the radiographic results there was a statistically significant difference between the groups (p=0.029 paired t-test) indicating that on an individual basis there was significant variation between the two measurement methods. Regarding the consistency of measurements, the postoperative radiograph and intraoperative measurements were within 2 degrees 48%, 5 degrees 75%, 8 degrees 90% and 10 degrees 95% of the time with two outliers. (Table 1)

**Conclusions:** Assessing acetabular component position in routine total hip arthroplasty has been shown to be unreliable even with experienced surgeons with mechanical alignment guides. [1,3] In minimally invasive total hip arthroplasty, routine visual cues are limited and mechanical instruments are difficult to place in the small operative wounds making an already difficult task even more difficult. CT based image guided surgery can has been shown to improve the acetabular component position intraoperatively. However, postoperative validation studies comparing the intraoperative computer assessment with the postoperative radiographic measurement are scarce. [2] In this consecutive series, which represents the author’s first experience with this technology, several conclusions can be made. First, the act of impacting a solid, porous coated, hemispherical cement-less acetabular component in minimally invasive hip surgery often leads to a final component position different from the intended position. Second, computer generated determination of implant position is reliable but care must be taken to make sure the reference arrays do not lose fixation during the procedure or spurious results can occur. Third, routine AP pelvis radiographic measurements are not accurate enough to determine whether the computer determined values are accurate. In spite of these measurement inaccuracies, the computer determined results and the radiographic results were within 10 degrees 95 % of the time which is far more accurate than results obtained with mechanical alignment tools. Finally, further validation studies need to be done with postoperative CT scanning to determine the accuracy of the intraoperative computerized measurements and determine the measurement errors inherent in the clinical setting. Given these limitations, computer assisted navigation improves the accuracy and reliability of acetabular component position over traditional mechanical instruments and can be utilized in minimally invasive hip surgery to assist in the appropriate placement of the acetabular prosthesis.
References:

Introduction: Most of the studies reporting cup measurements are performed on postoperative pelvic radiographs. Radiographic cup position depends on the pelvis spatial orientation on the table and its variability could introduce significant errors for cup measurements. Lewinnek and coworkers [3] took into account this relationship and attempted to standardize the position of the pelvis with respect to the X-ray table in a clinical study. Later, using the anterior pelvic plane (APP) as reference, Jaramaz and coworkers [2] introduced the concept of landmark-based measurements in the field of computer-assisted surgery for acetabular cup placement.

The purpose of the present study is to clinically validate a CT/X-ray matching algorithm by determining the measurements errors for cup orientation, compared to CT measurements.

Materials and Method: This is an analysis of postoperative pelvic X-ray and CT scans of 19 patients, who underwent bilateral (but not simultaneous) primary total hip arthroplasty (THA), guided by navigation tools. The computer-assisted system guided the acetabular cup placement, based on preoperative pelvic CT information. [1] The patients included had two preoperative pelvic CT scans, one before each intervention. The second of the two scans imaged the first total hip prosthesis and was included in this study, as the postoperative CT for the first replaced hip. Antero-posterior (AP) supine pelvic radiographs have been done routinely at 1 month, 3 months, 6 months and 12 months after surgery. First the software generated a synthetic pelvic AP X-ray, using CT pelvic images. A real pelvic AP X-ray was also displayed on the computer screen in the same time as the synthetic X-ray and the two images were manipulated, until the best intensity match was found. A CAD graphic cup model was then displayed. The user was able to manipulate the virtual projection and align it with real projection of the actual cup, until the best match was found.

The CT data acquisition was followed by defining the anterior pelvic plane (APP), used by the anatomic reference system. Images were then segmented with an intensity threshold set to a level where only the metallic cup is visually selected. This selection was performed in order to eliminate the metallic image artifacts due to the cup itself. To determine the true, anatomic orientation of the acetabular implant, a
graphic CAD (computer assisted design) 3D model of the cup implant was generated by the software and displayed on the computer screen and was manipulated and overlaid on the segmented cup surface model until the best possible match was found. The differences between Xalign and CT measurements for cup abduction and version were defined as abduction and version errors and used to validate the method. The pelvic orientation was measured both on CT scans and with Xalign method and is reported in terms of pelvic flexion and pelvic version angles.

**Results:**

*The ground truth: CT cup alignment and pelvis orientation*

The mean (±standard deviation) CT cup abduction was $52° ± 5°$ and ranged from $43°$ (minimum) to $59°$ (maximum). The mean acetabular cup version was $18° ± 7°$ (range $-0.5°$- $29°$). In CT scans, pelvis flexion angles ranged from $-14°$ to $15°$, with a $1.6°$ mean and a standard deviation of $6.5°$. The mean pelvic version angle was $1.4° ± 2°$ (range $-2°$-$6°$).

*Cup position and pelvic orientation from AP X-rays, using CT/X-ray matching*

The mean ($±$ standard deviation) acetabular cup abduction was $54° ± 4.7°$, ranging from $43.45°$ to $63.43°$. The cup version ranged from $-1.19°$ to $30.53°$, with a mean ($±$ standard deviation) of $18.68° ± 7.7°$. The measurement errors were $0.85° ± 1.3°$ (mean $±$ standard deviation) for cup abduction and $0.01° ± 1.99°$ (mean $±$ standard deviation) for cup version. The mean absolute pelvic flexion was $5.8° ± 3.8°$ ($±$ standard deviation) and its values ranged from $-10.7°$ to $16°$. The mean absolute pelvic version angle was $1.5° ± 1.5°$ ($±$ standard deviation).

**Discussion:** It is important to stress that the Xalign results for cup and pelvic orientation are all referenced anatomically. The mean errors ($±$ stdv), $0.85° ± 1.3°$, for abduction and $0.01° ± 1.99°$ for version, are considered to be very good. The pelvic orientation ranged from $-10°$ to $16°$ for pelvic flexion and between $-6.9°$ and $6°$ of pelvic lateral version. Nishihara and coworkers [4] reported recently a similar methodology. They used however a different approach to the CT/X-ray matching process. Finding the best possible match involved a certain dose of subjective judgment, which needs to be assessed by further research. The algorithm requires just one pelvic CT scan that could be obtained preoperatively or postoperatively, at any moment in time and then used for multiple postoperative X-ray measurements throughout the patient’s life.

**References:**

COMPARISON OF THR-CUP-ORIENTATION USING DIFFERENT NAVIGATION SYSTEMS

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Introduction: Orientation of an acetabular component is supposed to be important for the early as well long-term result of total hip arthroplasty (THR) [1-3]. Joint dislocation, component wear and impingement can result from misalignment of the acetabular cup in patients undergoing total hip arthroplasty. Navigation techniques claim to improve the accuracy of hip cup orientation compared to the non-navigated, manual method. Aim of this in-vitro study was to compare the the hip cup orientation when using different navigation systems and the non-navigated technique. In addition, the question, whether the experience of the surgeon influence the quality of cup position, should be answered.

Methods: Five different navigation systems were used: Vectorvision® 2, Hip 2.0, CT-based; Aesculap, DE; Navitrack™, CT-based; Centerpulse, CH; Navitrack™, CT-free; Centerpulse, CH; Orthopilot®, Acetabular Module Version 1.1, CT-free; Aesculap, DE; SURGETICS Station®, ESKA HIPLOGICS® V1.0, CT-free; Praxim, FR. CT-scans of a human cadaver pelvis were performed. A rectangular block comprising the left acetabulum was removed from the pelvis. A negative mould of this acetabulum block was used to produce 90 positives made of polyurethane foam. Before each cup implantation a new polyurethan acetabulum was placed into the pelvis specimen. Due to the fit of the mould, the position and orientation of the artificial acetabulum relative to the pelvis was constant. The whole pelvis was placed within a dummy. In order to adequately simulate a real surgery, the dummy was covered like in a real surgery.

An inexperienced, an experienced and an very experienced surgeon regarding manual THR (10, 70 and 480 surgeries respectively) participated. Non of the surgeons had any experiences with any of the navigation systems. For every hip cup an inclination angle of 30° and an anteversion angle of 10° was planned. Registration and calibration of the navigation systems were performed by a company representative. Each surgeon implanted five system specific hip cups using conventional manual technique and afterwards with each of the five navigation systems.

Following each surgery the acetabulum block containing the cup was removed from the hip specimen. After the surgeries the specimen was removed from the dummy and
fixed on a coordinate measuring machine (Mitutoyo Messgeräte GmbH, Germany). Inclination and anteversion were determined with an accuracy of ±0.5°. Statistical analysis was performed by means of analysis of variance (ANOVA) using SPSS for Windows (Version 9.0.1). Independent variables were the experience of the surgeon and the implantation technique (5 navigation systems and the non-navigated method). Dependent variables were the measured inclination and anteversion angles and the procedure duration. All statistical tests were performed with a confidence interval of 95% (a=0.05).

**Results:** The procedure duration of the very experienced surgeon was always significantly shorter than of the other groups (p<0.001). For the navigation groups maximum differences from the planned values of up to 10 degrees were observed for the inclination angle and up to 13 degrees for the anteversion angle. For every surgeon the standard deviation of the inclination and anteversion angles were higher for the non-navigated compared to the navigated techniques (Fig). For the inexperienced surgeon the standard deviation of the anteversion angle was about three times higher in the non-navigated group compared to the more experienced surgeons.

Significant differences between the surgeons regarding the inclination angle were observed for one navigated group (Surgetics-Station®: p=0.047) and regarding the anteversion angle for two navigated groups (Orthopilot®: p=0.019; Surgetics-Station®: p=0.011). The inclination angle achieved with the Navitrack™ CT-based system was significantly lower (p=0.014) and with the Vectorvision® system significantly higher (p=0.042) compared to the non-navigated group. The anteversion angles of two navigation groups were significantly better compared to the non-navigated group (Navitrack™ CT based: p=0.001; Orthopilot®: p=0.019, Vector vision p<0.001).

**Discussion:** The use of computer navigation helps the surgeon – independent of the level of experience – to place the acetabular component with less variability regarding inclination and anteversion. The probability of extreme cup positions (as it has observed for the non-navigated group) is reduced. If the cup inclination and anteversion is clinically important, navigation techniques should be used for every THR.

Depending on the type of the navigation system an accuracy of the cup placement of ±5° has been achieved in an ideal surgical situation. Errors caused by the referencing procedure have to take in count in a real surgery. In that case the experience of the surgeon is required to validate the cup orientation displayed by the navigation system.

**References:**

COMPARISON OF ROBOTIC VERSUS MANUAL IMPLANTATION OF CEMENTLESS PRIMARY TOTAL HIP REPLACEMENT - A PROSPECTIVE CLINICAL STUDY

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Introduction: The discussion whether the usage of a robotic system improves the clinical success of THR or not is being held on very emotional and subjective grounds[1;2]. Only the superior fit of a cavity reamed by a robotic system when compared to manual reaming is established. Whether this aspect is important or not was not shown. The purpose of this study was to provide objective information regarding the differences in clinical outcome between robotic assisted and conventional manually implanted THR using the same prosthesis type.

Materials and Methods: Inclusion criterion was the diagnosis of osteoarthritis. 154 patients (54 men / 100 women) volunteered to participate in the study and gave informed consent. The average age at operation was 70±8 years. All patients were provided with a modular S-ROM® (DePuy, a Johnson & Johnson Company, Leeds, UK) prosthesis with a cobalt-chromium head (Ø28mm). A spherical cementless press fit-cup (ESKA Implants, Luebeck, DE) with polyethylene inlay was implanted on the acetabular side. A similar antero-lateral approach to the hip joint with side position of the patient was used for both groups. Two different surgeons performed operations. Both had the experience of several hundred conventional manual as well as 25 robot-aided implantations of the S-ROM® prosthesis. Patients’ assignment to either group or surgeon was randomized. The robotic / manual group consisted of 74 / 80 patients. For the robotic group the ROBODOC® (Integrated Surgical Systems, Sacramento, US) with the complementing planning computer ORTHODOC® was used with two reference pins implanted. A helical CT (Siemens AG, Muenchen, DE) was carried out according to the manufacturer specified protocol. Then the CT data were transferred to the ORTHODOC® and transformed into a 3-D reconstruction. The planning of the S-ROM® prosthesis was carried out with an anteversion of 15°. For the patients of the manual group a pre-operative planning sketch was drafted with the usual X-ray templates taking into account the leg-length. All patients were examined clinically and X-rayed pre-operatively as well as post-operatively after 3, 6, 12, 24 and 36 months. The functional hip scores according to Harris, Merle d’Aubigné and the
Mayo-score (clinical) were calculated. The X-ray results were also considered for the post-operative Mayo-score (radiological). Furthermore, the difference between prosthesis axis and femur-axis was calculated from the post-operative X-ray. After 6 months the leg-length of the standing patient was assessed. Statistical analysis was performed by means of analysis of variance (ANOVA). All statistical tests were performed with a confidence interval of 95% ($\alpha=0.05$).

**Results:** Surgery had to be converted in $13/74=18\%$ of the robotic surgeries to manual due to failure of the system. Surgery duration was higher in the robotic group ($107\pm29$ vs. $82\pm23$min, robotic vs. manual, $p<0.001$). Leg length equality ($0.2\pm0.3$ vs. $1.0\pm0.9$cm, $p<0.001$) and stem varus-valgus orientation ($0.3\pm0.7$ vs. $0.8\pm1.2^\circ$, $p<0.001$) were better in the robotic group. After 6 months slightly more heterotopic ossifications were seen in the robotic group. After 6 months the robotic group showed a better Mayo-score ($64\pm15$ vs. $56\pm17$ p=0.01) and after 12 month a better Mayo-score ($73\pm7$ vs. $63\pm14$, $p<0.001$) and Harris-score $86\pm12$ vs.$73\pm17$, $p<0.001$), whereas after 24 month and 36 months no differences were found any longer. In the robotic group dislocation was more frequent ($11/61=18\%$ vs. $3/80=4\%$, $p<0.001$). Recurrent dislocation and pronounced massive limping was the indication for revision surgeries in the robotic group (non-infectious etiology, $9/61=15\%$ vs. $0/78=0\%$, $p<0.001$). During reoperation rupture of the abductor muscle tendon (pseudoparalysis similar to the rupture of rotator cuff) was observed.

**Discussion:** The robotic assisted technology showed advantages in pre-operative planning and accuracy of intra-operative procedure. Disadvantages are the high revision rate, the amount of muscle damage responsible for the higher dislocation rate and the longer surgery duration. It cannot be the goal to show that the robotic approach “reaches” the quality of the manual approach. The additional time and investment in machinery required as well as the additional burden for the patient (e.g. CT scan) can only be justified by a distinctively better performance. This study clearly shows that the described robotic approach, in its current form, is an endangerment to the THR patient. A neural injury rate of 7%, a dislocation rate of 18% and a revision rate within two years of key operation of 15%, such as demonstrated with the robotic group, are well below today’s (and even those of 25 years ago) standards for primary THR. The additional time and investment in machinery required as well as the additional burden for the patient (e.g. CT-scan) can only be justified by a better performance. We have shown that the described robotic approach, in its current form, is associated with considerable morbidity. The success of THR depends on many factors. The near future will show if the undoubtful improvement of planning and fit of the robotic procedure can be demonstrated at other centers experienced with the robot technique. It remains to be seen, whether a redesigned robotic approach is to be for common use and whether it has the potential to improve the results of THR.
References:

RETROGRADE DRILLING IN OSTEOCHONDROSIS DISSECANS OF THE TALUS USING ISO-C 3D BASED COMPUTER ASSISTED SURGERY (CAS)

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Introduction: The goal in the treatment of osteochondral defects of the talus in stadium I and II according to Berndt and Harty [1] is the revascularisation of the focus. Subchondral drillings of the focus allow a revascularisation. Retrograde drillings leave the chondral surface intact and is therefore advantageous compared with antegrade drillings. The use of CT based Computer Assisted Surgery (CAS) guided retrograde drilling of osteochondral lesions has been described with promising results as a new technique. Computed tomography (CT)- and fluoroscopy-based navigation systems in current use are limited in their flexibility. The drawbacks of fluoroscopy are lack of three-dimensional imaging intraoperatively. CT-based navigation still requires intraoperative cumbersome registration, extra preoperative planning, and imaging with further technical resources. In addition to the current method we also introduce an alternative technique of using ISO-C-3D based CAS guided retrograde drilling of the lesion.

Methods: All retrograde drillings in osteochondral defects of the talus in stadium I and II [1] of the talus after 01/06/2003 in a level 1 trauma centre were performed with ISO-C-3D navigation using the Surgigate system (Medivision, Oberdorf, Switzerland). The fixation of the Dynamic Reference Basis (DRB) to the talus was performed with a minifixateur system within the neck of the talus. Two pins are necessary to provide rotational stability. The drilling is performed with a modified navigated electrical power drilling machine (Powerdrive, Synthes Inc., Bochum, Germany). Intraoperatively trajectories are planned. The starting point of the drilling is at the lateral talar process for lesions located at the medial talar shoulder, and vice versa for lesions lateral talar shoulder. The trajectory and the image of the drill are overlapped to achieve an optimal result. The drillings were performed using a drill diameter of 4 mm to reduce drill bending. Time spent, accuracy, problems, surgeons’ rating (Visual Analogue Scale [VAS], 0-10 points) were recorded and analyzed. The accuracy of the drillings were assessed by ISO-C 3D.

Results: Six patients with osteochondral defect stadium II according to Berndt and Harty (n=1 lateral; n=5 medial) were treated since 06/2003. Analysing the time spend the overall time for preparation, including the placement of the DRB, scanning time
and planning of the trajectories was 580 s (500 – 750). In 1 (16 %) case an error during the data-transfer occurred and the scan had to be done twice. During the second scan and data-transfer no problem occurred. Within the Iso-C-3D scan performed after placement of the retrograde drillings all drillings were judged in correct position. The surgeons rating were VAS 9 (7.3-10) for the intraoperative helpfulness of the described technique. The accuracy was judged 8.5 (5.8-10). The clinical benefit was rated 8.5 (5.7-10). Due to the short use of this new technique no long term results of the outcome of the patients can be provide at this time.

Discussion: Retrograde drilling of osteochondral defects within the early stadium grad I or II are effective and minimal invasive [4]. Open debridement are sometimes necessary but require an osteotomy of the medial malleolus [3]. The use of navigated retrograde drilling is used shortly. Higher accuracy and good results in experimental and clinical studies were shown. Good results using CT based navigation and a non invasive extraanatomical fixation of the DRB were shown by Fink et al. [2]. Fluoroscopy based navigation is problematic within osteochondral lesions due to plain imaging. Within the first stages of these defects they might not be visible within the image. However, the ISO-C-3D based CAS allows good visualisation of the defect. Radiation protection for patient and personnel is another essential topic. The radiation of an ISO-C-3D based CAS guided drilling procedure is of course higher compared with an arthroscopically based drilling. However, the ISO-C-3D based CAS procedures produce less radiation than all conventional C-arm based procedures and CT based CAS. The advantages of the introduced technique are a real-time intraoperative three-dimensional imaging for the use of navigation without the need for anatomical registration and an immediate intraoperative control of surgical treatment. Due to the excellent visualisation of the defect within the early stages misplacements of the drilling can be avoided. With the possibility of a postoperative ISO-C-3D scan an immediate intraoperative control of the placement of the drilling is possible. Our results reveal that ISO-C 3D based Computer Assisted Surgery (CAS) guided retrograde drilling is an alternative to arthroscopically guided or open drilling for osteochondral lesions of the talus.

References:

COMPUTER ASSISTED TOTAL KNEE REPLACEMENT: COULD A TWO-PIECE CUSTOM TEMPLATE REPLACE THE COMPLEX CONVENTIONAL INSTRUMENTATIONS?

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Introduction: Current surgical techniques of total knee replacement (TKR) lack geometrical preoperative planning and chiefly rely on standardised surgical instrumentation (jigs). These jigs are invasive as they violate the intramedullary canal carrying higher risk of bleeding, infection, fracture and fat embolism. They are complex tools with numerous pieces of alignment guides, templates and cutting blocks. They increase the hospital inventory, workload on the sterilisation services and the learning curve for surgeons and nurses. They also increase the operative time and the risk of infection. In our laboratory a computer assisted patient specific templating system was developed with the purpose to completely replace the conventional instrumentations and address the deficiencies of the current TKR technique.

Materials and Methods: 17 TKRs were performed to evaluate our computer assisted patient specific templating (PST) system. The system involved a CT- based preoperative planning and designing of a two-piece custom template for 14 cadaveric and 3 plastic knees. PFC (DePuy/Johnson and Johnson) prosthesis was used in this study, as it is the most commonly used prosthesis in the UK. The manufacturer provided us with 3-D images -virtual prostheses- that represent different sizes of femoral and tibial components. Patellar replacement was not considered in this study. The CT data were reconstructed to provide 3D models of femur and tibia. Landmarks and axes guided proper alignment and placement of the prosthesis. Surgical simulation was performed to verify the accuracy of sizing, bone cutting and alignment. One femoral and one tibial template were designed in the form of cutting blocks with holes and slits to allow fixation and bone cutting. The final design of custom templates was transferred to a rapid prototyping machine to produce the femoral and tibial templates. The material of the templates has already been validated for surgical use and autoclaving in a previous investigation. Standard medial parapatellar approach was used. PSTs were uniquely positioned over the femoral and the tibial
articular surfaces following the specific patient geometry and secured with pins to provide additional stability. Traditional saw blades were used to make the various bone cuts through the slits in the PSTs. After implantation the knee was evaluated with regards to prosthesis sizing, accuracy of the bone cutting, range of motion and alignment.

**Results:** The two-piece template was successfully used to perform TKRs without resorting to the conventional surgical jigs. The outcome of this primary endpoint has answered our study question. The sizing of the femoral and tibial components was satisfactory. However sizing of polyethylene was not accurate as it normally depends on the soft tissue balancing which is difficult to determine in the preoperative stage. No obvious malalignment or restriction of range of motion was noticed. PSTs were easily accommodated within the bony and soft tissue restrictions around distal femur and proximal tibia. PSTs have been found to be user friendly. Some difficulties were experienced in positioning femoral templates but this was eliminated with subsequent modifications. The operative time for bone cutting procedure of both femur and tibia was gradually reduced and the average time was about 15 minutes.

**Discussion and Conclusion:** Computer assisted surgery can provide an accurate preoperative planning that could be transformed into a reproducible surgical performance. Navigational and robotic techniques have been recently introduced into orthopaedic clinical practice with encouraging results [2,4]. Patient specific templating confines the computer assisted work to the preoperative stage and could provide a user friendly, inexpensive alternative. There are reports of using individual (patient specific) templating in orthopaedic surgery [3]. However, its clinical application in TKR has not been popularised. Possibly because these techniques have not replaced the conventional instrumentations and the drawbacks of using the CT scan in these techniques could not be justified by the limited benefits. In our system the templates were designed to completely replace the surgical jigs and this has been demonstrated in our results. The use of CT scan here could be justified because the templates eliminated the drawbacks of conventional jigs; complexity, invasiveness, cost, and risk of contamination. The preoperative planning allowed selection of the prosthesis size and simulation of surgery. CT scanning is a drawback due to the risk of radiation and the cost. However, the radiation dose from knee CT is relatively low and CT scanning has been used routinely in some conventional surgical procedures e.g. Patellofemoral arthropathy [1]. The cost of PSTs could be as low as £ 50. Although this study revealed obvious advantages of the PSTs a further investigation is needed to compare its accuracy against conventional instrumentations.

**References:**

A COMPUTER-ASSISTED CONTROLLED DISTRACTION DEVICE TO GUIDE LIGAMENT BALANCING DURING KNEE ARTHROPLASTY

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Introduction: In knee replacement surgery, it is difficult to quantify the ligament system prior to making the bone cuts, at which point the surgeon can only try to correct for ligament imbalance (ie, tautness or looseness in the ligaments during flexion) rather than explicitly making a compromise between alignment and balance. A variety of tensor devices have been developed to assess balance following one or more bone cuts [eg, 4]. We propose a system [2] which improves on these by (1) being used after making only the tibial cut, (2) leaving the patella in its normal position, (3) applying a consistent distraction force throughout the range of motion of the knee, and (4) tracking the distraction with a computer-assisted navigation system. Our objective is to use only a few intraoperative measurements to characterize the ligaments and simulate their behaviors for different proposed implant positions. We combine two different approaches to determine the ligament insertions and lengths more robustly and use this information to predict the prosthesis size and position which optimally satisfies balance and alignment goals.

Materials and Methods: Our device uses a pair of inflatable bladders and pressure sensors to apply controlled distraction to the medial and lateral compartments of the knee. A computer-assisted navigation system is used to find the bone gap and display on a monitor the articular space and the transepicondylar line, which are used in positioning the femoral component in flexion. Because there is not yet unanimity regarding how to optimally measure or implement soft tissue balance, we provide means to acquire a variety of ligament measurements including digitized anatomical locations, bone-morphing-based estimates, and a model-based algorithm to estimate the insertions of equivalent multi-fibre ligaments that best model the constraints between the two bones during a rapid manual manipulation of the limb [1]. Depending on the surgical technique, ligament balancing is then performed with reference to the estimated ligament lengths. Our device could be used to measure the distraction forces at different flexion angles from which the stiffness of each modelled fibre can then be calculated and the optimal prosthesis size and position can be predicted.
**Results:** We tested our first prototype of the distraction device on two cadavers. The cadaveric knees were nonpathological and in very good condition. The bodies weighed 40 kg and 90 kg. The acquisition of the articular centers and the bone-morphing procedure were performed successfully. The tibial cuts were both 10 mm deep. On the first cadaver, the distraction was applied during manual manipulations of the leg and unfortunately the applied torsion tore a silicone joint between the right superior plates; this problem was solved with minor mechanical modifications. On the second cadaver, we found that the distraction was more difficult due to the heavy weight of the leg, and the surgeon had to initiate and help the distraction manually during the manipulations. We also found that manipulation of the foot produced variations in the measured forces and it was difficult to manually control these forces. Despite the difficulties, several trials were carried out in which we tracked the articular space, the ligament lengths and the distraction forces and the surgeon felt that the information we gathered would be useful if it were easier to obtain. We have therefore completed a redesign. Postoperatively, we asked the surgeon to indicate the ligament attachment sites on both a reference statistical model and a morphed version of this model which matched the intraoperative data; the difference in both cases was under 0.5 mm (1 triangle of the model), although the deviation of these points from the average of points digitized over the attachment sites was somewhat larger.

**Conclusions / Discussion:** Our initial cadaver trials were for the most part successful. The surgeon was able to use the tensor to assess soft tissue balance but requested some improvements which have now been completed. In contrast to most existing soft tissue assessment devices, the measurements can be made after a preliminary tibial cut, but prior to any femoral bone cuts and with the patella in its normal anatomical position. Before being tested in the clinical setting, further attention must be paid to robustness, sterilizability, storage and manufacturing cost. We anticipate that this tool will be more versatile and easy to use than existing options and can be adapted to a wide variety of prostheses and surgical techniques. Although some tools exist to address ligament balancing, comprehensive soft tissue assessment is key to finding the optimal approach. The ligament models derived from the various insertion location techniques can be coupled with approaches such as [3] to assess and predict ligament balance. Furthermore, the force measurement capability of our new prototype will allow us to characterize the stiffness of the ligaments during knee flexion and predict joint loading more accurately.

**References:**

Introduction: Robotic guidance can improve bone-cutting precision and reduce surgical invasiveness in total knee arthroplasty (TKA). Potential benefits include improved patient outcomes, accelerated recovery times, fewer instrumentation sets, and simplified surgical procedures. Large robotic systems have been proposed as a solution, though these guides typically present a considerable departure form the standard technique [1]. Miniature robotic guide positioning devices are now available, though existing devices require a high degree of bone exposure and do not always permit the surgeon to control implant alignment precisely in all relevant planes [2]. In addition, none of the existing robots are connected to a universal open system for all implants, such as the Praxim Medivision Surgetics Station®. The objectives of this paper are therefore to report on (1) the development of a new universal compact bone-mounted robot for TKA that can be precisely positioned in all anatomic planes and requires minimal surgical exposure of the knee, and (2) to describe the preliminary results of the first series of experiments performed on saw-bones and cadavers.

Design and Methods: In order to minimise the size, weight, and number of motorised degrees of freedom (DOF) of the robot, we opted for a hybrid manual/motorised guide that is positioned in the frontal and axial planes with computer navigation. Sagittal plane guide positioning is precisely actuated with two motors that are arranged in parallel and are contained inside a single unit. Automating guide placement in the sagittal plane permits the ‘universal’ guide to be positioned for any size or geometry of TKA implant, thus permitting integration into any computer-assisted surgical protocol (CASP). In addition, the modular design permits the use of various tools such as milling cutters. There is no need to immobilise the leg to the operating table. Once the optimal implant position and soft tissue balancing is planned using BoneMorphing algorithms, the surgeon navigates the fixation of the robotic guide. Nominal varus/valgus and internal/external rotation alignment is first navigated ‘free-hand’. Fixation is attained with an arch that clamps to the medial and lateral aspects of the distal femur. The clamping pins are inserted just proximal to the distal cutting plane, so that they are nominally perpendicular to the femoral mechan-
ical axis and parallel to the transepicondylar axis. Frontal and rotational alignment is then more precisely ‘fine-tuned’ to a fraction of a degree under navigation by two adjustment screws on the arch. The surgeon also has the option to augment the fixation of the clamped arch by inserting additional screws through holes. The robot axes are then registered relative to the femoral reference frame, and the surgeon can cycle through each femoral cut by pressing the foot switch. The modular design of the guide attachment pieces permit the robot to be used as a saw-guide or mill-guide, depending on the options incorporated into the CASP. The specific order of the femoral cutting sequence is also tailored to the dedicated CASP of the implant. Before making each cut, the surgeon can visually and numerically verify the position of the guide-plane with respect to the planned cutting plane by using a planar probe. After making each cut, the cut surface on the bone can also be verified with the probe.

Results and Discussion: The system has been integrated into the Praxim Medivision Surgetics open platform surgical navigation station. Initial experiments to assess the proof-of-principle and the clinical feasibility of the robot were first preformed on sawbones, and then on cadaver specimens. The initial experiments on saw-bones demonstrated that the fixation arch could be navigated ‘free-hand’ and clamped within 5° degrees of the planned implant position in the frontal and axial planes. In all cases the final position of the robot could be ‘fine-tuned’ with the adjustment screws so that the final guide position was brought to <0.5° (below the resolution of the camera) of the desired position in both planes for all cases. The same positioning protocol used in the saw-bone tests was also used in the cadaver trials with similar results. From the cadaver experiments, we found that the usability, visibility and stability of the guide during cutting was generally very satisfactory. The navigation interface for clamping and adjusting the orientation of the arch is straightforward and quick, taking the surgeon approximately 2 minutes. In comparison to conventional ‘5-in-1’ and even ‘4-in-1’ saw-guides, visibility of the cutting progress is improved since there is only one saw-blade guide which is repositioned for each cut. A milling configuration was also sucessfully tested for uni-compartmental knee arthroplasty, by making a ~9cm incision and mounting the arch percutaneously.

Conclusions: As surgical robots become smaller and more dedicated, their architecture can be optimised to suite the application, so as to minimise the disturbance on surgical workflow and operating time. We feel that miniature robotic tools are an effective means of improving precision in knee replacement surgery.

References:
FREEHAND NAVIGATION CUTTING FOR TKR SURGERY WITHOUT JIGS: SIMULATION OF BONE SAW CUTTING

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Introduction: Traditional TKR is relatively complex involving numerous jigs with precise cuts and intricate soft tissue procedures. Whilst navigation provides more accuracy and fewer outliers, and minimally-invasive techniques strive for smaller incisions, both tend to involve more steps and instruments making them appear to have increased operating time and difficulty. We must harness CAOS to make TKR surgery easier, faster and cheaper as well as better! Even the most advanced CAOS systems today struggle to offer these benefits simultaneously. In a similar approach to Brisson et. al. [1], if complex cutting jigs were eliminated by navigating cutting instruments directly, then TKR surgery would be faster, cheaper and easier. However, such process must be represented (simulated) on a computer screen, providing the surgeon with real-time feedback and corrections for instrument alignment and cut accuracy. This requires three tasks: 1) Tracking: Bone and cutting instrument position and orientation update through navigation, 2) Cutting: Incremental removal of bone and update of the bone shape with saw motion and, 3) Rendering: Realistic 3D display with feedback and corrective action for the surgeon. Cutting and Rendering form the critical path in terms of computational speed. For pre-surgical planning and training of surgeons and residents, the system should operate on a PC where conventional TKR templating is carried out. The focus of this study was to develop novel bone cutting simulation routines to determine whether adequately fast bone removal for TKR could be implemented on a regular PC. We hypothesized that the sequence of tracking, cutting and rendering could be simulated computationally at a practical rate to possibly eliminate the need for cutting jigs, and facilitate future less invasive procedures.

Materials & Methods: A standalone application was developed in C/C++ on a Windows PC, with an oscillating bone saw model rendered into a 3D port. Patient-specific bones models were created from CT data, and rendered with the saw. Two approaches for simulating bone cutting were compared: Volumetrics, which is known to be slower to render than surfaces, yield themselves more easily to the incremental changes of shape. Position/orientation data of 4 (3 passive, 1 active) reference frames were polled from an NDI Polaris infra-red tracker driven by the same application. Data was recorded by the executing code, logging the times taken by Tracking, Cutting and Rendering. Time was averaged for the 3-step sequence repeated over 200 times saw
motion steps in the volumetric approach, representing start to finish of the same cut of the distal femur. These measurement runs were repeated 5 times to estimate scatter of the results. Cutting incrementally removed bone elements (voxels) which coincided with the saw cutting tip. Its computational time depended on the cutting tip size, so all the experiments were repeated with cutting tip lengths of 1, 5, 10, 15 and 20mm in turn. In the surface approach, the time was averaged for the 3-step sequence from start to finish of the cut over 10 incremental steps, and repeated 90 times. With hollow surface models, cutting removed the bone/saw intersection, and patched the bone according to the saw geometry. Almost the whole saw blade was here treated as an 80mm x 30mm x 1.5mm rectangular block cutting tip. Heuristics were then implemented in the software for a hybrid of volumetrics and surfaces.

Results: With the volumetric approach, tracking processes took 25±9ms to 35±9ms on average in all 25 trials. Cutting took only 0.42±0.08ms with the shortest cutting tip, up to 1.7±0.16ms with the longest. The Rendering processes took longest; lasting 108±9 ms each time. Overall system refresh rate was therefore 140ms (approx. 7Hz). With surfaces, tracking took 28.2ms for the 90 trials. Cutting (which included patching) and kept track of the “history” of the bone shape, took 672ms on average. The Rendering processes here took an average of only 15.8ms, and overall system refresh time was 716ms (1.4Hz). With heuristics utilizing a hybrid of surface and volumetrics, above 20Hz refresh rate was achieved.

Discussion & Conclusion: The navigation Tracking process was almost the same in both approaches, as expected. Although Rendering of surface models was about 7 times faster than volumetrics, their cutting routines being hundreds of times slower made the resulting surface approach refresh rate of 1.4Hz practically too slow. Neither was the 7Hz rate of the whole sequence with volumetrics fast enough on its own since >25Hz were needed for smooth refresh for human visual use. The volumetric cutting process itself however was inexpensive time-wise (<2ms) and kept accurate ‘history’ of the reshaping. It could be allowed to always run in the background along with navigation (<30ms). During cutting, the surgeon’s focus would shift from alignment of the cutting tool with a desired plane, to checking of the exact shape being cut. For alignment, volumetric rendering would not be mandatory for good feedback of tool and bone positions, and so rendering/display was reduced to about 15ms instead of 100ms with volumetrics. The heuristic deployed alternated between many frames of surface display, and less frequently frames of the new bone shape with volumetrics. Updates of >20Hz were achieved and only slight blinking occurred. Because the fast volumetric Cutting process remained active here in the background, if the user needed to focus on the bone shape being cut they could dynamically change into volumetric rendering mode at 7Hz refresh rate. Many variations were tested with the open code to optimize speed, quality and level of detail required during cutting. By using a faster PC with a high performance graphical card and/or hardware accelerated rendering and multi-thread processing, the target of 25Hz refresh rate is achievable. Therefore bone removal with a saw could be simulated in real time on a PC, moving us towards TKR without jigs and smaller incisions.

References:

COMPUTER-ASSISTED MINIMALLY INVASIVE CURETTAGE AND REINFORCEMENT OF FEMORAL HEAD OSTEO-NECROSIS WITH A NOVEL, EXPANDABLE BLADE TOOL

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Introduction: In order to halt progression to collapse and to accelerate the reparative process of the necrotic lesions in femoral head osteonecrosis, various joint preserving procedures have been performed. Core decompression with or without bone grafting is the most popular procedure in the early stages. This procedure is performed through the lateral subtrochanteric route which is comparatively less invasive, but it has a limitation in curetting a large lesion through a long narrow hole. It has been reported that 20–40% of hips treated with this procedure in the early stages resulted in collapse. We think that collapse may be prevented if the necrotic lesions are curetted thoroughly and the deficit filled with reinforcement materials such as hydroxyapatite ceramics. For minimally invasive curettage of necrotic lesions, we have developed a novel, expandable blade tool which can be introduced into the femoral head through the lateral subtrochanteric route under navigation guidance. In this study, we evaluated the feasibility, effectiveness and accuracy of this tool in comparison with the Cebotome®, a popular conventional bone cutter, with respect to curettage of necrotic lesions in a Sawbone® femoral head model. Moreover, we evaluated the compressive strength of the Sawbone femoral head after the inside of the femoral head had been curetted with this tool and filled with hydroxyapatite blocks.

Methods: Our novel, expandable blade tool has a mechanism by which a 14–20mm long metal blade housed in the tip of a long 10mm-diameter metal cylinder is made to protrude. The blade swings on a hinge and protrudes outwards from the cylinder to an angle of 60 degrees. This tool is designed to be used after boring a hole into the femoral head from the lateral subtrochanteric portion of the femur with a drill of the same diameter. As the cylinder spins at high speed, the blade protrudes gradually, cutting a cone shaped section of bone away. The feasibility, effectiveness and accuracy of this tool were evaluated in comparison with a Cebotome® (MicroAire Surgical Instruments LLC), a popular conventional bone cutter, using Sawbones® (Pacific Research Laboratories) femur models. A typical, extensive necrotic lesion of femoral head osteonecrosis was created virtually, and pre-operative planning to curette the target necrotic lesion with these surgical tools was carried out on the three-dimensional model on computer so that the necrotic lesion was curetted maximally with each tool. The whole procedure of curetting the femoral head was performed under a CT-based navigation system with an optical three-dimensional position sensor, OPTO-
TRAK® (NDI). First, a guide wire was inserted from the lateral subtrochanteric portion of the femur into the femoral head according to the pre-operative planning. After drilling with a 10mm-diameter drill over the guide wire to within 4mm of the articular surface of the femoral head, the inside of the femoral head was curetted with the expandable blade tool or with the Cebotome in line with the pre-operative planning. After curettage, CT scans of the Sawbone femur were carried out. The volume of curetted necrotic lesion and that of sacrificed normal area were measured from the CT images. The procedure time was also measured. The trials were repeated ten times for each surgical tool. Statistical analyses were performed using the Student’s t-test with a significance level of 0.05. After curettting with the expandable blade tool, the cavity in the femoral head was filled maximally and manually with blocks of hydroxyapatite ceramics $3.3 \times 3.3 \times 5$ mm in size (HA Block®, Pentax). Compressive strength of the femoral heads was measured at the weight-bearing portion with a strength testing system (ServoPulse®, Shimadzu). Five specimens each were tested of: intact Sawbone femur models, models that had been curetted only, and models that had been curetted and filled with the hydroxyapatite blocks.

**Results:** The volumes of curetted necrotic lesion were $10.9 \pm 1.2$ cm$^3$ (mean ± SD) with the expandable blade tool and $5.4 \pm 0.8$ cm$^3$ with the Cebotome, this difference was significant. The volumes of the sacrificed normal area were $3.8 \pm 1.1$ cm$^3$ with the expandable blade tool and $2.1 \pm 0.9$ cm$^3$ with the Cebotome, again this difference was significant. The procedure times taken for the curettage after drilling the hole were $1.9 \pm 0.4$ minutes with the expandable blade tool and $7.5 \pm 1.7$ minutes with the Cebotome, this difference was also significant. The positional error of actual curetted area compared with the planned curetting area was within 2mm with both the tools. The compressive strength of the femoral head was $47.2 \pm 0.1$ MPa for intact Sawbone models, $18.6 \pm 4.7$ MPa for models that had been curetted only, and $46.3 \pm 2.0$ MPa for models that had been curetted and filled with the hydroxyapatite blocks.

**Discussion:** The volume of the curetted necrotic lesion was significantly larger and the procedure time was significantly shorter with the expandable blade tool than with the Cebovote. It is suggested that this expandable blade tool is both feasible and more effective than the Cebovote. The volume of sacrificed normal area was significantly larger with the expandable blade tool than the Cebovote, however, the compressive strength test showed that the femoral head which was curetted with the expandable blade tool and filled with hydroxyapatite blocks had compressive strength comparable to that of the intact femoral head. In terms of safety, a positional error within 2mm is thought to be accurate enough for actual clinical use. With the expandable blade tool, only the bone on the side part of the tool can be cut away, therefore the risk of breaking through the surface of the femoral head is low. Moreover, because the diameter of the cylinder of this tool is the same as the drilled long hole, this tool remains stabilized when the cylinder is spinning at high speed.

**Conclusion:** Curettage of necrotic lesions of the femoral head using the novel, expandable blade tool is both feasible and more effective than the Cebovote conventional bone cutter. Moreover, usage of this tool under a surgical navigation system is accurate enough for actual clinical use. This surgical tool enables minimally invasive and effective curettage of femoral head osteonecrosis.
DO NAVIGATION SYSTEMS ALWAYS TELL THE TRUTH? A STUDY OF INTRA AND INTER-SYSTEM VARIABILITY IN NAVIGATED TOTAL KNEE ARTHROPLASTY

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Introduction: Modern instrumentation in total knee arthroplasty has provided excellent long term clinical results. However, radiological studies showed that even an experienced surgeon may have significant variability in terms of limb alignment and prosthesis [4]. Computer navigation has been shown to improve the consistency of the operative results [2,3]. Most of these studies are based on post-operative long leg films which in itself lends to errors like limb position and rotation variation [3]. While imaging with computed tomography will accurately reflect the true accuracy of these navigation systems, this is not possible intra-operatively. We performed a study to assess 1) the true accuracy of the navigation systems, 2) correlation within and 3) correlation between the navigation systems.

Materials and Methods: Six cadaveric knees were used for the study. Two different navigation systems from Brainlab (Munich, Germany) and Stryker-Leibinger (Freiburg, Germany) were utilized and the results validated against each other. Two pairs of registration were performed for each knee with the two systems in alternate sequence (ie Brainlab, Stryker, Brainlab and finally Stryker system). For consistency, one single surgeon who was experienced in knee navigation performed all the registrations. As far as possible, the same points, surface areas and vectors were selected for all the registrations. After registration, a fully navigated total knee arthroplasty was performed with the Brainlab system and the P.F.C Sigma Total Knee Prosthesis was inserted (Depuy, Leeds, UK). The final results were compared between the 2 systems again. The parameters recorded include the pre- and post-operative limb alignment, knee flexion and extension as well as prosthesis position in varus-valgus, flexion-extension and rotational alignments. The depth of resection for the femoral condyle and tibial plateau were also determined for each system and compared with the actual resected amount. The results were analysed with the correlation test to find the correlation within each system and between the 2 systems.

Results: Within each system and between the 2 systems, the values measured in varus-valgus plane were most consistent. The correlation co-efficients (r) were consistently above 0.85. These include the pre-op and post-op limb alignment,
The femoral and tibial prosthesis angle relative to the limb mechanical axis. Measurements taken in the sagittal plane included the sagittal mechanical axis at full clinical extension, femoral component flexion relative to mechanical axis and posterior tibial slope. These values tend to be less consistent with correlation coefficient between 0.6 and 0.8. The correlation for femoral rotation was fair at best for registration based on the AP axis (r=0.4) and significantly poorer if based on epicondylar axis (r=0.08). Only the Brainlab system is capable of measuring the posterior condylar axis which is the most consistent (r=0.83). Similarly, the tibial rotation had significant lower correlation and even higher variation between the systems (r=0.04). Each system also measured the amount of bony resection slightly differently and this can vary up to 5mm.

**Conclusion:** Navigation systems are helpful in certain aspects of total knee arthroplasty. It has been shown that the process of registration is user dependent and can be a significant source of error [1]. There is good correlation within and between the 2 navigation systems for measurements in the coronal (varus-valgus) plane. The correlation in the sagittal plane tends to be slightly inferior. However, both systems are inconsistent for the femoral and tibial component rotation. Femoral component registration is most consistent with the posterior condylar axis, inferior with the AP axis and poorest with the epicondylar axis. This was understandable as the epicondyles were most difficult to define accurately. Unfortunately, the posterior condylar axis also bears little correlation with the patella tracking. Furthermore, tibial component rotation is even more inconsistent as it is difficult to define the medial third of the tibial tubercle. Given that tibio-femoral components malrotation can be a major cause of wear, patellar instability and post-operative pain after a total knee arthroplasty, this problem represents an unresolved issue in the total knee navigation systems. Even simple parameters like the amount of bony resection can vary considerably between the systems depending on their software algorithms. Navigation surgeons should realize the limitation of each system before relying on them completely in the clinical practice.

**References:**

EFFECT OF ONE AND TWO PIN ANCHORING SYSTEMS ON TRACKER STABILITY DURING TKA COMPUTER NAVIGATION

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Introduction: The use of computer navigation systems for total knee arthroplasty is becoming more popular. One issue not often addressed is the stability of the anchoring method used for attachment of the active or passive markers or trackers to the femur and tibia. This study investigated the stability of one and two pin anchoring systems for use with a commercial navigation system (Stryker Navigation, Kalamazoo, MI). Accuracy measures of infrared tracking systems do not always include the errors associated with any movement of the anchored trackers during the operative procedure and if a more rigid anchoring system can decrease the variability measures than this would be advantageous.

Materials and Methods: Five cadaveric lower extremities were utilized to test four different anchoring systems: a self locking one pin and a clamped two pin configuration (Hoffman external fixator, Stryker Inc, Allendale, NJ). Each anchoring system was tested with two different sized pins (4.0mm and 5.0mm for single locking pin and 3.0mm and 5.0mm for double pin Hoffman configuration). Each anchoring device was tested with both a metaphyseal and diaphyseal attachment position on the femur of each cadaveric specimen. A computer navigation system (Stryker Navigation, Kalamazoo, MI) was utilized for the study. Each lower extremity was attached to a universal joint and clamped to simulate a hip joint and then the registration process of the computer assisted navigation system was carried out. A 3.5mm unicortical screw was then placed to serve as a verification point on the distal femur. The tibial tracker was placed and left alone for the study. The femoral tracker had each of the four different anchoring systems placed both in the metaphyseal and diaphyseal regions for comparison. Incremental loads from 0 to 65 N were applied to each tracker anchoring device in line with the femoral shaft as well as perpendicular. A torsional load was also applied from 0 to 1 Nm in five increments. While each load was applied the change in distance to the verification point was recorded using the navigation system’s pointing device. The change in the clinical rotations was also recorded for each load applied. After each the incremental loads were applied the verification point was checked on final time to record any permanent change in the tracker position. The changes in the verification point distances as well as the change...
Results: With the 65N of load in line with the shaft of the femur the average distance change to the verification point was a maximum of 4.3 ± 1.6 mm and occurred with the 4.0mm single locking pin with a metaphyseal attachment point. With a 65N load perpendicular to the femoral shaft the maximum change was again with a 4.0mm self locking pin with a metaphyseal attachment and was 1.3 ± 0.8 mm. With regards to clinical rotations varus/valgus angles changed up to 2.5 ± 1.9 degrees, flexion changed 4.8 ± 2.0 degrees, and the rotation angles changed 4.1 ± 1.9 degrees with linear load applied to the 4.0mm pins with a metaphyseal attachment. When a load of 25N or more was applied to the attachment device the two pin configuration with 3.0mm and 5mm Steinman pins proved to provide significantly less variability in the verification point distance when compared to either single pin devices (p<0.05). Neither of the two pin configurations was statistically different when compared to each other or to a metaphyseal and diaphyseal anchoring point. With regards to varying torque only the 4mm self locking pin in a metaphyseal anchoring location was significantly more variable (p<0.05) from the other fixation types with a 2.1 ± 0.5 mm difference from the verification point on average under maximum torsion applied. When a torsional load was applied to the tracker the locking mechanism to the fixation pin failed in on several occasions between an applied torque of 0.5 and 1.0 Nm.

Conclusions: This study reports sources of errors in lower extremity alignment that may effect intraoperative measurements due to the quality of the fixation method for anchoring the trackers or markers to the femur and tibia. These sources of errors are not usually taken into consideration by manufacturers of navigation systems. It is apparent that the two pin fixation method along with a stronger tracker/marker coupling system can significantly decrease the variability in alignment and rotational measures. Although errors associated with infrared navigation systems is reported to be clinically negligible, the cumulative errors associated with the process must be taken into account. This study shows that significant errors may arise intraoperatively associated with the method of bony attachment utilized for rigid body detection. All surgeons should take careful measures to make sure that the markers or trakers once anchored to the bone are protected from outside forces to minimize these associated errors.

References:

THE RELIABILITY OF ANATOMIC LANDMARKS FOR DETERMINING FEMORAL IMPLANT ROTATION IN TKA SURGERY: IMPLICATIONS FOR CAOS TKA

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Introduction: CAOS TKA systems are currently being introduced to increase the accuracy and reliability with which TKR are performed. All of these systems align TKR implants and the affected extremity in the frontal and sagittal planes using the mechanical axes. Although the goal of all of these systems is to place the femoral components parallel to the epicondylar axis, the methods used by the various systems to achieve this goal vary. The purpose of this study was to determine the reliability of various anatomic landmarks for aligning the femoral TKR component parallel with the epicondylar axis.

Methods: CT scans were obtained on forty patients with osteoarthritis scheduled to undergo primary TKR. The following landmarks were identified on CT cuts made at three different depths from the distal joint line (8mm, 10mm, 12mm): 1) posterior condylar line; 2) anterior-posterior inter-condylar line(Whitesides’ Line); and 3) epicondylar line. The relationship of these lines was measured at each depth of CT cut. CT scans were obtained on all patients post-operatively. In twenty knees, the posterior-femoral condylar axis was used to establish rotation of the femoral component. The anterior-posterior cutting block was placed in 3 degree of external rotation relative to the posterior condylar axis. In twenty knees, the patellar groove (Whitesides’ line) was used to establish rotation of the femoral component. The TKR’s were performed using CAOS navigation techniques. The posterior condylar axis and epicondylar axis were determined intra-operatively using surface registration techniques. The rotation of the femoral component relative to the epicondylar axis was measured on the post-operative CT scans for all forty patients. The measurements were made by an observer unaware of the surgical technique used to determine rotation.

Results: The mean relationship of the posterior condylar line to the epicondylar line on the pre-surgical CT scans was 4.69° internal rotation (2° external-12° internal, SD 2.87). Mean relationship of Whitesides line to the epicondylar line was 0.07° internal rotation (9° external-11° internal, SD 3.62). These relationships changed substantially with the depth of the CT cuts. These changes were due exclusively to the change in locations of the epicondylar axis with depth of CT cut.
The variation between the posterior condylar axis measured on pre-operative CT scans and measured intra-operatively using surface registration techniques was 2 degrees (3 degrees internal-4 degrees external, SD 3). The variation between the epicondylar axis measured on pre-operative CT scans and measured intra-operatively using surface registration techniques was 3 degrees (4 degrees internal-4 degrees external, SD 3).

The mean relationship of the femoral component to the epicondylar line in the twenty TKR’s performed using the posterior condylar axis to establish femoral rotation was 1.5 degrees internal rotation (0 degrees external-5 degrees internal, SD 1.85). The mean relationship of the femoral component to the epicondylar line in the twenty TKR’s performed using the patellar groove was 0.5 degrees internal rotation (3 degrees external-2 degrees internal, SD 1.2).

Conclusions: The patellar groove (Whitesides’ line) gives a closer approximation to the epicondylar axis than the posterior condylar line in patients with osteoarthritis of the knee undergoing TKR. However, the relationships vary widely for both measurements. Whitesides’ line and the posterior condylar axis can be identified reliably on CT scans and do not change orientation, regardless of the depth of the cuts. The epicondylar line can be identified reliably on CT scans but changes orientation with the depth of the cut.

There was substantial variation between the posterior condylar line measurements made on the pre-operative CT scans and the measurements made intra-operatively using surface registration techniques. The was even greater variation between the epicondylar line measurements made on the pre-operative CT scans and the measurements made intra-operatively using surface registration techniques. It appeared difficult to reproducibly palpate the most posterior points of the posterior condyles using surface registration techniques. Moreover, it was difficult to precisely and reproducibly locate the epicondyles using surface registration techniques.

Femoral components aligned in rotation using the posterior condylar axis tend to be in internal rotation relative to the epicondylar axis. This occurs even when a conscious attempt is made to externally rotate the cutting block relative to posterior condylar axis! This internal rotation appears to occur for 2 reasons: 1) the posterior condylar line is relatively internally rotated (ave. 4.69 degrees) relative to the epicondylar axis; and 2) the posterior extensions of the positioning guide tend to place the device in internal rotation relative to the posterior condyles (especially if the femoral resection is performed before the tibial resection).

Femoral components aligned in rotation using the patellar groove are well aligned with the epicondylar axis(0.5 degrees internal rotation). This accuracy is achieved as the result of: 1) the reproducibility with which the patellar groove can be identified intra-operatively; 2) the use of a rotation guide that does not have posterior condylar extensions. Moreover, the rotational alignment achieved using the epicondylar axis is much more reliable and reproducible than that achieved using the posterior epicondylar line.
CAS TKR techniques should use the patellar groove (Whitesides’ line) to orient the femoral component in rotation. On average, the implant will be parallel to the epicondylar axis, regardless of the extent of distal femoral resection. However, there is likely to be some variation in the relationship of implants to this axis. However, this variation will be less than that which will occur if the posterior-condylar line is used to establish rotation.

References:

THE INTER-OPERATIVE ACCURACY OF THE TRANS EPICONDYLAR AXIS USING COMPUTER ASSISTED SURGERY

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Introduction: Several studies have shown that Computer assisted knee replacement achieves better coronal alignment than when done with conventional instruments. It is more difficult however to demonstrate accurate rotational alignment. Most systems allow rotation of the femoral component to be based on the trans epicondylar axis or the posterior condylar axis. While cadaver and CT studies have demonstrated accurate identification of the trans epicondylar axis (2, 3, and 4) it is more difficult to measure this in the operating theatre. We have performed a clinical study to demonstrate the reliability of reproducing the trans epicondylar axis inter operatively.

Methods: 20 patients had a Total Knee Replacement performed by a single surgeon with 3 years experience with IGS. A combination of PFC (Depuy) and NexGen (Zimmer) knees were implanted using the Vector Vision software (BrainLab). The trans epicondylar axis was used for operative navigation for femoral rotation and the difference between it and the posterior condylar axis noted. At numerous time points throughout the surgery the lateral and medial epicondyle points were re-acquired and stored. A program was written to analyse the data and to see if the axis was reproducible and to examine the maximal error in rotation.

Results: For all cases the standard transepicondylar axis used for operative cases was externally rotated compared to the posterior condylar axis by an average of 4.1° (range 1.0° - 8.8°). The re-acquired medial and lateral epicondylar points were then analysed to provide a maximum rotation error compared to the chosen standard trans epicondylar axis and to the posterior condylar axis. Taking the extreme values of the acquired points there was a variation in rotation for each patient, the minimum being 3.0° and the maximum 11.2°.

When the re-acquired points were averaged and a new epicondylar axis was calculated this reduced the range to a maximum of 1.8°.

Conclusion: Determination of femoral rotation inter-operatively can be based on a number of factors: the transepicondylar axis, the posterior condylar axis, the Whiteside line or on a balanced resection gap from the tibial cut surface. It has been demonstrated in this study that it can be difficult to reproduce the transepicondylar axis as accurately as the surgeon would wish and this has implications for image
guided knee surgery, especially with minimally invasive surgery potentially reducing the exposure. The widest variation occurred in an obese patient where it was difficult to localise the epicondyles. It may be more accurate to acquire a cloud of points and a best fit for the trans epicondylar axis then calculated as this may be more reproducible.

References:

VARIABILITY OF DIGITAL X-RAY MEASUREMENT FROM CT MEASUREMENT OF MECHANICAL AXIS OF TOTAL KNEE ARTHROPLASTY

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Introduction: Improved and consistent accuracy of implant position and limb alignment is the goal of computer assisted total knee arthroplasty. Less than accurate placement has been shown to have an increased failure rate [3]. Measurement of this accuracy has been controversial and some methods utilized are likely less accurate than the navigation system itself. Digital x-ray is the new emerging standard of technology. With this technique measurement software is included in the program and makes the calculations of angles to the nearest tenth of a degree. This is felt to be an improvement over use of standard x-ray and goniometer measurements.

In order to use this system routinely for documentation of accuracy this validation study was instituted. Similar to previous studies CT data was considered the “gold standard” for accuracy [1] Variability from this standard was measured and documented. Statistical evaluations were applied to the variability between the two systems of measurement.

Materials and Methods: This study was conducted in a retrospective fashion with approval of the Investigational Review Board. All patients signed a consent drafted for this study.

95 total knee arthroplasties in 78 patients had full lower extremity spiral CT scans and standing AP and lateral films taken post-operatively. The x-rays were done using the Kodak Direct View CR 900 system. Long leg alignment films are created in the Kodak system by placing four large cassettes (14”x17”) horizontally and “stitching” the images together digitally. This allows four very high resolution individual images as well as the long leg image. Many tools are available to manipulate these digital images as part of the Kodak CR 900 system. Included are magnification, distance and angle calculations as well as contrast. Using these tools even heavy patients that would have been nearly impossible in the past can be studied.

The angle calculations were done on a diagnostic workstation with a resolution of 2791x1605. This resolution allows calculation of angles to the nearest tenth of a degree. With contrast control even heavy patients that would have been difficult to measure with routine films could be accurately evaluated. All films were evaluated
and angles recorded independently by a research assistant then rechecked by the senior author. Both the assistant and the senior author were blinded to the CT data results.

The CT scans were performed on a Picker PQS spiral CT scanner with an Image size of 480 and Index of 10 mm through the entire leg, 5 mm through the knee. Thickness was 10 mm through the entire leg and 5 mm thickness taken through the knee. Patients were oriented feet first supine, with the feet taped together to decrease motion. A small posterior wedge was used for patient comfort. The pilot length was set at 500. Three pilots were necessary to scan the entire leg.

Radiation exposure was studied for the CT scans with a Thermo Luminescent Dosimetry System (LDS) for the first two of the study patients. The samples were studied at K and S Associates Inc., an accredited dosimeter calibration laboratory. The results revealed minimal exposure to the x-ray in both study and sensitive areas (heart). 0.0 cGy observed at the heart and 3.4 to 3.5 cGy in the pelvis area and 1.9 and 3.2 in the knee.

Images were sent from the Picker scanner in Dicom format to the Eclipse treatment planning station. The Eclipse Medical System by Varian is a very robust program that is used primarily in the planning of radiation treatment of cancer patients. This provides a very accurate system for measurement and manipulation of all 3 dimensional data in all planes. A three dimensional image is then created inside the Eclipse System. Using the plane of the CT scan a line perpendicular to the plane can be formed through the center of the knee. With the CT image magnified and the rotation of the limb corrected (using the posterior implant as the guide for rotation) distances could be measured for the centers of the ankle and hip relative to the knee center line in all three axis. The rotational correction isolated the variation in position to a varus valgus and flexion extension calculations. The measuring tool in the CT software was used to quantify the distances on the x and y axis on the ankle and hip cross-sections.

Knowing the distance from the center of the knee to the hip and the varus and flexion coordinate variations of the other two centers (ankle and hip), a trigonometric formula for determining the varus angle for the hip to the knee was calculated. The formula is ATAN2 (a,b)x180/Pi. In addition a flexion angle was determined using the same formula. In a similar fashion the varus angle from the knee to the ankle was determined. The sum the hip varus angle and the ankle varus angle is the varus angle of the knee. The sum of the flexion angles of the hip-knee and knee-ankle is the flexion contracture. If the varus angle is a negative it is reported as valgus and a negative flexion angle is hyperextension.

All radiographic data was compared to the CT data and variations were recorded. All degree calculations were rounded to the nearest tenth of a degree. No rounding of the CT calculations was allowed until the final calculation. Final variations of the measurements were recorded in tenths of a degree.

**Discussion:** Both CT and x-ray data had wide variation Mechanical axis on the x-ray was from -7 degrees (valgus) to 7.5 degrees (varus). The CT data was from -4.5 degrees (valgus) to 9 degrees (varus). CT data and X-ray data did not have a close
correlation. The mean of CT vs X-ray revealed a .42 degree shift of mechanical axis, the CT reporting a greater varus measurement. The significance of this variation is just below the 95% confidence level at 0.06. Individual variation was from 0-8 degrees with a mean of 2.2 degrees variation. This means that a measurement from an x-ray could be between 3.93 degrees less (valgus) and 4.77 degrees greater (varus) than the CT measurement (a spread of 8.7 degrees) this is not a very good agreement when studies distinguish alignment in 0-1, 2-3, and >4 degrees routinely [4].

**Conclusion:** This method of measurement of CT data has not been previously described but follows normal trigonometry methods that are well accepted. The differences in standing weight bearing and non-weight bearing may have an influence but the exact degree and amount is unknown. This variability of measurement between CT and X-ray calculations creates concern in how we measure the effect of improvements in alignment with computer assisted techniques. If the standing x-ray measurement technique is only accurate to a 8.7 degree range with a 95% confidence level and the data may need to be shifted .42 degrees further varus, then reporting results of standing x-ray in three groups (0-2 degrees, 3-4 degrees and greater than 4 degrees) may need to take this inherent measurement variability into account or demonstrate that the measurement technique used does not have this variability. This is not the first time significant discrepancy in measurements of total knee arthroplasty alignment has been reported [2]. At this time we now have such accurate navigation systems that further study needs to be done to improve and document accuracy of the measurement of results.

**References:**

COMPUTER ASSISTED GAP EQUALIZATION (CAGE) IN TOTAL KNEE ARTHROPLASTY

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Introduction: Malalignment and ligament imbalance in total knee arthroplasty (TKA) produce unequal loads on the medial and lateral tibial plateaus increasing wear of the components¹,³. A computer assisted gap equalization (CAGE) technique was developed using a knee balancing device (Stryker Xcelerate knee balancer, Stryker Howmedica Osteonics, Allendale, NJ) adapted with load cells and computer software enabling it to quantitatively measure soft tissue tension and angular alignment of the flexion and extension gaps. This computer assisted technique of knee balancing was compared to the conventional measured resection technique.

Methods: TKAs were performed using the posterior stabilized Scorpio knee system (Stryker Osteonics-Howmedica, Canada) on eight pairs of fresh-frozen cadaveric knees. Each side of the pair was randomized into one of two groups: control (measured resection technique) or CAGE. In the control specimens, bone was resected using the measured resection technique. Femoral rotation was determined using the epicondylar axis and soft tissue balancing was performed qualitatively. In the contralateral specimens (CAGE group), the gap resection technique was used with the CAGE device. Distal femoral and proximal tibial resections were performed first. With the knee in extension, soft tissues were tensioned and balanced quantitatively using CAGE. The knee was brought to 90° of flexion, the soft tissues were re-tensioned with CAGE and the posterior femoral resection was performed. Residual bone resections were made as necessary to create equally sized flexion and extension gaps under an equal soft tissue tension. The components were cemented. A posterior stabilized polyethylene tibial load transducer² that measured medial and lateral compartment loads acted as the tibial insert. The patellae were not resurfaced.

Outcomes assessment consisted of two parts: 1) Pre-component insertion balance: following final bone resections and soft tissue balancing, flexion and extension gap angular alignment and load symmetry were measured in both groups. 2) Post-component insertion: once components were cemented, a knee simulator applied loads to the muscles (150 N quadriceps, 60 N hamstrings) and the tibial load transducer measured medial and lateral compartment forces at five flexion angles (0°, 30°, 45°, 60°, 90°) to determine joint balance.
**Results:** 1) Pre-component insertion: Assessment of the angular alignment of the flexion and extension gaps showed a trend towards improvement in the CAGE group, but the difference between groups was not statistically significant (flexion p = 0.07, extension p = 0.27). There was a statistically significant difference (p = 0.02) in soft tissue tension symmetry between the flexion and extension gaps in the control group. In the CAGE group, this difference was not significant (p = 0.3) suggesting that gap soft tissue tension was better balanced than in the control group. 2) Post-component insertion: There was no significant difference in compartment load balance between the two groups at any flexion angle (two-way repeated measures ANOVA). Average lateral loads were higher than medial loads at all angles of flexion in both groups and showed statistical significance at 0° (p = 0.02) and 30° (p = 0.03) of flexion. Medial and lateral loads at 0° of flexion were significantly (p < 0.001) higher in both groups compared to the other angles of flexion.

**Conclusions:** CAGE improved gap alignment by increasing the accuracy of soft tissue balancing through real-time quantitative feedback, achieving an optimal posterior femoral condyle resection under soft tissue tension and providing a quantitative assessment of gap loads guiding residual bone resections.

Improved gap balance using CAGE did not translate into improved joint balance post-component insertion. A similar result has been shown clinically. Consistently higher lateral compartment loads may have resulted from a malrotated tibial component. Improved methods of determining tibial rotation or a rotating tibial bearing may achieve better results. Tension in the posterior capsule increases as the capsule becomes draped over the posterior condyles in full extension accounting for higher loads seen at 0° of flexion. Ideally, this should be accounted for when the gap loads are balanced prior to cementing of components. Finally, an uneven cement mantle and component design may account for a change in angular alignment.

CAGE improves knee balance pre-component insertion. Final knee balance remains unchanged. Further work is needed to translate the improved surgical accuracy into improved balance following component insertion.

**References:**

CAS-TKA REDUCES THE OCCURRENCE OF FUNCTIONAL OUTLIERS

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Introduction: The most consistently reported benefit of performing TKA using navigation technologies has been the reduction in limb and component alignment outside the commonly accepted range of three degrees and have a substantially larger proportion of implant alignment parameters within this accepted range. This improvement in the consistency with which limbs and implants are aligned has been associated with a reduced need for extensive soft tissue balancing. However, this improvement in alignment has not been shown to have an effect on the various measurements of clinical outcome. The purpose of this study was to compare the early functional outcomes of a group of patients who had undergone TKA with manual instrumentation with the early functional outcomes of a group of patients who had undergone TKA with navigation guided instrumentation.

Methods: Group I consisted of 60 consecutive patients who underwent cruciate retaining primary TKA with manual instrumentation. Group II consisted of 60 consecutive patients who underwent cruciate retaining primary TKA with navigation guided instrumentation. The two groups were similar with regard to diagnosis (100% osteoarthritis), age (average 67), sex (61% female) and size (average BMI 29). All patients followed the same pre- and post-operative treatment protocol. All patients were part of an IRB approved prospective study. Minimum follow-up was one year. Exams were performed by an observer unaware of the type of instrumentation used to insert the implants at 4 weeks, 3 months, 6 months and one year. Data were collected using the Northwestern Joint Reconstruction and Implant Service Registry, which includes: 1) SF 36, 2) WOMAC, and 3) The Knee Society Rating System (KSS).

Results: The average scores of the SF-36 and WOMAC were similar for the two groups. However, fewer patients in Group II reported visual analog pain scores greater than 40 at 6 weeks, 3 months and six months. At 12 months, the pain scores of the two groups were similar. The average Knee Society Scores for the two groups were similar at each reporting period. However, fewer patients in Group II had KSS scores less than 70 at 3 months, 80 at 6 months, and 90 at one year, than those in Group I. The average range of motion in Group II was greater by 8 degrees at 4 weeks and 3 months, but equal to the average range of motion in Group I at 6 and 12 months. However, the number of patients with less than 90 degrees of motion at each follow-up period was less in Group II than in Group I at each follow-up period. There were
fewer superficial wound infections in Group II than in Group I. The incidence of all other complications was the same for both groups. No complications specifically related to either the manual or navigation instrumentation techniques occurred.

**Conclusions:** The results of TKA performed using manual instrumentation have been reported by many investigators to be excellent for a very large proportion of patients. It has, therefore, been difficult to conceive in what ways computer assisted TKA's could improve these functional outcomes. The purpose of this study was to examine the impact, if any, of computer assisted TKA on the incidence of functional outliers. Although average functional outcomes were similar for the two groups, the results of this study indicate a consistent reduction in outliers in most measured parameters of functional outcomes. Peri-operative management programs for the two groups were identical. In particular, the guidelines for administering pain medication and providing physical therapy were similar for the two groups. The results of this study are parallel to the radiographic results comparing TKA's performed with manual and computer assisted instrumentation. In those studies, a reduction in outliers was consistently associated with the use of computer assisted techniques, regardless of the implant system used. Although ours was a prospectively performed study, its findings would have been strengthened had the patients been randomly assigned to one of the two study groups. Nevertheless, this study emphasizes the importance of examining the incidence of outlier functional results in the evaluation of computer assisted TKA surgery. This study indicates that the consistency of alignment achieved with computer assisted surgical techniques results in a corresponding consistency in clinical functional outcomes.

**References:**

COMPUTER ASSISTED REVISION TOTAL KNEE ARTHROPLASTY: A COMPARISON WITH THE CONVENTIONAL TECHNIQUE

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Introduction: Total knee arthroplasty (TKA) has been established as reliable treatment for pain relief and restoration of joint function in arthritic knees. In the last years the number of revision TKA increased continuously and has meanwhile reached an overall rate of up to 10 percent of all TKAs. A common cause for revision TKA is aseptic loosening of the tibial component. On the other side, knee instability after primary TKA has been discussed as an important factor for TKA-failure. This instability might be due to inequality of flexion and extension gap, inadequate correction of sagittal plane deformities or medial/lateral compartment disbalance. The primary challenge in revision TKA remains the restoration of an adequate joint line and joint stability. However, this might be complicated by a loss of bone stock and difficulties in identifying relevant bony landmarks [2]. Recently navigation systems have been developed to increase the accuracy of prosthesis implantation and component alignment in TKA. To our knowledge, there are no data about computer assisted revision TKA available in the literature. The aim of this study was to compare the radiological results of computer assisted revision TKA with the conventional technique.

Material and Methods: In a prospective study 50 patients were operated on for revision TKA either using a CT-free navigation system (n=25) or the conventional technique (n=25). Patients were assigned to these groups by the day of operation. Patients in both groups were comparable regarding age, gender and preoperative leg deformity and had comparable reasons for revision surgery. All patients were operated by one team which had already performed more than 120 computer assisted primary TKAs before starting the study. In both groups the modular DePuy P.F.C-Sigma™ / TC-3 (Warsaw, USA) knee system was used. In the study group, revision TKA was performed using the CT-free version of BrainLAB’s (Munich, Germany) VectorVision-System®. At the beginning of the operation, a reference frame was attached to the distal femur and the proximal tibia respectively with a bicortical pin, instead of intramedullary femoral reaming. The centre of the hip was determined by a pivoting algorithm. Additional information was given to the system by a surface data acquisition. Surface points were acquired with the old prosthesis in place. In the next step, implant analysis was performed by controlling the stability of the knee in extension, midflexion and flexion, further, the component-angles were documented.
After removal of the implants in place, the tibial resection was performed with a minimal bone resection. In cases which needed augmentations, a parallel cut was performed on the desired level. Then the distal femoral resection was performed with minimal bone resection. Ligament balancing was performed until a rectangular extension gap was achieved. Afterwards the rotational alignment of the femoral component was adjusted by using the gap technique provided by the system. With the information of the gap configuration and the planned joint line a calculation of necessary augmentation can be made. The axial limb alignment was evaluated on standardized pre- and postoperative full length weight-bearing radiographs. For determination of the joint line the method of Figgie et al. [1] was used.

**Results:** *Mechanical Leg Axis:* In the computer assisted group, the average deviation from the neutral leg axis was 0.78 degree (±1.1°, range: 4° valgus to 4° varus), while in the conventional group, it was 1.2 degrees (±1.7° range: 6° valgus to 5° varus) (p<0.05). 92 percent (23/25) of revision cases had a leg axis within a range of ±3 degrees in the computer assisted group compared with 76 percent (19/25) in the conventional group. In the computer assisted group, outliers exceeding ±3 degrees of varus / valgus deviation were seen in 2 cases (maximum 4°) compared with 6 cases in the conventional group (maximum 6°) (figure 5).

Component Alignment: For the femoral component, all patients in the computer assisted group (25/25) had a varus / valgus alignment within a range of ±3 degrees compared with 84 percent (21/25) in the conventional group. The mean deviation from the neutral leg axis was 1.2 degree (±1.4°, range 3° valgus to 2° varus) in the computer assisted group and 2.1 degrees (±1.6° range: 3° valgus to 5° varus) in the control group (p<0.05). For the tibial component, all patients in the computer assisted group had a varus / valgus alignment within a range of ±3 degrees compared with 94 percent (24/25) in the conventional group. The mean deviation from the neutral position was 1.1 degree ±1.2 degree (computer assisted) and 1.4 degree ±1.5 degree (conventional) (p>0.05).

**Joint line deviation:** 76 percent of cases (19/25) in the computer assisted group and 56 percent of cases (14/25) the conventional group had an elevation of the joint line of less than 4 mm. In 6 cases (24 percent) in the computer assisted and in 9 cases (36 percent) in the conventional group an elevation between 4 and 8 mm was found. While no patient in the computer assisted group showed an elevation of more than 8 mm, this was observed in 2 cases (8 percent) in the conventional group.

**Discussion:** The number of patients, who need revision total knee arthroplasty, has been increasing over the last years. A primary goal of revision TKA is to re-establish the correct joint line and axial alignment. For revision TKA no data exist about this range of tolerable leg alignment, however, one can assume that a comparable axial alignment of 3 degrees varus / valgus deviation also in revision TKA is associated with superior long term results. In the conventional technique intra- or extramedullary rods are used for orientation of prosthesis components in primary TKA. However, the use of these instruments might be associated with potential errors resulting from variations in anatomical shape or visual misjudgement. We found a significantly better postoperative limb axis for navigation-based revision TKA compared with the conventional technique.
Principles of successful revision TKA include restoration of the joint line to a normal position. Several studies focussed on defining useful landmarks and relationships. Elevation of the joint line more than 8 mm has been associated with an inferior patients outcome [3]. We observed a tendency towards a better restoration of the joint line (less than 4 mm) in the computer assisted group (76%) compared the conventional group (56%). In this study we used the CT-free version of BrainLAB’s (Munich-Heimstetten, Germany) VectorVision-System®, which has been designed for primary TKA. So far, measurement of distances between anatomic landmarks and the joint line can be only performed indirectly, however, a specific revision module is under development.

**Conclusion:** The use of a CT-free navigation system provides a significant improvement of prosthesis alignment in revision TKA. Alignment, range of motion and ligament situation as well as each step of bone resection can be verified and documented during surgery. Particularly, information about the size of the flexion and extension gap and the ligament situation is very useful during surgery. In future, the development of specific revision modules should offer the opportunity of exact intra-operative joint line calculation and planning of step-augmentation.

**References:**

CT-FREE VECTORVISION®
SYSTEM FOR TOTAL KNEE
ARTHROPLASTY – PROSPECTIVE
COMPARATIVE STUDY OF
NAVIGATED AND
CONVENTIONAL IMPLANTATION

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Introduction: The survival rate of total knee arthroplasties (TKA) will be influenced by the accuracy of the operative technique, especially accuracy of reconstructed mechanical axis (coronal plane), tibial and femoral component rotation (axial plane), tibial slope and extension/flexion of femoral component (sagittal plane). Also an optimal ligament balancing is crucial for a good clinical result and a minimal polyethylene wear.

Initial comparative studies [2,4] described an increased operative accuracy by using a navigation system for total knee replacement (TKR). After 20 CT-free navigated TKA a prospective comparative study of navigated and conventional implantation technique was initiated. Therefore the initial learning curve for the new surgery technique was finished.

Materials and Methods: The VectorVision® navigation system (BrainLAB, Germany) [1] consists of a workstation and an infrared light emitting camera. For detecting movements of the leg an infrared light reflecting reference array is fixed to tibia and femur. The pointer and cutting block adapter are assembled with passive fiducial markers for reflecting the infrared light to the camera. The work flow can be passed through by using the sterile draped touch screen.

For varus deformities and slightly valgus deformities the anterior-medial surgical approach to the knee joint was used and for severe valgus deformities the anterior-lateral approach was followed. Patient registration is performed by definition of anatomical landmarks (e.g. center of talus and femoral head, proximal tibial and distal femoral mechanical axis point) and an extended surface matching. With the information from the registration procedure a bone model of tibia and femur can be calculated based on saved CT-data sets of 50 real knee joints. Subsequently an accuracy check of adapted models must be performed. Planning procedure of component size and position can be undertaken intraoperatively. For navigation of tibial bone cut
The cutting block adapter is placed into the saw-slot. The cutting block is positioned according to the information presented on the touch screen of the navigation system.

After the bone cut has been completed an accuracy check of the tibial bone cut with the cutting block adapter can be performed. Information about deviation for varus/valgus, slope and resection hight will be given. In the same manner the femoral bone cuts can be performed computer-assisted.

The rotation of femoral component is defined by the ligament balancing modul. After the tibial and distal femoral bone cut and a soft tissue release for a balanced medial-lateral ligament tension in extension the extension gap between tibia and femur is measured. Subsequently the four in one femoral cutting block is positioned in such a manner that the same gap in flexion as in extension is achieved, as well as a well balanced medial-lateral ligament tension in 90 degrees of flexion. Ligament balancing in 90 degrees of flexion can be influenced by varying the rotation of femoral component. By using the ligament tensor the gap and the ligament tension for extension and flexion can be measured. In addition, the rotation of femoral component according to the posterior condylar line and the epicondylar axis can be checked. With the provisional components a last computer-assisted check of reconstructed mechanical axis, range of motion and ligament balancing can be performed before implantation of original prosthesis components.

Conventional TKR was undertaken in accordance with the official surgical technique instructions of the prosthesis producer (Zimmer Inc., USA). The Multi-Reference® 4-in-1 femoral instrumentation was employed.

200 patients – divided by a random generator into two equal groups - underwent a total knee arthroplasty. In one group the TKA was carried out computer-assisted while the other group was operated using the conventional technique. All patients had a primary osteoarthritis. No patella prosthesis were implanted. The following types of knee prosthesis were used: NexGen Mobile Bearing Knee (MBK), NexGen Legacy Posterior Stabilized (LPS) and NexGen Legacy Posterior Stabilized Flex (LPS-Flex). The follow up examination was carried out three months postoperatively. The Insall knee score was made preoperatively and three months postoperatively.

**Results:** The mean age of the navigation patient group was 70.3 years (55.1 – 82.5) and of the conventional patient group 72.1 years (57.3 – 84). The mean body mass index was as following: Navigation group 29.5; conventional group 28.4. The preoperative knee deformities were 5 central mechanical axis, 16 valgus deformities and 79 varus deformities in the computer-assisted group (mean deformity of 10.2 °, maximum 24 °). In the other group were 75 varus deformities, 17 valgus knee deformities and 8 patients had a central mechanical axis (mean deformity of 9.3 °, maximum 20 °). 45 LPS-Flex, 3 LPS and 52 MBK prosthesis were implanted in the navigation group. In the conventional group 47 LPS-Flex, 6 LPS and 47 MBK prosthesis were implanted. The mean duration of surgery for the computer-assisted group was 94 minutes (67 – 132) and in the conventional group 73 minutes (39 – 135). So the mean additional surgery time for computer-assisted TKR was 21 minutes. The mean Insall knee score was in the navigation group preoperatively 105 (60 – 144) and postoperatively 158 (73 – 198). In the conventional group it was preoperatively 105 (24 – 170) and postoperatively 157 (92 – 197). The mean range of motion in the navi-
gation group for extension/flexion was preoperatively 0/6/111 (minimum 0/30/80, maximum 0/0/140) and postoperatively 0/1/105 (minimum 0/10/80, maximum 5/0/130). In the conventional group the results for range of motion were as follows: Preoperatively: 0/4/108 (minimum 0/20/30, maximum 20/0/130), postoperatively: 0/3/103 (minimum 0/15/80, maximum 0/0/125). Accuracy of reconstructed mechanical axis (Mikulicz line) in the navigated group was excellent (+/- 2 degrees) in 82 %, good (+/- 4 degrees) in 15 % and poor (+/- 6 degrees and more) in 3 %. In the conventional group there were 59 % excellent, 33 % good and 8 % poor results for the mechanical axis (p = 0.008). The aspired tibial slope of 7 degrees was achieved in the computer-assisted group with excellent (+/- 2 degrees) in 94 %, good (+/- 4 degrees) in 6 % and poor (+/- 6 degrees and more) in 0 %. In the conventional group the results for tibial slope were excellent in 61 %, good in 32 % and poor in 7 % (p = 0.001). In regard to intra- and postoperative complications no differences have been found. In the computer-assisted group in 11 cases problems with the stability of the femoral or tibial dynamic reference base were experienced.

Discussion: The results of reconstructed mechanical axis were in the navigated group significantly better in comparision to the conventional group. In addition, the achieved tibial slope in the computer-assisted group was significantly more accurate. No differences were found for patients’ demography, preoperative knee joint deformity, pre- and postoperative Insall knee score and pre- and postoperative range of motion in both groups. For the navigated technique of total knee replacement the mean of additonal surgery time was 21 minutes.

Presently no exact anatomical landmarks are known for tibial component rotation. Conventional definition of femoral component rotation was compared with the information of the navigation system according to all different reference lines. In particular, for the intraoperative defined epicondylar axis substantial inaccuracies have been stated.[3] Because of the deficiency of exact anatomical landmarks for tibial and femoral component rotation the benefit from the navigation system is small. The femoral component position in sagittal plane (extension/flexion) must be adapted to the individual femoral antecurvation to avoid a femoral notching. Therefore, furthermore the advantages of navigation in sagittal plane are limited because currently exact mechanical methods are known which avoid a femoral notching by using the conventional instruments for implantation of the prosthesis.

Conclusions: Computer-assisted total knee arthroplasty can significantly improve results of reconstructed mechanical axis and posterior tibial slope. Because of the deficiency of exact anatomical landmarks for tibial component rotation the advantages of the navigation system are limited. It is necessary to upgrade the module for ligament tension adapted definition of femoral component rotation. The work flow of the navigation system should be accelerated to reduce the additional surgery time for computer-assisted TKA. In the future, it is believed that a navigation system will be very helpful for the new surgical techniques of minimal invasive total knee replacement which are being developed at this time.
References:


NAVIGATED VERSUS FREEHAND IMPLANTATION IN TKA. FIRST RESULTS OF A CONTROLLED, RANDOMISED STUDY

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Introduction: During the last decade, CAS (computer assisted surgery) and Navigation have become increasingly popular in orthopedic surgery. Today approx. 50,000 total knees are implanted in Germany every year, the majority in free hand technique. However, the number of navigated implantations is increasing every year. At the present day, the amount of navigated implantations is supposed to be approx. 1-2% [1]. Previous studies have shown, that the use of a navigation system can improve the alignment. However, due to the fact that usually just 2 plane X-rays are performed to control alignment and axis, for the rotation position of the femoral component no validated data is available. This study shows the first results of a randomised study, comparing navigation vs. free-hand-implantation in TKA with special interest to the rotation of the femoral component.

Methods: Since march 2003, all patients who accepted to participate in the study and signed the study protocol were followed prospectively. The protocol was reviewed and authorised by the local ethic commission (LÄK Baden-Württemberg, No. 138-03). We always implanted the “LCS complete” prosthesis (DePuy) with a mobile bearing / ap-glide inlay. All components were cemented and the patella has always been replaced. The Inclusion criteria for the study were: ASA ≤ 3, ADL-Score [2] more than 80 points, no local or systemic signs of infection and the acceptance of the study protocol. For randomisation the operation technique was strictly alternating: every free hand implantation was followed by a navigated implantation (VectorVision, BrainLAB, Germany), followed again by a free hand implantation at the next operation.

The clinical function of the knee was assessed according to the KSS-Score [3]. All patients had a pre- and postoperative CT scan of the operated leg for assessment of the leg alignment. At the AP scan of the CT the axis and alignment was measured in the usual way. The rotation of the femoral component was measured according to the technique described by Waidelich et al in 1997: The femoral neck axis (FNA) was defined by connecting the center of the femoral head with the center of the trochanter major. Then the rotation of the distal femur (pre-op) or the prosthesis (post-op) was defined by measuring the angle between FNA and the posterior condyle axis (PCA) of the distal femur [4]. Measurement of axis and rotation was performed by the Department of Radiology without knowledge about the operation technique (naviga-
Results: From March 1st until December 31st 2003, 50 patients meet the criteria mentioned above. One patient was excluded from the study because of implantation of a semi constrained prosthesis due to intraoperative instability. 49 complete sets of patient data were analysed: There were 25 navigated operations (Group A), and 24 free hand implantations (Group B). The average age in the navigated group was 72.8 years versus 69.9 years in the not navigated group. ASA score and preoperative mobility (ADL-Score) were almost equal in the two groups (Group A: ASA 2.4 / ADL 99.2 - Group B: ASA 2.3 / ADL 99.8). The preoperative alignment in Group A showed an average of 5.3° of varus deviation versus 3.9° of varus deviation in Group B. During implantation, no technical or surgical complication did occur in both groups. The average OR time in group A was 41 minutes longer than in group B. In the postoperative CT control 24 of the 25 navigated knees (96%) were found to be within the interval of ± 3° varus- / valgus deviation. In the not navigated group just 18 of 24 knees (75%) meet those criteria. The preoperative rotation of all distal femurs measured by the angle between femoral neck axis and posterior condyle axis was 7.5° ± 7.9° internal rotation with a range between 24° internal rotation (IRO) to 16° of external rotation (ERO). The postoperative rotation position in all knees was 6.6° ± 8.0° IRO (range 24° ERO / 13° IRO). The average _ of rotation in the navigated group was 0.3° ± 4.3° of external rotation (range 9° ERO – 8° IRO). In the not-navigated group we found an average _ of rotation of 1.9° ± 6.6° external rotation (range 12° ERO – 12° IRO).

In both groups we found one major complication leading to a reoperation: One patient of group A had a severe postoperative haematoma, one patient of group B had a superficial wound infection which was controlled by a single wound revision and an antibiotic treatment over a period of 4 weeks.

Conclusions: Navigation in TKA was introduced only a few years ago. However, there are already many publications on the subject. Clemens et al (2003) found that, statistically, there was a significant improvement in the mechanical axis in the navigated group of their patients. The study showed that 93% (navigated) vs. 72% (free-hand) of the operated knees are within the postoperative range between 3° varus / 3° valgus [5]. Our results confirm too, that the use of an intraoperative navigation system improves the overall alignment in total knee arthroplasty. However, with the introduction of navigation as a new intraoperative tool, there is always an associated risk of specific complications in the procedure. For example, an increase in operation time in navigated total knee arthroplasty is reported in all studies, but no report in literature is given about a higher incidence of infection due to the lengthening of the OR-time. In our study we found a significant longer OR time in navigated TKA too. Some of this extra time was needed because of special intraoperative documentation for study reasons, but navigation will always take longer as a free hand implantation. However, as reported in literature, we found no difference in the complication rate between the two groups.
The analysis of the average change in pre- and postoperative rotation position of the distal femur showed no difference in the navigated versus not navigated group. This was expected, due to the fact that rotation of the femoral component in the LCS knee is 100% dependent on the intraoperative ligament status. The Analysis of the clinical outcome and long term studies will possibly show if a special rotation position of the femoral component is associated with a better or worse outcome after mobile bearing TKA. However, at this point of the study no recommendation can be given according to the correct rotation position of the femoral component.

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CONVENTIONAL VERSUS COMPUTER ASSISTED TOTAL KNEE REPLACEMENT
A RADIOGRAPHIC ANALYSIS OF POSTOPERATIVE ALIGNMENT

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Introduction: In total knee replacement (TKR), alignment of the implant components and ligament balancing are the most predictive factors for the outcome. Malalignment is referred to as the main cause for aseptic loosening, as an eccentric load line leads to failure of the polyethylene inlay and the interface between bone and implant. Alignment being much easier to describe numerically, it’s implementation in conventional instrument sets as well as in computer assisted surgery systems is far more developed than the aspect of ligament balancing. The aim of our study was to assess the postoperative alignment with regard to the method of intraoperative guidance used in TKR.

Methods: Of 120 consecutive TKR operations done by the two senior authors (EH and FL) 40 were conventional manual and 80 were computer assisted by a passive (navigation) system with use of two different software versions (40 cases each). In the conventional manual group (A), Press Fit Condylar (PFC, DePuy a Johnson & Johnson Company, Warsaw, IN, US) prostheses were implanted with the Specialist Instruments, using extramedullary alignment guides on the tibial side and intramedullary alignment guides on the femoral side. In one of the computer assisted groups (B), Search Evolution (BBraun Aesculap AG & Co. KG, Tuttingen, DE) prostheses were implanted with the Orthopilot navigation system (BBraun Aesculap) using software release Version 3.0. In the other computer assisted group (C), Columbus (BBraun Aesculap AG & Co. KG, Tuttingen, DE) prostheses were implanted with the Orthopilot navigation system (BBraun Aesculap) using software release Version 4.0. All patients were followed up 6 to 8 months post-operatively and examined radiographically with a long leg standing antero-posterior (a-p) and a long lateral X-ray image. Five angles were measured: Mechanical axis as angle between mechanical femur and tibia axis in the a-p image; femoral and tibial component orientation in the coronal plane as angle between implant axis and bone axis in the a-p image; femoral and tibial component orientation in the sagittal plane as angle between implant and bone axis in the lateral image. For each angle, deviation from optimum was calculated. Additionally, an alignment index was defined as sum of the five deviations from optimum angles. For each angle and the alignment index, values were tested for differences between the three treatment groups using student’s t-test.
Results: Mechanical axis was 180.3±2.6 (177-188) deg in the PFC (A) group, 179.6±3.5 (171-188) deg in the Search (B) group and 179.7±1.5 (177-182) deg in the Columbus (C) group (not significant (n.s.)). Deviation from optimum was 1.9±1.8 (0-8) deg in group A, 2.7±2.2 (0-9) deg in group B and 1.2±1.0 (0-3) deg in group C (p<0.05 between B and C, the others being n.s.). Femoral component orientation in the coronal plane was 91.0±2.0 (89-96) deg in group A, 89.9±2.5 (86-98) deg in group B and 90.0±1.7 (87-93) deg in group C (p<0.05 between A and B, the others being n.s.). Deviation from optimum was 1.5±1.7 (0-6) deg in group A, 1.8±1.8 (0-8) deg in group B and 1.2±1.2 (0-3) deg in group C (n.s.). Femoral component orientation in the sagittal plane was 87.6±2.4 (84-91) deg in group A, 89.5±2.2 (84-95) deg in group B and 89.6±1.4 (87-92) deg in group C (n.s. between B and C, the others p<0.01). Deviation from optimum was 2.5±1.9 (0-6) deg in group A, 1.6±1.6 (0-6) deg in group B and 1.0±1.0 (0-3) deg in group C (n.s. between B and C, the others p<0.05). Tibial component orientation in the coronal plane was 89.7±1.6 (86-93) deg in group A, 90.2±2.0 (84-94) deg in group B and 90.0±1.0 (88-92) deg in group C (n.s.). Deviation from optimum was 1.2±1.1 (0-4) deg in group A, 1.5±1.4 (0-6) deg in group B and 0.6±0.8 (0-2) deg in group C (p<0.05 between B and C, the others being n.s.). Tibial component orientation in the sagittal plane was 84.1±3.5 (78-91) deg in group A, 87.7±2.3 (82-93) deg in group B and 87.9±1.9 (83-90) deg in group C (n.s. between B and C, the others p<0.01). Deviation from optimum was 3.8±2.4 (1-9) deg in group A, 1.6±1.6 (0-6) deg in group B and 1.3±1.7 (0-6) deg in group C (p<0.001 between A and B, p<0.01 between A and C, n.s. between B and C). Alignment index was 11.0±5.1 (3-25) deg in group A, 9.2±4.9 (2-21) deg in group B and 4.8±2.5 (1-9) deg in group C (n.s. between A and B, the others p<0.01).

Discussion: Our overall results represented by the alignment index show a significant better component alignment with the computer assisted implantation using software release 4.0. The deviations from optimum of the angles measured in the lateral radiographs, i.e. the slope of the components, show a significant advantage of the computer again for both software releases. The deviations from optimum of the angles measured in the a-p radiographs could not prove any statistically significant differences between the conventional manual and the computer assisted groups. Thus varus / valgus alignment seems to be easier to address by the surgeon’s mental registration of the situs than the anterior / posterior slope of the resection planes. Using an earlier navigation system (release 3.0), we were able to produce as good alignment results as with conventional instruments. With the current navigation System (4.0), we could even improve accuracy as indicated by the alignment index. Our results are limited by the fact that we had much less experience with the navigation system in Version 3.0 than with the conventional technique. The superior results achieved with the 4.0 navigation system might be due to a learning curve with computer assisted total knee replacement. Another reason might be a technical improvement in the system’s precision.

Conclusion: Our results indicate that current versions of computer assisted surgery systems which support ligament balancing as well as proper component alignment, and which also work with advanced implant designs, prove to be more precise than manual implantation techniques if used by an experienced surgeon.
COMPUTER-ASSISTED TOTAL KNEE ARTHROPLASTY – FIRST EXPERIENCES WITH A CT-BASED AND CT-FREE NAVIGATION SYSTEM

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Introduction: In many cases of suboptimal clinical results and early polyethylene wear inaccuracies of the reconstructed mechanical axis (coronal plane), tibial and femoral component rotation (axial plane), tibial slope and extension/flexion of femoral component (sagittal plane) can be found. In these cases a shorter survival rate of total knee arthroplasties (TKA) will be expected or the patients are not satisfied with the surgical result because of insufficient range of motion or persistent knee pain.

Initial comparative studies [3,4] described an increased operative accuracy by using a navigation system for total knee replacement (TKR). Our first experiences and results with a CT-based and CT-free navigation system will be reported.

Materials and Methods: For computer-assisted TKA the VectorVision® navigation system (BrainLAB, Germany) [2] was used. From October 2001 to April 2002 the CT-based and since May 2002 the CT-free module of the navigation system was applied. The VectorVision® system consists of a workstation and an infrared light emitting camera. For detecting movements of the leg an infrared light reflecting reference array is fixed to tibia and femur. The pointer and cutting block adapter are assembled with passive fiducial markers for reflecting the infrared light to the camera. The work flow can be passed through by using the sterile draped touch screen.

CT-based navigation system module

One week before the scheduled surgery date a CT-scan of the equilateral hip, knee and ankle joint was performed. For patient immobilization during the CT-scan the BodyFIX® system (Medical Intelligence, Germany) [1] was used because movements of the patient during the CT-scan will decrease the accuracy of the navigation system. For the hip and ankle joint 5 mm axial CT-slices and for the knee joint a 1.5 mm helical scan were done.

With an optical disk the CT-data set was transferred to a working station for the plan-
nring procedure. Following parameters for TKR can be planned with the CT-data set: Center of femoral head, center of talus, femoral mechanical axis, femoral epicondylar axis and posterior condylar line, femoral anatomical axis, farthest point on distal femoral condyles, medial third of tibial tuberositas, tibial mechanical axis and the femoral and tibial implant position finetuning. On a ZIP disk the data set of the planning procedure can be transferred to the navigation system in the operating room.

Navigation of tibial and femoral bone cuts cannot be done simultaneously. So the dynamic reference base (DRB) must be attached to the tibia before the registration of patient’s CT-data set of the tibia. Subsequently tibial bone cuts can be performed computer-assisted, the tibial DRB is removed and the same procedure must be done for femoral bone cuts. Rotation of tibial component is adapted to the definition of medial third of tibial tuberositas point and femoral component rotation can be adapted to epicondylar axis or posterior condylar line.

CT-free navigation system module

The patient registration is performed by definition of following anatomical landmarks: Medial and lateral malleolus, proximal tibial mechanical axis point, tibial anterior-posterior direction, center of femoral head by pivoting, distal femoral mechanical axis point, medial and lateral epicondylus, ventral femoral cortical bone. In addition the bone surface is registered by an extended surface matching of tibia and femur. With the information from the registration procedure a bone model of tibia and femur can be generated based on saved CT-data sets of 50 real knee joints. Subsequently an accuracy check of adapted models must be performed. Planning procedure of component size and position can be undertaken intraoperatively. The tibial cutting block is positioned according to the information presented on the touch screen of the navigation system. After the bone cut has been completed an accuracy check of the tibial bone cut with the cutting block adapter can be performed. Information about deviation for varus/valgus, slope and resection height will be given. In the same manner the femoral bone cuts can be performed computer-assisted.

The rotation of femoral component is defined by the ligament balancing module. After the tibial and distal femoral bone cut and a soft tissue release for a balanced medial-lateral ligament tension in extension the extension gap between tibia and femur is measured. Subsequently the four in one femoral cutting block is positioned in such a manner that the same gap in flexion as in extension is achieved, as well as a well balanced medial-lateral ligament tension in 90 degrees of flexion. Ligament balancing in 90 degrees of flexion can be influenced by varying the rotation of femoral component. By using the ligament tensor the gap and the ligament tension for extension and flexion can be measured. In addition, the rotation of femoral component according to the posterior condylar line and the epicondylar axis can be checked. With the provisional components a last computer-assisted check of reconstructed mechanical axis, range of motion and ligament balancing can be performed before implantation of original prosthesis components.

We compare the results of the first 20 patients of each study group (one with CT-based and the other with CT-free navigation system). All patients had a primary
osteoarthritis. No patella prosthesis were implanted. The following types of knee prosthesis were used: NexGen Mobile Bearing Knee (MBK), NexGen Legacy Posterior Stabilized (LPS) and NexGen Legacy Posterior Stabilized Flex (LPS-Flex). The follow up examination was carried out one year postoperatively. The Insall knee score was made preoperatively and one year postoperatively.

**Results:** The mean age of the CT-based patient group was 71.8 years (62 – 82.3) and of the CT-free patient group 69.1 years (55.1 – 80.6). 2 LPS-Flex, 3 LPS and 15 MBK prosthesis were implanted in the CT-based group. In the CT-free group 6 LPS-Flex, 1 LPS and 13 MBK prosthesis were implanted. The mean duration of surgery for the CT-based group was 103 minutes (79 – 134) and in the CT-free 82 minutes (79 – 122). In addition the mean time for the preoperative planning procedure for CT-based navigation method was 17 minutes. The mean Insall knee score was in the CT-based group preoperatively 110.2 (35 – 147) and postoperatively 175.8 (147 – 195). In the CT-free group it was preoperatively 109 (42 – 142) and postoperatively 171.2 (139 – 189). The mean range of motion in the CT-based group for extension/flexion was excellent (+/- 2 degrees) in 65 %, good (+/- 4 degrees) in 30 % and poor (+/- 6 degrees and more) in 5 %. In the CT-free group there were 60 % excellent, 30 % good and 10 % poor results for the mechanical axis. The aspired tibial slope of 7 degrees was achieved in the CT-based group with excellent (+/- 2 degrees) in 80 %, good (+/- 4 degrees) in 20 % and poor (+/- 6 degrees and more) in 0 %. In the CT-free group the results for tibial slope were excellent in 75 %, good in 25 % and poor in 0 %. In regard to intra- and postoperative complications no differences have been found. In the CT-based group in 2 cases and in CT-free group in 1 case problems with the stability of the femoral or tibial dynamic reference base were experienced.

**Discussion:** The results of reconstructed mechanical axis were in the two patient groups not significantly different. In addition, there was no significant difference in accuracy of the achieved tibial slope as well. No differences were found for patients’ demography, preoperative knee joint deformity, pre- and postoperative Insall knee score and pre- and postoperative range of motion in both groups. The shorter surgery time of the CT-free navigation method is based on an acceleration of the software work flow (planning and registration procedure) and an increased routine in computer-assisted TKR. The main disadvantages of CT-based navigation system are the costs for computertomography (time, organization) and that it is no ligament balancing module available for a control of reconstructed mechanical axis and of ligament tension balance.

**Conclusions:** The results for reconstructed mechanical axis for computer-assisted TKR were excellent or good for CT-based navigation method in 95 % and for CT-free navigation module in 90 %. For the tibial slope all results of both patient groups were excellent or good. Because of no significant differences in the results for CT-based or CT-free computer-assisted TKR and the advantage of the ligament balancing module in the CT-free software we prefer to use the CT-free navigation system.
References:

TKR ALIGNMENT USING IMAGE-FREE AND FLUOROSCOPIC-BASED NAVIGATION

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Introduction: Surgical navigation for total knee arthroplasty offers the potential to decrease morbidity while improving accuracy of the procedure. Potential benefits include improved limb alignment, ligament balance, and component positioning. Navigation methods include image-based and image-free methods. Image-free methods rely on kinematic methods of determining the hip joint center and direct digitization of ankle landmarks. The current study compares limb alignment results from the same surgeon and same implant using image-based and image-free methods.

Methods: 126 Computer-assisted total knee arthroplasties were performed using Smith-Nephew Genesis II components and navigation systems which incorporated these specific implants into the methodology. The image-based method incorporated fluoroscopy to determine the hip joint center of rotation and center of the ankle (Medtronic’s ION system). The image-free method used kinematic methods of determining the center of rotation of the hip and direct digitization of ankle landmarks (BrainLAB CT-free knee). This specific kinematic method of calculating the hip joint center does not require either physical stabilization or navigation of the pelvis. Full-length standing films were obtained postoperatively. Overall limb alignment as well as alignment of the femoral and tibial component positions were calculated.

Results: Results of limb alignment using the two methods is shown in table 1

<table>
<thead>
<tr>
<th></th>
<th>Image-based</th>
<th>Image-free</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>70 (70 with full length films)</td>
<td>56 (39 with full length films)</td>
</tr>
<tr>
<td>Femoral Component</td>
<td>0.3 degrees varus (0.9)</td>
<td>0.6 degrees varus (1.0)</td>
</tr>
<tr>
<td>Alignment Mean, (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibial Component</td>
<td>0.6 degrees valgus (1.1)</td>
<td>0.9 degrees valgus (0.9)</td>
</tr>
<tr>
<td>Alignment Mean, (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Limb</td>
<td>0.3 degrees valgus (1.0)</td>
<td>0.4 degrees valgus (0.9)</td>
</tr>
<tr>
<td>Alignment Mean, (SD)</td>
<td></td>
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</table>
Conclusion: This study demonstrates that computer-assisted total knee arthroplasty using virtual fluoroscopy and using image-free methods produce accurate limb alignment with very small standard deviations. These findings show that image based methods for total knee arthroplasty may be unnecessary, although the exact algorithms used to determine the center of hip rotation and the center of the ankle for image-free navigation are critical.
COMPUTER-ASSISTED FLUOROSCOPIC PLACEMENT OF LUMBAR DISC ARTHROPLASTY: A CADAVERIC STUDY

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Introduction: Disc arthroplasty has recently gained considerable interest in North America. The indications for LDA are similar to anterior lumbar interbody fusion (ALIF) and as such it can be assumed that once FDA approval is obtained as with “cage fusions”, a significant number of these implants will placed. Comparatively, the acute or early approach related to and gross misplacement complications associated with an ALIF should be similar for an LDA.[3,4] However, the final position of most interbody fusion devices, if placed reasonably contained within the disc space and subsequent fusion occurs, will have no clinical short or long term consequences. In contrast, LDAs’ attempt to replicate physiologic spinal kinematics and therefore relatively accurate placement of an LDA within the disc space is a requirement stated by all designers and manufacturers. Furthermore, based on total hip and knee arthroplasty data, a malpositioned LDA theoretically may have an adverse impact on the long term wear characteristics and hence survival of the implants, [1,2]. The purpose of this study was to evaluate a simple method for the accurate and reproducible placement of LDA using computer-assisted fluoroscopy.

Methods: LDA (A-MAV™ - Medtronic Sofamor Danek, Memphis, TN, USA) was performed on 3 fresh frozen cadavers at L3-4, L4-5 and L5-S1. The following image-guided insertion technique (FluoroNav™ -Medtronic Sofamor Danek, Memphis, TN, USA) was used at all levels: a percutaneous reference arc was attached to the anterior iliac crest; true posterior-anterior (PA) and lateral images (centered on the operative disc space) were obtained and processed by the navigational system; retroperitoneal exposure was carried out; the disc midline was identify by real time virtual localization using only the initial PA and lateral images; disc preparation and distraction was performed as per the manufacturers recommended technique; a updated lateral image was taken and processed after disc distraction; the entry point (midline), trajectory and depth of the endplate-keel cutting guide (retrofitted with passive tracker) was placed with real time virtual localization using only the initial PA and distracted lateral images; live fluoroscopic lateral images were taken to confirm the final depth of the cutting guide and LDA. The local spinal mid-sagittal plane of the each operative spinal disc level was indirectly defined by obtaining a true PA image; if the centered (within the image intensifier) projection of the spinous process of a given vertebrae equally bisects the associated pedicles the rotational orientation (sagittal plane only) of the C-arm (the x-y-z coordinates of which are
tracked) is grossly parallel to the mid-sagittal plane of that vertebrae; angular deviation from this sagittal plane was displayed in real time. The radiographic anatomical midline was visually defined from the true PA image by demarking the center of the spinous process above and below the operative disc space; medial to lateral translation of the instrument tip from this defined midline was also displayed in real time. Post-procedure fine cut CT scans (1mm slices) were performed and assessed for the rotational (in degrees) and translational error (medial-to-lateral (in mm)) of each vertebral body implant keel relative to the true mid-sagittal plane (defined by the line bisecting the spinous process and vertebral body). The number of fluoroscopic images and fluoroscopic time for each LDA placement was also documented. This included the images taken to get a true AP lateral and to confirm the final depth of the cutting guide and LDA.

**Results:** The average rotational and translational errors was 0.7° (0-3) and 1.7 mm (0-4). The average number of fluoroscopic images and time required for each disc level was 14 images (9-29) and 22 seconds (8-51-untrained novice C-arm operator).

**Discussion:** In North America, LDA has conceptually gained rapid acceptance by both patients and surgeons alike. A rising concern within the North American academic spinal community is that once these devices are FDA approved, the complications associated with malpositioned LDAs placed by non-experts (similar to the “cage-rage” of the mid to late1990’s) will significantly increase. However, in today’s evidence based environment this may erroneously compromise a procedure that if utilized for the appropriate indication(s) and is technically well executed, has the potential of being as beneficial to our patients as other total joint arthroplasty.

LDA represents a procedure in evolution and CAS has a potentially significant enabling role to facilitate reliable technical execution and hence improved patient outcome. Due to a variety of factors the acceptance of CAS, despite it proven benefits, has not been wide spread. These factors typically include the complexity of CAS the process, fiddle-factor and increased operative time. The results of this study describe a simple technique that facilitates relatively accurate placement of LDA at L3-4, L4-5 and L5-S1. Due to the single or two-level nature of LDA, this CAS-technique enhances the procedure without significantly changing the normal operative flow and hence time (this latter point needs to be proven in the clinical situation). In conclusion this technique offers a simple computer-assisted fluoroscopic method to minimize rotational and translational error for the placement of lumbar disc arthroplasty.

**References:**

NAVIGATED KYPHOPLASTY IN
ISO-C\textsuperscript{3D} DATA SETS IN THORACIC
AND LUMBAR SPINE FRACTURES,
A PROSPECTIVE STUDY

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Introduction: The National Osteoporosis Foundation (USA) estimates that nearly 100 millions of people are at risk of suffering osteoporotic fractures of the vertebral body. The independence in everyday life is threatened in approximately half the patients by a chronic pain syndrome. Patients with an osteoporotic compression fracture of the vertebral body have their mortality increased by 23\% [1]. Conservative treatment is often ineffective in terms of achieving a pain-free everyday life. Conventional spinal stabilization surgery involves a high morbidity. Cement augmentation of a vertebral body hemangioma was first done in 1987. Vertebroplasty and kyphoplasty are used in osteoporotic compression fractures. Through this a stabilization of the vertebral body is achieved and continuing painful deformation and instability is prevented. A pain reduction after a vertebral body augmentation is described in literature in 70-95\% of the cases, a re-entry into the usual daily activities was mostly possible. Complications in terms of an asymptomatic cement leakage when using this methods are observed in literature in 70\% of the cases for the vertebroplasty and 10\% for the kyphoplasty[3]. Serious complications with neurological losses as well as embolic complications are described in 6-7\% (2.5\% Kyphoplasty). The high complication rate caused by cement leakage remains problematic, together with the high radiation exposure of the surgical staff [4]. The advantages of computer-assisted surgery are not only the verified higher accuracy and precision compared to conventional surgery but also the reduction of exposure to ionized radiation[2]. The mobile SIREMOBIL ISO-C\textsuperscript{3D} permits an intraoperative three-dimensional acquisition of the bone structure. The 3-D data can be transferred together with the spatial coordinates to the linked navigation system. The surgical instrument is displayed immediately on the screen.

Methods: In our study we want to demonstrate the possibility of an accurate puncture of the pedicle for performing a kyphoplasty using a navigation system and three-dimensional image data from the SIREMOBIL ISO-C\textsuperscript{3D}. Within the scope of an prospective study from May untill December 2003 computer-assisted kyphoplasties were performed on 14 patients with 21 osteoporotic thoracic and lumbar spine fractures, on 1 to 4 vertebral bodies in each case. The duration of the operation was recorded together with the fluoroscopy time. Three-dimensional reconstructions were
created for all patients intraoperatively from sequential, isocentric radiographic projections. After the online transfer of the data to the navigation system a minimal invasive percutaneous, navigated puncture of the pedicle was performed. The position of the needle was controlled with a conventional fluoroscopy. The balloon dilatation and the cement augmentation were performed conventionally under fluoroscopic control. In a second scan, done after the augmentation the position of the puncture tunnel and the correct filling of the vertebral body were controlled. A cement leakage was excluded. Multiplanar reconstructions in sagittal, coronal and horizontal layering were created and documented from the postoperative data sets.

**Results:** The position of the needle was correct in all cases, corrections were not necessary. An additional visualization with the C-Arm was not required during navigation. The cement filling of the vertebral bodies was correct in all cases. A small cement leakage into the intervertebral space was detected in one case by the postoperative control scan. This did not result in an indication for a revision surgery. Cement leakages into the spinal canal could not be observed. Neurological or angiological complications did not arise. The average duration of the operation was 64 minutes for each vertebral body (ranging from 36 to 110 minutes). The average fluoroscopy time was 1.5 minutes, thereof 0.4 minutes for each of the 2 scans, during which the surgical staff was outside the control area. The fluoroscopy time of the conventional group is with an average 4.18 minutes far higher. Consequently this resulted in a significantly lower radiation exposure for the surgical staff and the patient. Postoperative complications related to the method used did not arise.

**Conclusions:** Through the combination of the SIREMOBIL ISO-C3D with an optoelectronic navigation system (SurgiGATE®) we were able to demonstrate, that the navigated kyphoplasty can be performed safely and accurately. The use of the navigation system prevents faulty punctures. Through the navigation in three-dimensional data sets, the occupational radiation exposure of the surgical staff can be reduced significantly. The inherent registration prevents the possible errors of the CT based navigation and facilitates a minimization of the operative access, as an intra-operative matching is no longer necessary. The tree-dimensional display offers the same information to the surgeon as a CT navigation would. Furthermore the three-dimensional display allows an instant control of the operative result, together with the possibility of an intermediate intervention.

**References:**

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A CT-FREE INTRA-OPERATIVE PLANNING AND NAVIGATION SYSTEM FOR MINIMAL-INVASIVE VENTRAL SPONDYLODESIS OF THORACO-LUMBAR FRACTURES

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Introduction: Treatment of patients with traumas and diseases of the spine is still an urgent problem of modern neurosurgery, traumatology, and orthopaedics. The last years are characterized by a tendency towards increase of a portion of surgical technologies among methods of treating patients with spinal pathology [1]. The most important elements of surgical treatment of such cases include reconstruction of supporting structure, and reliable stabilization of a spinal column in a proper position, permitting to achieve effective restoration of lost functions at an early stage. So far the main method of reconstruction of such structures is ventral spondylodesis with partial or complete substitution of an affected vertebral body using bone auto- or allografts. The limitation of conventional techniques lie in the difficulty in precise three-dimensional (3D) graft bed formation, in the high radiation exposure for spinal cord decompression, as well as in the uncomfortable combined handling of minimal-invasive approaches and imaging intensifiers. The goal of the reported work is to design and evaluate a CT-free intraoperative planning and navigation system for minimal-invasive ventral spondylodesis of thoraco-lumbar fractures.

Methods: Surgical instruments as well as image intensifier are tracked optically with the SurgiGATE® navigation system (PRAXIM MediVision, La Tronche, France). The complete computer-assisted procedure includes 5 steps, which are (1) fixation of dynamic reference base (DRB) to patient; (2) acquisition of up to 9 registered fluoroscopic images; (3) fluoroscopic images-based bi-planar reconstruction of anatomical landmarks; (4) interactive planning of graft bed; (5) computer-assisted navigation of surgical actions.

Following exposure, dynamical reference base (DRB) are attached to the patient. Then, up to 9 fluoroscopic images from different orientation were acquired and downloaded into the module. Based on calibration procedure recently introduced by our group for fluoroscopic navigation [2] a three-dimensional (3D) virtual reality based on pinhole camera model is established for each image, which allows visualization the virtual representation of the custom-made instrumentation as well as the
planned object in 3D form taking the acquired fluoroscopic image as the visualization background.

Following that, four deep-seated landmarks, which locates the four different corners of the graft bed in cranial-ventral, caudal-ventral, cranial-dorsal, and caudal-dorsal direction respectively, are acquired with bi-planar landmark reconstruction [3] using multiple registered fluoroscopic images. A user-friendly manipulator is provided for interactively planning the size and the shape of the graft bed by compare the difference of the projection of the graft bed model with the underlying anatomical images (figure 1). The shape and the dimensions of the planned graft bed are used for preparing autograft from donor area.

Finally, surgical actions such as the placement of the stabilization devices and the formation of the graft bed using a custom-made chisel are visualized to the surgeon by superimposing virtual instrument representations onto the fluoroscopic images. The distances between the instrument tip and each wall of the planned graft bed are calculated on the fly and presented to the surgeon so that the surgeon could formalize the graft bed exactly according to his/her plan.

**Results:** Starting from January 2004, a preliminary clinical trial has been designed to evaluate the clinical applicability as well as the application accuracy. Clinically relevant parameters such as blood loss, operation duration, as well as radiation time are recorded. Until now, 4 patients have been successfully supported by the system. Reduction of radiation exposure as well as operation duration has been observed.

**Conclusion:** Minimally invasive techniques are becoming more widespread in the surgical subspecialties. Standard open surgical procedures are being modified to become less invasive, with the intention of reducing recovery time, morbidity, and ultimately expenditure. However, there is a lack of technology. Our preliminary results demonstrate that (1) computer-assisted minimal-invasive placement of anterior spinal stabilization devices is feasible; (2) computer-assisted minimal-invasive graft bed formation in ventral spondylodesis is feasible; (3) the proposed system promises to increase precision and accuracy in 3D graft bed formation as well as in placement of stabilization devices, to reduce the intra-operative radiation exposure, to ease the development of artificial vertebra spacers, and to reduce the complication rates.

**References:**

EVALUATION OF 2D-3D REGISTRATION METHODS FOR IMAGE-GUIDED SURGERY

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Introduction: 2D-3D registration is the registration of 2D X-ray images to a preoperative 3D volume. It can indirectly and noninvasively give the relation between patient and 3D volume, which is a prerequisite for image-guided navigation. Existing 2D-3D registration methods have not been directly compared or only work for specific applications. Understanding and evaluating their performance is therefore an open and important issue. To address this challenge we introduce a standard evaluation methodology, which can be used for all types of 2D-3D registration methods and different applications. As an illustration of the methodology we focus on registration of vertebral bodies using an intensity-based method [2] and a gradient-based method [3]. For both methods the original implementations were available, though the intensity-based method had to be altered so it could use multiple 2D images.

Materials and Methods: The evaluation methodology uses images acquired with a clinical floor-mounted 3D Rotational X-ray (3DRX) system (Integris BV5000, Philips Medical Systems, Best, The Netherlands). During an 8 second run of 180 degrees around the patient the 3DRX system acquires 100 X-ray projections, which are used to reconstruct a high-resolution 3D volume. Since the 3DRX system is calibrated, the position of the 2D projections with respect to the 3D reconstructed volume is known accurately. Furthermore, the system is calibrated for distortion of the X-ray images. This enables the acquisition of ground truth datasets for all kinds of anatomical structures. In the evaluation methodology, the registration method input consists of 2D X-ray images, a 3D volume and the registration starting position, i.e. the initial offset from which the method needs to find the optimal 3D position. Methods are evaluated both on accuracy and capture range. The accuracy measure is the mean target registration error (mTRE) calculated over a set of evenly distributed points within a volume of interest. These points are transformed using the optimal transformation found by the registration method. Subsequently the transformed points are compared to the corresponding points in the ground truth position. The average displacement of the points defines the mTRE. The first method, the intensity-based registration method [2], tries to find the optimal 3D position by simulating X-ray projections (digitally reconstructed radiographs (DRRs)) for different positions of the 3D volume and comparing these to the X-ray images using a similarity measure called gradient difference. The search for the optimal 3D volume position stops when the best match between the DRR and the X-ray is found. The second method is a gradient-based registration method [3], which registers 3D volumes to 2D images by
searching for the best match between surface normals in the 3D volume and back-projected gradients of the 2D X-ray images. Points on the surface of the object of interest are determined in a preprocessing step and the normals to the surface at these points are computed. The gradients, representing the edges, in the 2D images are back projected to the 3D volume.

**Data and experiments:** Two defrosted segments of a vertebral column, both fixed in foam, were imaged with the 3DRX system. This resulted in the following data: two 3DRX volumes (one with three vertebral bodies in view and one with five vertebral bodies in view) and 100 X-ray projections per volume with a known relation to the 3DRX volume. For the registration, we used two images (90 degrees apart) from the 100-image run. Given this image information, both methods were initialized with the same 140 starting positions per vertebral body. In the evaluation methodology starting positions are randomly distributed around the ground truth position. In this example, ten random starting positions were generated per 1 mm mTRE interval in the range from 0 to 14 mm. The capture range of a method is defined as the highest mTRE of the initial position from which the method can still find the optimal position within reasonable accuracy (mTRE < 2 mm) in 95% of the cases.

**Results and Discussion:** The capture range of the intensity-based method was 4 mm mTRE with an average mTRE at registration position of 0.39 mm. The capture range for the gradient-based method was 6 mm mTRE with an average mTRE at registration position of 0.19 mm. The intensity-based method had increasing difficulty in finding the optimal position with increasing initial offset from the ground truth position. This could be due to the position optimization in this method. The gradient-based method seems to either find the optimal position or completely miss it, which facilitates failure detection.

**Conclusions:** A standard evaluation methodology for 2D-3D registration methods was presented. A very accurate ground truth is assured by utilizing data acquired with a calibrated 3D rotational X-ray system. The process of evaluating methods is standardized by using the same data, starting positions and evaluation criteria. This evaluation methodology can also be extended to different modalities, by using the same type of 3DRX acquisition and subsequently registering corresponding MR or CT data to the 3DRX data (which can be achieved with good accuracy [1]), thereby indirectly obtaining the MR to X-ray and CT to X-ray relationships also. As shown in this example evaluation, our evaluation methodology enables direct comparison of the two registration methods, which was not possible when only using the information available in the original papers.

**References:**

THE PLANNING OF FRACTURE TREATMENT USING DIGITAL TEMPLATES

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Introduction: Today the planning of long bone fracture reduction and stabilization is usually performed without computer assistance, on an X-ray film or a printout from a digital X-ray machine using pencils, rulers, transparent paper, and templates of fixation implants printed on transparent sheets [2]. The procedure is sometimes cumbersome and inaccurate, it is difficult to evaluate different treatment alternatives, and the more widespread use of digital X-ray devices in hospitals adds an additional step to the conventional planning because the images have to be printed [1]. In addition, the conventional method cannot be linked to modern intraoperative surgical navigation systems. These issues create the need for a computer based planning solution that operates on digital or digitalized image data instead of X-ray films.

Materials and Methods: This project aimed to realize digital template based fracture reduction and stabilization planning with the help of a software system for long bone trauma surgery. As a requirement, the system should run on any standard desktop or laptop computer, independent from the operating system and hardware platform used. This goal was achieved by using tools and libraries that are available on a wide variety of computer platforms. The multi-platform toolkit QT (Trolltech, Oslo, Norway) provided the basic portability. The entire application was coded in C++, and the GNU GCC (http://gcc.gnu.org) compiler that is available on most platforms was used for compilation of the source code. Currently, the developed application runs on Linux, Windows, and Solaris systems. A version for Mac OS X will be available at the time of the conference.

As a second goal we aimed to provide to surgeons an as easy as possible transition from the conventional paper based planning to the new PC based digital system. To achieve that goal the proposed system imitates the conventional approach as good as possible, while taking advantage of the possibilities of the PC environment by providing a set of advanced tools to the surgeon.

After startup the application presents two planning areas, one intended for a lateral X-ray of the fracture, the other one for an A-P view. Both areas can be arranged in a horizontal or vertical order to fit the intended planning work as optimally as possible.

As the first step X-ray data is loaded into the application. The data is either transferred through a DICOM network or loaded from an image file on the hard disk. The
first option allows direct data import from the radiology department. The second variant has been implemented for backward compatibility with scanned conventional X-ray films. Both images can be scaled independently to give the user a clear view of the case.

Within the X-ray image bone fragments can now be defined by selecting the polygonal circumference of each individual fragment using the computer mouse. To improve usability the polygons enclosing a fragment can be edited, i.e., points can be added, removed, or shifted to precisely describe the shape of each visible fragment. Once a fragment is defined satisfactorily, it is assigned a name for easier identification. Each fragment can then be moved and rotated individually on the screen to virtually reduce the fracture. To facilitate the reduction process it is optionally possible to load the X-ray image of a non-fractured bone that then may serve as a template of the morphology to be reconstructed. In the general case an X-ray of the contra-lateral side will be used for that purpose, and the software therefore allows mirroring the image.

At any time during the planning process it is possible to activate a set of measurement tools to perform length and angle measurements on the X-ray using the computer mouse.

When a satisfactory reduction of the fracture is achieved the stabilization of the fragments in the planned situation can be simulated. The contours of fracture fixation implants can be displayed. The implant shapes are provided by an implants database that has been developed at our institute. The planning application opens a browser to navigate through this database and to select a suitable implant in an A-P or lateral view. Once an implant is inserted into the fracture scene it is possible to change its parameters (e.g. length, diameter) to find a better fitting size. Its position and orientation with respect to the underlying X-ray image may be altered freely and interactively to simulate osteosynthesis.

On the left side of the screen a list is presented that contains all implants and fractures defined for the current planning including their names (see Figure). It helps managing the individual objects that can be manipulated with the mouse. For documentation purposes the planning work can be complemented with additional data describing the clinical case. These include information about the patient (name, age, and sex), the surgeon performing the planning, the date of planning, and any special remarks about this case as free-form text. This data together with the planning result can be permanently stored on the hard disk or printed out as a report for documentation purposes.

**Future work:** A number of software features will be implemented to extend the application and make it even more useful for surgeons. An important point is to improve the browser for the implant database. Advanced search functions will be realized as well as additional ways to sort the items and to restrict display to selected groups only rather than the entire database content. Moreover, the selection of the best fitting implant should be facilitated by taking values from the measurement tools as input into the database browser.
As a next point, the problem of non-standardized X-rays has to be addressed. X-rays are usually taken without perfect patient positioning. As a consequence, a perfect lateral or A-P view of an implant (as displayed by the current implementation) may not be appropriate. It is therefore planned to use 3D data instead of the 2D contours of the implants in the database to allow the user adjusting the implant view to the correct angle.

Furthermore, the A-P and lateral views could be linked. In the case that a lateral and an A-P view of a fracture are available for planning, each fragment is most likely present in both X-rays. It could therefore be helpful to have the possibility to link two fragments thus making them two views of the same fragment. Such connected fragments could then be manipulated synchronously, at least in the longitudinal axis of the limb. The same applies to implants. An implant is usually present in both views, so it would also be possible to link two implants together or to add them to both X-ray images simultaneously. Again, using 3D representations of the implants would facilitate the process.

In the long term it is planned to feed the stored planning data into a surgical navigation system. This would enable the precise intraoperative realization of the planned situation.

**Conclusion:** The platform independent approach we adopted allows the application running in any computer environment that might be present in a hospital. Together with the implants database the application may become a valuable tool in the hands of a surgeon.

Given the feedback we received so far, we believe, that the planning application we developed has a great potential to replace conventional planning of fracture treatment. It may be hypothesized that such an application will become a necessity that works together smoothly with the more and more popular digital X-ray systems.

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**References:**

THE ROLE OF COMPUTERIZED NAVIGATION IN FIXATING FEMORAL NECK FRACTURES


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Purpose: Cannulated screw fixation is a popular fixation method for femoral neck fractures (OTA 31B1, 31B2.1) for all age groups. Several studies regarding the number and optimal placement of screws for fixation were recently published [1,3,4,5]. Fracture reduction should be adequate on both AP and lateral projection. The number of drill attempts should be kept to a minimum. The desired lowermost point of insertion is above the lesser trochanter in order to reduce the risk of subsequent subtrochanteric fractures [1,3]. Therefore a lower insertion angle should be provided. Three screws are presumed to perform better than 2 or 4 screws based on recent biomechanical studies [3,5]. Better scattering or distance between screws is believed to achieve better stability [2]. The formation of an inverted triangle, where 2 screws (the base) are positioned in the upper portion of the neck and one screw is placed on the femoral calcar (the tip), is believed to be safe in preventing subtrochanteric fractures while providing better biomechanical performance [2,4,5]. Adhering to these guidelines is technically demanding and requires the heavy use of fluoroscopy, while multiple drilling attempts are hard to be avoided. The use of a fluoroscopic based computerized navigation system improves maximum accuracy in placing each screw being inserted in a single drill attempt. In addition, only two registration fluoroscopic images are required for the entire screw insertion procedure. The purpose of this study was to compare the accuracy achieved by the navigation based technique and the results of conventional technique in placement of cannulated screws.

Patients & Methods: Postoperative hip radiographs of 40 consecutive patients who underwent fixation of femoral neck fractures (OTA 31B1, 31B2.1) with 3 cannulated screws were retrospectively collected. All procedures were performed in the two campuses of our medical center by the same surgical teams. 20 patients underwent the surgery using the ION Fluoronav® StealthStation® Navigation System (Medtronic SNT, Louisville, CO, USA) and conventional fluoroscopy was used for 20 control group patients. For each patient, preoperative pelvis AP radiograph and postoperative AP and lateral radiographs of the operated hip were obtained. All radiographs were digitized and measured by a single evaluator, using a computer software. Screw parallelism, screw scattering, the distance between the distal screw and the lesser trochanter, joint penetration and the relative 3D formation of the 3 screws were assessed. Neck area relative coverage (%) was calculated as the product of distance between the outer screw borders at the fracture line divided by the fracture-
line length. The Shaft Screw Angle was defined as the angle between the femoral shaft axis and the longitudinal axis of each screw. The maximum difference among the 3 angles was determined. The Fracture-Screw angle was defined as the angle between the fracture line in the neck level and the longitudinal axis of each screw. The maximum difference among the 3 angles was determined. Spatial formation of the screws was qualitatively assessed by the three-dimensional arrangement of the screws at the neck and its approximation to an inverted equilateral triangle. The position of the triangle base was scored as “proximal” (=inverted triangle), “distal”, “rotated” or “no base”. The minimal distance between the most inferior edge of the lesser trochanter and the lowest entry-point of the most distally placed screw (on AP view only) was measured. Joint penetration was assessed by recording the minimal distances (axial & diagonal) between the screw tip and the bony rim of the femoral head articular line, for each screw. For each patient, postoperative complications were recorded, including AVN, collapse, penetration, infection, and subtrochanteric fracture. The follow-up period was at least 1 year. Mann-Whitney test and t-test were used for statistical significance.

**Results:** The Navigation assisted group and the conventional group were comparable in the average age of the patients (63.7±14.5 vs 70.5±16.8, respectively), gender (M/F ratio 9/11 vs 5/15) and fracture classification. In the navigation assisted group, the relative neck area held by the screws was significantly larger (58.2% vs. 51.3% p=0.03). The average maximal difference in the shaft-screw angle the fracture-screw angle was significantly lower in the navigation group (2.5° vs. 7.4° [p=0.001], and 2.5° vs. 8.1°, [p=0.001] respectively). Therefore, according to these parameters, the screw parallelism was significantly better in the navigation group compared to the conventional group. There was a clear tendency for less re-operations in the navigation group (2 vs. 6) and less overall complications (3 vs. 12).

**Conclusions:** Navigation significantly improves the accuracy of screw placement in cannulated screw fixation of femoral neck fractures. It enables to determine the exact screw length needed and to correct all the parameters of screw placement in all planes simultaneously before actually drilling the screw. Thus, better scattering and parallelism can be achieved. The system reduces the variability in the placement of the 3 screws in each patient and enables reproducibility of the surgical results among different patients operated by the same surgeon. With the use of the navigation system, even less experienced surgeons can achieve better screw configuration according to recently described recommendations [4,5]. Therefore a better mechanical stability and reduced complication rates can be obtained. As only 2 fluoroscopic images are required for the entire screw insertion procedure, the radiation exposure to the patient and the surgical team is minimized. These may also affect the clinical outcome.

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CLINICAL EVALUATION OF A COMPUTER-ASSISTED SURGICAL PLANNING TOOL DEDICATED TO COMPLEX ARTICULAR FRACTURE REDUCTION

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Introduction: The anatomical restoration of a fractured joint conditions its optimal functional and physiological rehabilitation. As, by nature, intact joints have inherent complicated geometry, fractured joints become very complex 3D puzzles. When performing an open reduction surgery, the difficulty induced by the geometrical complexity is increased by the restricted surgical access to the fragments as well as by the surrounding soft tissues. The preoperative planning step is thus mandatory. To enhance geometrical perception of the fracture configuration and to enable interactive virtual repositioning of the bone fragments, a planning tool was developed and further evaluated.

Material and Methods: In-house CT-based software was combined with special hardware to offer better depth perception and more intuitive manipulation [2]. 3D models of the fragments are therein generated from the input CTs; the models are then available for stereoscopic rendering and virtual manipulation through a Spaceball, both features borrowed from the virtual reality techniques. In order to evaluate this planning tool, a study was designed to avoid relying on the performances of a navigation system. The aim was to clinically estimate the value of our planning system as a stand-alone tool without the use of an assessment tool, which itself is not fully validated. To achieve this goal, we organised our study so that the gold standard would be the intact anatomy; explicitly, as the best repositioning of the fragments is given by their positions in the intact bone, we wanted to compare all reduced fractures to the intact configuration. As acetabular fractures are very complex injuries to treat due to the pelvis geometry and the difficult surgical approaches associated with open reduction, we tested our tool in the context of acetabular fractures. Five MDs and four medical students performed the tests on four plastic pelvises -cadaveric rigidity obliged us to use plastic models rather than cadaver specimens. Each intact pelvis underwent the following process: (0) insertion of fiducial screws, (1) CT scanning -intact, (2) fracture generation following a standard fracture pattern, (3) CT scanning -fractured, (4a) conventional reduction planning, or (4b) virtual reduction planning, (5) actual blinded reduction, (6) Iso-C³D imaging -reduced fracture. From the 1st step, we derived virtual 3D
models of the intact pelvises. In the 2nd step, we generated the following fractures: 1 T-shape, 1 both columns, 1 anterior column posterior wall transverse and 1 transverse fracture. An oscillating saw with blade thickness 1mm was used to initialise the fractures. Once the cut in the plastic bone was deep enough to match the intended pattern, the bone was broken by hand. From step 3, virtual models of the fragments in the fracture configuration were extracted, ready to be manipulated in step 4b. Step 4b enabled to collect, for each participant, the results of their virtual reduction. In step 5, we blinded the participants to avoid visual control and to evaluate the accuracy of the mental image of the fracture, constructed after either conventional planning or software planning. Another specificity of our setup was the environment in which the pelvises were plunged for the reduction. Mimicking a surgical approach was not possible, but we immersed the plastic models in a medium viscous enough to allow movement of the fragments when manipulated as well as immobility of the fragments once positioned. Furthermore, this medium, without being a tactile soft tissue simulation, was a good soft tissue simulation for the Iso-C3D imaging modality. In addition, the time spent performing the actual repositioning –no insertion of screws or plate fixation- was recorded. At the 6th step, from the Iso-C3D images, we could retrieve the achieved positions of the fragments after fracture reduction. As in step 0 some fiducial screws had been inserted into the intact pelvises prior to scanning and fracturing, a paired-point registration could be performed on the virtual models. Registration was applied between each virtual fragment of a pelvis and its virtual intact pendant. The resulting transformation matrix quantifies the shift of the fragment to its ideal position, which is given by its position within the intact pelvis.

Results: For each fracture pattern, the average time spent for fracture reduction showed to be shorter after software planning than after conventional planning. To reduce the T-fracture, it took an average of 6’41” (std. dev.=2’57”) after conventional planning, and 4’02” (std. dev.=1’26”) after software planning. The both columns fracture repositioning needed an average of 6’42” (std. dev.=2’42”) after conventional planning and 3’08” (std. dev.=1’44”) after software planning. For the easiest fracture pattern, the transverse fracture -the only one with two pieces and not three- the difference was not significant; the mean reduction time amounted to 1’59” (std. dev.=0’56”) after conventional planning, and to 1’42” (std. dev.=0’37”) after software planning. The quality of the repositioning was quantitatively evaluated from the registration matrix computed for each fragment. For all three-pieces fractures, although they have different shapes, we named the two smaller fragments Pubic bone and Ischium. In the following, the ± notation will be used to indicate the deviation from the mean -in millimetres for translation or degrees for rotation- within an 80% confidence interval. Due to the amount of data collected, we choose to present here only the results for the most complex fracture pattern. The T-Fracture reduction gave the following results. The pubic bone fragment obtained an average virtual translation misplacement of 5.31mm±2.03 and an average rotation misplacement of 6.91°±2.43, with a registration mean error of 1.14mm; after software planning, the average real translation misplacement was 2.80mm±0.37 and the rotation misplacement reached 7.40°±1.33, with a registration mean error of 1.47mm; after conventional planning, the real translation misplacement equalled 5.03mm±1.81 and the rotation misplacement was 12.62°±6.43, with a registration mean error of 1.40mm. For the ischial fragment, the average virtual translation misplacement scored 6.12mm±1.02 and the
rotation misplacement, 14.64°±3.34, with a registration mean error of 0.59mm; after software planning, the average real translation misplacement attained 3.33mm±0.71 and the rotation misplacement, 8.78°±2.52, with a registration mean error of 1.04mm; after conventional planning, the average real translation misplacement was 15.88mm±9.63 and the rotation misplacement, 14.95°±4.02, with a registration mean error of 0.93mm.

Discussion: The time results gathered during this study measure the aptitude to match the subjective geometrical perception of each participant during the planning step and how he relates it to the actual configuration. As, for each participant, the sequence of fractured pelvises to reduce was randomised -no bias due to learning process, it appears that software planning slightly improved the time performances. Which tends to prove, if the quality of the reduction is at least equivalent with and without software planning, that our tool reaches one of its goals, the improvement of the geometrical and spatial understanding of the fracture configuration. The quality of the reduction, especially in the results presented here, is far from anatomically satisfying. In [1], the authors state that, up to 2mm, an incongruence of the joint is considered clinically acceptable. This hardly occurred in our study. But the big shift values obtained for the real reductions can be explained. First, there was bone loss between the intact and the fractured models, due to the sawing with a 1mm thick blade. Then, once a fragment was repositioned, there was no 100% reliable way to ensure that it would not move at all anymore. The shift values obtained in the virtual cases are more surprising, but nevertheless show that our system tends to reproduce the geometrical difficulties occurring in reality. This statement is even more obvious with the rotation misplacements, which are important (Fig. 1). The angular displacements show that the main geometrical difficulty while repositioning is within the rotational component.

Conclusion: Our tool, which was initially developed as a planning system for complex articular fractures, although receiving high acceptance from the users, does not seem to be very effective as a planning tool. Nevertheless, our study shows that it enhances the 3D understanding and simulates well the spatial difficulties encountered in reality.

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Figure 1. Overview of angular error for the pubic fragment.
ACCURATE SINGLE X-RAY IMPLANT MEASUREMENTS

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Background: The standard postoperative follow-up procedure for total hip arthroplasty involves the assessment of implant orientation from anteroposterior (AP) radiographs to assure the surgeon that the implant is correctly aligned. Improper placement can lead to impingement and dislocation problems, greater amounts of polyethylene wear, and implant loosening. The long-term follow-up procedure typically involves obtaining a series of radiographs over a period of years to detect any changes in implant alignment or in surrounding bony tissue. Accurate implant orientation measurements provide useful feedback to the surgeon who, based on this information, may be able to detect a systematic bias and adjust his operative technique accordingly. Information about implant orientation is also used to determine the need for revision surgery and other additional interventions. In the case of computer-assisted surgery, an accurate measurement of postoperative implant orientation is desirable for use in testing overall system accuracy and the consistency of performance. The standard postoperative follow-up procedure involves the acquisition of 2D anteroposterior radiographs (AP X-rays). The orientation of the implant is then measured on the resultant radiograph. The accuracy of this measurement depends upon the orientation of the pelvis at the time the X-ray was taken. When using an AP X-ray it is commonly assumed that the anterior pelvic plane is parallel to the film plane. Unfortunately, this is not guaranteed by the standard radiographic protocol. Pelvic flexion can vary considerably even for the same patient [2]. These pelvic pose variations will negatively impact implant measurement accuracy. The purpose of the present study is to validate Xalign, a tool for measuring implant orientation from conventional radiographs with improved accuracy. By coregistering a radiograph with both a synthetic X-ray, which is generated from a CT scan of the patient, and a projection of the implant CAD model, Xalign recovers the true pose of the implant with respect to the patient’s anatomy. A single CT scan, preoperative or postoperative, can be used to analyze an entire series of X-rays. This study analyzes the system accuracy of Xalign by examining the error in the measured implant pose.

Methods: An acetabular shell was implanted in a hard plastic phantom pelvis. The model was mounted on an acrylic sheet in order to increase rigidity and to improve the definition of the pelvic plane. Three small metallic fiducial markers were fitted to the acrylic plate in order to create a well-defined pelvic coordinate system. Two of these fiducials were placed near the anterior iliac spine points. The third fiducial was mounted between the left and right pubic tubercle points. A CT scan, with an in-plane resolution of 0.781 mm/pixel and an inter-slice distance of 1.25 mm, was then obtained. The HipNav Preoperative Planner [1] was used to determine the actual
acetabular implant orientation from the CT scan. The implant orientation was determined to be 56.28° abduction and 5.70° version. After measuring the acetabular implant orientation, the implant was digitally removed from the CT scan in order to simulate a preoperative CT and to make the alignment process more realistic. The acrylic sheet and the fiducials were digitally removed as well. The OptoTrak system (Northern Digital, Inc., Ontario, Canada) was used to verify the Planner cup orientation measurement. The locations of the fiducials and the location and orientation of the acetabular cup were digitized relative to a pelvic tracker using a series of pointer probe collections. The abduction/version of the cup differed from the Planner measurements by less than 0.2° in abduction and by less than 0.3° in version. Four AP X-rays, one for training and three for testing, were taken of the pelvic assembly using the standard 40” source-to-film distance. A small metallic washer was used to mark the source position on the film. Three of these X-rays were taken with the pelvis in a near neutral pose and one was taken with a pronounced pelvic flexion of -11°. The source position ranged from above the bottom of the sacrum to above the top of the sacrum. A group of ten users volunteered to use Xalign to measure implant pose. The measurements were taken in the following manner. First, the user roughly aligned the CT based synthetic X-ray with the real X-ray. The user then instructed the system to perform an automatic CT/radiograph alignment using mutual information (MI) [3]. Following pelvic alignment, the user magnified the implant area of the film. Next, the CAD implant was roughly aligned to the X-ray image. Then, the user instructed the system to use another MI based automatic method to recover the cup pose. The user could then apply manual manipulations and the automatic method until they were satisfied with the match.

Results: The average error between the Xalign measurements and the Planner measurements was -0.05° in abduction and -0.37° in version with a standard deviation of 0.16° and 0.94° respectively. The range of values for abduction was -0.49° to 0.21° and -3.10° to 1.68° for version. We performed a paired t-test analysis using Microsoft Excel 2000 to determine if there was any significant difference (alpha > 0.017 using the Bonferroni multiple comparisons correction) in the results based on the X-ray image used. There was no significant difference between any pair of images.

Conclusions: Using Xalign with the automatic mutual information method for registration, the three-dimensional anatomic orientation of the acetabular implant can be determined very accurately from a single AP X-ray. Implant version can be measured with a lesser accuracy than abduction, but still within the practical range. Version accuracy might be improved by adapting Xalign to work with multiple X-rays views simultaneously and by using edge enhancing filters.

Acknowledgements: Statistics Consultant: Maria Mor.

References:
ALGORITHMS FOR INTRAOPERATIVE SEGMENTATION OF 3D FLUOROSCOPY DATASETS

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Objectives: To develop an ideal and efficient method for intraoperative segmentation of 3D fluoroscopic images.

Introduction: Today’s routine operating room imaging technologies consist mostly of 2D imagery based on ultrasound and fluoroscopy. Intraoperative 3D imaging modalities based on CT or on MRI are in development, but are far too expensive for routine use in most hospitals. The emerging mobile fluoroscopic 3D technology linked to a navigation system combines the advantages of CT-based and C-arm-based navigation. The intraoperative, automatic segmentation of 3D fluoroscopy datasets would enable the combined 3D-rendered visualization of surgical instruments and anatomical structures. This visualization would likely enhance the intra-operative planning step, surgical eye-navigation and the digitization of anatomical landmarks. Segmentation methods that were developed for CT or MR datasets cannot be directly applied to 3D fluoroscopy datasets due to specific artifacts; generated mainly by the low number of projections used for the reconstruction. Since little is known about the segmentation of 3D fluoroscopy datasets, we performed a thorough evaluation of several adapted standard algorithms using a large set of cadaveric and patient data. There is also the added constraint that any algorithm used be computationally efficient.

Methods: We collected a database of over 80 3D fluoroscopic images from human-made objects of known geometry, as well as from cadaveric and clinical patient data acquired from different anatomical regions focusing on bone structures. The images were acquired with a standard Siemens Siremobil IsoC³⁰⁰ scanner, and have a field-of-view of (12.8cm)³ with a (0.5mm)³ voxel size. Additionally CT and 3D fluoroscopy images were acquired from plastic bones using the CT data as ground truth.

For segmentation of the 3D fluoroscopy datasets, we first studied automatic intensity-based algorithms based on Otsu’s threshold selection [2] and on histogram fitting [5]. Histogram fitting failed in preliminary tests as there were no distinguishable foreground classes in image histograms.

Otsu’s optimal threshold selection was combined with the morphological operations [4] opening and closing, as well as connected-component labeling (CCL); the latter to remove regions representing less than 1% of the segmented volume. Several approaches were taken using these operations in combination. The most notable
approach was to threshold using the Otsu value, followed by an opening operation, then a closing, and finally by a CCL with 1%-removal.

The adapted region growing algorithm we investigated is based on a connected-threshold region growing, which grows from seed points ideally located in bone regions. Since the 3D fluoroscopic images have low bone-to-background contrast, we expanded the given connected-threshold method, by adding two constraints, to allow more freedom when growing in bone structures. The first constraint uses the gradient magnitude map of the image we wish to segment as a boundary condition for growing. The second constraint corrects for leaking into the background. The region growing method required several input parameters to control the segmentation, as well as for seed selection. We added methods to automate the parameter-setting.

Using the 3D implicit geodesic snake method [1], we selected the region-based method for segmenting 3D fluoroscopic images due to high levels of noisy and artifact-bound edges. The fine parameters were tuned to the individual anatomical regions and the segmentation was initialized using the result of our adapted region growing algorithm.

Finally, we began investigating the use of deformable models for use in the segmentation of 3D fluoroscopic images. We first examined the deformable model provided with the Insight Tool Kit library. The model is a mesh formed from a user-input binary mask, and it is deformed to the gradient edges in the input image. At this stage we observed the performance of this model for one dataset, wherein its deformation yields a satisfactory result, and we will continue to apply this approach to our full image database in future research.

**Results:** All the segmentation methods performed within acceptable time limits on a standard Desktop PC, though the implicit snake method (5-8 min) was less computationally efficient than the other, less sophisticated methods (1-2 min). The best segmentation results were obtained with datasets from long bones (tibia, femur), followed by datasets from extremities (hand, head, ankle, knee, wrist, elbow). The segmentations of spine (cervical, thoracic, lumbar), pelvis and shoulder datasets were generally of poorer quality using the studied methods.

In analyzing the performance of our intensity-based algorithm, we observed that Otsu’s method for optimal threshold selection produced adequate values for the cleaner, higher contrast images. The more corrupted images, where a separate foreground class was hard to detect in the histogram, posed a problem for the threshold calculator. The system, however, did not depend solely on the value for the Otsu threshold, and despite a badly-thresholded initial image, the rest of the system proceeded to improve the quality of the segmentation. We observed a tradeoff in our analysis, in that to achieve cleaner segmentations using this approach, relevant structures were often removed by this method as a consequence.

Better results were obtained using the adapted region growing method, which demonstrated that this approach was a sounder choice than the intensity-based approach discussed above. The two parameters that had the greatest influence on the segmentation control the growing and the edge-stopping. The ideal case is when the
algorithm is allowed to grow freely within seed areas and yet restricted from growing past bone regions. In practice, we observed that the edge-stopping parameter sometimes became too restrictive and prevented ideal segmentation of bone regions. We present a qualitative evaluation of the results of this method in Table 1.

The implicit snake method produced more accurate and smoother segmentations and was able to remove wrongly segmented regions. The result of the deformable surface segmentation was strongly influenced by its initialization. When initialized with a set of seed points similar to those used for the region growing method, the resulting segmentation was worse in comparison. The method performed well when initialized with a rather detailed and good estimate of the surface. Its use is therefore constrained to being an improvement upon a prior segmentation step. In our tests, we initialized the implicit surface with the outcome of our adapted region growing segmentation. Due to the long computation time, however, the method is currently unfit for an intraoperative setting.

**Conclusions:** The results of our experiments agree with the studies of Rock et al [3], which show adequate quality of 3D fluoroscopic images for smaller joints and highly inferior quality for other anatomical regions. We presented our analysis of different methods for bone segmentations from 3D fluoroscopy datasets acquired from a variety of anatomical regions. The implicit snake method provided the best results in regard to segmentation correctness, but was less computationally efficient. The adapted region growing method performed sufficiently well for extremities such that we plan its use in specific clinical applications for enhancement of anatomical orientation for the surgeon.

This study presents a step forward towards efficient and correct intraoperative segmentation of 3D fluoroscopy datasets, but there is room for improvement. As a next step we plan to continue examining the model-based approach for datasets from selected anatomical regions (spine and hip). The selected approach has been observed for one preliminary case, and yields a good segmentation while remaining computationally efficient. We will next apply the model to all anatomical regions in our continuing development of an ideal segmentation procedure for 3D fluoroscopic images.

**Acknowledgments:** This research was partially funded by Siemens Medical Solutions and the Swiss National Center of Competence in Research CO-ME. Our algorithms are based on the NLM-funded open-source Insight Tool Kit (www.itk.org).

**References:**

Table 1 – Qualitative results of the adapted region growing algorithm

<table>
<thead>
<tr>
<th>Noise / Artifacts</th>
<th>S (1-5)</th>
<th>f, g, and h</th>
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</tr>
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<td>L/M</td>
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<tr>
<td>Foot</td>
<td>L/M-H</td>
<td>4.6</td>
</tr>
</tbody>
</table>

**Legend:**
- **Input Image:**
  - Noise rate: Low, Medium, High.
- **Structures (S):**
  - 1: Heavy loss of structure in the segmentation.
  - 5: The ideal state, where bone is fully segmented.
- **Noise, Artifacts, Tissue (NAT):**
  - 1: Image mostly corrupted by noise and artifacts, and no pertinent forms can be recognized.
  - 5: Ideal. Noise, artifacts, or tissue are not segmented.
  - f: Controls growing.
  - g: Controls seed selection.
  - h: Controls gradient weight.
COMPUTER-ASSISTED SHOULDER HEMIARTHROPLASTY FOR FRACTURES OF THE PROXIMAL HUMERUS: AN IN VITRO COMPARISON WITH TRADITIONAL METHODS

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Introduction: The functional outcome and durability of shoulder hemiarthroplasty is related to the ability of the prosthesis to accurately recreate the normal anatomy [2]. Positioning of the humeral implant is traditionally based on referencing proximal humeral anatomic landmarks. Unfortunately, it is particularly difficult to achieve proper implant placement in the case of proximal humerus fractures, since most anatomical landmarks have been damaged. The objectives of this study were to develop a computer-assisted shoulder hemiarthroplasty system for treatment of fractures of the proximal humerus, and to evaluate this system in comparison to traditional methods in an in vitro model. Our hypotheses were that development of a computer-assisted shoulder hemiarthroplasty system can be achieved using current technology, and that accuracy and consistency of anatomical restoration will be improved, in comparison to traditional methods.

Materials and Methods: The study utilized 4 pairs of intact cadaveric shoulders, with a mean age of 69 ± 16 years. One specimen from each pair was randomized to the computer-assisted technique, while the contralateral shoulder underwent a traditional hemiarthroplasty. A simulated four-part proximal humerus fracture was created and a modular shoulder hemiarthroplasty system (Anatomical Shoulder Hemiarthroplasty System, Centrepulse Orthopaedics Inc, Austin, TX) was employed. For the computer-assisted procedure, relevant proximal humerus characteristics were determined from CT data using a coordinate system based on distal humerus anatomical landmarks and analyzed using custom-designed software which allowed the creation of computer simulations (Mimics and MedCAD, Materialize, Ann Arbour, MI). Real-time intraoperative feedback was provided by an electromagnetic tracking system (Flock of Birds, Ascension Technologies, Burlington, VT) and a custom-designed graphical surgical interface (National Instruments, Austin, TX). Analysis involved assessment of accuracy of anatomic restoration, following a postoperative dissection, by comparing the native (pre-surgical) and reconstructed (post-surgical) humeral anatomy. Statistical analysis utilized paired t-tests.
**Results:** The computer-assisted technique shows a trend of improved accuracy and consistency. The values for humeral head offset and articulation point were improved with the computer-assisted technique ($p<0.05$). The computer-assisted technique was, on average, more likely to overestimate the inclination angle, whereas the traditional technique caused an underestimation of the inclination angle compared to the native humeral geometry ($p<0.05$).

**Discussion:** Computer-assisted surgery is becoming more widely accepted due to its success in various areas of orthopaedics [4,5]. Accurate anatomic restoration has been shown in previous studies of shoulder hemiarthroplasty to be extremely important for achieving desired joint range of motion and satisfactory shoulder function [1,3]. This is the first computer-assisted shoulder hemiarthroplasty technique that has been reported. This novel technique allows patient specific anatomic restoration based on preoperative CT data, with real-time intraoperative surgeon feedback. Overall, the computer-assisted technique shows a trend of improved accuracy and consistency of anatomic restoration, in comparison to traditional methods. Our results have shown a statistically significant improvement in accuracy for anatomic restoration of humeral head offset and articulation point ($p<0.05$). With further investigation and refinement, this technique should allow improved anatomic reconstruction of the proximal humerus, potentially resulting in improved patient outcomes. The technique may also be a valuable resource for the laboratory training of inexperienced surgeons and residents.

**References:**

ANATOMOMETRIC ACL NAVIGATION USING BONE MORPHING: RESULT ON 150 PATIENTS

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\textbf{Introduction}: The aim of this study is to show the possibilities and the constraints of the image-free anatomometric Anterior Cruciate Ligament (ACL) navigation based upon the Bone Morphing concept (The word \textit{anatomometric} is used to describe that both anatomical and isometric properties are taken into account). This technique has been implemented on the open Surgetics station designed and manufactured by Praxim Medivision (La Tronche, France). The system is easy to operate using a unique double footswitch command.

The aim of the Surgetics application is two-fold:

a) Display \textit{biomechanical} measurements and \textit{anatomical} 3D information during the intervention in order to guide the surgeon according to his/her own criteria

b) Record an intra-operative report of the intervention, including all the relevant information.

\textbf{Material and Methods}: As for the instrumentation, the surgeon’s own preferred guides (equipped with retro-reflective markers) are used with the Surgetics navigation system under arthroscopy. The Surgetics protocol designed for ACL surgery is image-free and can be divided into four steps:

Installation and parameterization of the system including instrument calibration and passive flexion/extension of the knee

Bone Morphing \textregistered process for surface acquisition on tibia and femur

Planning and navigation on tibia and femur, including measurements of anisometry between the selected insertion points, and including visualization of possible conflicts of the virtual graft with the notch
Final check where the graft is assessed *qualitatively and quantitatively* in terms of anterior and external fiber impingement and anterior fiber (an)isometry.

Those steps and functions are detailed in [2,3].

**Results:** A series of 150 ACL reconstructions were performed successfully using this Surgetics technique.

Conclusion #1: The navigation system yields to a computerized description of the anatomy of the knee; indeed, based on tests on specimen, on the femur, we found a geometric correlation between the crest line of the anisometry chart given by the computer and the location of the anatomical insertion site of the natural ACL. Positioning the anterior part of the femoral tunnel in the most isometric area given by the computer (isometry concept) is equivalent to position it in the most anterior part of the original ligament (anatomy concept). This important result means that there is no contradiction between navigation and anatomy based placement: navigation helps to position the tunnels inside a large anatomical region.

Conclusion #2: The navigation system allows us to fit the tunnels the best to each patient’s unique anatomy. As described below, there was significant variation of tunnels placement using navigation in comparison with conventional techniques. This second conclusion remains dependant on the criteria chosen by each surgeon to define an optimal positioning according to anatomy and isometry.

In the following, we present the results obtained by one experienced surgeon in a group of 95 patients when using the system with his own criteria and comparing to a standard instrumentation (Arthrex, Naples FL).

Result #1: Compared to our standard instrumentation, 3 times out of 4 the system lead us to a more anterior and/or medial positioning of the tibial tunnel. Data were analyzed in 76 cases: 21 were unchanged with respect to the standard instrumentation within 3 mm (28%) and 55 were modified by more than 3 mm (72%). Details are presented in Table 1(a). It contributes to demonstrate conclusion #2.

Result #2: As for the positioning of the femoral tunnel, this series of interventions taught us that:

- The standard instrumentation alone (at least our usual instrumentation in our hands), cannot ensure an optimal anatomometric positioning of the central fiber of the graft on the femur. This result was already reported in [1].

- On the other hand, navigation allows the surgeon to choose the position of the tunnels using the information displayed by the system, among which the expected anisometry curve of the central fiber of the graft.

Result #3: This navigation system helps us to reduce the number of compulsory notch plasties performed at the end of the intervention. Using navigation as compared to our conventional technique, the number of compulsory notch plasties has been divided by 5. Using navigation, such notch plasties were only performed 1 time out
of 10, whether a preliminary notch plasty had been performed at the beginning of the intervention or not. See details in table 1.(b).

Result #4: This navigation system helps us to objectively assess the quality of the graft at the end of the intervention with two quantitative means:

- In terms of anisometry of the anterior fiber: the mean measured anisometry for the series of patients undergoing surgery assisted by the system was less than 3mm.

- In terms of contact-impingement: a residual contact or conflict between the graft fibers and the notch can be easily detected and treated.

**Conclusion:** The contribution of this navigation system is very valuable in clinical routine and the additional operating time of about 15% seems to us as a fair price to pay. It is only a powerful measuring tool which is very versatile; each surgeon can use it according to his/her own criteria for optimal placement of the graft.

In the hands of a very experienced ACL surgeon, in comparison with a conventional instrumentation, it has demonstrated that it influences the positioning 1) to reduce the anisometry to a mean value of 3 mm whilst it remains in the anatomical area and 2) to reduce the occurrence of final notchplasty by a factor 5 compared to conventional techniques. In particular, prospective studies are being carried out to evaluate the short and long-term incidence of a correct anatomometric graft positioning performed with the help of the system.

**References:**


Table 1(a): Modification of tibial insertion using navigation. In a series of 76 cases, 21 tibial insertions were not modified with respect to standard instrumentation, 55 were individualized using navigation data amongst which 61.8% were modified anteriorly, 32.7% were modified anteriorly AND medially, and only 1.8% pushed posteriorly.

Table 1(b): Percentage of notch plasties performed in conventional technique (91 cases) versus with navigation (86 cases)

1: percentage of plasties at the end of surgery (46/91 versus 10/86)

2: percentage of plasties at the end of surgery including initial plasty (24/54 versus 3/29)

3: percentage of plasties at the end of surgery without initial plasty (22/37 versus 7/57)
VIRTUAL IMPLANTS DATABASE FOR COMPUTER ASSISTED SURGERY: A NEW SYSTEM TO EFFICIENTLY ACCESS ORTHOPEDIC IMPLANTS FOR PLANNING AND NAVIGATION

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Introduction: Current computer aided surgery systems often display simplified shapes of implants or instruments[3,4]. Photo-realistic visualization of these objects greatly improves the usability of navigation systems, especially those that are based on calibrated fluoroscopic images[1,2]. Hundreds of different implants are used in trauma, prosthetic, spine and cranio-maxillofacial surgery. During surgical procedures that use CAS systems, an efficient technique allowing surgeons to choose the best fitting implant can help in reducing operation time and in improving accuracy.

Our goal is to establish a virtual implant database containing geometrical as well as calibration information for trauma implants and instruments. The goal is to allow different surgical navigation applications to navigate any number of different types of implants from this database. In the future this database will enable and facilitate the rapid integration of those surgical devices into existing or future Planning and Navigation systems by providing a standard interface.

Methods: We can summarize our development process in a fews steps: Domain Analysis, Methodology Setup, Unified data format definition and implant requirements, Implant Processing, Database Design, System Interface Design and Implementation, Test and validation client applications.

Design Methodology: Our development is based on the Unified Modeling Language (UML), Object Oriented (OO) and C++ programming techniques. We also use a Standard Query Language (SQL) database management system.

Unified data format definition and implant requirements: This step is still under development and the final result will be a well-defined Extensible Markup Language (XML) implant description file. This will allow semi-automatic implants update in the database through a dedicated administration tool.
Virtual Implant Database Design: During the database design, we created generic objects to handle each supported implant type. To add implants to our database, the information we need depends on the implant category and type (plate, screw, nail, etc.). The implant manufacturers provide to us: Implant geometry and additional information (implant CAD-Coordinate system, common coordinate points).

System Interface Design and Implementation: Our system is composed of three main parts: the implant data storage component, the core processing component and the published interface component usable by any CAOS application.

Results: After evaluation of existing database systems, we set up an implant database running on a Linux PC. Our implant interface provides CAS applications simultaneous communication and search algorithms for implants in a client/server mode. We currently support osteosynthesis plates, screws, nails and hip prostheses (stems, cups, and heads). The delivered solution can be used on Linux, Windows and Solaris operating systems. Some preliminary tests have been carried out with long bone fracture reduction planning [Xiao Dong and Vitanis Viton, 2003] and with digital template planning software [Christoph Anderegg, 2003]. Moreover, a virtual implant browser system was developed for multi-purpose demonstrations.

Conclusions: In order to address the current limitations in the way CAS systems manage orthopedic implants, we have developed a new system which allows CAS system independent access to implants. Compared to existing solutions our approach has many advantages: data reusability, security mechanisms, a robust database system, client/server architecture, and a framework for rapid application development (RAD) which allows CAS applications to focus more on surgical procedures. This project is still under development, and many additional features and research topics will be addressed in the near future: clinical tests, support of not only surface-based 3D objects but also volume-based 3D objects, improvement of search functionalities and the addition of intelligence.

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References:

TOWARD THE COST-EFFECTIVE IMPLEMENTATION OF CUSTOMIZED CAOS APPLICATIONS

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Introduction: Until now each new computer assisted orthopaedic surgery (CAOS) application is considered as an individual system, and its development is often time-consuming. These systems offer, however, similarities and common functionalities. Consequently, we envision the integration of programming techniques to enable the reuse and customization of already implemented functionalities as well as the automation of the application development process. Software components, which can be simply defined as building blocks from which an application can be composed, are essential to these technologies. We present here the specification and implementation of such software components for the development of CAOS applications.

Objectives: To enable the fast generation of highly customized software for computer-assisted planning in orthopaedic surgery.

Background: With the appearance of a set of methods and tools known as “generative programming” (GP), the software industry is currently undergoing fundamental changes. Analogous to the industrial revolution of the last two centuries the software industry is aiming nowadays to the automated production of software. Generative programming is a software engineering paradigm based on modeling software system families such that given a particular requirement specification, a highly customized and optimized intermediate or end-product can be automatically manufactured on demand from elementary, reusable implementation components by means of configuration knowledge [1].

Method: The integration of GP techniques requires focusing on a software system family, in our project we concentrate on CAOS planning applications. For feasibility reasons we restricted our focus and carried out a domain selection based on two considerations: the definition of the most clinically mature CAOS planning applications and the identification of the planning applications that would provide a reasonable collection of functionalities. As a result, we decided to focus on those CAOS systems that deal with CT based operation planning. Ours method follows a commonly defined process in GP. It consists first of implementing a set of components from which applications can be assembled, then designing a means of specifying an application member of the domain and finally, defining the configuration knowledge to allow the mapping between the specification and the application.
Results: We present here the results of the first phase of the previously mentioned method. We performed a domain analysis based on the following sources: published papers, user manuals, and discussions with expert developers. From the reviewed systems, we kept a set of 15 systems as our references, and we extracted a set of eleven features that would be sufficient to define any CT based planning application. All the considered applications require the functionality to load the patient data. They all provide 2D and/or 3D data visualization (with optional X-Ray simulation) allowing the surgeon to evaluate the problem and to define, if necessary, a surgical tool trajectory or some specific anatomical parameters. CT based planners usually allow the simulation of intraoperative actions such as implant/prosthesis positioning, osteotomy and fracture reduction. The most frequent post-operative outcome evaluation is a joint range of motion evaluation. Finally, the acquisition of landmarks is the most common preoperative request for intraoperative matching. For validation purposes we asked a group of six surgeons to assess the defined set of features. Then, based on our existing reusable software design environment (framework), we determined a common architecture and implemented the first set of components that are plug compatible with this architecture.

Discussion: Until now, CAS research development only addressed major issues such as safety and accuracy. More subtle issues like lifetime and cost effectiveness had not yet been satisfactorily investigated [2]. Orthopaedic surgical practice is continuously evolving due to new procedures being introduced and old procedures undergoing evolution. Thus, there is considerable risk for systems to rapidly become obsolete. Our approach addresses this issue by enabling rapid reconfiguration and evolution by means of unplugging obsolete components and plugging in new or evolved ones. Furthermore initial studies suggest that component based application engineering results in an improvement in programmer productivity, a reduction in time-to-market and a decrease in maintenance costs. Consequently, the introduction of GP, which relies heavily on component-based development, is a potential solution for improving the cost effectiveness of CAOS systems.

Conclusion: The achievement of the first phase of our investigation process gave us a partial confirmation of the assumption that the CAOS domain is a potential candidate for generative programming. We now aim to refine our set of components and to investigate the extent to which the implementation process can be automated.

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3D NAVIGATION WITH SIREMOBIL ISO-C3D IN FRACTURES OF THE PELVIS

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Introduction: The mobile SIREMOBIL® Iso-C3D (Siemens AG, Medical Solutions, Erlangen), is a mobile C-arm with true isocentricity and 190° orbital movement, it is the first device that allows the intraoperative three-dimensional representation of bone structures. This facilitates direct process and result control of reconstructive surgery [1 to 5]. The 3D workstation simultaneously calculates a high-resolution isotropic 3D data cube in the isocenter with an edge length of approximately 12 cm. The link established between the SIREMOBIL® and the navigation system with the integrated NaviLink™ (Siemens AG, Medical Solutions, Erlangen) interface makes it possible to transfer the generated 3D data directly to the connected navigation system. Injuries of the pelvis, especially with combined anterior and posterior instability, require the stabilisation of both the anterior and posterior pelvic ring. If the injury only involves the ligamental connections, then a transileosacral osteosynthesis with screws is the minimal invasive and biomechanical method of choice. The difficulty with this approach is the correct placement of the screws. Their position must be monitored intraoperatively in 3 planes (inlet, outlet and lateral viewing). The aim of this study was to evaluate the clinical advantages of 3D Navigation with Siremobil IsoC3D in Osteosyntheses of fractures of the pelvis.

Methods: In the period from August 2001 to December 2003 a total of 16 patients with fractures of the pelvis and screw osteosynthesis were registered in a prospective study. These patients required intraoperative linear surgical action, which in most cases included screw placement. All patients were treated by computer-assisted percutaneous transileosacral screw osteosynthesis or screw osteosynthesis of the anterior pelvic ring or the acetabulum. In this study we used the SurgiGATE® navigation system. In addition to the clinical baseline parameters the duration of the surgical intervention, fluoroscopy duration, and times required for navigation were also documented intraoperatively.

Results: 16 patients who underwent successful navigation with intraoperative Iso-C3D images were included in the study. A total of 29 drilling procedures were performed in the 16 patients. 12 patients underwent screw placements on the iliosacral joint, one of the anterior pelvic ring and two of the acetabulum. A postoperative CT was performed on patients who did not have a direct, postoperative control scan with the SIREMOBIL Iso-C3D. One screw showed an intraforaminal malplace-
ment without neurological defects. All other screws were correctly positioned during the postoperative controls. No infections or neurological complications were found postoperatively. In two cases a slight tangential screw thread penetration through the ventral sacrum was detected. The average fluoroscopy time for recording the 3D scans and performing the 2D control measures was 1.41 minutes.

Conclusions: This prospective study shows the clinical application of navigation with three-dimensional data sets from the SIREMOBIL Iso-C³D and automatic registration, for fractures of the pelvis. The purpose of the navigation system is to improve the precision with which screws are positioned and to reduce intraoperative false drillings and corrections. The reduction of intraoperative radiation exposure is likewise important. CT-based and C-arm-based navigation systems improve the screw placement quality in anatomically complex regions of the locomotorium and at the same time reduce the intra-operative fluoroscopy time. However, both procedures are subject to system-immanent limitations. Registration of the CT data set first requires a data set that is suitable for navigation, and hence it has to be custom made. The preoperative processing is time-consuming. While the registration is done automatically in C-arm-based 2D navigation, there are significant limitations with respect to the image quality and the display of complex, three-dimensional structures in 2D. Navigation with the SIREMOBIL Iso-C³D does not suffer all these limitations and disadvantages. The total average fluoroscopy time for recording the 3D scans and performing the 2D control measures is significantly shorter compared to the fluoroscopy time during standard procedures. Furthermore, all OR personnel can be located outside the control area when recording the 3D data set. The most important aspect is certainly the precision of the navigated actions. We found only one incorrect screw position in the entire Iso-C³D group. In this respect, Iso-C³D navigation is not only superior to the conventional approach, but also yields better results than the C-arm-based 2D navigation and CT-based navigation procedures that were normally used in our clinic. The results of our study reflect the trend described in the literature: Computer-assisted procedures yield an additional increase in intraoperative precision, whereas the greatest precision, as demonstrated here, is achieved with the new Iso-C³D navigation.

References:

A CT BASED SYSTEM TO CALCULATE RANGE OF MOTION OF THE HIP JOINT AND TO SIMULATE THE FEMOROACETABULAR RESHAPING

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Motivation: The conflict between the femoral head and the acetabular rim also known as femoroacetabular impingement (FAI) can be a cause of hip pain, limit range of motion (ROM) as well as lead to labral degeneration with acetabular cartilage lesions in young and physically active patients [1, 5]. This phenomenon is focused on motion rather than on the axial loading of the hip joint [1]. Therefore, an interactive 3D-visualization of the new pathogenetic concept is mandatory for a better understanding of this mechanism. There are two types of FAI, cam and pincer impingement. The former is caused by jamming of a non-spherical part of the femoral head into the acetabulum during hip flexion and internal rotation. The latter is the result of linear contact between the acetabular rim and the femoral head-neck junction due to acetabular overcoverage generally seen anteriorly. Surgically trimming the overdeveloped part of the acetabular rim and resecting the aspherical portion of the femoral head can increase impingement-free hip motion and should reduce pain as well as prevent further degeneration and osteoarthrosis of the hip joint. A new CT based computer system was developed to calculate the preoperative range of motion, to identify the acetabular and femoral location of impingement as well as to simulate the post-operative hip motion after the surgical reshaping.

Material and Methods: To perform impingement simulation with the assistance of the new system a CT scan of the patient’s pelvis has to be acquired, which includes approximately 10-cm of the proximal part of the femur and 4-cm of the distal femur covering the epicondylus area. On the basis of the CT data a virtual 3D model of the patient’s hip joint is created (segmentation). A pelvic reference coordinate system based on the anterior pelvic plane concept [5] is established using both anterior superior iliac spines and the two pubic tubercles. On the femoral side to calculate the anatomic coordinate system the strict geometrical definition presented by Murphy [3] is applied, for which the posterior aspects of the two femoral condyles, the femoral head, the knee center, as well as a point on the proximal shaft axis are digitized within the CT data. Next, the acetabular contour is marked on the 3D model to exclude undesirable impingement within the acetabular
socket area, which could limit the motion analysis to non-dysplastic hips. To calculate the range of motion within the individual virtual hip joint an impingement detection algorithm was used that has been presented before [2]. It enables fast and accurate calculation based on volumetric 3D models and can be used in any medical application to detect impingement between any anatomical structures and/or implant models. Applying this algorithm to the volumetric data of the patient’s hip joint allows the automatic simulation based on anatomic coordinate systems to perform ROM analysis. Passive manipulations of the hip joint are usually performed during routine physical examination. This motion can be simulated and quantified in an anatomically based way within flexion/extension, abduction/adduction, internal/external rotation as well as internal/external rotation in 90-degree flexion direction. Results are displayed to the surgeon numerically in a text field [Figure 1.]. Moreover, upon user request, the ROM and zone of impingement can be displayed in 3D for each analyzed motion pattern. Additionally, the impingement examination of the impingement-free hip motion performed virtually using the mouse is available. To provide more information about the shape of impingement zones, more detailed evaluation is possible. For this purpose, the range of hip flexion is defined manually by a user (e.g. 90° - 110°). Based on this definition, a combined joint motion is calculated in the abduction/adduction, internal/external direction. Moreover, the set of impingement points detected during those virtual examinations is plotted onto the 3D models of the pelvis and the femur. In order to simulate the correction of the hip joint deformity reshaping the virtual model of the patient’s hip joint can be performed. Within the pelvic approach, two points representing the borders of the overdeveloped part of the acetabular rim abnormality have to be defined with the help of a clock system [1]. They are used not only to determine the extent of the simulated osteotomy but also to modify the initially defined socket outline. On the femoral side, to simulate the surgical resection of the non-spherical part of the femoral head-neck junction, the width of the femoral head-neck junction has to be identified and measured as an angle formed between the axis of the femoral neck and the line connecting the center of the femoral head with the point representing the concavity of the femoral neck [4]. For this purpose, we provide to the user a tool, which helps her/him precisely localizing the rotation center of the femoral head and quantifying any abnormal contour of the head-neck junction. Using this information the 3D virtual reduction of an aspherical part of the femoral head can be achieved. At last, taking the new volumetric data into consideration, the automatic simulation of the increased ROM of the hip joint is repeated and results are presented in a written form.

**Results:** Extended in vitro studies (on plastic models and on cadaveric specimens) are currently being planned. First results will be available at the time of the conference.

**Conclusion:** This system will help surgeons analyzing the FAI mechanism and will provide them with an essential tool for preoperative planning. Moreover, this 3D computer-assisted method allows virtual exploring and evaluating an appropriate surgical treatment of the impingement hip of any individual patient. The CT scan data and the 3D models as well as the information about simulated impingement-free ROM and the collision zones will be used as the basis for intraoperative surgical navigation. Finally, in selected cases this should allow performing an efficient surgical
treatment through a minimally invasive surgical approach and/or potentially with the use of the hip arthroscopy.

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**References:**

Figure 1. The routine, passive examination of the hip joint motion is simulated and anatomically quantified results of flexion/extension, abduction/adduction, internal/external rotation as well as internal/external rotation in 90-degree flexion motion are displayed numerically. The range of internal rotation in 90-degree flexion and the zone of impingement for this motion pattern are presented. Moreover, the outline of the acetabular rim is visible.
A FORCE-SENSING DEVICE FOR LIGAMENT BALANCING IN TOTAL KNEE ARTHROPLASTY

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Introduction: Common causes of dysfunction after Total Knee Arthroplasty (TKA) are component loosening and instability, which are mainly due to a tibio-femoral misalignment or a ligamentous imbalance. While current surgical tools and navigation systems help to achieve a precise alignment and placement of the prosthesis, the ligamentous force balance is still qualitatively assessed by the surgeon through manual trial movements of the limb. An objective and quantitative measurement of the forces acting within the knee would help the surgeon to improve the accuracy of the ligament balancing procedure, thus ensuring a good joint stability and an increased prosthesis lifetime. Within this framework, we developed a force-sensing device for TKA that provides precise, real-time, quantitative measurements, while permitting the patella to be kept at its anatomical place and ensuring a small bone resection.

Materials and Methods: The developed force-sensing device consists of two sensitive plates, one for each condyle, a tibial base plate, which is fixed by customized surgical pins, and a set of lateral and medial wedges, which allow varying the tibio-femoral gap. Due to its small thickness (6mm), the device entirely fits inside the knee joint in the tibio-femoral gap with the patella in its anatomical place after an initial tibial precut. Each sensitive plate contains three deformable bridges instrumented with thick-film piezoresistive sensors, which have been designed to reach their yield point at a load of 500N. Applying a load in the sensitive area generates three vertical reaction forces, whose amplitudes are measured by the piezoresistive sensors and allow determining the amplitude and location of the applied load from the static equilibrium conditions. Knowing the force amplitude and the medial-lateral location of each condyle, the net varus-valgus moment of the contact forces, which is regarded as the parameter characterizing the ligament balance/imbalance, can be computed. Following a calibration, the intrinsic accuracy of the device was evaluated by loading the sensitive area with weights ranging from 0 to 100N applied at 20 evenly distributed locations. To validate that the device is suitable for the purpose of ligament balancing, a control experiment was performed with a plastic knee joint model equipped with adjustable springs, which played the role of the collateral ligaments. Different spring tensions were applied representing ten levels of medial and
lateral imbalance. According to laws of mechanics, a linear relationship between the spring tension and the net varus-valgus moment of the femoral contact forces should exist with the proportionality factor being the lever arm of the spring forces. Finally, the device was tested in a cadaver experiment by an experienced surgeon. After a standard opening of the knee, a tibial precut of about 6mm was performed and the device installed. The amplitude and location of the contact forces of the femoral condyles were measured in full extension before and after a ligament balancing.

**Results:** During the accuracy study, which validated the system’s calibration and functioning, the maximum force amplitude and location measurement error, i.e. the maximum deviation from the given weights and locations, were 1.4N and 0.6mm. In the plastic bone experiment, the expected linear relationship between the spring forces and the net varus-valgus moment was experimentally verified and the slope corresponded to the measured lever arms within 12%. This deviation is due to the cumulative effect of the intrinsic measurement error of the device, the adjustment uncertainty of the spring tension as well as the play in the mechanical fixation of the springs. During the cadaver experiment, the contact forces of each condyle ranged from 40N to 70N when no external forces were applied. When the surgeon manually applied varus-valgus loads, the maximal contact force reached 350-400N. Consequently, the design specification of 500N maximal loading seems appropriate. In a second step, the surgeon released the medial collateral ligament guided by the measurements of the device leading to a reduction of the initial imbalance of 1.25±0.12Nm to 0.15±0.12Nm. The ligamentous balance thus achieved was consistent with the surgeon’s manual perception of a balanced knee.

**Discussion:** The proposed force-sensing device for ligament balancing in TKA provides not only the tibio-femoral contact forces but also their resultant varus-valgus moment, which describes the ligament balance. Furthermore, the device offers the advantages of real-time measurements, of keeping the patella in its anatomical place during the measurement and of a minimal bone resection, which helps to preserve the joint line. The intrinsic accuracy of 1.4N and 0.6mm should be sufficient for this application. The plastic bone experiment affirmed the device’s suitability for the purpose of ligament balancing. The data acquired during the cadaver experiment demonstrated the suitability of the designed measurement scale. The agreement between these preliminary in-vitro measurements and the surgeon’s perception tends to confirm the soundness of the balance measurement principle. In conclusion, the design of the force-sensing device has been experimentally validated and shows a strong potential to provide useful quantitative information and effective assistance during the ligament balancing procedure in TKA.

**Acknowledgements:** The authors would like to thank the Swiss National Science Foundation for the financial support within the National Center for Competence in Research program Co-Me.
A HYBRID CT-FREE NAVIGATION MODULE FOR ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

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Introduction: The Anterior Cruciate Ligament (ACL) is the most commonly injured ligament in the knee. The standard treatment for this injury is an endoscopic reconstruction using an autogenous graft. While this type of technique causes minimal trauma, a recent consensus within the International Knee Society revealed that, in current clinical practice, approximately 40% of ACL grafts are being surgically misplaced. These misplacements can be partially attributed to the restricted local endoscopic view inherent with minimally invasive procedures. In 1999, a computer assisted surgery (CAS) system was developed at the M.E Müller Institute for Orthopaedic Research to perform the intraoperative planning and guidance for ACL reconstructions[4]. Initial clinical experiences with the system have been very positive[2] however, there have been some concerns expressed by inexperienced surgeons about the trial and error procedure of the ligament planning step. In order to address these concerns we have incorporated a navigated C-Arm into the system. This provides us with navigated fluoroscopic images which we are using to investigate the possibility of automating the ligament planning procedure.

Materials and Methods: Setup: Tracking of the patient and surgical instruments is performed by an opto-electronic navigation system (Optotrak 3020, Northern Digital, Canada) that tracks infra-red markers contained in marker shields. Interoperatively, surgeons must attach marker shields to the femur and tibia, and verify the calibration of tools, as previously described by Sati et al[4]. With the setup complete, the surgeon now acquires the fluoroscopic images to be used for planning and navigation. Image Acquisition: Conventionally, diagnostic x-rays are typically acquired before surgery to identify abnormal knee geometry. During surgery, this information remains on a light box, thereby requiring surgeons to make a mental link between the image data and the endoscopic view. Our original system was able to rectify this problem by allowing a diagnostic x-ray to be input into the system, and then allowing the surgeon to register the image with the patient by manually aligning the image with prominent digitized structures. By integrating a navigated C-Arm with the system, we can now provide surgeons with the ability to capture and upload navigated fluoroscopic images directly into the system. The use of the navigated images means that the images are automatically registered with other navigated objects in the system such as instruments and digitized landmarks. Landmark Acquisition: Surgeons can digitize any landmarks they feel are important for planning.
the ligament insertion points by simply running the tip of a tracked instrument over the surface of the landmark while pressing on a foot switch[4]. Planning: As in the original system, the insertion points can be identified with a navigated instrument (palpation hook, pointer etc) in one of two ways:1) directly under endoscopic control, or 2) with respect to digitized landmarks in a standard 3D view[4]. Now, with the integration of a navigated C-arm into the system, we can offer surgeons two additional planning alternatives: 1) using navigated fluoroscopic views, the surgeon can directly identify the insertion points on the images by positioning a cursor with a mouse, or 2) using one of the template-based planning methods incorporated into the system. Currently we have incorporated the planning methods of Bernard[1] and Klos[3]. These methods were identified from an extensive literature search as being the most suitable for adaptation to our system. These methods only calculate the femoral insertion point in the sagittal plane, therefore the tibial insertion point and the tunnel endpoints must be identified using one of the other planning methods. When the internal insertion points and the tunnel endpoints have been identified, the graft and tunnels are displayed in 3D views as cylinders. The diameters of these cylinders can be changed to match the diameter of the prepared graft. Any impingement that may result from the proposed reconstruction can now be visualized as the intersection of the graft cylinder with any of the intraoperatively digitized structures (usually the femoral notch) as the knee is moved into full extension. Drilling: With the planning complete, the system provides navigational feedback to help successfully execute the plan. Evaluation: The system is currently being evaluated in the laboratory using cadaveric specimens. The main objective of this evaluation is to evaluate the effectiveness of the image based planning techniques in reducing the planning time. Following this, we will conduct a preliminary clinical trial to evaluate the clinical accuracy of the proposed system. The results of this trial will be available around the date of CAOS 2004.

Discussion: In order to address areas of concern which were raised during initial clinical experiences with our previous ACL module, we have presented the details of a Hybrid CT-free Navigation Module for ACL reconstruction. Through the integration of the C-Arm navigation module and the template-based planning routines, we hope to alleviate the trial and error procedure of ACL insertion point planning. Successful trials of the template-based planning techniques will allow us to focus on automating the planning procedure.

References:

ACCURACY OF FLUOROSCOPIC COMPUTER-ASSISTED PEDICLE SCREW PLACEMENT THROUGH A POSTEROLATERAL FUSION: AN ASSESSMENT OF 20 CONSECUTIVE CASES

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Introduction: The insertion of pedicle screws however, can be a technically demanding procedure with a potential for significant neurological, vascular, or visceral injury. In-vitro and clinical studies using free hand or fluoroscopy-assisted techniques for pedicle screw insertion have reported misplacement rates ranging from 3% to 55% in the lumbar and thoracic spine. Placing pedicle instrumentation through a posterolateral fusion mass intuitively carries a significantly higher risk of pedicle wall violation compared to screw placement with normal anatomy. However the in-vivo accuracy of these conventional methods has not been reported. The purpose of this study was to evaluate the clinical accuracy of computer-assisted fluoroscopy for the placement of lower thoracic (T) and lumbosacral (LS) pedicle screws through a posterolateral fusion mass.

Methods: Our patient sample consisted of twenty consecutive patients at an academic teaching center undergoing revision spinal surgery for sagittal plane deformity and / or degenerative spinal disorders. The position of 84 pedicle screws consecutively placed in through a posterolateral fusion mass (LS (L1-S1) n=74 / T (T10-T12) n=10) was assessed. All screws were placed prior to any decompression and at an academic teaching center using the FluoroNav™ system (FluoroNav™ -Medtronic Surgical Navigation Technology, Louisville, CO,USA). True AP and lateral fluoroscopic images were utilized for all screws. Residents and fellows placed 50% of the screws. Postoperative CT was obtained in all patients. The scans were independently reviewed by a visiting spinal neurosurgeon (KSL) to determine pedicle screw position. The relative position of the screw to the pedicle was graded as follows: I - completely within the pedicle; II - pedicle wall breach less than 2mm; III - pedicle wall breach equal to 2-4mm; IV - pedicle wall breach greater than 4mm. Any borderline position was automatically down graded. If an osseous breach occurred, the direction (superior, lateral, inferior and medial) was classified. The final position of the screw tip (in or out confines of vertebral body, with or without visceral / vascular contact) and overall screw trajectory (ideal, straight, lateral, medial) were assessed. Any screw related complications were also assessed.
**Results:** Overall screw position within the pedicle was graded I in 81% (68/84) overall [83.8% LS (62/74) and 60.0% T (6/10) screws). Sixteen pedicle breaches occurred; 6 medial and 10 lateral. Fifty-six percent (9/16) of the pedicle breaches were secondary to a pedicle screw that was larger than the size of the pedicle (LS-5[2-L1, 2-L3, 1-L4]; T-4). Exclusion of these pedicle breaches resulted in an overall pedicle breach rate of 8.3% (6.8% -LS and 40%-T). Relative to the total number of screws (n=84) pedicle breaches were Grade II in 14.3% (LS=9/74; 5-medial; 4-lateral, T=3/10; 0-medial; 3-lateral), Grade III in 3.6% (LS=1; lateral, T=1; medial) and Grade IV in 1.2% (LS=2; 0-medial; 2-lateral, T=0) of screws. Errors in screw trajectory did not contribute to the number of pedicle breaches. There were 5 vertebral body breaches with no visceral or vascular contact. There were no clinically significant screw misplacements. No screws required revision. Pedicle or vertebral body breaches with a likely potential for neurological (> 2 mm medial / inferior breach) or vascular injury was 1.2% and 0% respectively.

**Discussion:** A variety of different techniques are currently utilized for the placement of thoracic and lumbar pedicle screws. The most common technique remains the conventional use of dorsal anatomical landmarks (free hand) with or without fluoroscopic assistance. In the clinical scenario of a previous posterolateral fusion (without pedicle screw fixation) normal anatomical landmarks are partially or completely obscured. Consequently the use of free hand screw placement techniques often necessitates a laminoforaminotomy for each screw (increased surgical exposure and time) and/or extensive use of multiplanar c-arm fluoroscopy. However, the clinical accuracy of these conventional methods or two-dimensional-CAS (computer assisted surgery) has not undergone critical in-vivo assessment.[1] In this study an all-encompassing pedicle breach rate of 19% demonstrated for screws placed form T10 to S1. Fifty-six % (9/16) of the breaches, however, were <2mm. Clinically, encroachment of the epidural space of up to 2mm is conservatively considered to be safe in most cases. Furthermore, although the use of CT analysis for pedicle screw placement has reasonable correlation with gross in-vitro inspection, it can be associated with 1-2mm of error due to metal artifact. Consequently the authors considered all grade II screws clinically acceptable. With this measurement error in mind the clinically relevant breach rate in this study was 8.3% (7/84). The design of this study allowed for a worse case scenario in-vivo assessment: independent reviewer, down-grading of any marginal breach (e.g. grade II- to-III) inclusion of breaches due to oversized screws or those with intentional lateral breaches (parapedicular screw insertion technique) and screw placement (50%) by supervised residents and fellows. Clinically there were no neurological injuries, no screw required revision. In conclusion, FluoroNav™ is a safe and practical adjunct for the placement of lower thoracic and lumbosacral pedicle screws through a posterior fusion mass. This technique reduces or eliminates the need for laminoforaminotomy assisted screw placement in the revision setting.

**References:**

ACCURATE DETERMINATION OF ACETABULAR COVERAGE WITH CONVENTIONAL RADIOGRAPHY

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Introduction: Femoroacetabular impingement has been detected as a novel major precursor of idiopathic ‘primary’ osteoarthritis in hip joints [2]. Anterior acetabular overcoverage is one of the pathomorphologic causes of this repetitive mechanical conflict. On an anteroposterior (AP) pelvic radiograph, anterior overcoverage is recognized by a ‘figure of 8’ shape of the projected anterior and posterior acetabular rims (‘cross-over sign’) [3] Standard evaluation, however, ignores largely variable changes in the appearance of the acetabular morphology and head coverage due to different individual pelvic tilt and rotation [4]. Thus, estimation of femoral head coverage based on plain pelvic x-rays without simultaneous knowledge of pelvic tilt and rotation is erroneous and approximate. The purpose of this study was to develop a computer software that compensates for pelvic malpositioning during the acquisition of pelvic radiographs and that allows performing more accurate measurements of the adult human hip joint morphology in a standardized “neutral” orientation.

Methods: Based on the assumption of a more or less spherical hip joint a software was developed that can reckon back the projected acetabular rims in a neutral orientation. Neutral pelvic tilt has been defined as a pelvic inclination of 60° [5] which can likely be measured on a lateral pelvic radiograph. As an alternative, the vertical/horizontal distance between the upper border of the symphysis (SY) and the sacrococcygeal joint (SCJ) on an AP x-ray were calibrated to estimate pelvic tilt/rotation by means of 20 cadaver pelves. External validation of the software was achieved on 10 cadaver pelves (20 hips) with wire-marked acetabular rims of which x-rays were taken in arbitrarily orientation of the pelvis. The amount of femoral head coverage was determined with the developed software and was compared to 3D-CT-based measurements for the neutral orientation as a golden standard. In addition, a theoretical analysis of the feasibility of the vertical/horizontal distance SY-SCJ as indicators for tilt/rotation was performed using the principle of error propagation according to a previously described scheme [1]. The influence of error in central beam positioning, variability of the film-tube distance, the error of identifying SY and SCJ on the plain radiograph and the variability of the pelvic anatomy on the estimation of pelvic tilt and rotation were investigated.
Results: A highly linear correlation between pelvic tilt and the vertical distance SY-SCJ and between pelvic rotation and the horizontal distance SY-SCJ was found for men and women ($R^2 = 0.99$). In this cadaver series, the pelvic inclination angle could be estimated with the help of this distance with an accuracy of $2 \pm 5.6^\circ$ (range, $-5^\circ$ – $13^\circ$) for men and $2.2^\circ \pm 4.2^\circ$ (range, $-5^\circ$ – $11^\circ$) for women. The total acetabular coverage could be determined with an accuracy of $0.4\% \pm 2.1\%$ (range, $-3.3\%$ – $3.5\%$) Theoretically, the angle of tilt/rotation can be estimated with the vertical/horizontal distance SY-SCJ with a precision of $\pm 8^\circ/\pm 2^\circ$. Therefore, the reconstruction of pelvic rotation can be assumed to be reliable whereas the one of pelvic tilt is limited to deviations greater than $\pm 1.8$ cm ($\pm 8^\circ$) regarding the vertical distance SY-SCJ due to individual sacral morphology.

Conclusion: This computer-assisted method enables the elimination of the influence of tilt and rotation when interpreting morphologic differences (dysplasia, retroversion) on a digital AP pelvic radiograph. It provides the surgeon with more accurate anatomically based measurements and allows reliable quantitative definition of femoral head coverage. The software is limited to more or less spherical hip joints and to AP pelvic radiographs acquired with a standardized imaging technique. For accurate measurement of acetabular coverage an additional lateral radiograph is mandatory. If not available, e.g. in retrospective studies, estimation of pelvic tilt is only reliable with a deviation of its indicator (vertical distance SY-SCJ) greater than $\pm 1.8$ cm ($\pm 8^\circ$). Introducing the easily applicable software and its standardization in clinical routine will lead to a substantial benefit in understanding hip pathomorphologies and will provide a more accurate planning and evaluation of surgical interventions for the correction of acetabular rim pathologies.

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References:

ANGULAR DEVIATIONS WHILE PINNING A TIBIA CUTTING BLOCK IN TKR

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Introduction: Computer assisted surgery and navigation systems enable the surgeon to position and align the implant in total knee replacement within fractions of a millimeter or degree. This is usually achieved by using the navigation system to precisely align the cutting block for the resections.

Very often however the desired adjustment is compromised by the process of pinning the block to the bone. During pre-drilling or direct impaction, the drill or the pins deflect when penetrating the hard cortical bone. In many cases the resulting alignment errors have to be accepted because further adjustment is impossible.

This study uses the PiGalileo TKR navigation system to quantify the alignment error induced by the pinning of a tibia cutting block in varus/valgus and posterior slope direction. After analyzing the results a technical solution was developed to achieve a precise, navigated tibia resection.

Methods: In a first stage the alignment achieved after the pinning was compared with the desired alignment prior to the pinning. The cutting block was adjusted with the help of the navigation system and the corresponding alignment data was measured and stored. Then the block was pinned and it’s alignment was measured and saved as well. The difference between the two measurements is the pinning error.

In a second step the measured cases were analyzed and were used to design a cutting block which allows the navigated adjustment of varus/valgus and posterior slope after the pinning.

Results: 38 surgeries were analyzed. The difference between the desired cutting block alignment adjusted with the navigation system and the alignment achieved after the pinning can be seen in table 1.

As a consequence to this quantitative analysis a new tibia cutting block was developed which allows an adjustment after the pinning within a range of ±5° for varus/valgus and +5/-3° for posterior slope.

Conclusion: It is documented, that the use of navigation systems leads to a significant improvement of the implant alignment in TKR, especially in the long axis. This
study clearly shows that the process of pinning the cutting block has a significant influence on the accuracy of the result. It is necessary to deal with this in an appropriate way. The adjustable tibia cutting block which was developed avoids these errors entirely and leads to a precisely guided resection.

<table>
<thead>
<tr>
<th>Direction</th>
<th>Average difference</th>
<th>Standard Deviation</th>
<th>Maximal difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior slope</td>
<td>1.4°</td>
<td>1.2°</td>
<td>4.0°</td>
</tr>
<tr>
<td>Varus/valgus</td>
<td>0.5°</td>
<td>1.0°</td>
<td>2.5°</td>
</tr>
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Table 1: The difference between aligned tibia block and pinned tibia block
CLINICAL EVALUATION OF A CT-FREE TOTAL HIP APPLICATION

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Introduction: Total hip surgery navigation has been proposed for the last few years in order to answer the short-comings of the current conventional technique. Systems are now available on CT-based technologies as well as image-less technologies. We still can find only few studies documenting post-operative leg-length, femoral offset, inclination as well as anteverision. Minimally invasive procedures for the hip are gaining in popularity and seem ideal procedures for surgical navigation. This study aims at documenting the performance of a CT-free hip navigation application in a true clinical setting at 2 centers, one of them performing MIS total hips.

Material & Methods: The hip application, Navitrack CT-Free Hip (OrthoSoft, Canada) has already been assessed in a cadaveric trial where it was found that angle measurements displayed by the system had an error of less than 5º in 99% of cases. Patients were operated in 2 different hospitals using either supine or postero-lateral MIS approaches. Pelvic registration was accomplished per-cutaneously. Acetabular reaming and cup impaction were performed under computer guidance. Using the same software, the femoral stem was installed in 2 different ways. In the first center, all patients were placed in a supine position. All femoral stems were broached under navigation, allowing real-time measurements of leg-length as well as lateral offset. In the second center, all patients were installed in a lateral decubitus using a postero-lateral MIS approach. Since no femoral tracker was used, before hip dislocation, the leg was placed in a stable position and reference points were digitized on the greater trochanter. The cup was navigated. The femoral stem was broached and installed as usual. The hip was then reduced, the leg re-positioned and the same reference points were re-digitized on the greater trochanter allowing calculation of leg-length as well as lateral offset. The femoral stem was then re-positioned as needed.

The pelvic tilt of patients relative to the horizontal plane of the operating room table was also computed by the software and displayed as positive in cases of anterior tilt and negative in cases of posterior tilt. Post-operatively, standard pelvic AP radiographs were taken and then digitized. The radiographs were all measured using a specialized software package in order to determine final leg-length, lateral offset as well as cup inclination and anteverision. Differences between the intra-operative software measurements and the post-operative radiographs were then noted for analysis. Finally, the precision of radiographic method for measuring leg length was evaluated.
by comparing the height of the non-operated limb to itself between the pre and post-operative radiographs in 10 patients. The influence of pelvic tilt on inclination and anteversion measurements was further studied by comparing these angles when measured on post-operative supine and standing radiographs.

**Results:** In the first arthroplasty center, 19 patients were operated using a supine patient position and a lateral approach. The computer system was used to ream and install the acetabular cup as well as broach and install the femoral stem. The average differences between the computer application measurements and the post-operative radiographs are as follows: 2.6º ± 2.1 for inclination, 2.3 ± 2.1 mm for leg-length, 2.6 ± 1.8 mm for lateral offset and 5.3º ± 6.0 for anteversion. The average pelvic tilt measured was 11.5º ± 6.9 anterior tilt. In the second arthroplasty center, 18 patients were operated in a lateral decubitus position with a MIS postero-lateral approach. The average differences between the computer application measurements and the post-operative radiographs are as follows: 3.2º ± 2.8 for inclination, 2.1 ± 2.0 mm for leg-length, 3.6 ± 2.5 mm for lateral offset and 4.9º ± 4.7 for anteversion. The average pelvic tilt measured was 4.3º ± 9.4 anterior tilt. There were no dislocations in either group. The average error for evaluating radiographic leg length variation on the non-operated limb was 1.8 ± 1.2 mm, as evaluated on 10 patients. For 34 patients, the values of post-operative cup inclination and anteversion angles were compared between their own supine and standing radiographs. On average, the inclination was increased by 2.2º ± 2.1 when measured on standing radiographs. The anteversion was increased by 3.8º ± 1.4 when measured on standing radiographs.

**Conclusion:** CT-Free hip navigation results were presented for 37 patients from 2 clinical centers using lateral as well as postero-lateral MIS approaches. For all cases the average leg-length inequality averaged less than 3 mm. Inclination and anteversion measurements were affected by post-operative pelvic tilt limitations, but yielded an average precision of 3º for inclination and 5º for anteversion. CT-Free hip navigation is a powerful adjunct in total hip arthroplasty and can reliably be used in the context of MIS hip arthroplasty.

**References:**

DIFFERENCES IN DETERMINING THE CENTER OF THE FEMORAL HEAD WITH AND WITHOUT PELVIC REGISTRATION

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Introduction: Improper restoration of the lower extremity mechanical axis is the most important cause of failure and patient dissatisfaction in total knee arthroplasty. With the introduction of computer assisted navigation systems for use during total knee arthroplasty this problem can be diminished to a large extent. Many reports in the literature have reported on the postoperative coronal plane alignment and the decrease in the number of outliers resulting with computer navigation systems [1-5]. One significant difference among systems is the handling of the pelvic registration and or the determination of the center of the femoral head. Many systems utilize direct imaging and surgeon chosen centers while others utilize calculated center of rotation algorithms for determining the center of the femoral head. Imaging and pelvic based navigation systems involve more invasive means of determining the center of the hip and if other routines that involve calculating the hip center are found to be as accurate then these will convey less morbidity to the patient.

Materials and Methods: To compare the results of using a pelvic tracker for determination of the center of the hip 15 total knee arthroplasty cases in the operating room were performed using a computer navigation system (Stryker Navigation, Kalamazoo, MI) using a pelvic tracker attached to the iliac crest. The data was then utilized to perform a post operative analysis of the data to determine the difference in coronal and sagittal plane alignment that would have resulted using a pinless algorithm. As a second test three whole cadaveric bodies were utilized to perform six lower extremity registration with and without pelvic tracker registration. These cadavers then underwent a spiral CT scan and had the center of the femoral head determined. The difference in coronal and sagittal plane alignments between the pinbased and pinless algorithms compared to the CT data was then calculated for each lower extremity.

Results: Results for the clinical cases comparing the pinless to the pelvic pin based algorithm found that a mean difference of 0.46 degrees in valgus and 0.71 degrees of extension would have occurred if the pinless algorithm was utilized compared to the pelvic pin based registration algorithm. When the cadaveric data was analyzed and
the CT scan based center of the femoral head determined and compared to the pin and pinless based algorithms a difference in valgus resulted for the pin based of 0.26 degrees and 0.34 degrees for the pinless. A difference of 0.26 degrees of extension resulted for the pinless based algorithm and 0.35 degrees for the pin.

**Conclusions:** Infrared based tracking systems are relatively accurate in measuring rigid body transformations. Other aspects of the system in measuring lower extremity alignment are not always provided or investigated. This study has determined that comparing the center of the hip as determined by CT scan based measures is not significantly different from those registration points calculated by the pin based and pinless navigation algorithms. Although the infrared technology itself is very accurate with less than 0.1 degrees and 0.5 mm of accuracy, the determination of lower extremity alignment intraoperatively relies on a multitude of calculations in an environment that is not always consistent from one case to the next. By investigating the other variables involved in calculating lower extremity alignment a surgeon can be better assured that the resulting lower extremity alignment is within an acceptable range. The pin based pelvic algorithm compared to the pinless pelvic registration for determining the center of the hip in this study was shown to result in minimal acceptable differences. The increased morbidity associated with the placement of pelvic tracker and or the increased use of radiographic imaging may not be necessary. The differences in alignment associated with this algorithm for determining the center of the femoral head were less than 0.5 degrees for both the coronal and sagittal planes. Although these associated errors are probably not detectable clinically, the cumulative errors associated with these systems must be taken into as well.

**References:**

ENHANCED ANATOMICAL ORIENTATION VIA INTRAOPERATIVE REGISTRATION OF COMPUTED TOMOGRAPHY AND 3D FLUOROSCOPIC DATASETS

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Objectives: To build a reliable and efficient region-of-interest (ROI) based rigid registration of preoperative Computed Tomography (CT) datasets with intraoperative 3D Fluoroscopy for enhanced anatomical orientation in CAS.

Background: The emerging 3D fluoroscopic technology has shown to enable less and minimally invasive techniques for many orthopedic surgeries. Yet development of 3D fluoroscopy technologies has had some recurring difficulties with noise and artifacts, mostly due to implant interference and image reconstruction. There are also several applications where the field of view of the scan (12.8cm) is too small for adequate anatomical orientation. Surgery in the pelvic area especially produces fluoroscopic images of bad quality, and interpretation of these images can be hard. Noise and artifacts prevent a successful segmentation and a subsequent 3D rendering of the anatomical structures for anatomical orientation.

In most cases, a preoperative CT scan of the patient is available for diagnostic purposes and preoperative planning, but remains unused during the surgery. An efficient and accurate registration of CT datasets to the fluoroscopic datasets gives the possibility to visualize the preoperative CT along with the intraoperative 3D fluoroscopy enhancing the orientation and thus reducing the duration of the surgery.

Design/Method: The registration algorithm was conceived as to need minimal intraoperative user input. Apart from the input images, the only parameter that must be given is an approximate transform from which the registration is initially computed. The transform is then optimized for best fit, which is measured using mutual information [1,2], optimized by a regular step gradient descent algorithm. During each iteration, the solution is refined towards a final registration of the images.
The measure of the mutual information was specifically designed to only generate random samples in a predefined ROI. This ROI is selected either with a mask or by thresholding the input images. These ROIs are then morphologically operated, i.e. dilated, and applied to the original images. The interest in ROI-based registration is mostly due to images where there may be some displacement between different bone structures and only one structure is of interest. This displacement may cause the general image to be misregistered, thus rendering the result unusable. By concentrating on the ROI, it not only speeds up the process but also assures that the relevant part of the image will be precisely registered. Every tenth iterations, the domain is resampled for a more mathematically accurate match. Note that this registration algorithm uses a multi-resolution approach, thus the sample number is calculated with respect to the resolution level, which equally enhances the computation speed.

The repeatability and stability of our algorithm was evaluated by multiple tests on plastic phantoms and cadaveric bone image scans. These tests specifically focused on spine, pelvis and ankle images. The CT scans were composed of 350 x 330 x 110 voxels; each voxel having a size of 0.35 x 0.35 x 1.25 mm. As for the 3D fluoroscopy images they were composed of 256³ voxels of 0.49mm in all directions. For each series of images, an initial high-resolution registration was done. Using a Monte Carlo Test (MCT) procedure for the six initial translation (x,y,z) and rotation (x,y,z) parameters, the optimal parameters were randomly perturbed with uniformly distributed noise of 10 mm/degree amplitude. This procedure was repeated several thousand times to record an appropriate number of sample tests. A correct registration was achieved below a maximal error of 0.25 mm in translation and 0.5 degrees in rotation with respect to the optimal parameters. Since most of the fluoroscopic images had an in-plane voxel size of 0.49 mm, this means that a correct registration would have a subvoxel precision.

Results: There were a total of 5349 tests made, out of which 4242 were successful, which is approximately an 80% success rate. This success rate even goes up to ~91% if MCT is done with 6mm/degrees noise amplitude and up to 100% with 4mm/degree noise amplitude. All these tests took between 1.65 minutes and 7.13 minutes, with an average of 2.32 minutes (std dev 45s), on a standard desktop Linux PC. The registration results were either highly precise for successful registration, i.e. within 0.16 mm in 99% of the cases, or quite badly registered, with 5mm minimal error for all parameters of failed registrations. No successful or failed registration had any parameters between 0.20mm and 5mm error; this may be explained by the fact that if the algorithm is successful, it will converge to the correct answer, otherwise its results will converge to a completely wrong answer. A small number of cases did not complete the registration process (0.25% of test cases), because the maximal mutual information attained occurred with no part of the images overlapping. These failed cases only occurred when at least two of the initial parameters were above a 7mm distance from the correct registration.

Discussion: Our ROI-based mutual information method has shown to be computationally efficient even on a standard Linux PC. The registration is precise and specifically set to match only the ROI. A thorough definition or any definition at all of a ROI is not necessary for the registration process to work; it is neither crucial for it to be exact and it may contain errors, an approximate region is fine. More importantly,
this ROI definition is done preoperatively on the CT scan, thus no intraoperative time is lost. The morphological operation on this region smoothes the optimization metric and makes it easier to obtain a successful registration, because more information around the ROI is taken into account.

As a preliminary conclusion, a correct registration is likely achieved if the user defines an initialization within 6 mm of the true solution via, for example, an initial pair-point registration. Our tests suggest that when visual validation of the registration result seems appropriate, then the registration is very likely correct. The user determines whether the registration is correct in a superimposed display of both datasets, and failed registrations are easily discernable since they seem to have a minimum error of 5 mm.

**Conclusions:** The rigid registration algorithm can be used effectively for the registration of CT and 3D fluoroscopic images. It has been proven to be very precise when successful and visually assessable when not. The computation is efficient yet there is room for improvement. Registration seems adequate for intra-operative use, more specifically in spine, ankle, knee and sacroiliac joint surgery.

**Future Work:** We plan to employ our registration tool for pelvic ring and sacroiliac surgery. Especially in minimally invasive treatment of fractures or disruptions of the pelvis, surface based registration of a CT dataset can be very difficult. Navigation by means of 3D fluoroscopic images with inherent registration is limited due to the scan volume of the existing 3D fluoroscope. The orientation in the acquired data cube is extremely pretentious, especially in the intraoperative situation. For that reason registration of an preoperative CT scan by means of an intraoperative Iso-C3D scan will probably be a reliable solution for non invasive CT registration. An additional benefit is the possibility of the intraoperative 3D visualization of reduction and implant position.

We are currently planning to extend this algorithm for use in piece-wise rigid registration of the vertebrae of the spine. Some modifications of the mutual information algorithm will also be implemented to consider soft probability masks.

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**References:**

EVALUATION OF METHODS FOR DETERMINING THE CENTER OF THE ANKLE FOR COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT

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Introduction: Several methods have been proposed to locate the center of the ankle joint for image-free computer-assisted total-knee-replacement surgeries, but the best method is unknown. Nofrini et al. evaluated a sample of anatomic algorithms and used CT-images to establish a gold standard, but they did not investigate kinematic algorithms [3]. Inkpen and Hodgson have suggested that anatomical methods provide a more repeatable determination of the ankle center than a ball-and-socket model of the ankle [2]. Shute and Hodgson compared a method that computed the midpoint between the maleolli with two kinematic algorithms but did not relate these results to a reconstruction of the underlying anatomy [4]. The purpose of this study was to evaluate seven different algorithms that determine the center of the ankle. We investigated the accuracy and precision of each technique and related their results to the underlying bony anatomy measured via magnetic resonance images.

Methods: We evaluated five anatomic methods and two kinematic methods for determining the ankle joint center in eleven healthy subjects and two cadaver specimens. For the anatomic methods, we established: 1) the midpoint of the most medial and most lateral aspects of the malleoli, 2) the midpoint of the most distal apexes of the malleoli, 3) the projection of the best guess of the center of the ankle onto the transmalleolar axis, 4) the projection of the tibialis anterior tendon onto the transmalleolar axis, and 5) the midpoint of the line connecting spheres fit to the malleoli. We repeated these methods ten times to characterize the differences between trials on the same subject. For the two kinematic methods, we first circumducted the foot and fit a sphere to the set of points defined by the motion of the calcaneus relative to the tibia. The center of this best-fit sphere was taken to be the center of the ankle. We also applied kinematic dyad theory [5] to establish a biaxial model of the ankle joint. The intersection of the calculated subtalar and talocrural axes in our model, when projected onto the transverse plane of the tibia, was then taken to be the center of the ankle [4].

Magnetic resonance (MR) images of the ankle, foot, and distal-third of the tibia were used to characterize the ankle geometry. We registered the MR images to the experimental data with an iterative closest point algorithm [1]. The center of the distal arti-
ulating surface of the tibia is the distal endpoint of the tibial mechanical axis [6]; this point served as the ground truth for our experiments. The location of this point was compared to the ankle center calculated from the various techniques. One-way analysis of variance (ANOVA) tests were performed to identify statistically significant differences between the methods.

**Results:** The most accurate and precise anatomic method was establishing the midpoint of the most medial and most lateral aspects of the malleoli (-3.5 ± 4.6 mm medial error, -2.9 ± 4.2 mm anterior error). This level of accuracy corresponds to less than an approximately 1-degree error in the alignment of the tibial component. The method that projected the tibialis anterior tendon onto the transmalleolar axis was the least accurate anatomic technique (17.1 ± 5.3 mm medial error, 1.5 ± 5.2 mm anterior error). For the kinematic techniques, the biaxial method had a better performance (3.1 ± 6.8 mm medial error, 0.6 ± 7.0 mm anterior error) than the sphere fitting technique (-12.4 ± 28.7 mm medial error, -4.2 ± 14.8 mm anterior error).

**Conclusions:** This study clarified the differences in performance between various methods that determine the ankle joint center. Nofrini et al. [3] reported similar results to ours in locating the midpoint of the malleoli plateaus but also reported the projection of the tibialis anterior to be significantly more accurate than what is reported here. Our results are consistent with Inkpen and Hodgson [2], which suggested that anatomic methods are more repeatable than kinematic methods. We found that establishing the midpoint of the most medial and most lateral aspects of the malleoli is a fast, accurate, and repeatable method that locates the center of the ankle.

**References:**

We report three new applications of image free navigation.

**Triplanar Osteotomy:** Reliable normalization of the femoral mechanical axis is difficult to achieve in correcting malunion. Image intensifiers poorly reflect the correction. A 60 yr old male with longstanding triplanar femoral midshaft malunion and medial compartment knee osteoarthritis underwent AO triplanar femoral osteotomy. Long leg X-Rays called for correction by 25° of extension, 25° of abduction and derotation of 30° with 2cm of lengthening. Navigation allowed mechanical axis correction using a temporary external fixator and definitive lateral DCP fixation. With markers in the proximal and distal femoral segments and standard reference points OrthoPilot™ defined the mechanical axis of the limb. Varus/valgus, flexion/extension, rotation and length is shown in real-time allowing accurate correction in all planes. This use of image free intraoperative navigation ensures a normal postoperative mechanical axis. This is the first reported use of navigation as an aid in correction of a femoral deformity.

**Revision Total Knee Replacement:** There is no literature on navigation in revision knee arthroplasty. The position of rigid body bicortical screws in the distal femur and proximal tibia was thought to prohibit the passage of stemmed implants. There is however a safe "posterior screw plane" keeping bicortical screws clear of the stemmed reamers and implants. We have used OrthoPilot™ in revision of both uni- and total knee replacements. Data acquisition was achieved by acquiring leaving the implants in situ. The variation in alignment noted with tilt of loose implants was less than 2°, this was minimised by ensuring the implants were seated at the time of data collection. Custom made localiser base plates fixed with monocortical screws are available. Alignment was achieved even with tibial bone loss requiring stemmed implants and structural grafting. With no literature comparing outcome of revision knee arthroplasty with alignment using conventional techniques we cannot determine any benefit to utilising this technique. We have navigated eight revisions and abandoned one. Alignment has been within the 3° varus valgus range. Logic suggests that in revision surgery alignment should be as important as that in primary knee arthroplasty.
Knee Arthroplasty and concomitant tibial nailing: A 78 yr old female presented with a valgus osteoarthritic knee with a mid tibial transverse fracture with both valgus and recurvatum deformity. Osteopaenia and gross deformity at the knee called for a combined procedure. A custom made revision stem was manufactured with distal interlocking screw holes. Using scaled radiology a correction osteotomy of the tibial valgus and extension deformity was planned. The required “apparent” navigated knee cuts were calculated given the need to acquire data for image free navigation with the deformity present prior to correction. The knee arthroplasty cuts were performed using the planned angles and the tibia was then reamed to take the revision stem. A corticotomy was made at the site of the tibial fracture. The assembled tibial base and custom stem was passed across the osteotomy correcting the deformity and cemented. The knee arthroplasty was completed. The stem was distally locked. Recovery has been satisfactory for both patient and surgeon. This application combining both osteotomy and revision navigation techniques has not been previously reported.

Conclusion: The future of navigation in Orthopaedics needs to be driven both by engineers and the imagination of surgeons.
FORCE PREDICTION MODEL FOR ROBOTIC SURGERY IN ORTHOPEDICS

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Introduction: Currently robotic surgery in orthopedics is mainly intended to improve the accuracy of operation in surgery. Total arthroplasty is one of the most active applications for robotic surgery in orthopedics. Since Robodoc\(^®\) system performed the first clinical THA at 1992, Robodoc\(^®\) and Caspar\(^®\) system have expanded their application to the TKA [3, 4]. Arthrobot\(^®\), which is mountable onto the femur, produced successful results in cadaver study [5]. The main job of orthopedic surgery robot is bone cutting with milling tools. A reliable method for predicting the cutting force as a function of the bone resection parameters allows us to design more intelligent systems for increasing accuracy and safety. Force predictions can also be used to simulate and optimize surgical techniques. While the analytical model for bone-cutting forces has not been studied sufficiently, Plaskos et al. [2] has studied the orthogonal bone cutting recently. However, many orthopedic robotic surgery systems adapted the medical milling tools, so we need the orthogonal bone-cutting model expanded to the milling operation.

Methods: Recently Plaskos et al. [2] studied the orthogonal cutting model of bone using the undeformed chip geometry to predict the cutting forces. The orthogonal cutting model can be applied directly to the sawing in orthopedics, but it must be expanded for the drilling or milling cutting. In milling process, the cutting edges movement is trochoidal. The ratio of rotational speed and feedrate is about thousand times during the operation in normal case. At this condition, the cutting edges movement can be approximated as the circular motion and the undeformed chip thickness can be assumed as the sine function. The cutting forces change as the milling tools angular position, but because the rotational speed is tens of thousand high RPM, mean cutting force is desirable for application. By integrating relevant equations along the cutting edge [1], the orthogonal cutting model can be expanded for milling model and we may predict the milling forces during the bone cutting. The predicted forces are tangential and perpendicular forces with respect to the tool movement. For the model parameters and verification, we used fresh bovine cortical bones for milling experiment. The cutting direction was the principal osteon direction. The cutting conditions were rotational speed, feedrate and cutting depth. No irrigation solution was applied. The feedrate was varied as 2, 3.2, 5.5 and 9.8(mm/s) and the cutting depth was changed as 0.3 and 0.5mm. The medical pneumatic tool, MidasRex\(^®\), was used at the rotational speed of 20,000~80,000 RPM. The TU31 round bur having 12 cutting edges was used. To measure the forces in each direction,
two loadcells from Bongshin® were attached perpendicularly to the pneumatic tool. The data recording was performed with BNC2090 AD converter from National Instrument®. The Non-contact type rotational speed meter RM1501 from Prova® was used for measuring rotational speed of the tool. Data collection was performed during the steady state of cutting process. We accomplished nineteen data sets in each cutting depths. Each data set has hundreds of measured values and was processed for mean values.

**Results:** As the milling force model, cutting forces and feed (feed/tooth) have logarithmic relations. The parameters of milling force model was determined by the least square method in each cutting depth. The results showed that the range of cutting forces in each direction (tangential and perpendicular cutting forces with respect to tool movement) was 0.33–3.3N. The larger feedrate and cutting depth increased cutting forces in each direction. The larger rotational speed decreased the cutting forces in each direction. The error was defined as the difference between measured and predicted cutting forces at the specified cutting condition. The statistics shows 0–10% of mean error and 13–25% of standard deviation in all cutting conditions. We can see the tendency of increasing errors in case of small rotational speed and large feedrate (large feed/tooth). The result shows that cutting force was about 20% smaller than predicted value at low rotational speed. We assume that this tendency may be influenced by parameter change with alternation of rotational speed as mentioned by Plaskos et al. [2].

**Conclusions:** We developed the cutting force prediction model of the ball end mill in the orthopedic robotic surgery. The developed model can predict milling forces about cutting depth below than 0.5mm and feedrate 2–9.8mm/s with the errors of 0–10% of mean error and 13–25% of standard deviation for bovine cortical bone. We assumed that the error was caused partly by inhomogeneity of bone and parameter alteration as cutting speed variation. The developed model can be applied for control algorithm of orthopedic robotic surgery, safety check system and design criteria for new robotic system.

**References:**

INTERDEPENDENCE OF SLOPE, VARUS/VALGUS, AND ROTATION IN DETERMINING DEPTH OF CUT ERRORS FOR THE DISTAL FEMORAL CUT AND PATELLAR CUT IN TKA SURGERY

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Introduction: Computer assisted navigation tools make it possible to measure slope, varus/valgus, and depth of cut at several intra-operative junctures to accurately place the prosthetic devices during the performance of a total knee replacement. As we acquired experience with these tools during the performance of TKA, we realized that these measurements are, in fact, closely interrelated. Errors of alignment in one plane can affect the alignment of the other planes as well. Furthermore, we recognized that certain types of alignment errors have particularly significant effects on other alignment parameters.

The patella is a small structure. Consequently, small absolute changes in alignment in one plane could result in large relative changes in another plane. Manual patellar instrumentation provides relatively little information about the orientation of the resection plane with regard to tilt and rotation. Moreover, navigation tools have not yet been developed to guide patellar resection. Consequently, many surgeons use a free-hand technique to cut the patella during the performance of a TKA.

The purpose of this paper is to present a model that allows surgeons to recognize easily the impact of one alignment error on other alignment parameters when preparing to cut the distal femur and patella during the performance of a TKA.

Methods: A mathematical model for the distal femoral cut was developed which calculated the change in depth of cut when the slope, varus/valgus, and rotation of the cutting block were varied. Depth of cut was analyzed at six points around the perimeter of the distal femur as well as the center of the femur. Slope was defined as the difference between the cut face and a line drawn perpendicular to the mechanical axis of the femur in the sagittal plane. Varus/valgus was defined as the difference between the cut face and the mechanical axis of the femur in the frontal plane. Rotation was defined as the number of degrees between a line drawn perpendicular to Whiteside’s line and the cutting block face. Various combinations of errors of up to +/- 5° in slope or varus/valgus and up to +/- 10° in rotation were analyzed to determine the impact of combined errors on depth of cut. These values were chosen
because they have long been used as the acceptable standard for successful TKA.

A mathematical model for the patellar resurfacing was developed which calculated the change in depth of cut based on slope, varus/valgus, and rotation. Depth of cut was analyzed at four points on the perimeter of the patella as well as the center of the patella. Slope was defined as the difference between the cut face and the axis of the patella in the sagittal plane. Varus/valgus was defined as the difference between the cut face and a line drawn between the low point of the facets. Rotation was defined as the number of degrees between a line drawn perpendicular to the apex of the patella and the saw blade. Various combinations of errors of up to +/- 5º in slope or varus/valgus and up to +/- 30º in rotation were analyzed to determine the impact of combined errors on depth of cut. These values were chosen because they represented the average error seen radiographically in a series of TKAs performed by the senior surgeon (SDS).

**Results:** Depth of cut on the femur varied most at the lateral and medial posterior portions of the cut. This is expected because the distal femoral cutting block is secured to the anterior surface of the femur. Of the three variables, slope had the most effect on depth of cut, causing a 2.6 mm deviation with a 5 degree slope. When rotation was present in addition to slope or varus/valgus, the net result was a slight change in both slope and varus/valgus as well as a worsening of depth of cut error. For instance, with a 10º medial rotation, 5º anterior slope, and neutral varus/valgus, the resultant cut actually had 0.9º valgus, 5.1º anterior slope, and a depth of cut error of up to 3.1 mm. If rotation, varus/valgus, and slope were all present, the results were often unpredictable: 5º anterior slope, 5º varus, and 10º medial rotation produced 4.2º slope, 4.2º varus, and up to 4.3 mm error in depth of cut.

Depth of cut varied only slightly (up to 3 mm) with the patella, as is expected due to its small size. This, however, is a very large relative change since the patella is rarely more than 15 mm thick. Slope and varus/valgus had equivalent effects, based on the model’s treatment of the patella as circular in shape. When rotation was present in addition to slope or varus/valgus, the net result was a significant change in both slope and varus/valgus as well as a slight change of depth of cut error. For instance, with a 30º medial rotation, 5º anterior slope, and neutral varus/valgus, the resultant cut actually had 2.5º valgus, 4.3º anterior slope, and a depth of cut error of up to 1.1 mm. If rotation, varus/valgus, and slope were all present, the results were often unpredictable: 5º anterior slope, 5º varus, and 30º medial rotation produced 6.8º slope, 1.8º varus, and up to 1.6 mm error in depth of cut.

**Conclusions:** Manual TKA instrumentation fails to alert the surgeon to the interdependence of alignment parameters. The mathematical model presented here highlights the impact of this interdependence, especially with respect to the slope of the distal femoral cut. The depth of the distal femoral cut is critical for the correct positioning of the distal joint line. Inappropriate cuts of the distal femur can result in either a residual flexion or hyperextension deformity. Even an isolated 2º error in slope (which would be difficult to appreciate visually) will create a 1 mm error in depth of cut. Rotation, while much more tolerant of error, is almost impossible to measure with current systems and is responsible for the interdependence of slope and varus/valgus. The use of navigation systems during the performance of a TKA allows
a surgeon to control for the interdependence of alignment parameters. Surgeons using manual instruments do not know the exact slope, varus/valgus and rotational position of the distal femoral cutting block. In order to minimize errors in making the distal femoral cut, surgeons using manual instrumentation should strive to place the cutting block in neutral position for varus/valgus and flexion/extension with regard to the mechanical axis and in neutral rotation with regard to Whitesides’ line. In particular, surgeons should strive to be sure that the cutting block is properly aligned in the sagittal plane, i.e. that the slope of the distal cut is correct, to minimize distal resection errors.

This model also highlights the importance of proper cutting alignment when working with a small bone such as the patella. The model indicates an interdependence of the patellar cuts that could have a substantial effect on the final orientation of the patella. In fact, in a separate study of CT scans of the orientation of the patella produced during the performance of TKR’s by the senior surgeon (SDS), it was clear that while proper alignment of the patella relative to the femoral component could be achieved with a high degree of accuracy, consistent alignment of the patellar cuts in each plane was difficult to accomplish. Until better instrumentation systems are designed, surgeons should use forgiving (round) patellar implants. It appears unlikely that anatomic patellae can be correctly oriented in all the required resection planes with current instrumentation.

Reference:

INTRAOPERATIVE ISO-C 3D IMAGING – VALUE AND CONSEQUENCES IN 122 CASES

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Introduction: Identification and interpretation of articular steps and hardware misplacement remains a crucial step during joint reconstruction. Long term outcome correlates with initial reposition and adequate fixation. Two dimensional intraoperative imaging modalities, as the c-arm, are not sufficient as three dimensional image modalities and limited in analyzing complex anatomic shapes of e.g. calcaneus, acetabulum, wrist, pilon tibiale or tibial plateau. An exact analysis of intraarticular steps and hardware placement is often limited. Therefore postoperative CT became the standard method on decision making and postoperative analysis of complex intraarticular fractures at different anatomic regions.[1]. A new mobile three dimensional c-arm (Iso-C 3D, Siemens, Germany) provides direct intra-operatively multiplanar image reconstruction, enabling the intrathepative control of articular steps and implant misplacement.[1] An immediate operative correction in same procedure becomes possible with this new mobile c-arm technique. We studied the value and the resulting intraoperative decisions based on the Iso-C 3D imaging in 122 different joint fractures on different anatomic regions within the last year at our clinic.

Materials and Methods: Between 1/2003 and 11/2003 randomly 122 different joint fractures were intraoperatively scanned with the Iso-C 3D. Initially the operating surgeons were asked about acceptance of using the system at the actual case and decision about further implementation in following cases was based on surgeons individual request. The Following fractures were analysed: (n= 19 ankle fractures; n= 13 forefoot; n=20 calcaneus; n=23 pilon tibiale; 19 tibia plateaus; n=11 wrists; n=9 spine; n=8 pelvis fractures). Positioning of all patients or extremities was done on full carbon tables (VIW AS, Maquet, Germany). Starting initially conventional c-arm imaging (VISTA, Ziehm, Germany) in defined planes was done in all cases. A secondarily sterile draping of the whole situs was done in all cases. Multiplanar reconstructions were obtained from 100 fluoroscopic images the Iso-C-3D provides during one automatic scan protocol. The scans were performed intraoperatively directly after open or closed reduction and internal fixation of articular joint lines was done. Surgeons were able to analyze joint reconstruction, screw misplacement and decision of necessary corrections based on the multiplanar reconstructions intraoperatively, compared with the conventional c-arm images. Decisions about remaining articular steps and implant misplacements were done and necessary corrections performed. Based on the surgeons decisions post operative CT scans were performed.
Quality and congruently compared to Iso-C 3D images was assessed. The data about the intraoperative use, the users, the indications, the set up time, preparing and consequently resulting intraoperative decisions were analyzed.

**Results:** A total of 122 intraoperative Iso-C 3D scans were performed. Caused by artefacts 5 scans were not useable. Two times the system crashed. Three patients in local anaesthesia moved during the scan. Finally 112 different cases could be analyzed. The scanning procedure time itself takes 120 seconds (s) in every case. Radiation time was 20 s/case. Set up time including positioning of the system took 190s (150-840 s). Time of analyzing the multiplanar images on the Iso-C3D monitor and comparison to the conventional c-arm images took 240s (126-500 s). In 17 clinical cases (15%) a direct intraoperative correction resulted either in implant change (8%) or correction of reduction (7%), caused by articular steps > 2mm, screw or k-wire misplacement. In all cases conventional c-arm images did not reveal the significant step or misplacement, correction decision were all based on the Iso-C 3D. In another 8 cases (7%) significant steps or misplacements were identified in c-arm images and confirmed in the Iso-C 3D images. One subchondral k-wire seemed to be identified intrarticular on c-arm images, while the multiplanar images revealed exact subchondral placement. Post operative CT scans were done in 47% of all cases, they confirmed the Iso-C 3D results and were congruently. Quality was considered sufficient and good in all cases. No significant intraarticular step or hardware misplacement was missed with the Iso-C 3D. At the first four month of the study five surgeons requested the Iso-C 3D for their cases, comparing at the following seven month a total of 10 surgeons wanted to use the system frequently.

**Discussion and Conclusions:** Two dimensional intraoperative imaging does not allow precise identification of all articular joint steps and hardware misplacements. Intraoperative visualization remains problematic and conventional c-arm images are not always sufficient. The Iso-C 3D provides three dimensional intraoperative images regarding the detection of remaining intraarticular steps and implant misplacements. Direct intraoperative decisions and corrections become possible. The acceptance under surgeons staff is high. Potentially in postopCT’s identified articular steps and hardware misplacements can be avoided. Thus total costs, operation time and extra effort for usually necessary revision surgery could be neglected. Even if essential data about exact numbers of safed operations, costs and safed post operative CT scans is yet not available, the potential of the advantages of intraoperative imaging are pointed out. Besides the Iso-C 3D remains a regular mobile c-arm and can be used as this additionally in all cases. However necessary set up time including scanning and preparing of the multiplanar images as well as special trained personnel is still necessary for the introperative use of the Iso-C 3D. Extra costs for postoperative CT’s and safed reoperation have to be compared by initial Iso-C 3D costs.

**References:**

STEM AND CUP PLACEMENTENT IN NAVIGATED MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY - RESULTS OF A CADAVER STUDY

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Objective: To compare the cup and stem position in matched pairs of cadaveric hips performing a minimally invasive total hip arthroplasty (MIS-THA) either by using manual guidance tools or by the STRYKER Hiptrack Navigation System.

Background: Minimally invasive techniques are currently introduced to THA. Our workgroup has developed a direct anterior single incision approach. Special instruments have been designed for retraction and implantation. Instruments are navigable with the STRYKER Hiptrack system. Perfect positioning of the acetabular and femoral component are among the most important factors in THA. Malpositioning may result in significant clinical problems such as dislocation, impingement, limited range of motion or extensive wear.

Design/Methods: In twelve fixated human cadavers hemispherical pressfit cups (TRIDENT, Stryker, Alledale, NJ) and straight femoral components (ACCOLADE, Stryker, Allendale, NJ) were implanted. All implantation were done through the minimally invasive direct anterior approach. On one side the surgery was performed with special MIS instruments. On the opposite side the navigation system was used for placement of the implants. The aim was to achieve an alignment for the cups with 45° of inclination and 15° of anteverision in reference to the frontal pelvic plane. For the stem the goal was to position the stem in 0° of varus/valgus relative to the proximal shaft axes. This plane and the resulting cup positions were measured on CT-scans with a 3D imaging software (Stryker-Leibinger, Freiburg, Germany).

Results: The Innsbruck MIS approach to the hip could be performed in all cases. For both groups cup and stem position where within the range of variation reported in the literature. Yet, variance of the deviation from the goal was higher in the conventional group for both inclination and anteverision with the medians for the navigated group for inclination, anteverision and stem position being closer to the goal than in the conventional group.

Conclusion: The described minimally invasive approach to the hip is feasible and renders results comparable to those reported for conventionally operated THA. By the use of the navigation system tested it is possible to increase placement precision.
Introduction: Navigation systems help to place the resection guides in the desired position during total knee replacement (TKR) implantation with a higher precision than conventional, surgeon-controlled instruments [1, 2]. However, the actual resection orientation can be different from the expected one, due to poor fixation of the guide on the bone, poor guidance of the saw blade or inhomogeneous bone quality [3]. We measured the discrepancy between the expected and actually performed orientation of the distal femoral and proximal tibial resection during TKR implantation.

Methods: We analyzed 78 cases of TKR implantation with the OrthoPilot non image based navigation system. We measured the 3D orientation of the resection guides for distal femur and proximal tibia, and compared it to the actually performed resection. We compared these two measurements for each direction with a paired Student t-test. We also defined the rate of non optimally oriented resections for each direction.

Results: There was a significant difference between the expected and performed resection orientation for AP, lateral and vertical planes of the proximal tibia resection, and for vertical plane of the distal femur resection. A discrepancy of 2° or more was observed in 1 case for the orientation of the lateral tibial resection, and in 1 case for the orientation of the lateral femoral resection. A discrepancy of 2 mm or more in the height of resection was observed in 6 cases for the tibia resection and in 18 cases for the femur resection.

Discussion: Precision of the resection guides systems during total knee replacement implantation is less than optimal. It might be improved by a better fixation of the guides on the bone and by replacing the conventional saw blade by a burr.

References:


ROTATIONAL MOVEMENT OF AN OSTEARTHROTIC KNEE DURING FLEXION.

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Introduction: Rotational movement during flexion is an important feature of the knee kinematics [1]. The restoration of a normal rotational movement might be important during total knee prosthesis (TKP) implantation [2]. However, each knee has its own rotational movement, and it might be difficult to define a “mean” kinematics which could be suited to all cases. Navigation systems might help to study this movement on an individual basis [3, 4].

Methods: We analyzed 141 cases of TKP implantation with the OrthoPilot non image based navigation system. We measured before any bone resection or ligamentous balancing the following angles:

- coronal mechanical femoro-tibial angle in full extension without varus/valgus stress;

- coronal mechanical femoro-tibial angle in full extension with maximal reduction of the deformation with a manually applied varus or valgus stress according to the previous measurement;

- coronal mechanical femoro-tibial angle at 90° of knee flexion without varus/valgus stress;

- coronal mechanical femoro-tibial angle at 90° of knee flexion with maximal reduction of the deformation with a manually applied varus or valgus stress.

As no knee showed a significant ligament instability of the concavity of the deformation, we considered that the manual reduction of the deformation corrected the degenerative cartilage and bone loss in extension and in flexion, and was representative of the femoro-tibial angle without any cartilage and bone loss.

We compared both reduced femoro-tibial angles in full extension and at 90° of knee flexion with a paired Student t-test in the whole group and according to the initial deformation.

Results: Mean reduced femoro-tibial angle in full extension was 1.7°. Mean reduced femoro-tibial angle at 90° of knee flexion was 3.4° (p < 0.000,1). 14 cases (10%) had an internal rotation movement during flexion, 84 cases (60%) had no rotation move-
ment during flexion, 43 cases (20%) had an external rotation movement during knee flexion. Valgus knees experienced more often an external rotation movement than varus or neutral knees (55% vs 30% - p < 0.01). There was a positive correlation between the initial reduced deformation and the amount of external rotation during knee flexion (p < 0.01).

**Discussion:** Rotational movement during knee flexion is individually defined, with a trend to a more frequent external rotation for valgus knees and internal rotation for varus knees. This conclusion might question the routine implantation of the femoral component with external rotation.

**References:**

STUDY ON A DEVELOPMENT OF MIS ROBOT FOR THA

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Introduction: Total hip arthroplasty is a surgical procedure that replaces a damaged or fractured hip joint with an artificial femoral stem and acetabular insert. Many surgery robot for THA have developed and used in surgery. ROBODOC® have been applied clinical application and showed improved results in fit of implant, alignment.[2,3] In addition, there are other robots that have bee developed in KAIST.[1,4] Previous developed surgery robot systems are showed improved results in fit of implant and alignment than manual surgery. But, previous surgery robot systems need large incision to fix robot with femur. In this study, we proposed a new surgery robot for THA that can reduce incision than previous surgery robot. And we made a prototype of new robot for THA. And, we suggested a surgical procedure for our robot. We did experiment with prototype to evaluate its performance in time for milling femur, implant fit, alignment error. We also expected incision to use our prototype.

Methods: Previous robots for THA uses bone clamp to fix robot withy femur. Using bone cavity needs large incision. To reduce incision, proposed robot is fixed in femur cavity using robot supporter. Robot supporter is inserted into femur and fixed by press-fit. In robot supporter, there is a revolute joint. So, robot can be rotate along bone cavity. And, robot has three degrees of freedom. The stem has cylindrical shape. So, three degrees of freedom is enough to mill femur. Considering stem size, workspace was defined 25*50*80(mm). Proposed robot is fixed to bone directly so robot must be light. In this study, weight of robot is limited to 2 kg. We design a new surgery robot for THA that can satisfy the design requirements. And we made a prototype of proposed robot.

We suggested a surgical procedure for our robot. A surgical procedure are as following
1. Surgeons prepare femur by manual procedure.
2. Surgeons expands femur cavity using femur.
3. After reaming, robot supporter is inserted and fixed into bone cavity.
4. Robot is installed on supporter and robot machines femur to make shape of stem cavity in femur.
5. After milling, robot and supporter is uninstalled and stem is inserted into femur.

Along suggested surgical procedure, we did experiments to estimate performance of robot using sawbone®. We measured timer for milling, implant fit, alignment error. For alignment error, we measured anteverversion error and varus/valgus error. And we expected incision using human dummy.
**Results:** In 4 sawbones, time for milling was 13 min. Fit of implant was 87.9%. Anteversion error was 2.7°. Varus/valgus was 1.0°. Incision was supposed about 10cm in human dummy.

**Conclusions:** In this study, we suggested a new surgery robot for THA and made prototype. Proposed surgery robot is fixed with femur using robot supporter. So, It is supposed that incision can be reduced in THA. using proposed robot. And in experiments using sawbones, it is supposed that implant fit, alignment error are acceptable. We must consider narrow bone and curved bone in future works and modify robot design.

**Acknowledgements:** This work has been supported by the Human-friendly Welfare Robot System Engineering Research Center(HWRS-ERC), KAIST in Korea.

**References:**

3. William L. Bargar, Andre Bauer, Martin Borner : “Primary and revision total hip replacement using the robodoc® system”, Clinical orthopaedic and related research, No.354, pp 82-91
A NEW FUNCTIONAL DETERMINATION OF THE HIP JOINT CENTER FOR COMPUTER-ASSISTED TOTAL KNEE REPLACEMENT

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Introduction: Image-free computer-assisted total-knee-replacement systems have generally employed functional methods to locate the hip center. The motion of the pelvis during the rotation of the hip can introduce noise that may compromise the accuracy of functional methods. Two techniques have been used to compensate for this noise. The first option involves recording then eliminating pelvic motion prior to determining the hip center [1]. This is undesirable because it typically requires insertion of a pin into the pelvis. The second option involves using optimization techniques that compensate for the motion of the pelvis [3], but an algorithm that can compensate for noise in this way has not yet been completely described and critically reviewed. Piazza et al. [2] recently presented a robust functional method; while their results are promising, it is unclear if the errors can be attributed to the method or to the collected motion data. Our study describes and evaluates a “pivoting” algorithm to locate the hip center. We tested its performance with six motion patterns and with the introduction of simulated noise in kinematic data.

Methods: We conducted a series of experiments with a ball and socket joint that simulated a femur and pelvis. We investigated six motion patterns: flexion and extension with a maximum angles of ±15 degrees (pattern “15”) and ±30 degrees, circumduction with flexion and abduction angles of ±15 degrees and ±30 degrees (“Cir 30”), and combinations of flexion/extension and ab/adduction with maximum angles of ±15 degrees and ±30 degrees. Each motion pattern was repeated ten times. During the motion trials, we measured the position \( \text{PelvisP}_\text{Femur} \) and orientation \( \text{PelvisR}_\text{Femur} \) of the femoral reference frame with respect to the pelvic reference frame. We calculated the hip joint center (HJC) with

\[
\text{PelvisP}_\text{Femur, Calc} = \text{PelvisR}_\text{FemurLHJC} + \text{PelvisSHJC} \quad (1)
\]

where \( \text{FemurLHJC} \) is a vector, in the femoral reference frame, originating at the HJC and terminating at the origin of the femoral frame and \( \text{PelvisSHJC} \) is a vector expressing the HJC in the pelvic reference frame. For data from a given motion trial, we calculated the location of the HJC by using a linear least-squares technique to solve for the vectors \( \text{FemurLHJC} \) and \( \text{PelvisSHJC} \) that minimized the difference between the measured \( \text{PelvisP}_\text{Femur, Meas} \) and calculated \( \text{PelvisP}_\text{Femur, Calc} \) positions of the femoral reference frame. Once \( \text{FemurLHJC} \) was known, its direction was reversed to express the HJC as a vector from the origin of


the femoral reference frame. We used this new vector, $Femur-L_{HJC}$, as the hip center in the femoral reference frame. To establish the true HJC in the femoral reference frame, we digitized approximately 200 points on the surface of the ball of the joint. We computed the best-fit sphere to these points and compared the center of this sphere to the HJC determined by the pivoting method. We evaluated the method’s sensitivity to noisy data by introducing random noise of varying amplitudes (1 mm, 5 mm, 10 mm, 15 mm, and 20 mm) into the measured position of the femoral reference frame from the “Cir 30” and “15” trials. We computed the center of rotation with these noisy data and determined the change in the location of the HJC. One-way analysis of variance (ANOVA) tests were performed to identify statistical differences in the mean errors for the six motion patterns, and the Tukey-Kramer method was used to further investigate significant results. The level of statistical significance was set at $\alpha=0.05$.

**Results:** The mean errors for single-plane motion patterns (e.g. flexion/extension) were significantly larger ($p < 0.001$) than the mean errors for single-plane motion patterns (e.g. circumduction). The smallest mean error of $2.2 \pm 0.2$ mm occurred with motion pattern “Cir 30”, and the largest mean error of $4.2 \pm 1.3$ mm occurred with motion pattern “15”. The largest amount of input noise (20 mm) increased the mean error of the “Cir 30” motion pattern by $1.1 \pm 0.4$ mm and increased the mean error of pattern “15” by $15.8 \pm 8.4$ mm.

**Conclusions:** The pivoting method is an accurate and fast technique to locate the hip center, and its performance is minimally affected by reasonable limits of motion and the presence of noisy motion data. Stindel et al. [3] reported that random noise of 7mm induced a $4.5 \pm 2.3$mm error in their computation of the hip center, in comparison with the $1.1 \pm 0.4$mm reported here. Piazza et al. [2] applied a pivoting method to data recorded in human subjects and presented a best-case mean error of 5.0 mm and a worst-case mean error of 18.0 mm, but their experiment lacked a gold standard. Our analysis with the mechanical linkage provides a gold standard and complements their study with human motion data. Future work is needed to investigate the use of this pivoting method in a surgical setting.

**References:**

A NEW MINI-INVASIVE METHOD TO LOCATE THE CENTER OF THE HIP IN TOTAL KNEE ARTHROPLASTY USING COMPUTER ASSISTED SURGERY

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Introduction: Though it has become a predictable and reproducible operation, Total Knee Arthroplasty still remains a challenging procedure. Good alignment and soft tissue balancing are both necessary to optimise functional and long-term radiographic results. Crucial anatomic landmarks are used during the Total Knee Replacement (TKR) procedure to reach the surgical goal. One of these landmarks is the center of the hip, which is difficult to acquire because situated deep in the groin. Computer Assisted Technology allows accurately locating the center of the hip. The most recognized method consists in pivoting the hip joint while a CCD camera follows two trackers inserted in the iliac crest and the femur. This technique requires an iliac crest approach, which is unusual in TKR surgery. A new algorithm has been developed to avoid any tracker fixation in the iliac crest. The aim of this study was to determine whether or not this new algorithm was accurate and precise enough to locate the center of the hip without any iliac crest tracking.

Methods: Using three fresh normal cadaver hips we conducted two studies. The first involved one cadaver and was a comparative study between two techniques: technique A with iliac crest tracking and technique B without such tracking. An intra and inter-observer study with anatomical measurement control allowed us to compare the two techniques. The second study involved two cadavers and compared the robustness of the hip center with respect to the range of motion (5°, 8°, and 10 degrees of hip circumduction) of the manipulation.

Results: Regarding the first study, no statistical differences were found between technique A (Mean = 0.67, SD = 0.15) and B (Mean = 0.66, SD = 0.32) used to locate the center of the hip. The algorithm was not manipulator-dependent and enabled us to locate the center of the hip, with respect to its anatomical location, within 1.2 degrees. Concerning the second study, a range of motion less than ten degrees negatively affected the result. Hip circle (HC) of 5° (mean = 0.67, SD = 0.46), HC of 8° (mean = 0.81, SD = 0.52), HC of 10° (mean = 0.60, SD = 0.21). The best fitted circle of movement is greater than ten degrees.
Conclusion: Technique B, which uses only one tracker in the femur, was as accurate as technique A, which needs two trackers around the hip joint. There was no statistical difference between techniques A and B, and there were no intra and inter-observers statistical differences either. The center of the hip is certainly the most difficult landmark to acquire during the TKA procedure because of its location deep within groin soft tissue. A wide variety of surgical instrumentation has been designed to determine accurately the center of the hip such extramedullary and intramedullary instrumentation which is used today to align the femoral component. Finding a method capable of locating the center of the hip is valuable, especially when the leg presents an important femoral deformity or in the case of obese patients [8]. Our study showed that the maximum error obtained with both methods was 1.2 degrees in the first experiment and 1.91 in the second, which is fair with regard to TKA goals. However, we have to take into account the overall error in lower limb calibration that can affect our ultimate goal. In conclusion, this new algorithm, which does not require any iliac crest fixation, is accurate and precise enough to locate the center of the hip. However, this technique has to be performed carefully. For the technique without iliac crest tracking, 75% of results had a margin of error of less than one degree and 95 % of the results had a margin of error less than 1.5 degrees. Practically speaking, the iliac crest tracking system still remains the best technique. The technique without iliac tracking fails about two times out of 100 acquisitions, which suggests the need for a control system that would allow the manipulator to acquire hip center coordinates again in the event of failure. Additional clinical validations are currently being conducted in order to confirm the results of this cadaver experiment.

References:


Acknowledgements: Gilles Schockmel, Christian Fremmel.
### Table I: Statistical analysis: Comparison between Technique A and Technique B

<table>
<thead>
<tr>
<th>Tracking</th>
<th>Iliac crest tracking Technique A</th>
<th>Iliac crest free Technique B</th>
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<tr>
<td>Standard Deviation</td>
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<td>Maximum error</td>
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<td>P value</td>
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</table>

### Table II: Comparison between 5°, 8°, and 10° hip circles (HC) manipulations

<table>
<thead>
<tr>
<th></th>
<th>5° HC</th>
<th>8° HC</th>
<th>10° HC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>0.67</td>
<td>0.81</td>
<td>0.60</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.46</td>
<td>0.52</td>
<td>0.21</td>
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<tr>
<td>Maximum error</td>
<td>1.91</td>
<td>1.91</td>
<td>0.92</td>
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</tbody>
</table>
ACCURACY OF FREEHAND CUTTING IN SIMULATED TOTAL KNEE SURGERY

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Introduction: The surgical technique for total knee replacement involves numerous jigs and fixtures and a complex sequence of steps. In a report of 673 knees, a valgus angle of 4-10°E was achieved in only 75% of cases [3]. Navigation techniques have improved the consistency and facilitated ligament balancing, but jigs and fixtures are still required [1]. The Precision Freehand Sculptor was developed to shape bone surfaces with a burr using the computer screen as a guide [4]. We experimented with such a system and achieved RMS accuracies of a simulated tibial surface of better than 1 mm [2]. Recently, we proposed Freehand Navigation where bone cuts could be carried out with the aid of bone images, cutting planes and an oscillating saw image on the computer screen [5]. In the current study, we investigated the accuracy of freehand bone cutting and whether an arm support would enhance the accuracy.

Materials and Methods: Horizontal Cuts with ERGO REST: This experiment simulated resection of the proximal tibia, represented by a 63 x 43 x 40 mm block of polyurethane foam. It was clamped with the upper part of the block projecting. Two 20 mm wide metal bars were placed 5 mm from each side of the block in an AP direction, with their surfaces 13.2 mm below the top of the block indicating the target depth for the surgeon to cut. An arm support (ERGO REST) cradled the surgeon’s forearm and allowed all translations and rotations in the horizontal plane. The control was a 12 mm thick slotted jig pinned to the test block exactly 13.2 mm from the top. The surgeon was seated during the tests and the block was horizontal. The surgeon cut 20 blocks with the arm unsupported (freehand), 20 with the arm support and 20 with the jig, alternating the methods. The times were recorded.

45 Degree Cuts With Rigid Arm Support: A second set-up was used where the block was at 45° and the surgeon was standing while cutting. This more closely simulated surgery. The arm support here was a smooth rigid bar onto which the surgeon rested the forearm about 10-15 cm from the wrist. Three surgeons each cut 15 blocks, five with each method.

To measure the accuracy of the cuts, the blocks were mounted reproducibly in a vice and a Microscribe G2X 3-D digitizer (accurate to 0.01 mm) input points from the cut surface to the computer. Rhinoceros 3D CAD software was used for the analysis. To determine the angle of the cuts in the frontal and sagittal views, a flat metal block was placed on the cut surface, simulating the placement of a tibial component on the cut
surface. Points were then digitized from the top of the block. The software calculated the best-fit plane and the two angles.

**Results:** *Horizontal Cuts with ERGO REST: Depth of cuts:* Freehand: 1.6" 0.66 mm from target; Arm support: 1.2" 0.87 mm; Jig: -0.21" 0.26 mm. **Frontal angle:** Freehand: 0.63" 0.56E; Arm support: 0.72" 0.48E; Jig: 0.29" 0.20E. **Sagittal angle:** Freehand: 1.2" 0.69E; Arm support: 1.1" 0.95E; Jig: 0.56" 0.43E. **Time taken:** Three Methods: 16-17 seconds (jig time did not include setting up and pin placement).

**45 Degree Cuts With Rigid Arm Support:** *Depth of cuts:* Freehand: 0.70" 1.6 mm; Arm support: 0.69" 1.5 mm; Jig: -0.18" 0.17 mm. **Frontal angle:** Freehand: 0.68" 0.59E; Arm support: 0.66" 0.63E; Jig: 0.34" 0.23E. **Sagittal angle:** Freehand: 1.5" 1.2E; Arm support: 1.2" 1.1E; Jig: 0.68" 0.50E. **Time taken:** Three Methods: 17-19 seconds.

**Discussion:** Bone cutting using jigs and fixtures produces errors due to a non-central intramedullary rod, cutting jig placement, movement of the jig during cutting, and some bending of the saw blade [3]. However, freehand cutting using a reciprocating saw is also subject to the errors such as blade bending and flutter, imprecise control by the surgeon, surgeon experience and skill, and the visual guide system, whether mechanical or computer-assisted. Our tests were designed to provide an estimate of how accurately and consistently bone cuts can be made freehand, without the aid of jigs and fixtures.

**Conclusions:** Using our simple model for resecting the upper tibia, surprisingly accurate and consistent results were obtained for the frontal and sagittal angles, better than those obtained in actual surgical procedures [3]. It appeared that the rigid support of the arm rest improved accuracy, whereas too much freedom of motion was no advantage. Surgeons with moderate to high experience produced better results than trainees. From the point of view of accuracy, both freehand and arm support bone cutting have the potential for improving the results over jigs and fixtures with reduced time and complexity.

**References:**

ADVANTAGES IN NAVIGATION IN TOTAL KNEE REPLACEMENT AFTER HIGH TIBIAL OSTEOTOMY

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Objectives: Goal of this presentation is to underline importance of navigation in total knee replacement after high tibial osteotomy.

Introduction: Early high tibial osteotomy can stop progression of varus knee osteoarthritis, but in most cases it only procrastinates for few years total knee arthroplasty, so it is not unusual to implant total knee prosthesis after high tibial osteotomy, which makes it more complicated compared to regular knee prosthesis. Beside common problems like implant removal, scar tissue close to new skin incision, or patella baja there are problems more difficult to face like mechanical axes correction and tibial plate resection. As a matter of fact it is often necessary to implant a prosthesis in a medial compartmental osteoarthrosis but with a valgus axes which brings to resects more bone on the medial side instead of lateral side and it is definitely difficult to create a perfect femoro-tibial alignment.

Navigation reduces incidence of wrong positioning. Once anatomical landmarks required by the navigation software are registred, it is possible to find ideal tibial plate cut, and virtually view final positioning of the prosthesis.

It also allows, during navigation or at the end of it (depending on the system used) to evaluate ligament balancing, letting the surgeon decide which component adjust in case of unbalanced joint. Victor et al. have already proved femoral-tibial axes is reliable.

Patients and Methods: In our Orthopaedic Department in Ospedale San Salvatore of Pesaro we treated twelve patients with previous high tibial osteotomy out of fifty-four computer assisted total knee arthroplasty. In all cases a fluoroscopic based computer assisted technology was used. All patients had a Genesis II total knee prosthesis implanted. Seven patients out of twelve were women, none of the patients had bilateral surgery. Average age was 67,4 (maximum age was 72, and minimum was 63). Five years and six months were average time from previous high tibial osteotomy. In seven cases the right knee was affected, in five cases it was the left side. In 8 cases an opening wedge osteotomy was previously done and in four closing wedge osteotomy. When still present internal fixation devices from previous surgery were removed the same day of knee arthroplasty. After hardware removal, reference frame were positioned, instruments verified and finally tourniquet was positioned. In all cases median anterior access was used, no matter where the hardware from
previous were positioned. In two thirds of the cases both femoral and tibial components were cemented. In rest of the cases only tibial component was cemented. All cases had preoperative and postoperative weight bearing x-rays in AP and lateral view to determine the varus-valgus alignment and the positioning of the prosthesis. The femoral-tibial axes was determined after surgery by the computer.

**Results:** In all cases it was possible to complete the computer assisted total knee arthroplasty procedure. No intraoperative complications like fracture or hardware breakage during removing or need of bone graft occurred. No postoperative complications occurred like skin necrosis, haemathoma, late skin repair, deep vein thrombosis or infections occurred. Surgical time to implant the computer assisted prosthesis progressively lowered due to the training and experience acquired. At the moment it is possible to implant a computer assisted total knee prosthesis in 60-80 minutes. Removal of previous hardware implants of tibial osteotomy added average 10 minutes to the total procedure. No significant blood lost during hardware removal or computer assisted procedure was registered compared to simple total knee arthroplasty.

Although they were difficult cases we had good weight bearing correction with deviation from optimal axes inferior to 1°. Coronal femoral alignment averaged 0.5° from femoral mechanical axe. Coronal tibial alignment averaged 0.7° from tibial mechanical axe. Average tibial slope was 3°.

Fluoroscopic navigation turned out to be of great value thanks to an instant feed-back in surgical steps, especially in the tibial resection which was difficult to set by hand due to the previous osteotomy.

**Conclusions:** Computer assisted orthopaedic surgery allows a perfect varus-valgus alignment of the prosthetic components. It is often possible in osteoarthritis to correctly implant knee prosthesis without computer assistance, but this becomes hard to achieve in cases when weight bearing axes are difficult to determine due to the severe anatomical deformities of the degenerative process. After high tibial osteotomy a plate resection is difficult because proximal tibia is shifted lateroinferiorly and asymmetric.

Although we have treated few cases and we have a short follow-up, our limited experience suggests to use computer assistance in cases previously treated with a high tibial osteotomy to avoid excessive tibial plate resection, to correct mechanical weight bearing axe, and to correct soft tissue imbalance.

**References:**

COMPUTER-ASSISTED FREEHAND NAVIGATION FOR TKR

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Introduction: The goal of this project is to investigate the viability of a surgical technique using ‘freehand navigation.’ This describes making cuts on bones for implant components using direct visualization on the computer screen, without requiring jigs or fixtures. Current navigation systems help in the alignment of jigs for bone cutting, but do not offer direct feedback on the cutting itself. With the proposed computer-assisted navigation system we hope to demonstrate the advantages of direct feedback on bone cuts made during surgery using the freehand technique [2, 5].

Materials and Methods: Block and bone cutting experiments were carried out using the following methods. MiniBIRD Tracking System: The miniBIRD (Ascension Technology), a pulsed DC magnetic tracker, was used to track an oscillating saw (Linvatec) and to serve as a digitizer. The digitizer was used to record reference points on the block or bone for drawing and aligning the computer graphics. Navigation Control Software: The navigation software incorporated digitized images into a graphical interface where they were accurately spatially represented. The software was written in C++ using Microsoft Visual C++ on a Windows XP platform with OpenGL as the graphical interface. It was run on a PC with a Pentium 4 Intel Processor, 256 MB RAM at 2.59 GHz. Block Cutting System: Tests were performed using solid rigid polyurethane foam blocks with a density similar to that of cancellous bone (0.32 g/cm³). Each block was secured in a vice and digitized so that a 3D model of the block appeared on the computer screen with a plane at the desired location for cutting. Three surgeons cut ten blocks each using the freehand technique. Bone Cutting System: Standardized plastic bones were obtained for cutting. The bones were CT scanned and acquired in DICOM format. By using 3D rendering software (Mimics, Rapidform) these images were stored as a polygonal mesh in STL format. Digitization of key landmarks enabled the bones to be displayed in the virtual space. Measurement System: To measure the accuracy of the cuts, a Microscribe 3-D digitizer (Immersion Corporation) was used to input points from the cut surface to the computer. Rhinoceros, a 3D CAD program, was used for the analysis. To determine the angle of the cuts in the frontal and sagittal views (ideally zero degrees), a flat metal slab was placed on the cut surface, which simulated the placement of an implant component. Points were then digitized from the top of the slab. The software calculated the best-fit plane and angular errors. Flatness of the cut surface was measured by digitizing on a 10 x 7 grid, determining the best fit plane and calculating the distribution of least squares deviations of the points from the plane.
**Results:** Block cutting tests have shown that surgeons using the freehand method with computer guidance were able to cut blocks within 1.83”1.67 mm of the target thickness. The frontal angle was 0.943”0.775E and the sagittal angle was 1.23”0.913E from the target angles. Bone cutting tests have not yet been concluded.

**Work in Progress: Shell Morphing:** If the freehand navigation technique were to be used on patients, it would be a great advantage to generate accurate 3D bone models without a preoperative CT scan. Our approach is to use 3D Morphing, which is the transformation of a template model (standard) to a desired model (patient specific) by mapping key reference points from the surface one bone model to the other [1]. **Surgical Simulation:** A test set-up will be fabricated to replicate the conditions of surgery as closely as possible. A dummy on an operating table will have a leg secured in a special rest. Key landmarks on the bone will be digitized to produce a morphed model that is patient specific. The navigation software will determine TKR component size and placement, and the appropriate cutting planes will appear on the rendered bone. The surgeon will cut each plane using the computer screen as a visual guide. An instrumented spatial linkage may be incorporated into the system if tests prove it as a more accurate alternative to the current tracking system.

**Discussion:** Bone-cutting using jigs and fixtures produces error due to a non-central intramedullary rod, cutting jig placement, movement of the jig during cutting, and bending of the saw blade [3]. Freehand cutting using an oscillating saw is subject to errors as well: blade bending and flutter, imprecise control by the surgeon, surgeon experience and skill, and the visual guide system, whether mechanical or computer-assisted. Tests without computer guidance showed that freehand bone-cutting has the potential for improving the results over jigs & fixtures with reduced time and complexity. Preliminary tests with the system we have developed suggest that these results can improve with computer guidance.

**References:**

AN IN VIVO RSA STUDY ON THE POLYETHYLENE MOBILITY OF A MOBILE BEARING TKR

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Introduction: Implant fixation and polyethylene wear have been recognized as long-term causes of failure of total knee arthroplasty [1,2]. Recent designs have sought to make contact surfaces more congruent, even though the increased congruency may lead to prosthetic constraint. Mobile-bearing prostheses were created to optimize polyethylene wear through highly congruent matched surfaces, while removing constraint by allowing the components to slide with each other[1]. A question has been raised as to how many degrees and millimeters these inserts move when implanted in a patient [5]. This study analyzes the kinematics of a meniscal-bearing TKR by the RSA technique to investigate “in vivo” the meniscal displacement in the Interax“ I.S.A (Stryker Howmedica®, Limerick, Ireland) cemented prosthesis in weight-bearing conditions. Secondarily, by analyzing the polyethylene motion we tried to explain the kinematics of a mobile-bearing total knee prosthesis PCL retaining.

Methods: For this study, we enrolled 31 patients (32 knees). The mean age at the time of surgery was 69 years (range: 27-79). For RSA purposes [3], both tibial and polyethylene components were equipped respectively with 3 and 6 tantalum markers. After 16.4 months (average follow up time), we submitted patients to weight-bearing investigations under stress conditions using the well-know RSA protocol [3]. This set of exams included examinations performed during supine and upright stances, limb rotations and knee flexion. Since RSA system accuracy is 0.2 mm for translations and 0.3° for rotations, we considered displacements ranging between ±0.3° and ±0.2 mm. to be invalid. Statistical analysis was performed using the t-test and GLM repeated measurements with Bonferroni’s test. For all tests p<0.05 was considered significant.

Results: The clinical results, according to the HSS, were satisfactory (mean score: 80.4; range: 66-98). The RSA results revealed that in every exam (upright stance, flexion as rotational stress series), the mobile insert displaced always along the transverse and sagittal axes, and rotated longitudinally. Others directions of movements resulted to be negligible. Measurements of the inlay axial rotations revealed external rotational displacements when an internal stress was induced, or during squatting. Starting from extension, at 70° of flexion the inlay resulted to be externally rotated of about 2±2 degrees (mean±standard deviation of the mean). The meniscus, with a torque applied on the internal direction of the knee as well as in maximal internal rotation, displaced externally of 2±2 degrees. On the contrary, the polyethylene tended to
internally rotate when an external stress was induced. Whereas an external rotating torque was applied, 27 menisci displaced internally (-3±2 degrees) while the maximal external rotation produced an internal inlay displacement in 17 cases (-3±2 degrees). Passing from supine to simple weight bearing, an equal distribution of internal (14 cases, 2.3±1.2 degrees) and external (16 cases, -2.6±1.6 degrees) rotations of the meniscus was found. On the contrary, any statistically significant difference between anterior and posterior displacements was pointed out in all the exams performed. Inlays seemed to displace forward likewise downward, without any pre-defined pattern. Similar behavior was found for the translations along the transverse axis.

**Conclusions:** To the authors knowledge, no RSA study “in vivo” focusing on monitoring polyethylene displacement over time in mobile-bearing total knee prostheses is available in the literature and none of them have tried to quantify this mobility under weight-bearing conditions with a high accuracy technique, such as RSA. Data obtained suggest that longitudinal rotations are present in all prostheses and that follow a homogeneous pattern of motion. On the contrary, the transverse and sagittal translations did not show any prevalent pattern of motion in any exams, as it was impossible to determine if the inlay moved predominantly backwards or forwards and medially or laterally. Hypothesizing that the meniscal displacement during flexion is guided by the femoral rollback, results should have shown a constant polyethylene displacement but our data did not confirm this hypothesis. Therefore we deduced that femoral roll-back is not homogeneous in all patients and cannot be related to the conformity of the articular surface in the range of motion between 0 and 40 degrees. In the same way, we could not assess that ACL absence leads to paradoxal kinematics as suggested by Banks, and Stiehl [2,4], in fact even though ACL was resected in all patients, this abnormal kinematics was not always present. Finally, we can say that meniscal displacement seems to reflect adaptation to the individual joint biomechanics, rather than a plain reaction to the particular stress applied and that the inhomogeneous kinematics of patients’ knees implanted with Interax® I.S.A mobile-bearing knee prosthesis represents the result of continuous search for balance by muscles in a totally changed anatomy.

**References:**

ASSESSMENT OF INTRAOPERATIVE KNEE KINEMATICS AFTER TKA USING A COMPUTER NAVIGATION SYSTEM

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Introduction: Improper restoration of the mechanical axis is the most important cause of failure in total knee arthroplasty. With the introduction of computer assisted navigation systems this problem can be diminished to a large extent. Many reports in the literature have reported on the postoperative coronal plane alignment and the decrease in the number of alignment outliers[1-5]. Although, postoperative outcome measures of total knees are extensively reported, there have not been any reports concerning deformity correction intraoperatively throughout a range of flexion. This intraoperative data, both before and after total knee replacement can provide insight to pathomechanics of the arthritic knee and the amount of correction obtained to the surgeon during the procedure. The purpose of this study was to review the results of varus and valgus deformity correction in 152 consecutive computer assisted total knee replacements deformity correction throughout a range of flexion as recorded by a computer navigation system.

Materials and Methods: Data from 152 consecutive patients undergoing computer assisted total knee surgery by four surgeons were utilized. These include 94 females and 58 males with an average age of 66 years. The average weight of these patients was 199 lbs with a BMI of 32.3. 74 of the knees were left sided and 78 were right sided. OA was a major diagnosis in about 148 cases (97.36%) and rheumatoid arthritis in 3 cases (1.97%). Aseptic necrosis was the diagnosis in 1 patient (0.65%). A computer navigation system (Stryker Navigation, Kalamazoo, MI) was utilized for all patients. Initial range of motion and kinematic data was recorded after exposure and registration but before any bony cuts or soft tissue resection was made. To record the data the knee was ranged gently from full extension to full flexion and then back to full extension by the surgeon and the points captured by the computer algorithm. After the total knee components were implanted and the surgeon felt satisfied with soft tissue balancing but before closure of the knee, the kinematic data was once again recorded throughout a flexion arc. The system records values at a minimum flexion angle, a maximum flexion angle and at 0, 30, 60, and 90 degrees of flexion. The patients were then broken down into varus and valgus deformity and the pre-procedure and post-procedure data averaged and a paired student's t test utilized to
compare the correction data to the pre-procedure data. The data obtained prior to total knee implantation was also compared statistically to determine if the calculated clinical deformity differed throughout a range of motion.

**Results:** Deformity in the preoperative group ranged from 17.5 degrees varus to 20.5 degrees valgus (average of 7.8 ± 4.5 degrees varus and 4.6 ± 3.8 degrees valgus). The average of the 112 patients with a varus deformity was 0.8 ± 1.5 degrees, while the average of the 40 patients with a valgus deformity was 0.09 ± 1.4 degrees. When the deformity recorded prior to the procedure in minimum and maximum flexion were compared the difference was extremely significant with a p value of <0.001. The deformity recorded in minimum flexion was not statistically different in 30 degrees of flexion (p=0.09) but was when compared to 60 degrees flexion (p=0.006). In the postprocedure group deformity ranged from 0.9 + 1.4 degrees varus to 0.1 + 1.5 degrees valgus from minimum to maximum flexion but no statistical difference in the recorded deformity was found (p = 0.478). The deformity results compared throughout a range of flexion after implantation of the total knee resulted in no statistical difference from minimum to maximum flexion.

**Conclusions:** With computer assisted navigation systems final component position and mechanical alignment can be checked easily and reliably. Our study includes patients with the presence of a significant varus or valgus deformity preoperatively and with use of a computer assisted navigation system the postoperative group not only had less than 1 degree on average deformity but had no significant change in deformity throughout all flexion angles recorded. The data we present now determines that deformity is present throughout a range of flexion preoperatively but is not constant through the flexion arc. Furthermore, with the use of a computer assisted navigation system, an optimal alignment throughout a range of motion can be obtained.

**References:**

COMPARISON OF CT BASED AND IMAGE FREE NAVIGATION WITH THE NAVITRACK™ SYSTEM IN TOTAL KNEE REPLACEMENT: OVERALL ALIGNMENT, COMPONENT POSITION AND COST COMPARISON

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Introduction: CT based and image free navigation demonstrated advanced postoperative alignment in total knee arthroplasty. CT based applications are more time consuming but enable a accurate preoperative planning. The precision depends on the quality of the CT scan and the registration. Image free systems allow a fast intraoperative access to axis control, but the accuracy depends of intraoperative kinematic analysis and precise probing of landmarks. We wanted to check if there is a relevant difference in the alignment outcome in the different applications to justify the one or other application.

Materials and Methods: We analyzed in each application with the Navitrack™ System 40 consecutive cases. Used prosthese were the Natural Knee 2® and the INNEX® prosthesis. Overall alignment, tibial and femoral component placement was measured on long standing X-rays. Alignment index [1] was determined for both groups. Surgery time and loss of blood were recorded. A cost calculation of the complete procedure has been done.

Discussion: Mean surgery time in the CT based group was 105 minutes, in the image free 101, mean blodloss was 1563 ml CT based versus 1135 image free. In the CT group overall alignment was in mean 180,58 ° (range 172 - 186°) image free mean ankle was 180,5° (Range 176 – 186). In the range of 3° there was more cases in the image free group. Single ankles for tibial and femoral component placement were similar in both groups. In the CT based group there was one outlier of 8° valgus resulting of 5° malpositioning of the tibial component and 3° of the femoral component. Cause of necessary CT scan and CT data management the costs for the CT based navigation was significant higher in this group.

Conclusion: Either with CT based as with image free application with Navitrack™ System precise overall alignment and component positioning in total knee arthroplasty is possible. In comparison to manual studies [2] there are lesser and lower
outliner in this study as shown in other studies with navigation systems [3,4]. The benefit of preoperative planning tools in CT based navigation leads in standard TKA not in better results than in image free navigation. Therefore this more expensive and technical sophisticated procedure is not necessary and appropriate for routine use. Especially in limited budgets in health care systems easy to use and less time-consuming systems as image free System are favorable. The possibility in the testet system for use in CT based and image free navigation in total hip replacement, total knee replacement and spine surgery allows a cost sufficient indication related use of navigation in times of limited budgets.

References:

COMPARISON OF DISTAL FEMORAL TKR BONE CUTS BY FREEHAND NAVIGATION VS. CONVENTIONAL CUTTING JIGS

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Introduction: Beyond offering more accuracy and fewer outliers in TKR surgery, navigation should allow minimally-invasive surgery with smaller incisions and faster recovery time by making TKR procedures radically simpler. CAOS and navigation should help reducing the complexity for surgeons and enable precise cuts without the numerous jigs needed. In an early study in Pittsburgh [1], this concept was examined with a novel clutch-modulated bone shaver. In a different study [2], we demonstrated that it was practical to give sufficiently fast and meaningful computer graphical feedback on the progress of freehand bone cutting with a saw, without jigs. With novel routines, the computational burden of calculating and re-display of an incrementally changing bone shape under freehand navigated cutting was demonstrated with a standard PC. However, is it possible to achieve even reasonable cuts, let alone produce “better” and “faster” ones with directly navigated instruments, and without jigs?

The specific goals of this study were to evaluate the results of a freehand cutting image-guided navigation system for TKR under development in-house. A large number of experimental TKR distal femur cuts for a commonly used implant were made with graphical feedback guiding a conventional bone saw in the hands of a surgeon without any jigs. The resulting cuts were compared with those using conventional cutting jigs. The time taken and the “quality” of each cut were quantitatively assessed, observing also the surgeons’ likes/dislikes about the implementation to guide its future progress.

Materials and Methods: An experimental CT-image based CAOS system evolved from over 3.5 years of hardware integration with fully in-house developed software code in C/C++ for PC running Windows. It utilized an NDI Polaris infra-red optical tracker for direct navigation of a conventional battery-driven oscillating bone saw fitted with passive reflective reference frames. The saw was fully rendered through a realistic surface model. The whole saw was “registered” as one rigid body treating the small oscillatory range of the saw blade as part of a slightly wider cutting tip.
18 identical physical bone models were cast with a suitable foam material from a mold to replicate one original distal femur based on the female right knee from the Visible Human Project (VHP) [3]. The mold was itself set around a Stereo Lithographic Rapid Prototyping model, whose STL file was generated in-house from the VHP data-set for that femur. Therefore, all the cast bone replicas made for cutting, and the computer surface (and volumetric) virtual models in the user graphical interface were based on identical anatomic geometry. This was verified by measurement of overall dimensions which showed differences of less than 0.5mm wherever inspected.

The experimental cuts were the five planar fixation distal femur plateaus for a widely used TKR implant. A standard combination cutting jig made by the same implant manufacturer was used for alignment and cutting for comparison. For the freehand cutting results, optical reference frames were fastened to the saw and the cast bone specimen. Both were “registered” with a robust algorithm which was tested independently. The system displayed 3D realistic models of the saw, the bone, and the planes along which the blade should be orientated. The user was able to see the actual cutting on the physical bone following its desired path from the PC screen. Alternatively the user could follow the progress of the cut on the screen on the virtual bone as described in [2].

Simple measurements with a protractor and a digital caliper were made to evaluate all the cuts made. Four important angles representing the orientation of the five cut surfaces were measured treating the most inferior horizontal cut surface as a reference. The orientation (angle) of each surface measured was the average of the angles measured along 6-8 predetermined Anterior-Posterior (AP) planes, at constant intervals Medial-Laterally (ML). Angles do not sufficiently capture the cuts’ accuracy as the same basic orientations could be achieved with plateau surfaces cut too small or too large with parallel surface offsets. Therefore, the length of three of the plateau surfaces were measured, each at the same 6-8 predetermined planes and averaged. Therefore, each synthetic bone specimen yielded 3 lengths and 4 angles for its cut surfaces. Whilst the means of such measurements captured the average basic shape of the resulting specimen with the five cuts, the deviations from the mean within each bone were a measure of the unevenness of the cut surfaces.

Two experienced arthroplasty surgeons and one engineer performed the experiments with a strict protocol. Each made the same number of cuts after familiarizing themselves with the saw and synthetic cast bone material for 3 minutes on a raw rectangular piece of foam. A user would then perform all 5 main cuts on a cast bone sample using the conventional TKR combination jig. Each user was then allowed only one (non-documented) practice attempt on a cast bone sample using freehand navigation. Five separate cast bone samples were then cut in turn by that user freehand with navigation and no jigs, in three separate sessions. Each experimental run timed the completion of cutting all 5 distal surfaces. Each (cut) specimen was photographed and documented for later measurements as described above.

**Results:** The surgeon’s comments about the utility of this technique, and their qualitative assessments of the cuts were most encouraging for the concept’s feasibility and potential. As shown in the figure, it took both surgeons almost the same time of
about 16.5 min to cut with the jigs. However, it took them an average of just under 10 min to cut freehand. The engineer took more than 30 min with the jigs, and about 12 min freehand. To enable a simple interpretation and comparison within a confined space here of the quality of cuts from the large number of measurements, the results for each cut surface were averaged to depict the shape of the resulting bone graphically from a sagittal viewpoint. The profiles for each surgeon and the engineer were plotted separately in the figure. Each shows the desired (ideal) profile, the cuts made using jigs and the profile of each bone cut freehand. The shaded area surrounding the curves shows the outer-most envelope within which the worst ever deviations were measured anywhere on the ML depth before averaging. Of course, no such extreme profile was ever present, as that would have had to combine the worst possible deviations in cutting from all the tests, into one.

**Discussion and Conclusions:** Even if the times measured for the engineer were not allowed to skew the results (because of his less experience with conventional jigs), the surgeon’s data showed at least 35% reduction in cutting time with the Freehand Navigation system, compared to jigs. This was achieved with an early version of the system, and with minimal practice in its use by the surgeons. The deviations of the freehand cuts from the ideal in terms of quality were of the same order as those with the jigs, and in some cases better. With jigs eliminated however, many possibilities would open up for radically less invasive surgery. It is interesting to revisit the engineer’s cuts in terms of duration and quality. Four times faster cutting was achieved with freehand navigation in this case, which has implications for easier TKR for the trainee surgeon. The encouraging results with faster cutting invite us to subject these executed cuts, and others for the proximal tibia, to even more rigorous quantitative assessment by full 3D digitization to compare with those of the jigs. An objective method is sought to verify that mechanical fixation of the implant had not been compromised. These results add to the early works of [1] and [2] to harness CAOS for cheaper, faster, easier and possibly better minimally invasive TKR surgery without cutting jigs.

**References:**

Freehand Navigation bone cuts compared with conventional jigs

**Surgeon 1**
Average time:
With jigs: 16.5 min
Freehand: 10.8 min

**Surgeon 2**
Average time:
With jigs: 15.8 min
Freehand: 8.9 min

**Engineer**
Average time:
With jigs: 20.2 min
Freehand: 12.3 min
FREEHAND NAVIGATION CUTTING FOR TKR SURGERY WITHOUT JIGS: ASSESSMENT OF DISTAL FEMORAL CUTS VS. CONVENTIONAL JIGS

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Introduction: Beyond offering more accuracy and fewer outliers in TKR surgery, navigation and CAOS should allow smaller incisions and make surgical procedures radically simpler by enabling precise cuts without the numerous jigs needed. This concept was examined in [1] with a novel clutch-modulated bone shaver. In a different study [2], we demonstrated that it was practical to give sufficiently fast and meaningful computer graphical feedback on the progress of freehand bone cutting with a saw, without jigs. However, is it possible to achieve even reasonable cuts, let alone produce “better” and “faster” ones with directly navigated instruments without jigs? The specific goals of this study were to evaluate the results of a freehand cutting image-guided navigation system for TKR under development in-house.

Materials & Methods: An experimental CT-image-based CAOS system was built with in-house software in C/C++ for PC running Windows. It utilized an optical tracker for direct navigation of a conventional oscillating bone saw fitted with passive reference frames. The saw was rendered as a surface model “registered” as one rigid body treating the small oscillatory range of its blade as part of a slightly wider cutting tip. 18 identical foam bone models were cast from a single mold. The mold was set round an STL Rapid Prototype (RP) model of one distal right femur, whose STL file was generated in-house from data of the Visible Human Project. Therefore, all the cast bone replicas made for cutting, and the computer surface virtual models in the graphical interface were based on identical anatomic geometry. The experimental cuts were the five distal femur plateaus for a widely used TKR implant were. A standard combination jig made by the implant manufacturer was used for alignment and cutting for comparison. In freehand cutting, the saw and cast bone specimen, both with optical reference frames, were “registered” with a robust algorithm which was tested independently. The system displayed realistic 3D models of the saw, bone and the plane along which the blade should be orientated. The user was able to see the cutting on the physical bone following its desired path from the PC screen. Alternatively the user could follow the cut on the screen on the virtual bone as described in [2]. Simple measurements with a protractor and a digital caliper were made to evaluate the cuts. Four
angles representing the orientation of the five cut surfaces were measured treating the most inferior cut surface as a reference. The orientation (angle) of each surface measured was the average of those measured along 6-8 selected Anterior-Posterior (AP) planes, at constant intervals Medial-Laterally (ML). The length of three important plateau surfaces were also measured, each at the same 6-8 predetermined planes and averaged. Each specimen thus yielded 3 lengths and 4 angles for its cut surfaces. Two experienced arthroplasty surgeons and one engineer performed the experiments. In a strict protocol, each made the same number of cuts after practicing with the saw for 3 minutes on a rectangular piece of identical foam material. Each user performed all the 5 cuts on a cast bone replica using the conventional combination jig. The user was then allowed only one (non-documented) practice using freehand navigation. Five separate cast bone samples were then cut freehand by that user, in three separate sessions. Each experiment timed the completion of 5 distal surface cuts, which were then photographed and documented for later measurements.

Results: The surgeons’ main comments highlighted the “utility” of this technique. Their qualitative assessment of the cuts were also most encouraging for the concept’s feasibility and potential. It took both surgeons almost the same duration of about 16.5 min to cut with jigs, yet it took one an average of 10.8 min, and the other 8.9 min to cut freehand. The engineer took >30min with the jigs, and about 12 min freehand. The worst standard deviation (integrated along the ML line) of any freehand cut from the ideal was within 2.7º, and the equivalent measure with jigs was within 1.8º, indicating the expected more “planar” surfaces with jigs. As for the mean angles, indicating overall orientation of the surfaces, the worst for any surface in freehand cutting was within 5.3º whilst it was 5º with jigs. To enable a simple interpretation and condense the large number of measurements, the results for each cut surface were averaged to depict the shape of the resulting bone graphically from a sagittal viewpoint. Plots were made of the cut profiles for each surgeon and the engineer separately, each comparing the desired (ideal) profile to the one using jigs and those of each bone cut freehand.

Discussion & Conclusions: The surgeon’s data showed at least 35% reduction in cutting time compared to jigs using this early version of the system, and with minimal practice in its use. The deviations of the freehand cuts from the ideal in terms of quality were of the same order as those with the jigs, and in some cases better. With jigs eliminated however, many possibilities do open up for radically less invasive surgery. Four times faster cutting by the engineer was achieved with freehand navigation, which has implications for easier TKR for the trainee surgeon. These encouraging results invite us to subject these executed cuts, and others for the proximal tibia, to even more rigorous quantitative assessment by full 3D digitization to compare with jigs. A method is sought to verify that mechanical fixation of the implant would not be compromised. These results add to the other works of [1] and [2] to harness CAOS for cheaper, faster, easier, and possibly in the future better, minimally invasive TKR surgery without cutting jigs.

References:
COMPUTER ASSISTED KNEE ARTHROPLASTY; EXTENT OF IMPLANTATION ERROR

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Introduction: The process of cementing the prosthetic components to bone following bone preparation in CAOS can add error introducing a gap between planned and achieved component positions in knee arthroplasty. Any process that adds error following computer assisted bone preparation weakens the accuracy claims of CAOS. Plain x-rays are insufficient a tool to quantify this implantation error. We demonstrate the use of X-ray computerized tomography to investigate this further. [1]

Materials and Method: Our active constraint robot (Acrobot)[2,3] was used to prepare a series of plastic bones that were individually CT scanned and planned for unicompartmental component implantation. Following the bone preparation the prosthetic components were fitted to the bone without cement and scanned. A further CT scan was performed with the components cemented to the bones.

These scans were use to calculated transformation matrices that were compared showing the difference between the component positions prior to and following cementation.

Results: 15 sets (femur and tibia) of plastic bones were used. The difference between pre cementation and following cement implantation positions ranged from <1° to 4° and between <1mm to 3mm.

Discussion: Accuracy/inaccuracy outcomes remain the key CAOS issue. Computer assisted systems allow optimal planning and accurate bone preparation procedures. This study has documented the extent of the post-operative bone preparation error, even meticulous implantation with cement does result in a range of deviations from plan. With such precise bone cuts, any cement changes implant position, while normally prepared bones usually have gaps as a result of ‘normal’ sawing and routing techniques.

While these deviations may not be significant clinically they add ‘noise’ to the impact of CAOS on knee surgery and outcomes. This work has led to a modified bone preparation and cementation technique. We recommend that minimal cementation be used.
References:


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COMPUTER ASSISTED PATELLO-FEMORAL REPLACEMENT; A MECHANISM FOR OPTIMISING ROTATION

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Introduction: Patello-femoral arthroplasty was introduced in the 1950’s. Since then many different types of patello-femoral arthroplasty have been trialed with varying success (1-6). These studies show failures relate to poor surgical attention to soft tissue balance and prosthetic alignment. Lack of attention to the underlying causes of maltracking is the principle cause of revision surgery after patello-femoral arthroplasty, the prosthesis having a low failure rate secondary to aseptic loosening. The Avon patello-femoral arthroplasty (Stryker, Howmedica, Osteonics) has been designed to reproduce accurately the congruity of the natural patello-femoral joint throughout its range of movement, in particular it facilitates accurate tracking of the patella in the trochlear groove. Computer assisted surgery has been developed to allow accurate implantation of prosthesis. Numerous studies relating to total and medial unicompartmental knee arthroplasty are abundant in the orthopaedic literature. The aim of our study was to assess intra-operative navigation and its ability to produce a safe, reliable and reproducible way of obtaining correct implant position in patello-femoral arthroplasty. This methodology has the potential to reduce failures and hence decrease revision surgery if correct alignment is achieved during primary surgery.

Methods: Four patients underwent patello-femoral arthroplasty using the Avon prosthesis during 2003. All patients had symptomatic osteoarthritis radiographically proven which had failed conservative management. The implants were navigated into position using the windows based Stryker Leibinger system. All operations were performed under prophylactic antibiotic cover with the use of a tourniquet. The approach to the patello-femoral joint was through a midline skin incision and a medial parapatella approach. The patella was dislocated and the Avon jigging system in conjunction with the navigation system was used to determine a femoral cut external rotation angle of approximately 5 degrees. The external rotation angle allows patello-femoral tracking in line with the anatomical pull of the Quadriceps vector. The navigation system also enabled the femoral cut to be parallel to the long axis of the femur. All implants were cemented into position. Patients were rehabilitated under the guidance of the physiotherapists and were allowed to fully weight bear as pain allowed. The patients were assessed clinically and radiologically at regular intervals post-operation.
Results: No patients were lost to follow-up. The series consisted of 2 females and 2 males. The average age of the patients at the time of surgery was 52 years old (range 35-63 years). The mean follow-up was 8 months. No short or long term problems relating to surgery were encountered. The average Oxford knee score was 24 (range 19-30). All had excellent results using the Crosby and Insall scoring system. Radiologically all plain radiographs showed good congruency of the patello-femoral joint.

Conclusions: Patello-femoral arthroplasty has become an established treatment strategy in treating patients who have failed conservative management. Many studies have been conducted into numerous prosthesis that are currently on the market, all having varying degrees of success (1-6). These studies showed that failures were related to poor surgical technique especially in relation to soft tissue balance and component alignment. Our study addressed component alignment with the use of computer assisted orthopaedic surgery. Intra-operative navigation using the Stryker Leibinger system enable accurate external rotation alignment to be achieved in the femoral component. This has theoretical biomechanical advantages in enabling the patello-femoral joint to be positioned in a more anatomical congruent position as well improving the joint reaction force in respect to the quadriceps vector. At present our study has small numbers of patients and a short follow-up duration. However we have demonstrated that intra-operative navigation in performing the Avon patello-femoral arthroplasty is safe, reliable and reproducible enabling excellent short term clinical and radiological results. With accurate implant positioning in primary surgery this has the theoretical advantage of reducing revision rates and hence increasing the long term survivorship of the prosthesis.

References:

Introduction: In this study we present a new method to analyse the double-bundle (DB) ACL reconstruction, based on the use of a navigation system to track passive motion and to digitize anatomical data and successive computer elaboration of the kinematics. The system allows a reliable analysis also of secondary kinematic constraints and, on cadaveric specimen, also a reliable study of the relationship with anatomical features [1,2]. This study describes the acquisition and elaboration protocol of the methodology and reports a case study to investigate the effect of tunnel orientation in DB ACL reconstruction on the kinematics of the reconstructed knee.

Materials and Methods: We performed the comparison of two DB techniques for ACL reconstruction in one cadaver knee, using an optical navigation system to record relative motion of the tibia and the femur and to digitize anatomical data.

Limb preparation. The femur was fixed to the experimental desktop with a clamping device, while the tibia was left free to move like in the standard operating room setup. Femur was fixed horizontally with tibia, at 90deg of flexion, perpendicular to floor in order to minimize external forces, like varus rotation, and have a physiological passive range of motion, moreover this kind of setup let surgeon have an easy access to the internal part of the knee.

Tests. The passive range of motion, the internal/external rotation at 90deg of flexion, at maximum force, and the drawer test, at maximum force, were recorded twice by the same operator in the ACL intact knee with the patella in situ. Then the ACL was dissected, and the ACL-deficient knee kinematics was examined performing again the same protocol. The gracilis and semitendinous tendons were sutured together with the tibial insertion left intact. A tibial tunnel was performed. two femoral tunnel with different orientation were performed, one that we call “horizontal”, and one that we call “vertical”. They differ from orientation respect to tibia plateau. The tendons were passed through the tibial tunnel, over the top, in the horizontal tunnel and in the tibial tunnel again. The tendons were then clamped and cinematic tests were repeated.

Computer analysis: In particular we computed: The range of motion (PROM), as the rotation, the antero-posterior (AP) laxity, the internal-external (IE) laxity at 90°, Elongation and orientation of the fibre joining the centres of the insertion areas of the original ACL of the two bundles and of the reconstructed ACL during kinematic tests.
**Results:** The passive range of flexion was the same in all cases, although small differences were found in the initial attitude of the joint in full extension. The position of both bundles of the reconstructed ACL with the two techniques was very similar and inserted laterally in the tibial and distally in the femoral tunnel. The elongation and orientation of the reconstructed ACL bundles were similar both in the horizontal and vertical case, and differed in their position and orientation from the central fiber of the natural ACL, especially in extension. The anterior bundles of the reconstructed ACL resulted isometric during PROM, like the normal ACL central fibre, while the posterior bundle decreased its length in flexion by almost 20%. Also the orientation of the anterior bundles of the reconstructed ligament with respect to the tibial plateau was similar to the normal one and decreased in flexion. The orientation of the posterior bundle of the reconstructed ACL with respect to the tibial plateau varied much more during PROM. The orientation of both anterior and posterior bundles of the reconstructed ACL with respect to the femoral notch were quite similar, and increased less than normal ACL during PROM. It is interesting to remark that the attitude of the knee at 90° was slightly different for normal and reconstructed knees and therefore the elongation during IE and drawer test showed a different trend. AP and IE laxities varied according to the ACL state.

**Discussion and Conclusions:** The experimental setup was successful in providing a comparison among normal knee, ACL-deficient knee and reconstructed knee from the kinematic point of view, avoiding the problem of individual variability and lack of data on 3D kinematics. In our experiment the ACL elongation and general orientation of the ligament was restored by both techniques [2,3]. However only the vertical tunnel was able to restore the natural AP and IE stability of the knee. It performed better than the horizontal one, which appeared unable to fully control AP laxity and constrained IE rotation more than the normal ACL. Therefore a first analysis of the experimental data showed that the femoral tunnel orientation had a significant effect on the final knee behaviour. It can be noticed that this result appears surprisingly different from the classic single bundle technique, were the control of AP laxities increases when the orientation of the femoral part becomes more horizontal [4]. This result may be due to the physical behaviour of the tendon wrapping around the femoral condyle with different length and therefore forces in the two DB techniques and absent in the single-bundle one.

**References:**

CT-BASED COMPUTER-ASSISTED KNEE ARTHROPLASTY: COMPARISON WITH THE CONVENTIONAL PROCEDURE (PRELIMINARY STUDY)

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Introduction: Recent developments in computer-assisted surgery has made the use of the preoperative information intraoperatively. It enabled the orthopedic doctors to perform precise intraoperative surgery based on preoperative planning. This study evaluated the value of the CT-based navigation system on the total knee arthroplasty.

Methods: From October 2001 to September 2002, a prospective study including a consecutive series of 60 patients for CT-based computer assisted knee arthroplasty and the 2nd series 20 patients for conventional procedures was conducted. Etiology for surgery included osteoarthritis (75) and rheumatoid arthritis (5). The same surgeon performed all operations. Radiographic assessments included lower extremity split scanogram, knee AP and lateral view. Postoperative radiograph measurements included the mechanical axis and the femoral and tibial angles. The perioperative assessments included surgery time, blood loss and hospital stay.

Results: The computer-assisted group displayed significantly less mechanical axis deviation (1.59 ± 0.76°) when compared to the conventional group (3.07 ± 1.61°) (p < 0.05). The mechanical axis between 180.0 ± 2.0° (Good results) was 65% in the computer-assisted group and 45 % in the conventional group (p < 0.05). In the coronal view, the femur valgus _ and the tibia perpendicularity _ angles do not differ significantly between the two groups. In the lateral view, the posterior slope angle of the tibial components was 88.6°± 1.21°in the computer-assisted group when compared to 85.7°+ 1.56°in the conventional group (p<0.05). The computer-assisted group exhibited less perioperative blood loss than the conventional group (465 ± 247ml VS. 588 ± 215 ml, P<0.05). The computer assisted group had significantly longer operation time than the conventional group (143±36min. VS. 116±28 min, P_0.05). However, the learning curve effect gradually reduced after 20 patients (P_0.05).

Conclusions: CT-based computer assisted navigation surgery in total knee arthroplasty was safe and precise when compared to the conventional procedures. Besides, the blood loss is also less in the navigation group. For patients with severe varus or valgus deformity due to arthritis, failed previous high tibial osteotomy or traumatic arthritis with deformity, the navigation systems can minimize incorrect alignment.
Long term follow up is required to assess the benefits of CT-based computer assisted navigation surgery in the longevity of prosthesis and patients’ functional outcomes.

References:

RESULT OF THE BRAINLAB CT-FREE NAVIGATION SYSTEM IN TOTAL KNEE ARTHROPLASTY: COMPARISON WITH THE CONVENTIONAL PROCEDURE

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Introduction: Restoration of the mechanical axis as well as a good ligament balancing are important factors for the success in total knee arthroplasty. This study evaluated the effect of the CT-free navigation system in total knee arthroplasty.

Methods: From October 2002 to December 2003, 24 patients with bilateral advanced osteoarthritis of knees were enrolled in this study. All patients received CT-free computer-assisted total knee arthroplasty in one knee (Study group) and conventional methods in another knee (Control group). The same surgeon performed all operations. The PFC Sigma knee prosthesis were implanted with cement fixation. The navigation system used in this study was VectorVision Knee (BrainLAB, Munich, Germany). Radiographic assessments including lower extremity split scanogram, knee AP and lateral view. Postoperative radiograph measurements included the axial alignment mechanical axis and the femoral valgus and tibial perpendicularity angles. Perioperative assessments including tourniquet time, blood loss and hospital stay were compared between two groups.

Results: The study group displayed significantly less variations (1.59 ± 0.76°) in mechanical axis deviation when compared to the conventional group (3.07 ± 1.61°) (p < 0.05). The mechanical axis between 180.0 ± 2.0° (Good results) was 75% in the computer-assisted group and 45% in the conventional group (p < 0.05 chi-square test). In the coronal view, the femur valgus (_) angle was 96.2 ± 2.7° in the computer-assisted group when compared to 93.8 ± 3.2° in the conventional group (p<0.05). The tibia perpendicularity _ angles did not differ significantly between the two groups. In the lateral view, the posterior slope angle of the tibial components was 89.5 ± 3.6° in the computer-assisted group when compared to 85.7 ± 3.1° in the conventional group (p<0.05). Postoperative blood loss was less in the computer-assisted group than in the conventional group (420 ± 208 ml in the former compared to 545 ± 186 ml in the latter, P<0.05). Statistically significant differences existed in mean surgery time (116 ± 28 min in conventional group, 143 ± 36 min in computer-assisted group, P<0.05). The new ligament balancing tool is useful in achieving optimal soft tissue release with balanced collateral ligament as well as balanced flexion and extension gap. There were no severe complications among both groups.
Conclusions: Our preliminary results suggest that the CT-free VectorVision navigation system improved surgical accuracy and reduced blood loss in TKA when compared to the conventional technique. The system does not require preoperative planning and avoid excessive radiation exposure when compared with CT-based navigation version. The further study is needed to evaluate the long term efficacy in the survivorship of the implanted prosthesis and patients’ functional outcomes.

References:

INSTITUTING TKA NAVIGATION IN A COMMUNITY SETTING

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Introduction: The Stryker Surgical Navigation unit was introduced into our OR environment in August of 2003. The author had previously been exposed to version 1 software and had chosen not to pursue introduction in 2002. The introduction of version 2 software and instrumentation blocks made introduction into our institution a reasonable undertaking.

Since that time 48 TKAs have been performed by 2 surgeons who have employed the navigation. 35 TKAs (8 bilaterals) have been performed using SurgiNav with the Scorpio PS TKA system – utilizing navigation of cutting jigs as well as documentation of pre and post-implantation alignment and stability. The remaining have used the navigation to assist in placement and documentation of the LCS TKA system.

The technical problems encountered were:
- proper pin placement relative to cutting jigs and implants, maintainence of pin stability
- identification of predictable landmarks
- establishing skin incisions appropriate to operation
- consistent use in bilateral TKA patients
- identification of appropriate step-wise approach to evaluation and implantation that was surgeon specific
- proper education of OR personnel
- establishing a user-friendly instrument tray
- develop mechanism to work through software in timely fashion

Identify personnel responsible for maintaining equipment

Complications included incomplete analysis due to poor pin placement (2), incision modification (2), and non-displaced femur “crack” (1). No other complications have occurred and successful TKA has been achieved in all 48.

Organizational problems included establishing a means to obtain the unit in a highly cost-conscious environment, establish validity of the approach to interest marketing personnel, promotion of approach as appropriate and useful to TKA, and working with manufacturer and hospital financial personnel to monitor cost-benefit aspect of the new technology introduction.
IN-VIVO THREE-DIMENSIONAL KNEE KINEMATICS ANALYSIS AFTER TKA COMBINED WITH THREE-DIMENSIONAL LOWER EXTREMITY ALIGNMENT ASSESSMENT SYSTEM

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Introduction: Single plane image matching procedure using fluoroscopic images and three-dimensional (3D) component computer models have been a golden standard of the in-vivo knee kinematics analysis after total knee arthroplasty (TKA), and numerous literatures have reported the knee kinematics after TKA using the procedure. Some authors especially highlighted the “condylar lift-off” phenomenon that is thought to be the cause of eccentric polyethylene wear. However, the procedure is able to assess only the relative motion between femoral component and tibial component by calculating the medial and lateral femoral condyle points closest to the flat tibial base-plate. It does not take the geometry of the tibial insert into account. We have developed the three-dimensional lower extremity alignment assessment system (3DLEAAs) and adapted the image matching technique of 3D computer bone and component models to the system for application to the 3D evaluation of component alignment after TKA. Previous study demonstrated that component alignment relative to the bone was accurately determined by this system (maximum error was less than 1 mm in distance and 1 degree in orientation). By application of this system to the fluoroscopic knee kinematics analysis after TKA, it has been possible to analyze knee kinematics taking the component alignment relative to bone, entire lower extremity alignment, and the geometry of the tibial insert into account. Objective of current study is to examine the availability of this system.

Materials and Methods: 1. Reconstruction of 3D computer models of patient’s femur and tibia: Computed tomography (CT) examination of the patient’s femur and tibia were performed before TKA. Three-dimensional computer models of femur and tibia were reconstructed from the CT data and the coordinate system and reference axes such as transepicondylar axis (TEA) and were installed to the 3D models of femur and tibia in advance, and saved in the PC. GCA is the axis that is the line connects the center points of the spheres representing the medial and lateral posterior femoral condyles.
2. Three-dimensional evaluation of component alignment relative to bone after TKA. Biplanar (A-P and 60° oblique) CR projections of entire lower extremity of patient were simultaneously taken in standing position by use of the specially-designed cassette holder with a mobile cover for simultaneous projection, and the data was downloaded to the personal computer (PC). The images of the 3D bone models of patient were projected onto the biplanar CR images by the inverse operation of the projection matrix that was obtained by camera calibration procedure performed in advance using a calibration frame. Then the contours of the 3D bone models were matched to the contours of the images of bone in CR images. By performing this procedure, post-operative 3D alignment of femur and tibia were calculated. Next, 3D computer models of the femoral and tibial component were projected onto the same biplanar CR images in similar manner and the contour of the 3D component models were matched to the contour of the components of CR images. Performing this procedure, the 3D component alignment relative to bone and relative position between femoral component and tibial component were three-dimensionally assessed. These information were saved in the PC.

3. Image matching procedure of the post-operative bone and component models to the fluoroscopic image: Four knees (4 patients) were examined. After the 3D evaluation of component position using the 3DLEAAAs described above, the knee movement was recorded by the fluoroscope in sagittal plane. We captured lateral images of the knee movement from the fluoroscopic video. A total of 5 images were obtained every 30° from full extension to 120° flexion, and downloaded to the PC. The distortions of the images of fluoroscope were corrected in advance by use of the calibration grid attached to the C-arm. Then, the 3D computer models of the femoral and tibial component were projected onto the each fluoroscopic image, and the 3D relative position between the femoral component and tibial component were calculated by matching the surface contour of the component models to the surface contour of the component image of the fluoroscopic image. When the matching procedure was performed, the information of 3D position of the femoral component relative to the tibial component that were calculated at the time of above mentioned post-operative component position analysis using biplanar CR images, used as the initial position of the motion analysis in order to reduce the error in determining out of plane rotation and translation. By performing this procedure the spatial position of the femoral component relative to the tibial component was accurately calculated at each knee flexion angle.

4. Analysis of knee kinematics after TKA: Knee kinematics was analyzed by use of translation of the estimated contact points (ECPs). ECP was obtained by calculating the minimum distance between the femoral component and tibial insert. The medial and lateral ECP were showed on the joint surface of the tibial insert. Analyzing the antero-posterior (A-P) and vertical translation of the medial and lateral ECP made it possible to evaluate the relative A-P and vertical motion of the femoral component relative to the tibial component. The incidence of the “Condylar lift-off phenomenon” was also assessed. The phenomenon was defined as the separation of the femoral component and tibial insert more than 1mm. Knee kinematics was evaluated also by the translation of TEA. The translation of this axis was compared with the location of the helical axis of the knee motion.
**Results:** 1. The motion analysis using the ECP: In all the knees, both medial and lateral ECPs were slightly translated posteriorly to the anteroposterior center line of the joint surface of the tibial insert from full knee extension to 30° flexion. This meant the sliding of the femoral component. The lateral ECP was translated posteriorly from 30 to 90° knee flexion despite the medial ECP was stayed at almost same location. The maximum length of the translation from 30° to 90° flexion was 3.2 mm medially and 20.1 mm laterally. This meant the medial-pivoting motion of the femoral component. Both medial and lateral ECPs were slightly translated posteriorly from 90° to 120° knee flexion.

2. Tilting of femoral component relative to tibial base-plate in coronal plane were observed in 2 knees in 90° flexion. However, there was no condylar lift-off phenomenon in this series. Tilting of femoral component in coronal were occurred by the rotation of the femoral component resulting in that one condyle attached the lower potion of convex geometry of the tibial insert while the other femoral condyle attached the lower potion. Therefore, no separation of both component was observed.

3. The analysis of the helical axis of femur and the TEA: In the all knees, the helical axes of the femur were existed very near to the TEA from 30 to 90° of knee flexion. The helical axes seemed to be slightly anterior and proximal compared to the TEA from full knee extension to 30° flexion, and slightly distal compared to the TEA from 90° flexion to 120° flexion.

**Discussion:** Published literatures about 3D knee kinematics after TKA have reported some kinds of motion patterns such as medial pivoting, femoral roll-back, and condylar lift-off. These knee kinematics may be regulated by the factors such as soft tissue balancing, cruciate retaining or substituting, component design, and also component alignment and post-operative entire lower extremity alignment. Therefore, it is thought to be necessary for knee motion analysis after TKA to take component alignment and post-operative entire lower extremity alignment into account. The most serious limitation of single plane image matching procedure is the difficulty of reducing the error in determining out of plane translation and rotation. The advantages of our system are the reduced this kind of error by use of information of 3D relative position of both components obtained from biplanar post-operative CR images, and this is the reason why it has been possible to analyze knee motion taking the geometry of tibial insert into account. From the results of this report, this system was thought to be useful to analyze the knee motion after TKA in detail. These kinematics analysis may help to detect ideal component alignment of TKA.

**References:**

Introduction: Multiple authors have demonstrated improved implant position with optically tracked computer assisted surgical technology [1,2,3,4,5]. Most studies have compared the effect of computer assistance after the “learning curve” with randomized studies occurring concurrently. Although this is a preferred statistical model, a closer approximation of incorporation of an improved surgical technique is a study of consecutive surgery pre and post adoption of computer navigation.

Methods: With IRB approval the first forty-three consecutive patients with 59 total knees done using computer navigation by a single experienced surgeon were requested to participate in the study. Thirty-six patients with forty-seven knees agreed to participate. The control group was 58 consecutive patients with 78 knees done just prior to beginning navigation. 36 patients with 48 knees agreed to participate in the control group. All knees were the Genesis 2 posterior cruciate substituting or retaining. The decision for posterior cruciate substitution was made clinically if too much PCL laxity was problematic after performing the posterior cruciate retaining procedure.

The Computer navigation System was a BrainLAB Vector-Vision CT free system for Genesis 2 using the rough cut first software. The desired alignment was neutral with no varus or valgus. All navigated cases were included even if final alignments could not be determined intraoperatively due to loss of position of the reference array after tibial and femoral cuts were made. Most of the loosened array problems occurred in the first twenty cases. In order to document this process of changing from mechanical instruments to navigated instruments no cases were excluded during this “learning phase”.

All knees were studied for implant position using Standing long leg alignment AP films and routine lateral X-rays using the Kodak Direct View CR 900 digital X-ray system. The angle calculations were done on a diagnostic workstation with a resolution of 2791x1605, calculate angles to the nearest tenth of a degree.

All knees were also scanned on a Picker PQS spiral CT scanner. Images are sent from the Picker scanner in Dicom format to the Eclipse treatment planning station. A three dimensional image is then created. Using the plane of the CT scan a line perpendi-
cular to this plane can be formed through the center of the knee. With the CT image magnified and the rotation of the limb corrected, distances could be measured for the centers of the ankle and hip relative to the knee center line in all three axes. The measuring tool in the CT software was used to quantify the distances on the x and y axes on the ankle and hip cross-sections. Knowing the distance from the center of the knee to the hip and the varus and flexion coordinate variations of the two centers, a trigonometric formula for determining the varus angle for the hip to the knee was calculated. The formula is \( \text{ATAN2} \left( \frac{a}{b} \right) \times 180/\pi \). In a similar fashion, the varus angle from the knee to the ankle was determined. The sum of the hip varus angle and the ankle varus angle is the varus angle of the knee.

**Discussion:** Mechanical Axis in the control group varied from -7 degrees (valgus) to 6.5 degrees (varus). The navigated group varied from -7 degrees (valgus) to 7.5 degrees (varus). The results of the two groups were not statistically different. However, variability did continue to decrease with experience. The final 17 cases did show a statistically significant reduction in variability (\( p = 0.015 \)) with no cases more than 2.5 degrees from neutral alignment on CT.

**Conclusion:** Computer navigation has not yet become a standard technique. As this technique is further accepted, a natural history of the learning curve and how this will affect alignment outcomes becomes important. If a center adopts computer assistance and cannot demonstrate improved alignment immediately, it may not mean that the surgeon, software, or technique is at fault but merely a natural progression through the learning curve. It is not known whether a more experienced surgeon may actually take longer to accept the computer data actually increasing the length of the learning curve.

**References:**

MINI INVASIVE COMPUTER ASSISTED BI-UNICOMPARTIMENTAL KNEE REPLACEMENT

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Introduction: Nowadays all around the world every orthopaedic surgeon can choose different valuable solutions in the treatment of knee osteoarthritis. However in exceptional cases such as intra-articular deformities following bycondilar tibial plateau fractures or bi-compartmental (medial and lateral) arthritis with no involvement of the femoral-patella joint in patient younger than sixty still remain a challenge for the orthopaedic surgeon. In literature many surgical procedures have been advocated but without no definitive achievement. Furthermore the location and importance of sensory receptors in the anatomic structures around the knee are not understood fully. Therefore in total knee replacement (TKR) preservation of anatomic structures like the cruciate ligaments seems important, especially in consideration of functional aspects such as gait, muscle activity, and proprioception. Likewise unicompartimental knee replacement (UKR) is a valuable solution for the treatment of knee osteoarthritis preserving both bone stock and all ligaments with an improved joint position sense. Patients with a UKR in one knee and with a TKR in the other have been reported to perceive their UKR as more normal in comparison with their TKR. The Authors present their experience of performing a mini-invasive bi-unicompartimental knee replacement assisted by a computer navigation system trying to obtain both a correct alignment and a soft tissue balancing in the above mentioned exceptional cases.

Materials and Methods: From January to December 2003, the Authors treated 5 patients (5 knees) with bicompartimental arthritis of the knee. There were 4 female and 1 male, no patients was obese. The mean age was 66 and in all the cases there was a bi-compartmental (medial and lateral) arthritis deformity with both ACL and PCL intact without any pain at the femur-patella joint. In 3 knees there were an history of previous bycondilar tibial plateau fractures. All the patients had previously undergone to multiple surgical procedures (average: 3.5). Orhophilot (4.0 version) navigation system (Aesculap, Tuttlingen, Germany) was used during the surgery to assist prosthesis alignment and placement. In all cases a minimal surgical approach was used (7 to 9 cm skin cut). The patients were assessed using a UKR dedicated outcome score, Italian Uni Users Group (G.I.U.M.) score, pre-operatively and at the latest follow-up. The GIUM score is based on a sum of positive or negative values (Table 3a, 3b). A score of 76 to 100 indicate a normal result, 51 to 75 an almost normal result, 26 to 50 an abnormal result, and 0 to 25 a poor result. Pre-operatively the mean GIUM score was 49.1 (range 26-63).
Results: During the surgical procedure we did not experienced any problem due to the computer assisted alignment system. The mean surgical time was 103,2 minutes. During the follow-up we did not registered any vascular or septic problem. At the latest follow-up the mean GIUM score was 80.2 (range :75-94). The average femoral-tibial angle was 179° (range 177°-181°). All the patients had a good ligament balancing using the computer assisted spreader device. Up to now we did not registered any loosening or infection. Despite the short follow-up and the small series, all the patients were satisfied and had soon returned to their previous occupation. Furthermore each patient would have had the same surgical procedure again.

Conclusions: In literature there are no reports in using bi-unicompartimental knee replacement and many orthopaedic surgeons are sceptical about this high demanding surgical procedure. However recently in literature it has been assumed that the implantation of two sledge prostheses on the medial and lateral condyles could not change proprioceptive abilities 2. According to their previous experience using bi-unicompartimental prosthesis, the Authors underline how the computer navigation system is a great support for these implants, above all for ligament balancing, the real problem in this surgical tecnique. They did not registered any detachement of the bone block tibial spines, a quite common complication with the traditional alignment techniques because of wrong balancing and cuts. The Authors emphasize this real mini-invasive surgical approach to the treatment of the knee arthritis, above all in young patients with post traumatic deformities.

References:

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Introduction: Correct component alignment and soft tissue balancing have been cited as two of the most important components of successful knee arthroplasty surgery. Alignment of the components is dependent on many factors including accurate pre-operative planning, normal bone morphology to which standardised instruments are applied and accurate placement of these instruments with the surgeon's skill. Incorrect alignment caused by a variation of any of these factors can lead to abnormal wear, premature mechanical loosening of the components, and patellofemoral problems.

Computer navigation systems which are widely used in Europe and Australia, are now gaining popularity in the U.K. and North America. Their aim is to provide more accurate component implantation through digital mapping of standard anatomical landmarks and kinematic analysis. A number of studies have suggested that there is improved component alignment when this technology is used.

Navigation systems have continued the evolution of total knee arthroplasty, which includes many milestones. In the continuing quest to produce better results, surgeons are now being faced with a new challenge of minimally invasive approaches. This has been spurred on by the success of minimally invasive unicompartmental knee replacement. However, the technical problems of resecting the distal femur, proximal tibia as well as producing chamfer cuts remains a challenge. Two groups of MIS TKR have emerged—conventional and computer assisted MIS TKR. The latter clearly has the advantage of allowing accurate placement of bone cuts as well as verification of the resected level. Many systems will also enable soft tissue management of these difficult procedures. The use of these systems also allows for newer approaches to be used during surgery.

This paper describes the development of a MIS TKR procedure that is universal to both sides (medial and lateral) of the knee and can be used as a mid vastus or quadriceps sparing technique. It is also computer assisted and does not use any IM instrumentation.

The aim of this study was to assess the safety and effectiveness of Computer Assisted TKR through minimally invasive incisions.
**Materials and Methods:** Between July 2002 and September 2003 extensive cadaveric research was undertaken to look at the problems faced in performing minimally invasive total knee arthroplasty with computer assistance. From this a unique system of computer navigated side cutting blocks where developed that allow the surgeon to perform in situ cuts without dislocating the knee.

The Stryker knee navigation version 2.0 was used together with specialist minimally invasive side cutting blocks. Both were tested extensively in cadavers to assess the safety and reproducibility of bone cuts. The technology was then combined with both a ‘mini’ mid vastus approach and a quadriceps sparing approach to assess the feasibility of implantation of the conventional Scorpio condylar knee arthroplasty. Following successful completion of a short cadaveric study a proof of concept study was undertaken on 26 patients to assess the clinical effects on these patients.

All patients had their surgery performed by a single surgeon (SKC) at the department of elective orthopaedics at Brighton and Sussex University hospitals. Twenty patients had a computer assisted mini mid vastus approach and six patients had a lateral quadriceps sparing approach.

The mini mid vastus approach involves a 2 cm split in the VMO fibres at the 11 or 2 O’Clock position followed distally by a parapatellar tendon split. The medial gutter is freed and a curved resection block is placed against the medial side of the femur under computer guidance and the distal femur is cut from medial to lateral direction. The patellar is left in situ. Next the same femoral resection guide is used to cut the proximal tibia. Once again the patella is left in situ and the knee is not dislocated. Thus a universal cutting block is used on both bones.

Following verification of the cut surfaces, the patellar is retracted laterally and the chamfer cuts of the femur are performed, followed by the keel cuts of the tibia. The surfaces of the bone are then prepared and the components are cemented with Simplex cement. The tibia is cemented first followed by the femur and the polyethylene insert placed last. Ligament balancing is performed at the trial component insertion stage.

The order of cuts and the instrumentation is the same with the lateral quads sparing approach.

For all patients the length of surgery from skin to skin was recorded. The time it took the patient to achieve 90 degrees of flexion and straight leg raising was also recorded as was the time it took from the end of surgery to the patient first walking. All patients had retransfusion drains and the blood loss was recorded. Lastly patient length of stay and complications were recorded together with component position on long leg films.

The results show the range of surgical time from 100-180 minutes, the time to achieve 90 degrees flexion and straight leg raising from 1-9 hours post surgery. The patients took from 3-12 hours to walk with a frame following release of the tourniquet. The length of stay of these patients ranged from 2-5 days. Blood loss ranged from 200-1180 mls. Radiographic analysis showed femoral component varus/valgus ranged from 89-94 degrees, whilst tibial varus/valgus ranged from 87-91 degrees.
There were 2 superficial wound infections, which resolved with antibiotics.

Discussion: Any minimally invasive procedure should be either soft tissue sparing, bone sparing or both. The procedure described uses the standard Scorpio implant and is therefore only soft tissue sparing. However it can be clearly seen from the results that these patients perform spectacularly well after surgery with rapid recovery in terms of mobility, flexion and length of stay in hospital. These results mirror those of Bonutti, Tria and Laskin but the component alignment is certainly more accurate and reproducible. The question remains as to why these patients perform so well. It is our belief that the use of in situ cutting with minimal dislocation of the joint prevents soft tissue trauma to the entire joint capsule and surrounding muscles and greatly accelerates patient rehabilitation. However whilst this proof of concept study clearly demonstrated it as a safe procedure, we still require proper randomised controlled trials to clearly demonstrate its advantage over the convention technique.
NAVIGATION THROUGH ORTHOPILOT IN TOTAL KNEE PROSTHESIS: ADVANTAGES AND SIGNIFICANCE

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Introduction: Computerized navigation in knee prosthesis surgery is a real assistance whether for the general economy of the surgery and for the solution of particular technical problems. Navigation system allows to perform correct tibial and femoral bone cuts and to restore the mechanical. Applying navigation system with a minimally invasive surgical technique (MIS) knee prosthesis can be very useful to reduce the surgical injury.

Infact it’s very important to avoid opening femoral and tibial intramedullary canal besides to perform a small skin incision, a midvastus approach and without patellar eversion.

The aim of this study was to determinate the accuracy of navigation system (Orthopilot 3.1 and 4.0) in TKR. We also report our experience in the association of the navigation system with a mini-invasive surgical technique (Columbus total knee replacement - Aesculap) and mini tools.

Material and Method: From September 2001 to September 2003 in our Department 48 total knee replacement with Orthopilot navigation system (3.1 and 4.0) were performed in 48 patients. The mean age of patients was 69 years (62 to 80). The indication for surgery included varus gonarthrosys for 44 cases and valgus gonarthrosis for 4 cases. Search Evolution TKR with traditional surgical approach and assistance of Orthopilot was performed for the first 25 cases. The remaining 23 patients underwent Columbus Total Knee System with a MIS technique using Orthopilot 4.0. In these cases skin incision was about 10 cm, the patella was shifted laterally without eversion, reference frame has been placed with a closed technique distant about 4 cm from the skin incision. Reduced size of cutting blocks and “free hand technique” were the changes of Columbus instrumentations.

All patients were evaluated at the mean follow-up of 14 months, from 26 months to 6 months. For each case was evaluated: the time of surgery, the post-operative blood loss, if the surgeon had to converted in manually approach, the complications during and after the operation. The clinical and radiographic parameters studied were: mechanical axis, range of motion and varum-valgus stability. The length of skin incision at the beginning and at the end of surgical procedures were recorded for all cases operated with MIS.
**Results:** The results of this study were evaluated in two groups (group 1 and 2) of all cases. Group 1 included patients operated with traditional surgical approach; instead inside the second group were involved mini-invasive surgical technique.

The surgical time for group 1 was included in the range of 55 to 120 minutes; post-operative blood loss averaged out at 550 cc; no cases of operation manually concluded.

The mean mechanical axis was 180°, with a standard deviation of 3 °. Complete extension was obtained in all cases, flexion up to 120° in 15 cases and up to 110° in 10 cases. Varum-valgus stability is satisfactory in all cases. In group 2, the following surgical parameters were reported. The time of surgery was between 65 and 140 minutes, the average post-operative blood loss was 500 cc, no case of operations manually concluded was reported. The average length of incision was 11 cm; in 4 cases the length of incision was 10 cm at the beginning and 14 cm at the end of surgical procedure. No complications related to modified instrumentation were reported. The average of mechanical axis was 180°, with a standard deviation of 4°. Complete extension was obtained in all cases, flexion up to 120° in 17 cases and up to 110° in 6 cases. Varum-valgus stability is satisfactory in all cases. No intraoperative or postoperative complications were reported in both groups and no immediate or late infections occurred. No case of TVP. No revision was performed at the moment in both groups.

**Conclusions:** Two types of navigation system are now available in total knee replacement: image-free or cinematic and image based navigation system. In cinematic navigation system, dates acquired in operating room and referred to standard models are used. In image-based system, fluoroscopy images acquired in operating room are used; the CT scan-based system is now used very little. Orthopilot system is a image free system; the main advantage of this system is that the use is very easy because doesn’t need any pre-operative exams, in the operative room fluoroscopy isn’t necessary and the time of acquiring dates for navigation is little. Orthopilot system offers numerous advantages to perform a total knee prosthesis. According to other report (Stulberg 2002) [1], the Orthopilot navigation system is safe without complications related to the use of this device. But this system has more advantages. Pre-operative preparation is the same of traditional implants, without CT scan or intra-operative X-rays and without additional surgical procedure. The peri and post-operative blood loss is less than traditional total knee replacement, due to the procedures that avoid opening of femoral and tibial intramedullary canal, generally necessary to obtain a correct orientation of components; this makes it possible to eliminate use of the pneumoischamaic sleeve and decreases the risk of embolia. Operation time is substantially super imposable to the traditional Method: the positioning of pins, the acquisition of hip rotation centre, the cinematic points on the knee and ankle do not extend the operation time. Orthopilot [2,3] in particular allows to minimize mistakes due to intramedullary lining up in large diaphysis canals, evaluate the space accuracy of osteotomic cut and the contextual thickness of bone to be removed, to obtain a soft tissue balance. The association of navigation system with mini-invasive surgical technique is particularly advantageous; in fact as shown by our results the clinical and radiographic results are excellent and the procedure is very safe. In this way it’s possible to perform good bone cuts to restore optimal mechan-
ical axis and to perform the soft tissue balancing, checking this procedure step by step, without the necessity of a large skin incision. No penetration in the medullary canal with alignment devices reduces the intra and post operative blood loss; this reduction is more with use of mini-invasive surgical technique, as showed from our results. Also the clinical results are slightly better in group 2, particularly the postoperative degrees of flexion probably because of damage of quadriceps is lower with a MIS than traditional surgical approach. The use of navigation system associated with MIS reduce the risk of malpositioning or intraoperative complications reported with MIS alone. The learning curve is not so long; in fact the average time of surgery is not very different from traditional Orthopilot system.

References:

PERCUTANEOUS 2-PIN FIXATION FRAMES FOR COMPUTER-ASSISTED TKR: SAFETY AND STABILITY

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**Introduction:** Surgical navigation of total knee arthroplasty has the potential to improve both short and long-term outcomes and decrease morbidity following primary total knee arthroplasty. Common problems that can be improved or eliminated by surgical navigation include: Improper alignment of the femur or tibia, improper sizing of the femur leading to notching or overstuffing of the patello-femoral joint, malrotation of the components which can lead to excessive wear and patellar maltracking, elevation of the joint line, leading to patella baja and/or PCL imbalance, improper ligament balancing in flexion and extension, and bone marrow and fat embolism syndrome. However, computer-assisted navigation of TKR requires the use of reference frames affixed to the femur and tibia. The use of these frames has potential risks. Variation in practice exists between frames affixed percutaneously or through the primary incision and frames fixed with a single or two pins.

The current study documents experience of performing computer assisted total knee arthroplasties performed using 2-pin, percutaneously fixed reference frames.

**Methods:** 126 computer assisted total knee arthroplasties were performed by the same surgeon using the same implants (Smith-Nephew Genesis II). 70 procedures were performed using image-based virtual fluoroscopy (Medtronics Ion System) and 56 procedures were performed using image-free methods (BrainLAB CT-free knee). The procedure was performed by affixing reference frames percutaneously to the femur and tibia using 2-pin fixators. Hip and ankle data were acquired prior to elevating the tourniquet. Alignment and ligament balance were assessed and all bone cuts were tracked using navigation. Post-operatively, limb alignment was assessed on full limb standing films.

**Results:** One of the 504 percutaneous pin sites became infected, requiring antibiotic treatment. The tip of one 3mm fixation pin broke on insertion and was left in situ. No 4mm or 5mm pins have broken. One femoral frame shifted and required reregistration. One tibial frame shifted after all of the components had been implanted. Both shifted at the fixator-frame junction. No pins loosened. There were no vascular or nerve injuries. Alignment on long-leg radiographs were measured in the 102 limbs and showed femoral component alignment mean of 0.4 degrees of varus (SD 1.0), tibial component alignment of 0.8 degrees of valgus (SD 1.2) and overall alignment of 0.4 degrees of valgus (SD 1.0).
Conclusions: Percutaneously placed 2-pin fixators are stable and safe to use and result in facilitate accurate limb alignment following computer-assisted TKR.
PROSPECTIVE RANDOMISED CT-SCAN STUDY: TRADITIONAL VS COMPUTER ASSISTED TOTAL KNEE ARTHROPLASTY

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Introduction and Purpose: After first report on computer assisted total knee arthroplasty (TKA) [2], navigation guided surgery in TKA is expected to improve the accuracy of lower limb alignment and joint stability compared to that achieved with standard procedure [5]. We performed a prospective randomised study to compare the accuracy of bone cuts in TKA performed with or without the computer assistance. CT-scan was exploited to evaluate the outcome measuring automatically angles of interest.

Materials and Methods: Forty patients affected by varus knee (primary arthritis) were treated, under general or epidural anesthesia, by the same surgeon receiving the same cemented posterior stabilized total knee implant trough a standard approach. Patella wasn’t resurfaced in any case. Pneumatic tourniquet was cuffed on just before skin incision and deflated after components cementing. The arthrotomy was performed through a midline skin incision and a medial parapatellar capsular incision. Overweighted or obese patients (i.e. with a body mass index > 28) were excluded. Patients were randomly assigned to two matched groups: the study group consists of 20 patients that were operated with computer assisted instrumentation guided by a kinematic CT-free navigation system controlled by an interactive dedicated software, while the control group consists of 20 patients that underwent standard procedure with traditional ancillary instrumentation (intramedullary femoral guide and extramedullary tibial guide). The mean age was 72.1 ± 7.5 years for the study group, and 68.2 ± 5.9 for the control group. Male/female ratio was 5/20 and 3/20 respectively. Preoperative varus angle was 11.2° ± 1.7 in study group and 10.4° ± 2.4 in control group. Expected postoperative ideal values of angles were: 6° of valgus (anatomical axis) for the femoral cut in AP view (assuming as acceptable a value between 4° and 8°), 90° for the femoral cut in lateral view (assuming as acceptable a value between 87° and 93°, in absence of anterior notching), 90° for the tibial cut in AP view (assuming as acceptable a value between 88° and 92°) and 3° of posterior slope for the tibial cut in lateral view (assuming as acceptable a value between 1° and 5°). All angular values were intraoperatively verified in real time with the dynamic feed-back of the computer in study group, while were predetermined setting the guides on fixed values in control group. Femoral component rotation was predetermined in both groups setting the cutting guide at 3° of external rotation (this parameter will not be analysed). Preoperative and postoperative evaluation was done.
blindly by an independent observer on CT-scans with a calculation software to achieve maximum of accuracy in measuring angles of interest. Statistical analysis was performed using Student’s t-test for interval data and the chi-square test with Fisher’s exact test for categorical data; p values < 0.05 were considered significant.

Results: No cases of deep venous thrombosis, nor infections, nor other major complications occurred in both groups. Length of hospital stay and postoperative recovery of function were similar in the two groups. Dimensioning of components was correct in all cases and in none case occurred a notching of the femoral anterior cortex.

The mean procedure duration (time between incision and closure) was 130 minutes in study group (maximum 164 minutes, minimum 88 minutes, difference between maximum and minimum 76 minutes) and 97 minutes (maximum 115 minutes, minimum 67 minutes, difference 48 minutes) in control group (p < 0.001). Splitting the study group in the first 10 cases and the second 10 cases, the mean length is respectively 135 minutes and 123 minutes (p < 0.005). Postoperatively in AP view femoral valgus angle (compared to expected value of 6°) was 6.8° ± 0.8 in study group and 7.4° ± 2.0 in control group (n. s.). The valgus value assumed as acceptable (between 4° and 8°) was meet in 20 cases in study group and in 16 cases in control group (p < 0.01). In lateral view the bony femoral cut (compared to expected value of 90°) was 90.7° ± 1.2 in study group and 89° ± 1.8 in control group (n. s.). The value assumed as acceptable on this plane (between 87° and 93°) was meet in 19 cases in study group and in 17 cases in control group (p < 0.05). In AP view the bony tibial cut (compared to expected value of 0°) was 1.3° ± 1.1 varus in study group and 0.9° ± 1.7 varus in control group (n. s.). The value assumed as acceptable on this plane (between 88° and 92°) was meet in 20 cases in study group and in 18 cases in control group (p < 0.05). In lateral view tibial posterior slope (compared to expected value of 3°) was 2.3° ± 1.2 in study group and 1.8° ± 1.8 in control group (n. s.). The posterior slope value assumed as acceptable (between 1° and 5°) was meet in 20 cases in study group and in 20 cases in control group (n. s.). Total blood loss at 24 hours was 1147.7 ± 264.0 millilitres in study group and 1061.3 ± 249.9 millilitres in control group (n. s.).

Discussion: The difference between the longest and the shortest procedure is larger in the study group; that means an initial lack of surgeon confidence managing the new tool. Intraoperative data acquisition at beginning of navigation, in fact, is time consuming as well as step-by-step check of jigs position on the monitor. But we must consider that the learning curve affects the procedure duration: in this series the longest operation (164 minutes) was the first we done and the shortest one (88 minutes) was the third from the last. The statistically significant difference between the first 10 cases and the second 10 cases confirms this trend.

Focusing on standard deviation for each angular value, it is possible to appraise how in study group this interval is narrower compared to control group; that could means a greater reproducibility of the results under the navigation system control. This observation is confirmed by the statistically significant difference emerging for some angular values assumed as acceptable that were meet in an higher number of cases in the study group. Other reports demonstrated similar better results [1, 4].
CT-scan managed by a calculation software is effective to study angular parameters in TKA follow-up due to his accuracy. It represents, for study purposes, a valid alternative to standard Xray which reliability is scarce [3]. Of course it isn’t usable routinely because its high cost.

**Conclusions:** Disadvantages of a navigation system are costs and lengthening of operative time. Our feeling is that improving confidence with the computer interface, operative timing will decrease to an acceptable value. On the other hand spreading of the technique will lower the costs of both hardware and software. The current advantages are the accuracy of limb alignment and joint stability. For these reasons outcomes can be improved performing total knee replacement under a navigation system control.

**References:**

CT-FREE COMPUTER-ASSISTED KNEE ARTHROPLASTY: A PRELIMINARY STUDY

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Introduction: Recent developments in navigation systems have enabled the orthopedic doctors to perform precise surgery based on preoperative planning. This study evaluated the value of the CT-free navigation in total knee arthroplasty using Zimmer NexGen CR total knee system.

Methods: From July 2003 to December 2003, a series of 14 consecutive patients with advanced osteoarthritis of knee were enrolled in this study. All patients received CT-free computer assisted navigation total knee joints arthroplasty using Zimmer NexGen CR total knee system. The same surgeon performed all operations. The navigation system used in this study was Vectorvision system (BrainLAB, Germany). Radiographic assessments included lower extremity split scanogram, knee AP and lateral view. Postoperative radiograph measurements included the mechanical axis and the femoral and tibial angles. Perioperative assessments included surgery time, blood loss and hospital stay.

Results: The overall deviation of mechanical axis was 1.68 ± 0.85 degrees. Twelve patients (84%) had excellent results with deviation of mechanical axis within 2 degrees. In the coronal view, the femur valgus angle was 94.2 ± 2.1 degrees and the tibia perpendicularity angle was 90.5 ± 1.7 degrees. In the lateral view, the posterior slope angle of the tibia was 86.8° ± 2.1°. Perioperative blood loss was 465 ± 247 ml. The mean tourniquet time was 78.6 ± 8.9 mins, the mean hospital stay was 7.2 ± 3.1 days.

Conclusions: CT-free computer assisted navigation surgery in total knee arthroplasty was safe and precise. In addition, the improvement of software can further assist the surgeon in soft tissue balance during total knee arthroplasty. For patients with severe varus or valgus deformity, the use of navigation systems can minimize incorrect alignment. Long term follow up is required to assess the benefits of CT-free computer assisted navigation surgery in the longevity of prosthesis and patient functional outcome.

References:


MECHANICAL AXIS DEVIATION AFTER NAVIGATED IMPLANTATION OF KNEE SURFACE REPLACEMENT PROSTHESES

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Aim: To determine prospectively the mechanical axis of the lower limb after navigated implantation of knee surface replacement prosthesis and to evaluate the learning curve.

Materials and Methods: We conducted this prospective study to determine the mechanical axis of the lower limb. Measurement of the mechanical axis was done by one examiner using a navigated ultrasound device (ZEBRIS). All LCS total knee prosthesis were implanted with the help of the MEDIVISION navigation system. Inclusion criteria in this study were primary total knee arthroplasty due to primary or secondary gonarthrosis and an age limit of 90 years. Exclusion criteria were hip or ankle stiffness. All patients were operated upon by two experienced knee surgeons.

Results: The mean follow-up period for the patients were 2 month (range, 1 to 3 years). The average age for the 26 male and 23 female patients was 67.4 years (range, 40 to 89 years) and the average Body Mass Index (BMI) was 29.3 (range, 17.7 to 42.0). The right knee was replaced in 23 patients and the left knee in 26 patients. In 18 cases the navigation system failed during the operation due to technical reasons and a conventional implantation was performed. The mean mechanical axis of the lower limb in all patients measured $179.4^\circ$ (range, $174^\circ$ to $183^\circ$). Ninety percent were implanted within the normal axis limits of $180^\circ +/- 3^\circ$. There were no statistically significant difference between the navigated and the failed navigated implantations.

Conclusion: By applying navigation principles in total knee arthroplasty, the incidence of postoperative mechanical axis deviation can be reduced. However even in the hand of navigation experienced orthopaedic surgeons, the system used in our study was not running very stable. Due to the small number of patients we can not show if the patients had a real benefit of the navigation system. With our first 49 patients, we could not pass the learning curve.
SCORE PROSTHESIS: EARLY RESULTS. COMPARISON OF A SERIES OF 60 TKA COMPUTER ASSISTED WITH 60 CONVENTIONAL TKA


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Introduction: Total knee replacement using Score prosthesis can be performed using conventional or computer assisted procedure. The aim of this study is to compare our results after computer assisted procedure with those after conventional procedure.

Material and Methods: Among 200 consecutive TKAs performed between May 2002 and December 2003 (5 surgeons in one department), 60 were computer assisted (Praxim, Surgetic, Score system, CT-free module, bone morphing). We compared early clinical and radiographic results of these 60 computer assisted TKA (group A) with 60 conventional TKA performed during same period (group B).

To assess clinical results we used the International Knee Society score in preoperative and postoperative with a minimum follow up of 6 months. To assess radiographic results all patients had, pre and postoperative (3 months), computerised weight bearing standing long radiographs and lateral view. We analysed femoro-tibial mechanical axis (by convention varus deformity was less than 180°, and valgus deformity more than 180°), femoral mechanical axis and tibia mechanical axis in the coronal plane and tibial slope and femoral implant flexum on the lateral view. All measurements were done with the soft Metros. ANOVA and Pearson khi-tow test were used to determine differences in axial alignment between both groups (level of significance p<0.05).

Age (69 years for group A, and 68 years for group B), gender (44 women and 16 men for group A, 36 women and 24 men for group B), size (average BMI 29.5), side (29 right and 31 left for group A, and 25 right and 35 left for group B), preoperative clinical status (IKS 91/200 for group A, IKS 89/200 for group B), diagnosis (all osteoarthritis, 46 varus and 14 valgus for group A, 41 varus and 19 valgus for group B) and amount of deformity (170.2° (157-178) for varus and 187° (181°-198°) for valgus in group A, 170.2° (154-179) for varus and 188° (181°-199°) for valgus in group B) showed no statistical difference.
Results: Mean follow up in the 2 groups was 9 months (6 months to 15 months). Clinical results showed no statistical difference with an IKS score of 174.5 in group A (154-198) and of 173 in group B (151-198). Considering global femoro-tibial mechanical axis, 85% of patients had an angle at 180° within +/- 3° in group A, compared with 65% in group B (p=0.036). 5 patients in group A showed axis deviation greater than 4° (maximum 6°), and 20 patients in the group B (maximum 8°) (p=0.002). For varus deformity (46 in group A, 41 in group B), average mechanical femoro-tibial axis was 179.2° (174.5°-183.7°) in group A and 177.4° (172°-182.5°) in group B (p=0.004), average femoral mechanical axis was 89.7° (85°-96°) in group A and 88.5° (82°-93°) in group B (p=0.02), and mechanical tibial axis was 89.4° (86°-92°) in group A and 88.9° (84°-92°) in group B (p=0.09). For valgus deformity (14 in group A, 19 in group B) there was no evidence of statistical difference. Considering the tibial slope there was no difference between the 2 groups (90.4°). Femoral implant flexum was 1.45° (-3°, +5°) in group A and 2.78° (-2°, 6°) in group B (p=0.009).

Discussion: This study, according to the literature [1, 2, 3] showed better reliability in coronal plane with computer assisted procedure. Global mechanical axis and mechanical femoral axis showed significant difference. There was no difference in mechanical tibial axis since we used during conventional procedure a combined intra and extra-medullary guide. Using a new sagittal reference in computer assisted procedure explains the difference observed in the femoral implant flexum.

Conclusion: Early clinical results showed no difference between the 2 groups. As mechanical limb alignment has been demonstrated to be influential in determining implant survival, better long term results should be expected with computer assisted procedures.

References:

SOFT TISSUE TREATMENT IN TKA WITH A MODERN NAVIGATION SYSTEM AND A FLOATING PLATFORM KNEE-SYSTEM. EXPERIENCE AND PITFALLS IN 250 CASES

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Objectives: Mobile bearing knees seem to be superior to fixed bearing knees concerning range of motion and reducing of pain. But they are non-forgiving systems concerning malposition of the components. With modern navigation systems the number of malpositioned components is clearly reduced.

Background: Literature clearly shoes, that mobile bearing knees are forgiving malrotation of the components up to a defined amount. But most of them are not forgiving imbalance between flexion- and extensiongap, which is clearly optimized by a modern navigation system.

Design/Methods: The emotion-knee-system is a new development by B.Braun Aesculap. It is a single radius design for the femoral condyles and the patella groove and has a floating platform on the tibial side. With this clear geometrical design the instrumentation can easily been supported by the OrthoPilot-TKA-Navigation system.

Results: Experience and pitfalls with the first 250 implantations are reported. Difficulties with the hip algorithm are meanwhile solved. Today there is a clear workflow, step by step navigated, to find the ideal positon of the femoral component concerning rotation, ap-position, size and resection height. As an additional result all 250 patellae were centered.

Conclusions: With the OrthoPilot System 4.08 a stabil platform for the navigation of TKA including femoral rotation and soft tissue balancing is generated. The additional needed amount of time, 15 – 20 minutes seems to be worth wile.
THE ACCURACY IN LOWER EXTREMITY ALIGNMENT OF TOTAL KNEE ARTHROPLASTY USING COMPUTER-ASSISTED NAVIGATION SYSTEM

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Introduction: Along with the development of hardware, the recent development of computer and navigation system has led to the introduction of robotic surgery and computer-assisted surgery. Several authors reported that navigation was a technique in total knee arthroplasty (TKA) to assist surgeon to reproduce the exact anteroposterior and lateral alignment [1,2,3]. Therefore, we assessed the accuracy of lower extremity alignment in TKA which was performed using computer-assisted navigation system.

Materials and Methods: We reviewed 50 TKAs (group A) using manual alignment system and 50 TKAs using navigation system. In postoperative 2 months radiographs, we measured the femur-tibia angle, mechanical axis deviation, inclination of femoral and tibial component. We determined the value within optimum±2°as ‘excellent’, within optimum±3°as ‘acceptable’ and over optimum±3°as ‘outlier’. We used Orthopilot® 4.0 (Aesculap, Tuttingen, Germany) as computer-assisted navigation system. Statistical analysis was carried out using Independent Student t-test and Pearson chi-square test. Statistical analysis was performed using SPSS for Windows Release 11.0 (SPSS, Chicago, Illinois). All analyses were set at the 95% confidence interval for significance.

Results: In anteroposterior radiographs, the frontal inclination of femoral component to anatomical femoral axis showed outlier in 12 knees (24%, group A) and 2 knee (4%, group B). Another frontal inclination of femoral component to mechanical axis showed 15 (30%) and 2(4%) outliers in each group. In anteroposterior radiographs, the frontal inclination of tibial component showed no outlier in both groups (p=0.068). Postoperative femur-tibia angle was 4.4±4.0° valgus in group A and 7.1±1.5° valgus in group B. There were 19(38%) and 5(10%) outliers in each group (p=0.005). Mechanical axis deviation was 1.4±4.7° varus in group A and 0.3±1.8° valgus in group B. There were 28(56%) and 3(6%) outliers in each group (p=0.031). Forty-six(92%) mechanical axis of navigation group existed within central 1/3 of joint line and thirty(60%) mechanical axis of manual group did within central 1/3 of joint line(p=0.001). In lateral radiographs, there was no difference in the sagittal inclination of femoral component between two groups (p=0.161). But the sagittal inclination of tibial component showed 34(68%) and 0 outlier in each(p=0.001).
Conclusions: Navigation system helps producing more ‘excellent’ and ‘acceptable’ results and less ‘outlier’ than manual alignment system does. The alignment of lower extremity after TKA can be more accurate by using navigation system than by using conventional mechanical alignment system.

References:

ACCURACY OF COMPUTER TOMOGRAPHY-BASED NAVIGATION SYSTEM FOR TOTAL KNEE ARTHROPLASTY

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Introduction: Optimal postoperative axial alignment of the lower extremity is fundamental to achieving long-term survival of total knee arthroplasty (TKA). In several large series of total knee implantation, ideal positioning of the components was achieved in at best 70–80% of patients using intramedullary or extramedullary alignment rods.

As a solution to the problems and inherent limitations using conventional TKA systems, several computer navigation systems have been developed such as the image-free system, image-based system, and fluoroscopic system. Excellent radiographic results of TKA have been reported using these systems. [1,2,3] The accuracy of computer-assisted TKA, however, has not been fully evaluated, as most of the studies evaluated the quality of implantation using postoperative anteroposterior and lateral whole-leg radiographs. Radiographic measurement is well known to have limited accuracy.

This study aimed to evaluate the accuracy of the computed tomography-based image-guided knee replacement system with regard to femoral and tibial bone preparation using cadaveric specimens. The accuracy of bone preparation was evaluated by direct measurement using an extramedullary alignment rod without radiographs.

Materials and Methods: The accuracy of the image-guided knee replacement system was evaluated with nine lower extremities, which were retrieved from five embalmed cadavers. Vector Vision® knee 1.1.1 (Brain LAB Inc., Heimstetten, Germany) is an image-guided knee replacement system, which is based on patients’ data obtained from computed tomography images. This system not only enables meticulous preoperative planning, but also allows optimal placement of the components using three-dimensional navigation.

Computed tomography data acquisition

First, computed tomography data were obtained. A 50-mm section of the femoral head, a 200-mm section whose midpoint was the knee joint, and a 50-mm section of the distal tibia were scanned with a 2-mm slice thickness. The data were transferred to the navigation system and reconstructed into a three-dimensional model.
Preoperative planning

The mechanical axis of the femur was defined as a line drawn from the center of the femoral head to the knee center, while that of the tibia was defined as a line drawn from the center of the tibial spines to the center of the bearing surface of the distal tibia. Varus/valgus alignment of the femoral and tibial components was planned so that the mechanical axis passes through the center of each component perpendicularly. Rotational alignment of the femoral component was planned to be parallel to the surgical epicondylar axis, while that of the tibial component was planned to face toward the medial third of the tubercle. The system demonstrates the optimal component position and size with virtual simulation using the Press-Fit Condylar Sigma knee system (Johnson & Johnson Professional, Inc., Rayham, MA).

Registration

A surface-matching algorithm using a passive marker wireless system enables the navigation system to show where the patient is positioned in the operating room and to correlate this position with the three-dimensional model. Patient registration was performed in the following manner. After the pelvis was firmly fixed to a vise and a reference array was attached to the distal femur, the lower extremity was gently pivoted about the hip joint in order to find the center of the femoral head. This procedure adds accuracy regarding the estimation of the center of the femoral head to the subsequent surface-matching procedure. Then, surface registration was performed until an estimated error of registration of less than 2 mm was attained. This error was not a particular point error, but a mean error between the data-points and the model-points computed by the system’s surface-matching algorithm.

Navigation

According to the system’s plane navigation, the distal femoral and proximal tibial cutting guides were fixed with pins and bone cuts were made with a standard saw blade. After that, rotational, anteroposterior, and mediolateral positioning of each component were again navigated and the special instruments with reference bars, which were parallel to the mediolateral axes of the components, were implanted. An extramedullary alignment rod can be securely equipped to these special instruments perpendicularly.

Measurement

Measurement was performed on the photograph, which was assumed to be perpendicular to the extramedullary alignment rod (Fig. 1). Whether or not a photograph was actually perpendicular to the extramedullary rod was confirmed by a circular presentation of the extramedullary rod on the picture. On these pictures, a line, which bisected and was perpendicular to the reference bar, was drawn, and this line represented the mechanical axis of each component. The closest distances from the center of the femoral head and center of the bearing surface of the distal tibia to these lines were measured as gap distances based on the scale. The femoral and tibial lengths were also measured. Then angular errors, which represent the angular gaps from the
real mechanical axis in the varus/valgus direction, were calculated from these
distances by the following trigonometric formula:

\[
\tan (\text{angular error (°)} \times \frac{2\pi}{360}) = \text{gap distance (mm)} / \text{femoral or tibial length (mm)}.
\]

**Results:** The mean gap distance and angular error of the femur were 2.0±1.7 mm
and 0.3±0.3° (mean ± standard deviation), respectively. The mean gap distance and
angular error of the tibia were 5.6±4.3 mm and 1.1±0.8°, respectively.

**Discussion:** This is the first study to directly evaluate the accuracy of a CT-based
image-guided system using cadavers. Our results show that CT-based image-guided
knee implantation provides almost perfect component alignment with less than 1°
error for the femur, and excellent alignment with less than 3°error for the tibia. The
accuracy of this system in the coronal alignment would be more than adequate for
clinical use.

Patient registration is the most important procedure for successful computer-aided
TKA. In this study, better results were obtained for the femur than the tibia. One of
the reasons is that the estimated surface registration error of the femur was signifi-
cantly less than that of the tibia. This difference in errors might have resulted from
the fact that the area, which can be used for surface registration, is smaller in the tibia
than in the femur. Another reason for better results in the femur was that the center
of the femoral head was accurately estimated again by pivoting the hip joint.

Whether or not computed tomography is necessary for computer-aided TKA is
another matter of controversy. Several clinical studies on computer-aided TKA using
kinematics-based systems, which have incorporated postoperative radiographic
examinations, have shown improved accuracy of knee implantation. The image-free
system is able to find the mechanical axis of the lower extremity by intraoperative
analysis of lower extremity kinematics or digitization of bony landmarks. The advan-
tage of the image-free system over the CT-based system is that the image-free system
does not require preoperative imaging or planning. Its accuracy to define the center
of the ankle, however, is inferior to that of the CT-based system. Also, the image-free
system is not appropriate when the pivoting method is used alone to detect the center
of the femoral head in patients with an impaired range of hip joint motion. One of
the greatest advantages of the CT-based system is that three-dimensional preoperative
planning, including component sizing, is possible in conjunction with three-dimen-
sional component alignment and simultaneous bone coverage. The information
obtained from three-dimensional images is of great benefit to both the surgeon and
the patient, because CT images enable meticulous preoperative planning, and thus,
this system should provide consistent accuracy and adaptability to anatomical vari-
ance.

**Conclusions:** Preliminary experiments on cadavers show that CT-based image-
guided knee replacement can improve the accuracy of total knee implantation.
Marked deviations from ideal alignment can be almost entirely avoided by using this
system. Consequently, the long-term outcome for patients is expected to be greatly
improved.
References:


Figure 1

Pictures taken cranially from the femoral head (left) and caudally from the distal tibia (right), which are perpendicular to the extramedullary alignment rod. Measurements were performed on these pictures based on the scale shown.
THE IMPACT OF COMPUTER-ASSISTED PLANNING ON KNEE ARTHROPLASTY

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Introduction: In working with the Acrobot system, we have used a series of spatial constraints to determine which regions the surgeon may move the cutting tool within, and which the robot will prevent him/her from entering [3,4]. These regions have been generated from the patient’s bone surfaces and mechanical axis of the leg, and from the prosthesis geometry using proprietary pre-operative planning software. This planner uses CT images of the leg to arrive at 3D bone models, alignment axes and prosthesis positions. A double-blind study to show the accuracy of the Acrobot system has required that, in addition to using the planning software to prepare constraint regions for the robotic cases, the pre-operative planning is done for conventional surgical cases. This provides identical types of pre-operative information for an independent observer to assess the outcomes relative to a planned procedure.

From discussions with surgeons using the planner in the conventional arm of the trial, a number of factors have become apparent. Firstly, surgeons claim that the planning software allows them to modify how they perform surgery using the manual jigs: rather than relying on the preset angles of the jigs, they may attempt cuts corresponding to the patient’s overall leg geometry instead of the local geometry around the knee. Secondly, surgeons are claiming that, as a result of planning, they are improving how they use their jigs and are becoming more accurate. Thirdly, having a surgeon plan in advance a procedure where they have previously relied solely on a series of jigs has led to a greater discussion of exactly what is important in the positioning of unicompartmental components on the knee. This has highlighted a range of philosophies in positioning, sizing of components and sizing of bearing surfaces.

At the current stage of the Acrobot clinical trial, feedback from the surgeons regarding improvements to their manual performance is largely anecdotal as the trial has only just begun. Surgeons’ progress will be evaluated retrospectively at the end of the trial and improvements in their performance presented. In addition, studies are planned to compare the post-operative results of surgeons with and without access to pre-operative CT based planning for manual surgery.

In a parallel activity, the planning system is being used to assess surgery where the outcomes were poor and plan new knee arthroplasty and revision surgery. The system
has the ability to plan surgery for all knee implants, providing surface models of the components can be supplied by their manufacturers.

The planning protocol: The patient’s leg is scanned using CT. A slice spacing of 4mm is used around the femoral head and ankle, and 1mm around the knee itself. By scanning at the hip and ankle, the overall geometry of the leg is obtained whereas simply scanning around the knee would require assumptions to be made regarding the local anatomical axis against the mechanical axis (for example, while $7^\circ$ is often quoted [1], measurements from our Acrobot clinical trial have indicated that, depending on the patient, this may vary from 6 to approximately 9 degrees). The 1mm slices around the knee itself give an appropriate resolution for three-dimensional reconstructions including osteophytes, and, as far as the robotic arm of the trial is concerned, a good model for surface based registration [2]. The radiation dose has been estimated at 1.2 mSv per scan.

The CT data, normally consisting of approximately 370 slices in total is then transferred to the planning workstation. Currently a 1.2GHz Pentium III based lap-top is used, allowing the planning system to be taken wherever is most convenient for the surgeon to update and validate the plans.

The dataset is segmented into individual bones. From this, three dimensional renderings or two dimensional slices can be shown to the surgeon allowing him/her to assess the quality of the patella-femoral and femoral tibial joints to determine the practicality of implementing a unicompartmental approach or total knee replacement. The segmentation process is largely automated, although a small amount of intervention is sometimes necessary around the knee itself, particularly if the surgeon requires a complete rendering of patella and osteophytes in addition to the main geometry of the femur and tibia. Typical interactive segmentation time is of the order of 10 minutes.

Longitudinal radiographs are presented, allowing the surgeon to identify features at the hip, ankle and knee, determining bone mechanical axes against which the prosthesis components can be aligned – local anatomical axes at the knee can also be marked on and the relative angles between mechanical and anatomical axes determined. The prosthesis position and angle is initially set on these radiographs, and the size determined. In the current planning protocol, the femoral component is placed approximately centrally on the condyle and the posterior curve aligned with the posterior curve of the condyle on the assumption that this will show less wear than the distal part.

This process is comparable to the use of templates on film radiograph images, however, as the images used within the planner are derived from the CT data, no scaling errors exist, and the surgeon can be reasonably confident about the sizes of the prosthesis chosen at this stage.

The surgeon has access to the CT slices and views detailed prosthesis models overlaid to check and, if necessary, finely adjust the component’s size and position on the bone. This allows tibial overhang to be minimised and fine adjustments to be made to flexion/extension positioning on the femur.
Currently the segmentation is performed by Acrobot staff or a radiographer. Also, preliminary sizing and positioning of components can be generated which are then modified by the surgeon. This process reduces the surgeon's overall planning time to a few minutes for standard cases. For more complex cases, the planner still gives the surgeon the flexibility to resize components, and adjust their positions until satisfied with the plan.

In the case of post-operative assessment, the segmentation time may be increased as the metal prosthesis will cause artefacts requiring a manual clean-up of the images. It is also possible to perform segmentation at varying threshold levels, allowing the bone to be imaged or an existing prosthesis extracted. The longitudinal radiographs and CT slice images are used to overlay models of the prosthesis onto the existing one in the image, which is translated and rotated until the positions of the model and the real part match. The alignment of the existing part may then be read from the screen in angular form, allowing an existing varus/valgus slope, posterior/anterior slope and internal/external rotation to be determined. Again, the surgeon is provided with hard-copy of relevant images showing the condition and geometry of the existing joint.

Results: At the time of writing it has not yet been proved that, by using the planner, a surgeon’s appreciation of the geometry of knee replacements is changed or improved, either by using plans for each case, or as a result of an increase in knowledge of general knee geometry through use of the planner. It is expected that such results will be available at the time of the conference.

Initial indications from our trials with the Acrobot robotic system are showing that aligning the curve of the femoral prosthesis component with the intact posterior surface of the condyle provides a balanced flexion-extension gap. As the trial continues, more data will be available to assess this and will be available at the conference.

Conclusions: By using the planning system with a number of surgeons, it has become apparent that each surgeon has his/her own views regarding how prosthetic knee components should be positioned on the femur and tibia. The planning system is versatile enough to cater for each different approach.

The fact that the planner/Acrobot combination can produce an equal flexion-extension gap leads us to believe that the planning system can plan a balanced knee, and that a manually cut bone using gauges, will reflect, reasonably accurately, the positions of components on the plan.

Assessment of patients complaining of problems, and possible planning of revision has been useful, in one case allowing a unicompartmental component to be used in a revision, although at this early stage comments on its usefulness are subjective. It is expected that as the planner is used more routinely, further cases will provide more evidence as to its efficacy.

References:

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Introduction: The precise reconstruction of the mechanical axis in navigated hip- and knee-joint replacement depends on the safe and precise determination of the center of the hip-joint. Under OR conditions the limited range of motion, joint deformation and movement of the patient’s pelvis relative to the tracking system are influencing the measurement. This influences the outcome in precision and the usability of the navigation system in particular for patients with outcome deteriorating factors (obesity, strongly deformed joints, ankylosis).

In a first generation of kinematic analysis a second marker at the pelvis was used to compensate for pelvis movement appearing due to the manipulation of the patient’s leg. As algorithm the sphere-fitting method was used. As alternative to the movement compensating pelvis marker the gentle, displacement-reduced kinematic analysis was proposed [4]. To improve the accuracy in case of limited range of motion an alternative algorithm based on the minimal amplitude point method is proposed, still not compensating for pelvis movement. Compared to the sphere-fitting method this algorithm needs approx. one third of the range of motion to achieve the same accuracy [5]. External compensation of pelvis movement or the reduction by gentle manipulation are still necessary.

In a 2nd generation of kinematic analysis for spherical joints the pelvis movement is corrected arithmetically. The algorithm uses the principle of rotation coordinate systems [3, 5] and is tolerant towards pelvic movement. Pelvic movement is unavoidable in particular under critical patient-conditions (reduced ROM or obesity). In the 2nd generation algorithm it could be compensated without using a reference base fixed through an additional incision at the patient’s pelvis. Using the parallax compensating x-ray-projection method [6, 2] no reduction of precision due to pelvic movement was detected. However, the algorithm used significant computing time.

Objective: The 3rd generation of algorithm has the aim to further facilitate the determination of the hip joint center by saving time and by enhancing the accuracy and robustness in difficult patient conditions.
**Materials and Methods:** Multiple global centers of rotation relative to the local coordinate system are calculated in parallel again using the principle of rotating coordinate systems. The local coordinate system is represented by the skeleton fixed femoral reference.

A statistical blunder detection method [1] and simultaneous adjustment of the multiple global centers lead to a higher stability of the system.

In a clinical study comparing the 2nd and 3rd generation algorithm the data acquisition and processing time was analyzed.

A second study compared the level of precision achieved with both algorithms. 50 consecutive patients were operated with the 2nd generation algorithm and the accuracy of the leg axis was analyzed using the parallax compensating x-ray projection method [6]. Then the 3rd generation algorithm was applied to the data of these 50 patients.

**Results:** The mean data acquisition and processing time could be reduced from 1:04 min (4.53 min 0:27 min) to a mean of 0:24 min (1.09 min – 0:07 min).

The average error of the femoral mechanical axis increased insignificantly (8.3mm ° 1.2° to 8.8mm ° 1.3°) (Figure 1).

**Discussion:** Shortening the OR times and reduction of costs require efficient and robust procedures also in complex tools such as navigation systems. The increasing use of navigation systems expose them to surgeons of various experience and to ‘easy’ and ‘difficult’ cases. To prevent errors due to uncritical use the navigation systems has to be as fault tolerant as possible.

This 3rd generation hip center determination is an example for the potential of interdisciplinary cooperation, in this case mathematics and medicine, to develop specific fault tolerant methods.

With a view towards minimal invasive total joint procedures and the desire to use navigation systems safely in every day’s practice this algorithm constitutes a further milestone.

**References:**


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Figure 1: Precision of hip joint center $2^{\text{nd}}$ versus $3^{\text{rd}}$ generation algorithm
**TOTAL KNEE PROSTHESIS COMPUTER ASSISTED. WHICH KNEE CENTER TO DETERMINE MECHANICAL AXIS IN SAGITTAL PLAN? CONSEQUENCES OF DIFFERENT OPTIONS**

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**Introduction:** Of the technical factors important in achieving a successful total knee arthroplasty (TKA), mechanical limb alignment has been demonstrated to be most influential in determining implant survival. Computer assisted surgery allows to implant knee prosthesis, and first published results show better reliability in frontal plan compared to conventional procedure.

Whatever is the system chosen for computer assistance, principle is to acquire the 3 centers of inferior limb (hip, knee, ankle). It is easy to define these different points in frontal plan, but what about in sagittal plan? According to hip and ankle there’s a consensus, but about knee (tibia and femur) many options are offered. The aims of this study are:

To compare the anatomic femoral sagittal axis (simulated by intramedullary guide, in a conventional TKA) and the mechanical femoral sagittal axis (determined center to center in TKA computer assisted).

To compare size and position of the femoral implant in a conventional procedure and in a computer assisted TKA.

To analyse the consequences of the knee center variation in the sagittal plan.

**Material:** 18 dry cadaverics femurs (8 men and 6 women, 9 right and 9 left) were obtained and were radiographed with a strict lateral view (computerised radio).

**Methods:**

1–Introduction of an intramedullary guide (8 mm of diameter) and radiographic control on lateral view (computerised radio).
2–Bone morphing of the femur and planification of the femoral implant (Score prosthesis), named « computer assisted position ».

3–Conventional procedure was performed. A Score Femoral implant was placed.

4–The computer acquired this position, named « conventional position »

5–Sagittal position and size of the femoral implant were analysed and compared between computer assisted and conventional procedure.

**Results:**

1–Intramedullary guide (8 mm of diameter) is constrained by antero-posterior femoral curve. The extra-medullary portion is parallel to distal anterior femoral cortical (-0.5° to 0.5°, average 0°).

2–Sagittal femoral mechanical axis is at 4° of recurvatum of sagittal femoral anatomic axis (1° flexum to 6° recurvatum, average 4°).

3–In the TKA computer assisted the Femoral implant was more in recurvatum and was oversized compared to a classical procedure. The more the femur is curved, the more the difference increased.

**Conclusion:** Determination of sagittal knee center is influential on sagittal position (flexum / recurvatum) and on size of the femoral implant : the more the sagittal knee center is anterior, the more the femoral implant is in recurvatum position and the more the implant is oversized (compared to a classical procedure).
UNIVERSAL CUTTING BLOCKS IN NAVIGATED TOTAL KNEE ARTHROPLASTY

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Introduction: The development of navigated total knee arthroplasty has recently split into two different directions. Today’s commercially available navigation systems are either restricted in the implant type usage or are implant independent, so called “open systems”. The argument for the implant dependent systems is their assistance in sizing of especially the femoral component. The open systems argue with more flexibility and their independence of the implant type.

The cutting jigs of the Leibinger-System allow a three dimensional adjustment of the already fixed jig. Our aim was to find out whether the quality of the bone cuts and the time for positioning the cutting jig was sufficient for routine their use.

Material and Methods: In a prospective comparison trial at the orthopedic department of the Martin-Luther-University Halle-Wittenberg we evaluated modern cutting jigs for their routine use.

The Leibinger cutting jigs is first fixed to the bone in a rough position. The final adjustments are then easily made with the navigation system. For this adjustment the jig features three screws for each varus/valgus, flexion/extension and the resection height. The surgical approach used was always direct anterior or midvastus approach. The first cut was the tibial, followed by the distal and anterior femoral. In a series of 40 primary TKA, we looked at the exact timing for the positioning of both the conventional (n=20) and the universal (n=20) cutting jigs. The time from holding the jig to the bone to its final position for cutting was recorded. Secondly we compared the resection lines and angles of the cutting jig with the real bone cut. We navigated with the Leibinger-System Version 2.0 by Stryker.

Results: The average time for the initial fixation, the adjustment and the final fixation of the universal versus the conventional cutting jig for all three primary cuts (tibial plateau, ventral and distal femoral) was 2:56 minutes (2:08 – 3:37) compared to 6:24 minutes (3:11 – 9:07). The tibial cut always had the shortest time of 2:25 minutes (2:08 - 3:13) for the universal and 4:22 minutes (3:11 – 5:49) for the conventional jig. The anterior femoral cut took 2:51 minutes (2:19 – 3:34) and 6:19 minutes (4:06 – 8:09) respectively. The longest time was consistently used for the distal femoral cut with 3:23 minutes (2:57 – 3:37) versus 8:28 minutes (6:20 – 9:07). The total time of all three cuts for the was 9 minutes (8:48) for the universal and about 18 minutes (18:12) for the conventional jig. In previous trials we showed that navigated
operations with the conventional jig took 22 minutes longer than without navigation. This was reduced to 13 minutes with the universal cutting jig.

The average deviation in angle and position of all cutting jig slot to the real bone cut was 0.6° (0-1.5) for the universal and 0.8° (0-1.8) for the conventional jig.

Discussion: With the use of the universal cutting jigs the time for positioning and adjustment could be more than halved. This is achieved by the possibility to adjust the roughly fixed jig into its final position. Initial malpositioning of the jig can now be corrected without removing the jig from the bone. With the help of navigation the first rough positioning of the jig is easy. It is then fixed with two straight pins first followed by a diagonal pin (x-pin) for more stability. Now the jig position can be adjusted in all three dimensions without having to recite any pin. This is not possible with the conventional jig. One main problem with the old jig were little movements on inserting the pins in an angle to the cortical bone as it often is at the medial tibia. The time for positioning the distal femoral cut is prolonged by the difficult insertion of the pins due to soft tissue, angulated bone and cartilage overgrowth. Once the conventional jig is fixed only minimal adjustments were possible. Often pins had to be recited prolonging time considerably. Less time was used to position the ventral femoral cutting jig. This was easier due to the already made distal cut and its plane surface of trabecular bone. A reason for repositioning the anterior cut was to prevent ventral notching. Here we have to criticize the Leibinger System that does not implement the ventral cortex of the distal femur. In general the distal femoral cut was easier if the anterior cut was made first. The universal cutting jigs showed a high stability on the bone and were only minimally displaced through the sawing process. This stability, mainly through the x-pin, was shown in the only small deviation of the real bone cut. Responsible for this deviation is the fit of the sawing blade in the cutting jig, the flexibility of the blade and a large jig-bone distance. The flexibility of the blade leads to a decreased slope for the tibial cut and a increased extension of the distal femoral cut. To avoid this deviation a sharp blade should be used with high oscillations and little force. Also an exact fit of the blade inside the cutting jig slot and a small jig-bone distance improves the cut quality.

Conclusion: The use of navigation in combination with universal and adjustable cutting jig lead to an improved soft tissue oriented implantation technique. The cutting jigs are well integrated into the Leibinger philosophy of the universal navigation system. The jigs can be recommended for the daily routine usage. Agreeing with other authors we experience, that the universal cutting jigs together with the navigation allowed a improvement in the quality of implantation of TKA compared with conventional instrumentation controlled by the surgeons hand and eye [1]. They improve the workflow and reduce the operating time considerably. Of course, the advantage of computer-assisted technique is the measurement of the steps of TKR procedure with a high accuracy [3]. The results are promising, but the value of computer assisted surgery in TKA has not been demonstrated an its usefulness still needs to be evaluated [2].

References:

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Fig. 1:

universal, 3-D-alignment cutting jig (femur)


IN-FIELD ACCURACY ASSESSMENT FOR OPTICAL POSITION SENSORS

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Introduction: Evaluation of accuracy is integral to the evaluation of the safety and efficacy of computer assisted surgery (CAS). Numerous authors²–⁴ have reported on various aspects of system accuracy and methods of evaluating it. Accuracy in image-guided surgery is normally reported as a chain of errors that compound together to end up with an overall system accuracy. The system accuracy includes components due to position sensor error, tool error, scanning, fiducial localization (FLE), fiducial registration (FRE), target registration (TRE), etc. Although generally not the biggest source of error, the position sensor tends to be an expensive and integral equipment component whose accuracy is essential to the overall accuracy of any CAS procedure. There is an interest in developing methods and techniques of evaluating the accuracy of these devices, both to compare them to competing technologies, but more importantly to ensure that they are still in calibration. The latter will help rule out equipment failure as any cause for loss in overall system accuracy. Procedures do exist for ensuring systems are in calibration. Normally these involve returning the camera to the manufacturer, where they are compared to data obtained from a calibrated coordinate measuring machine (CMM) that is traceable back to a NIST standard. The complexity, logistics, and the costs involved in this operation ensure that these types of tests are rarely performed. Other checks are routinely performed are generally not pure tests of the position sensor alone, but rather application specific tests of the tool-camera system. There are also industry standard protocols including the ISO 10360 series of standards, the ASME B89.4.1¹, and the German VDI/VDE 2617.

Methods: We assessed a number of in-field calibration protocols conducted on a number of Polaris position sensors. Protocols included the NDI Accuracy Assessment Kit (“AKK”), a protocol related to the ASME B89.4.1 Pt 3 test (“B89”), and a protocol related to the ISO 10360 E test. The position sensors tested included ones that were out of calibration and had been returned to NDI for recharacterization, and position sensors that had been newly manufactured and were properly calibrated. The in-field accuracy results for each protocol were compared to accuracy assessment results that were obtained from a CMM-based volumetric protocol (the protocol on with the specified accuracy is stated). Although the in-field calibration protocols are too different from the volumetric protocol to be compared directly, their results can be judged by correlating them to the volumetric protocol results. Gauge repeatability and reproducibility studies were also done.

Results: The AAK protocol assessment results were shown to correlate well (R²=0.85) with the accuracy results obtained from the CMM protocol. The correla-
tion results confirmed that the AAK protocol was able to successfully identify Polaris position sensors that were significantly out of calibration. The AAK protocol was also shown to be repeatable and reproducible. Too few results have been obtained for the other two protocols at this point to make any claims concerning their efficacy.

Discussion: The three in-field methods are completely different in approach. The B89 and ISO 10360 methods made fewer assumptions on the method of camera failure and tested both active and passive accuracy in a method that attempted to replicate the volumetric accuracy portion of their respective standards. The B89 used single markers rather than complete rigid bodies and exercised as much of the camera volume as possible in a cube 560 x 560 x 700 mm. The ISO 10360 method used a digitizing probe and therefore includes errors inherent in localizing the probe tip. By contrast the AAK measured the distance variation between passive rigid bodies held rigidly fixed on a bar of known length. A subset of the volume was tested that spanned approximately the same distance as the B89. The AAK method was far faster to perform, taking less than 10 minutes, and the ISO 10360 could be done within a half-hour, once some expertise had been developed. The B89 method took about an hour.

Conclusions: The NDI AAK protocol is not meant to replace users’ existing calibration protocols, but rather to complement them. The assessment results that it provides are meaningful only within the context of the users’ specific application accuracy demands. Users are also cautioned against using any of these tests as proof that the camera is sufficiently accurate for use for any particular application without confirming that they relate well to the actual application. It is only after careful evaluation of the requirements of the application that any such claim should be made, and only in conjunction with specific user determined testing protocols. For example, poor tool design or bad registrations may cause the overall system accuracy to be poor, even though the camera may be properly calibrated.

References:

INFLUENCE OF LOCATOR GEOMETRY AND BLOOD STAINS ON CAOS ACCURACY

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Introduction: In CAOS systems, different types of measurement technologies are used. Most of the navigation systems on the market use optical tracking devices to track locators. The locators are either used as reference locators, rigidly fixed to bone, or as mobile locators, used as manual pointers or attached to instruments. The typical measurement is relative which means the position of a mobile locator is determined relative to a reference locator.

Locators of passive systems are equipped with 3..4 retro-reflective spheres. During a measurement, these spheres reflect back infrared light to the camera. During surgery, bloodstains or water can spoil the retro-reflective spheres and thus interfere with the reflection. This leads to inaccurate measurements.

Different locator designs show different sensitivity to these problems. The number of spheres per locator is also an important factor: With 4 or more spheres, the locator is over-determined and thus less sensitive to stains. The distance between the spheres on the locator is also a very important factor: The larger, the less sensitive to measurement errors and the more precise. The surgeon however likes to have the locators as small as possible.

Objectives: The aim of this work was to analyze the influence of bloodstains on the accuracy of measurements. Since the influence depends heavily on the geometry and size of the locator, different types of locators were analyzed. The chosen geometry and size of the analyzed locators represent some locators found in current optical CAOS systems.

Methods: On a fixed base, a rigid and large reference locator, which is photogrammetrically robust and stable, was mounted. The size of the reference locator was 5 times the size of all measured mobile locators. By using such a large and robust reference locator, measurement errors of the reference locator are insignificant.

For all measurements, the following different types of locators relative to the reference locator (image see table ‘Results’) were used:

3 spheres in the same plane, distance between spheres approx. 5 cm
3 spheres in the same plane, largest distance between spheres approx. 9 cm

4 spheres in the same plane, largest distance between spheres approx. 9 cm

4 spheres, the central sphere is 3 cm above the main plane, largest distance approx. 12 cm

Very large reference locator with 5 spheres in order to reduce measurement errors between the optical tracking device and the reference locator

Measuring procedure:

The camera was positioned in an unfavorable but realistic way.

Each locator (a..d) was fixed on a rigid base together with the reference locator.

The position and orientation relative to each other was measured.

With mathematical and empirical methods the one sphere on the locator with the highest influence on the measurement accuracy was chosen. This most sensitive sphere was “bloodstained” using a single black spot with 2 different sizes. The chosen size was of equivalent status as observed on spheres during OR procedures.

One measurement each was performed with a small and a large blood stain and the difference to the first measurement was calculated in all 3 degrees of freedom.

Furthermore the maximum error was evaluated by shadowing one sphere until the navigation system could not recognize the locator any more.

In order to minimize the measurement error of the optical tracking device, we used a class 1 classified optical tracking device according to [1]. Additionally all measurements will be performed with a class 5 optical tracking device, in order to have a direct comparison of 2 optical tracking devices. We used the Polaris camera of Northern Digital, Inc.

**Results:** The results indicate the measurement error in each direction induced by bloodstains for each locator design as indicated in table 1.

**Conclusion:** In case of a blood stain, water or other optical interference, the navigation system still measures without problems and the surgeon has no indication of the possible point and angle measurement errors. Because of this, the locator design is an important safety factor. Under the given circumstances, it can be recommended to strictly use reference and mobile locators with 4 spheres, in order to have more robust measurements. By using a locator with 3 spheres, significant errors can occur.

**References:**
1. Precision and Validation of Optical Tracking Devices, J. Stifter et. al. Special Poster CAOS 2003, Marbella
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<td></td>
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<td>0.6°</td>
<td>0.3°</td>
<td>0.4°</td>
<td>0.3°</td>
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<tr>
<td>Large blood stain</td>
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<td>2.5°</td>
<td>1.8</td>
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<td></td>
<td>2.3°</td>
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<td>Maximum</td>
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Table 1: Measurement error in each direction induced by bloodstains for each locator design.
MINIMALLY INVASIVE IMAGE-GUIDED TECHNIQUE USING A TABLE MOUNTED DYNAMIC REFERENCE BASE FOR ACETABULAR COMPONENT POSITIONING

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Introduction: Advances in computers and imaging systems have allowed for the evolution of the application of computer-assisted orthopaedic surgery (CAOS). The principle of CAOS incorporates the mapping of body structures and surgical instruments onto a relative, fixed 3 dimensional coordinate system in space.1 The combination of computing power and imaging techniques allow real-time feedback in guiding surgical execution across a variety of invasive procedures. Independent of the surgical procedure, the goals of CAOS are to facilitate the performance of the surgical procedure while increasing the measurement of the precision of the technique thus enhancing potential for a favorable outcome.1

Techniques for the application of C-arm, fluoroscopic-based image guided surgery have been established for many surgical disciplines.2 Validation of fluoroscopic-based image systems is reported to be acceptable within 2 to 3 millimeters.3 Of current debate is the location of the dynamic reference base (DRB). As computer guided surgery is designed to be minimally invasive, elimination of additional invasive procedures to affix a dynamic reference base to the patient would reduce additional surgical risk to the patient.

The purpose of our cadaveric study was to develop a computer assisted orthopaedic surgery (CAOS) technique for positioning and fixation of non-cemented acetabular components for total hip arthroplasty (THA) employing and validating the accuracy of a table mounted dynamic reference base (DRB).

Materials and Methods: One group employed patient mounted DRBs while the second group employed a table mounted DRB. After standard preparation of the acetabular cavity, a virtual fluoroscopy image guidance system was utilized to provide fluoroscopy based image guidance (Fluoronav - Medtronic-Sofamor Danek). Anterior-posterior and lateral (orthogonal) fluoroscopic images were then acquired. The system was then used to navigate acetabular component insertion.
The acetabular component was attached to a trackable insertion device to create a “virtual” component. The virtual component allows for the real-time tracking of the component within the prepared acetabular site in two simultaneous planes (depth and version). Accuracy of the component was followed using the previously acquired fluoroscopic images. Fluoroscopy was also used to verify trial placement and the final implant position in both groups.

Discussion: This cadaveric study demonstrated the ability to accurately navigate acetabular component placement in a minimally invasive. It further demonstrated that a table-mounted dynamic reference base was as accurate and can be less invasive than a patient-mounted dynamic reference base.

Mounting the requisite dynamic reference base on the table rather than the patient eliminates instrument crowding implant collision and line-of-sight problems frequently encountered with optical tracking. Navigation of the virtual nail allowed for the real-time correction of both depth and version of the hip screw without multiple fluoroscopic images. Reductions in radiation dose and surgical time will be realized in this generally technically demanding procedure. Further work is necessary to investigate the usefulness of this application.

Conclusion: A table-mounted dynamic reference base can be use in the computer-assisted placement of acetabular components for THA. Provisional image guided fixation can extend the benefits of minimally invasive computer assisted orthopaedic surgery to the treatment of these challenging procedures.

References:

THE INTERDEPENDENCE OF PLACEMENT OF THE REFERENCE RELATED TO THE ISOCENTRE - A SOURCE OF ERROR IN ISO-C3D NAVIGATION?

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Introduction: In the past it could be demonstrated that computer-assisted methods could significantly improve surgical operations. With the help of navigation image data can be dedicated precisely to the operating field, so that the localisation of critical anatomic topology is relieved. By computer-assisted surgery the correlation between the patient’s images (virtual object), the patient’s anatomy and the surgical tools can be performed (Tracking) [1]. Light emitting diodes (LED) are detected by a CCD - stereo camera system. A calibration of surgical tools with the LED’s is obligatory to explore the position and orientation in space. The registration is a crucial process of navigation in the field of orthopaedic surgery. The conventional method of registration is pair-point registration (PPR). In both modalities, raelity and viruality, three not collinear corresponding points were determined and the transformation between both points calculated. In practice, anatomic or implanted synthetic landmarks (fiducials) are used. The registration with help of invasive markers (fiducials) allows an exact synchronisation of data, but requires an additional surgery [2]. By the use of Iso-C-3D navigation the registration results self-acting at the moment of intraoperatively data acquisition. For this a LED implemented tool plate is fixed to the C-arm and its position can be determined by the navigation system. After the determination of the registration matrix the relatively position of 3D reconstruction volume and the tool plate can be calculated. The reference base must be fixed onto the therapeutical object. If it is placed inside the optical path, artefacts can reduce the image quality. The aim of this study was to evaluate the interdependence of the reference on the isocentre and to determine the maximum distance to the isocentre.

Material and Methods: A T-shaped bloc was manufactured of synthetic bone material (Synbone, Switzerland) with the size of 92 x 50 mm (cube 1, Region of Interest ROI) and 335 mm x 50 mm (cube 2, for the fixation of the reference base). On cube 1, 9 PVC markers (2mm diameter) were placed symmetrically, one exact in the middle for determing the iso-centre. On cube 2 check marks were determined in the distances of 50 mm, 100 mm, 150 mm, 200 mm, 250 mm, 300 mm und 350 mm.
from the centre to place the reference base. Altogether 35 Iso-C-3D scans were taken, for each distance of the reference base to the isocenter five times. The Iso-C-3D Siremobil® was used. For the scanning the model was placed on a carbon fibre table and with the help of a laser placed to the isocentre. With a rotation of 190° 100 single images were generated. This data set was transferred via NaviLink-interface (Siemens) to the navigation system in the mode of Iso-C-3D navigation. As navigation system the Surgigate® (Medivision, Oberdorf, Switzerland and an Optotrak 3020 optoelectronic localizer (Northern Digital Inc) was used. The registration was analysed by “reverse verification” with a pointer in a manipulateable three-dimensional holder. At all 35 measurements were performed. The mean error was calculated from the average of the 9 markers and 5 scans. The data obtained was evaluated by a professional statistician using SPSS (Version 11.5, SPSS Inc., Chicago, IL).

**Results:** The mean error of registration amounts to 0.04 mm (0.04 –0.05 mm) up to a distance of 200 mm and beyond 200 mm 0.25 mm (0.24-0.26). The accuracy was significant lower (p< 0.0001) with a distance more than 200 mm.

**Discussion:** Computer-assisted methods could lead to a significant and qualitative improvement of the results of surgical interventions. The registration is a crucial process of navigation. As source of error anatomical pair-point registration was several mentioned in literature next to incomplete resp. deficient acquisition of data, segmentation and drill bending [1]. With the help of a training curve, a couple of them could be reduced in most instances. The self-acting registration at the moment of data acquisition reduces the incidence of errors within the complete process of navigation. The results advise that the registration significantly degrades the further away the reference base is placed form the isocentre. The error values were between 0.04 and 0.25 mm; this accords to the clinical requests. In the study of D. Ritter et al. an error value of 1.00 mm could be arisen [3]. Reason could be the use of POLARIS (Northern Digital, Inc., Canada) as position measurement system. We used a more precise position measurement system. In this study it could be shown the interdependence of the reference distance on region of interest (ROI). The reference base should not been placed in a distance more than 200 mm from the isocentre within navigation in the field of pelvis and long bone surgery. The placement of the reference base to close to the optical path causes relevant artefacts, which can complicate the locating of lesions. For this reason PVC markers were used instead of high-grade steel or titanium. Whether or not artefacts causes distortions during the registration will be looked at in another study. In this case the development of radiolucent reference bases could produce relief.

**References:**

A VIRTUAL UNIVERSITY FOR ORTHOPAEDIC RESEARCH

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Introduction: Recent advances in conventional and computer assisted orthopaedic surgery (CAOS) have resulted in improved clinical outcomes. CAOS uses computer-based technical systems to support the surgical procedures using such imaging modalities as computed tomography (CT) and Magnetic Resonance Imaging (MRI) for data acquisition. Building on this, the approach extends to preoperative planning, surgical simulation and optimisation, intra-operative navigation and robotic systems guidance. With less time available, greater multicentre collaboration and increased researcher mobility, our aim was to design, build and test tools to manage a robust academic research process in orthopaedics. The European VOEU-project (Virtual Orthopaedic European University, EC-Project IST-1999-13079, Information Society Technology Program) has developed an infrastructure for clinicians to use computer assisted surgical tools with dedicated interactive media. This work continues the implementation of the dynamic review [3] approach to data management for orthopaedic research.

Materials and Methods: To enhance access and control of these virtual workspaces an eXtensible Mark-up Language [1] (XML) based interface was developed, which links the educational environment of the Web Based Training (WBT) scheme to document resources and to clinical data collection from ongoing trials in Orthopaedics. A secure environment built upon ‘web’ services, allowed users access to these tools via a conventional Internet browser, providing instant access to the multimedia library resources, simulation, clinical trials, and case logs. Users see a customized view of the system based upon their expertise and privileges, matching clinical, educational and research experience to specific trials and relevant background information. The process involves first selecting the participants of the trials, as either associate investigators or internal reviewers. Data is collected either by the automatically generated data entry form or by a modified web form to enhance the interface. Authors may then prepare & store gestational draft papers in a protected environment with a focused discussion forum.

Discussion: Evaluation was completed using ‘on-line’ forms, with structured data, incorporating standard orthopaedic outcome test scores. One trial with over 2800 patients studying the screening of paediatric orthopaedic cases, demonstrated the scalability of the system [4]. The user interface, accessing clinical trials, surgical
logbooks and technical paper drafts, demonstrated 87% (n=18) ‘good’ or ‘very good’ usability performance. Planned evaluation with 100+ clinicians establishing a regional research and education network is ongoing. This integrates with the philosophy of seamless training of individuals through formal specialisation training to continuing professional development. Present functions of the service include ‘on-line’ trial template generation, web form trial data entry & statistics package. Multiple Journal formats are supported.

Dynamically reviewed material can be submitted to the library peer review process to ensure up to date material based upon established clinical trials and on-going trials, with respect to case reports and alerts. By offering pervasive access via Internet browsers, it is possible to establish forwarding to national and international trials centres for analysis.

The virtual university provides tools for clinicians supporting the research & learning of information and clinical skills & was developed with CAOS data collection in mind. The principle concept is to provide individuals with their specified research & learning material. In many postgraduate training programmes clinical research is an integral part of this and so it is brought into the mainstream of orthopaedic training by integrating seamlessly with the educational toolkit for surgical training.

The system provides a distributed architecture [2] for institutions to manage multiple centres, advancing surgical standards through research and education. The tools are generic, applicable across laboratory and clinical disciplines. It lends itself to ongoing data collection for longitudinal studies, managing larger and larger databases allowing greater stratification of the data. The system provides a working environment for secure academic discussion of the non-repudiable traceable results.

The aim of the project was to design and build effective digital training tools that improve the efficiency of surgical training. The aim of such services is now to expand, both to other surgical disciplines and beyond its European origin.

References:

INTEGRATING CAOS IN ORTHOPAEDIC EDUCATION FOR NOVICE SURGEONS

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Introduction: In recent years, the number of the orthopaedic procedures performed with robots or navigation systems increased, which requires the educational and training modules for the surgeons to master new CAOS (Computer Assisted Orthopaedic Surgery) techniques. This is a main objective of the EC-Project “VOEU” (Virtual Orthopaedic European University), which was ended in middle 2003 but will be continued in the framework of VOU (Virtual Orthopaedic University), an initiative of CAOS International. In the VOEU-Project, different components were developed to build an integrated learning environment for the training and education of the different CAOS techniques. However, the most of the educational modules developed in the framework of VOEU-Projects treated explicitly only the CAOS-related aspects, which are separated from the complete clinical workflow. Therefore they are more suitable for the experienced surgeon. As CAOS has grown into an established technique, the orthopaedic education for the novice surgeons should also include the material about CAOS. The medical Faculty of Aachen University has recently launched a new project “VIKAMed” (Virtuell Interactiver Kurs zur studentischen Ausbildung in der Medizin) to develop Web-based multimedia learning system to help medical students (novice surgeons) in preparing the orthopaedic internship. The methodologies and technologies that come into being in the VOEU-Project were further developed and adapted for the new task in the VIKAMed-Project. Both the basic orthopaedics and CAOS are covered such that aspects of the CAOS is treated implicitly in the context of the complete workflow of the clinical routine, i.e. from anamnesis, diagnostics to therapy including the CAOS technique.

Methods: Using the concept of case-based, problem-oriented learning, the learning material in VIKAMed-Project was organised in form of anonymised patient cases, which can be classified in 5 categories: Upper Extremities, Pelvis/Hip, Lower Extremities, Spine, and Orthopaedic Pediatrics. Before participating the orthopaedic internship, the students should do the preparation by working with these patient cases to get familiar with the clinical routine of orthopaedics. To enable the flexibility of time and place of learning, the Web-based solution was selected for the technical realization. To motivate the students in the self-learning, about 20 questions were elaborated for each case so that the student can work with the case in an interactive course by trying to solve the problem he is confronted with. These questions are carefully prepared to cover the important decisions and critical procedures with chronological order in the
clinical workflow. Help of different levels (from general information to contextualised hints) was supplied when the students cannot answer the question properly after his 1st, 2nd and 3rd attempt. Meanwhile, the student has always the possibility to view the patient record whose content is dynamically updated during his learning (working) process of the case. The patient record includes all clinical data available in the different phases of the workflow (patient history, imaging, laboratory data, etc.). In addition, there is an online orthopaedic textbook available as the systematic knowledge base for consulting. Because the preparation of learning material in medicine is very time-consuming and complicated, we have introduced some advanced software technologies like Learning Object Classes to standardize and simplify such procedure [1]. Three LO Classes were used in VIKAMed to build the interactive course: Multiple-Choice Questions (MCQ), Clinical Indicating or not Indicating (CI), Clinical Chronological Order (CCO). While LO Class only defines the general structure and common behaviours, its instance, LO, is filled with concrete content and can be used to present the questions in the interactive course. Different multimedia elements like images, animations, videos and Java3D Applet can be embedded in these LOs so that complex anatomical structures or surgical procedures can be visualized intuitively. The content of the patient record was also standardized to a common structure with several reserved fields for specific information. The advantage of such standardization is that a Learning Content Management System (LCMS) can be used for storage and maintenance of the learning material. Thus in the authoring and tutoring subsystem, a web front-end can use server-side script like ASP/PHP to access the content in the database.

Results: The development in the VIKAMed-Project contains mainly two parts of work: one is the establishing of the technical infrastructures, like LCMS, the authoring system to input the patient case, tutoring system to present Learning Object in the interactive course. Another is preparing the learning content, including the patient record as well as the questions for the Learning Objects. After fixing the specification about the structure of the learning content, a relational database was defined as the repository of the learning material in Microsoft SQL Server 2000. A first patient case was prepared to be fed into the database and check the conformance the database definition. Then the tutoring system was implemented to render the different Learning Objects. Meanwhile, the authoring system is also developed to provide the author support in preparation of the learning content. After the technical infrastructures were stable, about 10 further patient cases have been selected by the clinical partners to be contributed in the VIKAMed-Project. The patient records were digitalized and anonymized before they were input into the LCMS. After final evaluation by the medical faculty, the system will be integrated in the curriculum of medical students.

Conclusion: In this work, we try to put the education of CAOS-related techniques in the integrated framework of the orthopaedic education for the novice surgeons so that the CAOS is regarded as an indispensable part in the complement workflow in the clinical routine. The technical infrastructure established in the VIKAMed-Project uses advanced software technologies like Learning Object Classes which can be easily reused and extended for further application.

References:

3D INTERACTIVE SEGMENTATION OF BONE FOR COMPUTER-AIDED SURGICAL PLANNING

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Introduction: In this paper we describe an original and interactive segmentation approach to efficiently and accurately construct patient specific virtual 3-D bone models for applications such as virtual surgical planning or generation of rapid prototyping models [5]. This approach provides the user with an instant volume view of the segmentation result in order to improve efficiency of the cumbersome segmentation task. We embedded this approach into a comprehensive pipeline consisting of a statistical algorithm reducing metal artifacts, an image-filtering algorithm based on Markov random fields and a dedicated implementation of the Marching Cube surface generation algorithm. All processing steps are represented as modules embedded in the software framework Julius [2], handling essential steps like data management and visualization.

Material and Methods: Ten CT scans with 512\(^2\) voxels and spatial resolutions ranging from 0.4 to 0.5mm were used to test our pipeline. First, we identify and select regions affected by metal artifacts for processing using statistical noise estimation. The selected regions then undergo non-linear interpolation diminishing artifacts. The following Markov Random Fields [1] algorithm is implemented as a regularization process, iterating over the image until the stability or minimum energy is reached. The minimization of the noise produces noise free images. Thanks to the statistical theory, noise estimation allows this algorithm to be automatic, without any user parameter tuning. In parallel implementation, the computation time on a whole volume (e.g. 50 Mbytes) can be reduced up to a few minutes. Volume rendering by 3-D texture mapping is used to initially render the CT data set. Compatible with OpenGL [4], this technique allows real-time volume rendering with an update rate of 10Hz for 600\(^2\) pixels to visualize a volume-texture data of 512\(^2\) x 128 voxels on an Onyx 3200 IR3. Segmentation results are interactively displayed in 3-D as well as on axial, coronal and sagittal slices allowing the user to inspect the whole volume from arbitrary angles. This has been realized for two bone segmentation Methods: region growing and thresholding. Threshold segmentation is to distinguish pixels or voxels within an image by their gray value which can be integrated directly into the visualization pipeline by hardware color mapping. A lookup table for the color mapping is generated and scaled within two initial thresholds. Since visualization of a dynamic color mapping is hardware accelerated and can be manipulated by the user, the segmentation process is displayed real-time in 3-D. Region growing segmentation
looks for regions of voxels with similar intensities. First, seed points are chosen interactively within the region on the image where bone is present. From these points, the iterative process investigates all neighboring voxels for similarity. To achieve real-time visualization of the region-growing algorithm in 3D, the algorithm is split into computational more and less expensive tasks: a computational growing on the original data and an updating module that handles growing for the visualization pipeline. Finally we reconstruct a surface model from the segmented volume by a dedicated implementation of the Marching Cube algorithm [3] that is not applied on a binary volume derived from segmentation but rather on threshold values directly from the user. For region growing, the isosurface values associated to the binary volume are computed and used for surface extraction. This allows us to take into account the original Hounsfield units for tri-linear interpolation and gray-level gradient shading.

**Results:** We were able to achieve interactive segmentation with an update rate of at least 10 Hz reducing the time required for bone segmentation. Especially the 3-D assessment before surface generation helped to efficiently encounter segmentation errors and correct parameters when necessary. The statistical estimation of slices affected by metal artifacts reliably worked for all studied cases. Reduced artifacts improved image quality and greatly enhanced final models compared to non-processed data. The Markov random fields image filtering reliably removed noise and enhanced edges. Finally the iso-surface based Marching Cube algorithm was able to preserve small anatomical details that were lost when applying the algorithm on the binary volume derived from the same segmentation.

**Conclusions:** We have presented an interactive 3-D approach of region-growing as well as threshold segmentation that helps to segment bone from CT data more efficiently. We embedded this new segmentation tool into a dedicated processing pipeline consisting of algorithms for image filtering and surface reconstruction. This pipeline was implemented into the platform independent software framework, Julius and reliably generated accurate 3D Models of bone.

**References:**

A NEW MODEL BASED APPROACH FOR MARKERLESS FLUOROSCOPIC NAVIGATION

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Introduction: Today fluoroscopic navigation is usually based on x-ray projections calibrated on the basis of biplanar marker arrays arranged in calibration cages fixed in front of the x-ray image intensifier. Distortions are related to mechanical as well as electromagnetic effects. Markers visible in the images are being interpolated resulting in “quasi-markerfree” images. However, the calibration cage significantly reduces the working diameter of the C-arm which might cause problems in the case of adipose patient and lateral positioning on the OR-table. Within the MINARO project, funded by the German Research Foundation (DFG), we developed a computer assisted planning system for Revision Total Hip Replacement (RTHR) combining the advantages of fluoroscopic navigation and robotics [1]. Instead of computer tomography we chose fluoroscopy due to its flexibility and standard intra-operative availability. Using filtered cone beam back projection algorithms modern C-arm systems allow the creation of three dimensional volume models similar to computer tomography. Therefore a series of up to 100 x-ray projections rotating the C-arm for 180 degree is necessary. However, we demonstrated that 3D reconstruction of the bone cement in RTHR is possible on the basis of a deformable model and 3-5 multiplanar x-ray images only, reducing costs and radiation significantly [1]. To enable an optimal and potentially automatic segmentation (and 3D reconstruction) of the bone cement within marker free X-ray images, we developed a new model based calibration approach simulating the distortion of an X-ray image intensifier. In contrast to new but still very expensive digital flat panel C-arms, X-ray image intensifier based fluoroscopes especially require distortion correction. The distortion mainly consists of a pin-cushion distortion, caused by the curved input screen of the x-ray image intensifier, and an s-shaped distortion, caused by electromagnetic fields deflecting the electron beams within the image intensifier. In contrast to electrostatic fields, magnetic fields can not be shielded entirely. Due to the high velocity of the electrons even small magnetic fields cause noticeable deflections. Moreover, all fluoroscopy systems, including flat panel detector based ones, have to be calibrated regarding the projection geometry including mechanical deformation of the C-arm. All known approaches for x-ray calibration have in common, that they are based on constant boundary conditions. As the direction (and amplitude) of the magnetic field is not constant with respect to the image intensifier and due to the mechanical deformation of the C-arm, current systems need an intraoperative three dimensional calibration cage. The projections of small calibration markers have to be visible in each
image to compute the adequate online correction. These overlaying markers reduce the contrast and thus complicate automatic segmentation algorithms. Moreover, the three dimensional form of the calibration cage reduces the small workspace of the C-arm. One possible approach for marker free imaging could be based on Look-Up-Tables acquired by preoperative calibration. For the camera calibration this approach might work, as the deflection of the C-arm depending on its orientation has been determined to be reproducible. However, this is not true for magnetic distortion as the magnetic field is being influenced by surrounding devices.

**Materials and Methods:** For a marker free intraoperative calibration of image intensifier based fluoroscopy we developed a model based approach simulating the entire imaging process of the intensifier. The models constants are being obtained by a preoperative calibration process based on two X-ray images of a calibration object with steel pellets arranged on concentric circles and an attached magnetic field sensor. During the intraoperative application, earth gravitation and magnetic field sensors provide the necessary sensory input for the non constant parameters of the calibration algorithm. The model simulates the distortion that would be caused by the measured sensor data and thus gives the input data for a global dewarping algorithm. Sensors have been fixed together with the calibration cage onto the image intensifier of a Philips BV 400 fluoroscope. To calibrate the model constants, we acquired two perpendicular images with the attached calibration cage including the sensor. After the calibration process, the calibration cage has been replaced with a reference object of known geometry for a series of images rotating and moving the C-arm following a defined test protocol. These images have been calibrated using the sensory input data. Finally accuracy has been calculated by matching the dewarped image onto the known geometry of the reference object.

**Results:** The used model based approach for marker-free intraoperative X-ray calibration reaches a distortion reduction of about 90 % with an arbitrary position and orientation of the C-arm. Maximal deviation within the field of view was less than 0.3 mm. The calibration process acquiring two X-ray images is easy to use, but the following necessary calculation of the image intensifier model still requires a computation time between 4 - 12 hours on a conventional personal computer. However, this calibration theoretically has to be performed only once for each C-arm. Based on the pre-calibration, the intraoperative dewarping of images for an arbitrary C-arm position can be done within 8-12 seconds.

**Discussion:** The model based approach for x-ray image intensifier calibration has shown two advantages – no markers reduce the contrast or hide important anatomical structures and the full size of the C-arm workspace can be used. The quite long computation time for the initial calibration can be reduced by optimizing our actual algorithms. However, this calibration has to be done only once per image intensifier and not before each use and intraoperative image correction only needs a few seconds.

**References:**

ANALYSIS OF THE COXOFEMORAL JOINT STABILITY DURING A SEQUENTIAL SECTION OF SOFT TISSUES WITH THE HELP OF THE HIPLOGICS® NAVIGATION SYSTEM

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Introduction: 1200 to 1800 out of 60 000 total hip arthroplasties have to face the difficult problem of instability and dislocation each year in France [1]. The two major factors to explain this phenomenon are: the wrong orientation of the components and the muscular decoaptation as a consequence of the periarticular muscles weakening during surgical approach. Even if the orientation problem is actually so far from being perfectly mastered and even if surgical navigation systems will provide some very interesting elements, it seems from now on mandatory to perform the less possible damaging surgery in order to avoid any weakening of the periarticular musculotendinous coats. The pelvitrochanteric muscles are strong stabilizer of the hip, as well as capsule. But during an academic postero-lateral approach their section is required. Therefore the postero-lateral approach is known to expose the patient to an higher risk of dislocation than anterior approach [2]. Taking these anatomic remarks into account we decided to modify our postero-lateral approach, to take care of the soft tissue and to avoid any muscular section and capsulectomy. The purpose of this work is to demonstrate, thanks to hip surgical navigation system Hiplogics®-Universal from PRAXIM, that this new surgical approach provide more stable hips and to asses the function of each anatomical structure in the hip stability.

Materials and Methods: For the purpose of this study we have used the SURGETICS workstation (PRAXIM-France), and the HIPLOGICS UNIVERSAL software. The protocol implemented can be used with any prosthesis available on the market. This application was developed to perform total hip arthroplasty without pre-operative imaging, thanks to an imaging techniques known as “bone morphing” and based on the deformation of an elastic statistical model of bones. No specific development has been done for the purpose of this study which was performed with the data provided by the marketed application. During the CASP (Computer Assisted Surgical Protocol), we had the ability to capture the screen which presents the multidirectional variations of the location of the hip center. The values displayed are computed with respect to the location of the native hip center recorded in the beginning of the surgery before any soft tissue section. The study was performed on 10 hips coming from 5 fresh cadavers. Thanks to a dynamometer we were able to apply a calibrated reproducible traction to the hip. This traction was applied to the great
trochanter along the femoral neck axis. Then we were able to quantify the medio- lateral, cranio-caudal and anterior-posterior displacement of the hip center (under traction), during a sequential section of the soft tissues. A descriptive analysis of the Results Has Been Performed To Describe The Multidirectional Laxity Observed.

Discussion: Preliminary results we’ve got during the analyzes made with the specimens, confirms the existence of an important laxity during the postero-lateral approach. This phenomenon is made perfectly clear if a complete capsulotomy is performed in association with a complete section of the pelvitrochanteric muscles.

This quantitative assessment of the soft tissues give us the scientific knowledge to explain why capsular preservation importance is praised by a lot of orthopaedic surgeons [1]. In our daily practise we have know decided to be as minimally invasive as possible and to take care of piriformis muscle’s tendon and quadratus femoris muscle during the surgical postero-lateral approach. This new way of performing the postero-lateral approach allows a strengthened stability of the hip joint after surgery and should decrease latero-posterior dislocations in our patients. However, only a long term prospective, randomized and large scale clinical trial will be able to confirm the first results observed on these quantitative data. If the balance of the soft tissue is now well known and implemented in CASP for the knee joint, the same concept is not really taken into account at the hip joint. The measurements given by the hiplogics system allowed us to bring this new concept into hip surgery. This show clearly that, used as measurement tools, navigation systems will help us to change the future of hip surgery.

Conclusion: Supplying quantitative spatial data during the surgery, such as the hip center, coxo-femoral joint lateralisation and multidirectional laxities, operated limb’s length, planning-cup (anteversion, inclination) and femoral stem anteversion, allow improving surgical procedures based on objective quantitative data. Furthermore, this quantitative approach of the periarticular soft tissues influence on hip stability is at the heart of new mini-invasives approaches developed in a safety context.

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COMPUTER ASSISTED ARTHROPLASTY; APPROPRIATE IMAGING FOR ASSESSMENT OF IMPLANT POSITION

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Introduction: CAOS systems have received bad press because some investigators have failed to detect any differences in outcome on post-op plain X-rays. These trials have allowed surgeons to avoid the use of CAOS systems on the grounds that they make no difference. The contribution of CAOS to knee arthroplasty whilst becoming more recognized [3, 5] still requires more robust outcome measures to demonstrate its efficacy. We report the use of low cost, low radiation CT as a surrogate outcome measure.

Using these techniques we have investigated ways of presenting data to the surgeon for post operative assessment of knee arthroplasty.

Materials and Method: All patients are pre-operatively CT scanned in fine detail of knees (1mm slices) but with minimal dosage at hips and ankles (4mm slices). The limb is stabilized with the use of a radiolucent splint whilst the patient is being scanned. The radiation effective dose per scan is in the range of 1.2 mSv. Each case is planned on a work station by first defining the mechanical axis of the limb, wire frame models of the implants are accurately sized and positioned to plan the reconstruction of the joint.

Surgery is then performed either conventionally or with computer assistance. A further CT scan is performed a few days post surgery with fine details of the knee again using the splint with the effective radiation dose being as low as 0.1mSv.

For post operatively assessment surface models from the pre operative plan is co-registered with the post-operative CT scan. Transformation matrices are computed for the knee components and show the position in space of the prosthesis relative to the pre operative plan revealing differences between the planned and achieved positions in all three planes.

Results: This method is accurate to within 0.5° and 0.5mm
Results show a range of differences between planned and achieved depending on the mode of surgery used. For conventional cases there was outcome variation between surgeons. In the computer assisted group the results achieved were within a much narrower envelope.
Discussion: Whilst accurate component positioning is essential to the success to knee arthroplasty[2,4] demonstrating post operative results is crucial. Plain x-rays although helpful in giving a general idea of the post operative result remains an inadequate tool for accurate post operative assessment of knee arthroplasty. It is a poor tool to demonstrate significant outcome differences between various computer assisted techniques[1]. It is practically impossible to accurately compare the mechanical axis of the limb with pre and post operative plain x-rays, far less comparing plans made on plain x-rays with post operative films, any attempt at this exercise will result in high doses of radiation to the patient far exceeding our CT protocol doses and still not achieve the accuracy we demonstrate on CT.

Conclusion: When evaluating the impact of CAOS systems, 3-D imaging methods are necessary. These allow the surgeon to show just how accurately he has performed his procedure. A transformation matrix provides vector values that indicate the accuracy with which the planned procedure was performed. Any method of post-op imaging that does not use this technique runs the risk of the investigator failing to detect a difference in outcome.

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INFLUENCE OF FEMORAL COMPONENT ROTATION ON PATELLA KINEMATICS

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Introduction: Although overall total knee replacement (TKR) is successful, revision occurs in approximately 5% to 8% of all cases. Complications, such as patello-femoral pain contribute to suboptimal clinical outcomes. The majority of patello-femoral complications might be associated with abnormal patellar tracking and rotational femoral component malalignment is an important cause for it. In particular, the accuracy and amount of tranverse plane rotation of the implanted femoral component is of critical importance. A prosthesis implanted with an incorrect amount of rotation can lead to a variety of problems. These include poor patella tracking, asymmetrical patellofemoral joint contact, incorrect varus-valgus positioning in flexion, difficulties in rotational alignment of the tibia in extension, and the necessity of anterior femoral notching. Excessive internal rotation of the femoral component causes a shift into valgus alignment with knee flexion and also an increase in the Q-angle. This has deleterious effects on patella tracking. 3-D patellar tracking for femoral component malposition in TKR was measured. The influence of the patella spatial position for the same knee implant (Scorpio®) in fixed and mobile bearing version was evaluated also.

Methods: 6 cadaver specimens were harvested and the knees resected with the use of the Stryker Navigation System. Implantation of the TKR was performed with the Navigation System. A special holder for the femoral component was developed. This enabled the femoral component to be rotated in steps between 10° internal (IR) to 10° external rotation (ER) along the long axis of the femur. In an adapted testing machine a quadriceps load of 500 N was applied to flex each knee up to 90°. Testing was first conducted with the knees intact. All specimens underwent the same test regime from IR to ER in incremental 5° steps. The fixed and mobile TKR was analysed in the same individual cadaver specimen.

Results: The spatial (tilt, shift) position of the patella relative to the femoral coordinate system was changed with any femoral component malposition. Overall, as expected there was a scattering of the data but the shape of the patella kinematic behaviour was comparable. There was only a slightly not significant difference between the patella tracking for the specimens loaded with 100N compared to those loaded with 500N.
In case of 10° IR or ER femoral rotation the values for patella tilting and shifting showed larger values than the 5° situations. The patella kinematic between the fixed and mobile bearing situation showed differences for the various malrotated situations.

**Conclusion:** Femoral malposition resulted in different patello-femoral kinematics in both knee designs. Internal femoral malrotation showed a different kinematic pattern than the external compared to the normal knee. This cadaver experiments may lead to better understanding of anterior knee pain.

**References:**

MRI BASED SYSTEM TO VISUALIZE THE LOCUS OF THE DYNAMIC LOADING AXIS ON THE KNEE DURING GAIT

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Introduction: We developed a CT-based program to demonstrate the locus of the dynamic loading axis of the lower limb on the proximal tibia joint surface during gait using CT images [1, 2]. We added an option to reconstruct patient specific bone models of the lower limbs using MR images instead of CT images. Purpose of this study is to demonstrate how the option works.

Methods: Six reflective ball markers of gait analysis were attached to the skin of a healthy volunteer at the following anatomical landmarks: lateral thigh, bilateral epicondyles of the femur, anteromedial point of proximal tibia, medial malleolus of the ankle, and lateral malleolus of the ankle. The reflective ball markers contained gadolinium-diethylene triamine pentaaacetic acid in its interior. MR images of the lower limb with the ball markers were taken for two different ways. One was taken for the range of whole lower limb (Group A). The other was taken for the range of partial lower limb around the hip, knee, and ankle joints (Group B). MR images were taken with the knee at full extension and the ankle joint at 0 degrees of dorsi-flexion in supine position. The MR sequence was 3D Fast SPGR, TE In phase (4.2msec), TR 9.0msec, Flip angle 15deg, Band width 31.25kHz, FOV 42cm, Thickness 2mm, Location per slab 64 (discard: 4 slices), Matrix 256*256, 1 NEX, Freq direction R/L, 1min 27sec/slab. In Group A, MR images of whole lower limb were obtained by connecting the every slab of the lower limb in the 3D coordinates. In Group B, MR images of the whole lower limb were obtained by matching each location of hip, knee, and ankle joints in the 3D coordinates. Motion capture data and force plate data during gait were acquired using an infrared position sensor and a multi-component force plate. The 3D skeletal surface models of the femur, tibia, and ball markers were reconstructed from axial MR images. Using positional relationships between bones and markers, the relative motion of the femur and tibia during gait was calculated by matching markers from MR images with markers from motion capture data. The loading axis of the lower limb was defined that the axis passed through the center of the femoral head and the centroid of the distal tibia joint surface contour. The locus of the dynamic loading axis on the knee joint was defined as the point on the prox-
imal tibia joint surface that intersected with the loading axis of the lower limb. Next, we compared the locus from CT-based program with the locus from MRI-based program. We obtained the CT images and MRI images of whole lower limb from one patient who had bilateral osteoarthritis of the knee. MR images of the whole lower limb were taken according to the way of Group A. CT images of the whole lower limb were taken according to the previous way of this system with the reflective skin ball markers contained gadolinium-diethylene triamine pentaacetic acid in its interior. Motion capture data and force plate data during gait were acquired. Two sets of 3-D skeletal models of the femur, tibia and reflective markers were reconstructed from CT images and from MR images. Movement of skeletal structures from CT images and the movement of skeletal structures from MR images were calculated by matching markers from the same motion capture data. The each locus of the dynamic loading axis on the proximal tibia joint surface during gait from MR images and CT images was visualized. At the heel contact, loading response peak, and terminal stance peak during gait, we calculated points of the dynamic loading axis on the proximal tibia joint surface in each locus. Measurement error was defined as the differences in point locations between the locus from CT images and the locus from MR images.

**Results:** In group A, MR images of whole lower limb were connected with seven parts of slab and total MR axial images of whole lower limb were 408 slices. It was enough to detect the bone surface on MR axial images to reconstruct the 3D surface models of the femur and tibia for this program. We could visualize the locus of the dynamic loading axis on the knee joint during gait using MR imaging. In group B, MR images of partial lower limb around joints were connected with five parts of slab and total MR axial images were 324 slices. Even in group B, it was enough to make the locus of the dynamic loading axis of the lower limb moved along the proximal tibia joint surface during gait. 3D surface models of femur and tibia from CT images and MR images were almost the same in appearance. The each locus of the dynamic loading axis on the proximal tibia joint surface during gait from CT images and MR images was almost the same. At the heel contact, loading response peak and terminal stance peak during gait, the measurement error for point locations between the locus from CT images and the locus from MR images were within 4% of joint width in the lateral direction on the proximal tibia joint surface.

**Discussion:** In MRI-based program, it is advantage for the patient to take no X-rays, but it is disadvantage to take a long time to obtain MR images of whole lower limb. It was about 11 minutes to take MR images of whole lower limb in Group A. So we need to care the patient motion artifact during MRI.

**Conclusions:** We reconstructed patient specific bone models of the lower limbs using MR images instead of CT images. We could visualize the locus of the dynamic loading axis on the knee joint during gait using MR images.

**References:**

MUSCULOSKELETAL MODELING AND MOVEMENT ANALYSIS IN PREOPERATIVE SURGICAL PLANNING

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Introduction: Force generating capacities of skeletal muscles depend on many factors, and can be considerably affected by changes consequent to surgery [1]. For instance, the distance between insertion areas of a muscle, its force line of action in relation to the joint center, and the length variations rate can be modified after orthopedics surgery. Moreover, in pathological cases, primary limitations are combined with compensation mechanisms [5], and this can result in abnormal efforts of musculoskeletal structures and yield secondary diseases. This risk can be reduced by balancing the working condition of muscles and ligaments, improving the functional recovery after surgery. This work is aimed at providing an estimate of the working condition of muscles and ligaments that would result from arthroplasty, by using biomechanical modeling combined with data from movement analysis.

Methods: Three-dimensional models of bones are implemented in a software that allows to match the individual anatomy of a patient, based on diagnostic images. Anatomical reference points are pre-defined in which the muscles and tendons are attached. Via-points and wrapping surfaces are defined according to anatomy [2]. The lines of action of muscles acting at the hip and knee joints are defined by considering the different paths of both central and periphery lines, which are obtained by imposing a constant volume constraint. Kinematic data are collected by movement analysis techniques, and consist in the 3-D Euler angles for each lower limb joint. The protocol of gait analysis has been described elsewhere [3]. It’s based on stereophotogrammetry and includes the analysis of spine, pelvis, and lower limbs. A data base of normal subjects (N=200, age range 5-82 years, both sexes) was collected in several years of activity, and allows us to select the proper control population to be used as a reference. In a smaller number of normal subjects walking up and down stairs was analyzed [4]. Additional data are available concerning the sitting down and standing up from a chair, and rising from a squatted position. All these mentioned motor tasks are relevant for people who undergo hip or knee joint replacement. The average curves of each selected sub population, age matched with the subject analyzed, were used to activate the musculoskeletal models. A virtual motion of the patient was thus obtained and the muscle lengths and velocity of change of muscle length were computed for all the above mentioned motor tasks. These data were compared to data obtained from real acquisition of the patients. The difference in length excursion and muscle velocity were analyzed, as well as the change in length
of the main ligament fibers. Then the surgical intervention of joint arthroplasty was simulated, and muscle length and ligament length was calculated under the same kinematic conditions by changing the relative position of the prosthetic components. The method was developed in a prototypal form and was tested on 5 patients affected by gono-arthritis and 5 patients affected by coxo-arthritis, both before and after arthroplasty.

**Results:** By comparing the muscle length excursion and ligament length in simulated movements and in real movements collected in ten patients before and after surgery, the residual limitations could be relatively well understood. In fact the change in the working conditions of the muscles and ligaments were quantified, and in several instances the reduced capacity to produce force and moment could be explained through analyzing the change in the post-surgery geometry. The most relevant results are the quantitative approach and the tools that have been developed, which can be profitably included in a computer assisted procedure for orthopedic surgery.

**Discussion and Conclusions:** A systematic application of the method described above and a quantitative assessment of the patients’ performance, can help identifying the best criteria for hip and knee joint replacement, and defining the optimal position and orientation of the prosthetic components. As the method is based on diagnostic images and morphometric modeling, it is intrinsically suitable for inclusion in a computer assisted surgery procedure. The optimal parameters of the implant can be directly transferred to a computerized intra-operative procedure to guide the surgeon for an optimal application. This would result from a trade-off between the selected geometry of the prosthesis, that is imposed by the dimensions of the anatomical parts, the severity of the joint damage, and by clinical considerations, and the functional constraints that can be simulated pre-operatively. The simulation offers the possibility to check for bone interference and to assess the range of length excursion of muscles and ligaments. The lever arms of the muscle-tendon line of action can also be analyzed. By inputting data from different, meaningful, day-life, motor tasks a prediction of the functional capability and limitations that will be residual after surgery is possible. An effort is to be done to make this procedure easy to use and more adaptable to individual anthropometry, taking into account for example the bone deformations.

**References:**

PROCEDURES FOR THE INTEGRATION OF HETEROGENEOUS DEVICES IN CAOS SYSTEMS

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Introduction: The commercial CAOS systems that are distributed today in Spain have several commercialization problems due to, overall, its high price and low flexibility for the integration of future equipments, subsystems and tools that allows the reuse of the basic components which constitute the system for other interventions and specialties. Since the trackers are the most used devices in CAOS systems, we think that the development of low cost trackers integrated into architectures that allow the interconnection to any subsystem, could be a good way to reduce the price of these products. The principal objective of this work is to allow the development of low cost equipments for CAOS systems. To achieve it, our group has focused its work on two simultaneous tasks. On one hand, artificial vision equipments are being used for the development of the tracking systems as an alternative to the acquisition of traditional trackers, that put up the final price of these equipments and, on the other hand, the reuse of the components that constitute the CAOS system which, without any doubt, will increase its use. This will suppose a good option for the acquisition of these equipments when they were used by several users. In order to achieve this goal, it is necessary to implement an architecture that allows the definition of specifications which should meet the equipments that constitute the systems, and the interchange of information among them.

Tracker design: The optical tracking systems are based on triangularization theories, by means of the determination of the coordinates of the projected points over two or more cameras. The basic bibliography on artificial vision defines these equations, so that the development of these systems depends on, in a large extent, the quality of the CCD sensors, normally cameras, the design of the localizer system and the instruments that are to be localized, as well as the processing of the information gathered by these sensors. With the reduction in price of the hardware, essentially because of the proliferation of digital cameras based on CCD sensors, it is possible to develop trackers with an excellent resolution and high tracking speed. Traditionally, the trackers calculate coordinates of the points in the scene that are monitoring. These points are infrared leds that, in conjunction with adequate filters placed in the lenses of the cameras, allow the scene that the cameras are seeing, can be reduced into such points, which are easier to detect and to incorporate into surgical tools. Our group is working on this idea and we think that, in short, we are going to
be able to have available data that reassure the validity of the development with estimated precisions under 1 mm, at work distances in between 3 and 5 m of the tracker.

**Global architecture:** If we want get the reutilization of these devices, the information that they provide, must be understood by every device that could be used in a CAOS system. To perform this, we are developing a communication architecture. It allows that each device of the system can send and/or receive information from the rest. Besides, the architecture is configured to get maximum security and flexibility. Security, to assure that the required information reaches the target device in the minimum time and flexibility, because the structure of the architecture allows the interchanging or insertion of new devices without changes in the controller. Among the principal objectives of the communication architecture are the independence of specific hardware and software, using open standards when available and providing at the same time the required levels of security, essential in these applications. The core of the communication is the message passing interface. For this specific task, the connectionless UDP protocol has been used. The absence of a connection allows a small time response in the message process and has the advantages of minimizing the total net overload and improving the security. The advantage of using an open architecture is that several alternatives can be used without the need to redesign the system and reducing the cost of it. For example, an Ethernet based hardware has been used, but other alternatives can be chosen in case that the Ethernet solution is not totally satisfactory. Also, the use of TCP/IP based protocols allows the physical independence of the system because it can be executed in only one or among several computers. This is because a server-client philosophy has been used. This decision allows an easy integration of other subsystems that could need a lot of cpu time, as in graphical applications (for example MRIs and CTs). In this case, these subsystems can be executed in a different computer than the one who is running the core of the communications. Then, the computer running the communication server would not be overloaded allowing, at the same time, that the alarms that could be triggered during the task would be processed immediately, enhancing the global security of the system.

The hardware independence is also a desired objective, because in the development process of any application it is possible/necessary the introduction of new devices that had to be integrated with the rest and/or the replacement of the current devices for others with better performances. The development of interfaces that virtualizes the hardware assures this independence. So, after an analysis of the expected behaviour of each element of the system, a basic interface has been developed for each one. Now, the introduction of a new device will only require the software writing of this interface to be able to be fully utilized by the rest of the system. This design assures the flexibility of the system allowing its enhancement in an easy way.

**Conclusion:** With this work, we want to demonstrate that it is possible to perform a standard communication procedure for interchange information among CAOS devices. We are testing this architecture with poli-articulated robots and force sensors and the global results are very right, the devices are heterogeneous and the CORE system does not need to add any hardware for the good work of it. Now, we want to integrate our tracker in this architecture and to use the planner of Navimetric S.L., a Spanish factory of medical software, to perform the whole architecture proposed and test the results.
CLINICAL VALIDATION OF A NOVEL SPRING LOADED TENSIONING DEVICE AND COMPUTER ASSISTED NAVIGATION

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Introduction: Since routine spacer blocks do not necessarily load the joint space symmetrically, if either the bone cuts are asymmetric or the ligaments are not evenly balanced, a tensioning device that applies a constant load to the medial and lateral joint space separately and which can collapse or expand on each side independently should be able to provide a better evaluation of ligament tension and allow the computer software to better plan the appropriate bone cuts or ligament release. The tensioning device comprises 2 linked plates contacting the femur and tibia separated by two independent springs in the medial and lateral compartments. It can be positioned precisely in the joint with the navigation system and this device was designed in order to allow a dynamic evaluation of joint stiffness during all range of motion with patella in situ. The springs apply a consistent known force on the compartments, while at the same time the gap produced by the applied forces is measured by the navigation. This study integrates previous article[1] on the validation of the tensioning device and reports the first phase of the clinical validation of the tensioning device, including first qualitative comparison with standard navigated technique and consideration on the use of the device.

Materials and Methods: A spring loaded mechanical device was designed with a constant 6kg load in the springs for each compartment For the clinical evaluation the device was inserted into flexion and extension spaces after the tibial cut was performed in routine computer assisted total knee arthroplasty. The gap produced by the applied forces is measured, by the navigation system, as the distance between tibial cut and most distal points on condyles in extension or most posterior points on condyles in flexion. At same conditions a set of solid spacer blocks were inserted to obtain a gap able to balance the knee according to surgeon’s sensitivity, this gap was used as reference and compared with the gap obtained with the spring device. The clinical evaluation was performed in order to determine whether there was a difference between the gaps as indicated by both the tensioning device and the spacer blocks. Five experienced orthopaedic surgeons were involved in a randomized study producing 58 complete data sets. Eight measurements (medial and lateral gap, in flexion and extension for tensioning device and spacer blocks) were taken intra-oper-
atively using the ligament balancing features of Vector Vision system. Repeatability of measurements performed with the spring device was defined as the occurrence of same values obtained with the device and by surgeons with spacer blocks.

**Results:** Difference between the tensioning device and the spacer blocks in flexion is 0.2mm medially and 0.0mm laterally, while in flexion it is 1.3mm medially and 1.6mm laterally, moreover the alignments of resulting femoral cuts obtained with spring device can be considered the same of the alignments obtained with spacer blocks (difference is <1°). Data highlighted that knee has a different behaviour in flexion and extension. Applying the same force with the tensioning device the resulting gap in extension (10mm medial, 10.5mm lateral) is lower than the one in flexion (10.5mm medial, 12.5 lateral). The percentage of values around the average in the range of 1mm is 52.6% - 59.6% medially and 40.4% - 42.1% laterally, showing a higher variability on lateral compartment, while the percentage of values in a range of 2mm is 75.4% - 82.5% medially and 63.2% laterally, confirming the variability.

**Conclusions:** Traditional spacer blocks are unable to load the medial and lateral joint space independently which may compromise the surgical plan. A tensioning device which loads the joint space independently with a constant load should theoretically allow proper planning of the bone resections and ligament releases during reconstructive surgery. The spring loaded tensor device coupled with image navigation and compared to independent spacer blocks performed by different surgeons revealed that there is no statistical difference between the gaps obtained with spacer blocks and tensioning device in extension, while in flexion there is an average difference 1.4mm, it revealed also that there was greater surgeon variability in the use of spacer blocks compared to the tensioning device. Furthermore, the device produced results that were similar to the results obtained by the spacer blocks especially when surgeon’s variation in technique was taken into account. This data also revealed, as would be expected clinically, that the joint space is less in extension than in flexion after the tibial cut is performed[3]; surgeons with the help of spacer blocks apply less force in flexion in order to obtain the same gap during range of motion, the spring device, applying always the same force, is opening the joint more in flexion. Furthermore, when evaluating the lateral joint space, the tensioning device has a greater variability than the spacer blocks[4]. In this series of patients, a spring loaded tension device decreased surgeon variability in the assessment of ligament tension and, when coupled with computer navigation, allowed the surgeons to appropriately plan the femoral resection to create balanced flexion and extension spaces.

**References:**

THE HIPLOC®: AN INNOVATIVE DEVICE TO TRANSFER THE LEWINNECK REFERENCE SYSTEM INTO THE SURGICAL FIELD

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Introduction: Even if total hip replacement can be considered as the major improvement of the past 50 years in orthopaedics surgery, there are still some issues that lead to prosthetic failures and revision surgery. Among these issues, it has now been clearly demonstrated that component orientation (cup as well as the shaft) is a major factor of long term survivorship in hip replacement. Actually, hip dislocation, impingement, pelvic osteolysis and acetabular loosening are usually the results of an improper positioning of the acetabular cup with respect to the specific anatomy of the patient. Therefore a tremendous work has been done to optimize the intra-operative placement of the hip components. But even with experienced surgeons, using conventional techniques, it is difficult to reach the “safe zone” described by Lewinneck in [1] since no mechanical device is accurate enough as demonstrated by DI GIOIA III in [2]. Today the main issue remains the definition of an absolute reference system. This means a reference system independent of the position of the patient on the operative table and than could be used in lying as well as in standing position. As it is clearly demonstrated in the literature, the relationship between the spine and the pelvic bone results in permanent changing of the anteversion and inclination of the pelvis, during the life of the patient. Therefore, the anterior pelvic plane is now well accepted as an absolute reference system. This plan is defined by the two points located on bilateral anterior superior iliac spine and one point located at the midpoint of the bilateral pubic tubercles. Digitizing these three points when the patient is lying on his back is quite easy and can offer an accurate localization of the reference plane for anterior approach. In case of postero-lateral approach the patient stand in lateral decubitus position and anterior and posterior blocks are used to stabilize the pelvis during the surgery. When theses blocks are placed, it becomes almost impossible to accurately digitize the pubic and the controlateral iliac spine. In case of anterior approach in supine decubitus, it is also quite difficult to acquire these three points through draping. Therefore we developed an innovative device called HIPLOC® that is used to: a) make an accurate acquisition of the three reference points b) Transfer these references into the surgical field after the draping.

Material and Methods: The Hiploc® is a device made of two separated parts. The inferior part will be named as the base of the Hiploc®, the upper part as the satel-
The satellite of Hiploc® holds a rigid body that will be used as a reference system for the pelvic bone. Two Hiploc® are used for each surgery which is performed in two consecutive steps. **First step:** The patient is lying on his back, the base of the first Hiploc® is fixed to the pelvic bones. The satellite is then firmly locked to his base thanks to a specific design of the two parts that allow a perfect fitting between them. The Hiploc® is then calibrated and the surgeon can digitize the three calibration points with the help of a specific passive tracker in a non sterile environment. **Second step:** The satellite is removed of its base. For postero-lateral approach, the patient is set in lateral decubitus position. The base of the Hiploc® is therefore now located under the draping. Then a second sterile satellite is fixed to the first base over the draping. During this entire second step we assume that the base is strictly fixed to the pins and that it does not move with respect to the pelvic bone. Because of the specific shape of the base and its satellite we are able to find again the perfect fitting between the two pieces. The design asserts a perfect reproducibility of the satellite, whatever the draping thickness is. A second registration of the Hiploc® is then performed and we are now able to express the location of the three reference points in the new reference system. This approach has been validated on cadavers and is know in use in our clinical daily routine.

**Discussion:** The Hiploc® system allows an accurate localization of the anterior pelvic plane in supine position without the interference of stabilization blocks, and the transfer of these points in the sterile surgical reference system. Its major drawback relies on the necessary two steps procedure and the associated risks such as pain or infection on the iliac side. However we claim that this is the only way to obtain an accurate reference system for postero-lateral approach as well as for anterior approach because of the draping. At this point of the discussion one must underline that the consequences of a bad determination of the anterior pubic point in the sagittal plan can lead to a one to one error in the quantification of the anteversion of the acetabular cups. Since an error of ten millimetres in the antero-posterior localization of the pubic point gives a 10° of error on the anteversion values. Specifically in fat people, the acquisition of the anterior pubic point must be acquired in supine position, while depressing the fat in order to be as close as possible of the bony structures. This is totally impossible to perform such acquisition in lateral decubitus with stabilization blocks in place, and very difficult in the supine position after draping. Concerning the controlateral iliac point, the issues are the same, but the consequences of an error on its localization are lower. Because of the major role played by the anterior pubic point in the definition of the anterior pelvic plan we do believe that this two step procedure is acceptable with a reasonable balance between benefit (on the accuracy) and the increasing risks.

**References:**

A NOVEL APPROACH TO BONE MORPHING USING STATISTICAL SHAPE MODELS

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Introduction: Progress in computer technology during the past decade has had an unquestionably profound effect on computer assisted orthopaedic surgery. CT based CAS systems are widely available, but they have the disadvantage that the CT acquisition induces a high radiation dose to the patient. A clear trend is visible towards methods that can eliminate such scans but still provide 3D guidance comparable to CT based systems. This is especially useful in orthopaedic surgeries such as total knee and hip arthroplasty (TKA), where often only a pre-op diagnostic X-Ray is available. Our objective therefore is to develop a CAS system that can provide 3D guidance, using minimal information such as digitized landmark and bone surface points. This is an extrapolation problem of obtaining a complete surface representation from an sparse set of digitized points. The extrapolation procedure also called bone morphing was first proposed by Fleute et al[2]. They fit the morphed model surface to sparse intra-operative data via jointly optimizing morphing and pose. Chan et al[1] optimize morphing and pose separately using an iterative closest point method. In this paper we present a novel and robust approach to bone morphing.

Methods: The first step is to build a deformable model from training database of bones. We build a statistical shape model based on principal component analysis (PCA) that helps to capture the legal variations in the shape for a given class of images. Three steps are required to build the model: (a) Acquisition of training shapes; (b) definition of point-to-point correspondence; and (c) statistical analysis. Since the application focus is on hip and knee surgery we chose to establish the proof of principle of our method on the proximal femur. 14 CT scans of the proximal femur were segmented and surface models of the bones were computed. Correspondence among the shapes was initially established using a landmark driven tool, and then optimized based on the MDL criteria[4] to generate an optimal PCA model.

Bone Morphing is the process of recovering the patient specific 3D shape of the anatomy from the few available digitized landmarks and surface points. This is achieved by solving for the shape parameters that minimize the residual errors between the reconstructed model and the cloud of random points. In our method we compute a Mahalanobis distance weighted least square fit of the model by having additional terms in the objective function that minimize the Mahalanobis shape distance. This novel method operates directly in the PCA shape space incorporating the full set of possible variations. The interesting fact is that the computation is very
fast as shape parameters are determined by solving a single linear system of equations. The morphing method consists of two steps: (a) Initially a small point-set of anatomical landmarks with known correspondence to the model is digitized. This is used to register and initially predict the patient anatomy to the model. (b) To improve the prediction additional points can be interactively incorporated via iterative closest distance correspondence. A color coded feedback given to the surgeon shows regions where the prediction is accurate and regions where the prediction could be improved.

Results: We have evaluated our method using a series of leave-one-out experiments. Three anatomical landmarks, the femoral notch and the upper and the lower trochanter are used as the set of points to register the model to the patient anatomy. The remaining points are added randomly so that they occupy different locations on the bone surface. The computation time is approximately 1 sec per update. We studied two different correspondence methods for incorporating additional points into the estimation scheme. The first was to use the implicit correspondence implied by the modeling. In this scenario we obtained very good estimates with a mean error of 2.59 mm with as few as 6 digitized points, the statistic cumulated over all leave-one-out experiments. Building a model using a larger training set can enable to get a better estimate even with low number of points. In the second scheme the correspondence was established via closest distance. This is the realistic case, as no correspondence would be available in a real scenario. The mean error across all leave-one-experiments with 6 digitized points was 3.85 mm. The errors were larger due to mis-correspondences and hence more points would be needed to get a good estimate.

Discussion: In this paper we have demonstrated a novel technique to predict the three dimensional model of a given anatomy using statistical shape models. Our scheme is novel in that it operates directly in the PCA shape space and incorporates the full set of possible variations. It is computationally efficient and fully interactive, as additional bone surface points can be incorporated in real-time. There are a number of extensions that we plan to incorporate to this basic idea. We plan to incorporate bone contour points from Ultrasound (US) images. We also plan to incorporate patient variables and measurements from X-ray images into the morphing process. The primary application that we focus is on total hip and knee replacement. The proposed technology brings a variety of advantages to these orthopaedic procedures, such as improved accuracy and safety, often reduced radiation exposure, and improved surgical reality through 3D visualization and image overlay techniques.

References:

HARDWARE-ASSISTED 2D/3D INTENSITY-BASED REGISTRATION

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Introduction: 2D/3D intensity-based registration is to find a pose such that its digitally reconstructed radiograph (DRR) of a 3D image matches a given 2D image. Generating DRRs is an essential part of intensity-based registration. It is a computationally-intensive process, which can be done using volume rendering techniques like ray-casting or texture mapping. This process can be accelerated by using professional hardware such as the VolumePro boards (Terarecon, USA), or by precomputation such as the Transgraph [1] method. Recently, 3D texture mapping can be done using off-the-shelf video cards, and DRRs can be generated in real time without any precomputation. This work examined the use of a consumer-grade video card in doing 2D/3D intensity-based registration of the knee. The accuracy of the registration was compared to a point-based registration method.

Materials and Methods: Two human cadaver knees with soft tissue intact were prepared by implanting at least seven tantalum beads in each of the femur and tibia. The knees were imaged using computed tomography (CT) with a slice thickness of 1.25 mm, for 160 slices. A series of fluoroscopic images were taken at various flexion angles. Each calibrated fluoroscopic image was registered with the coordinates of the implanted beads obtained from CT [3]. The same image was also registered with the CT volume by using DRRs. Generation of DRRs was done by hardware-assisted 3D texture mapping using an NVidia GeForce FX 5800 video card. A preprocessing of the CT was done such that the femur and tibia were separated into two CT volumes, so that only one of the bones would show up in a DRR. This process needed not to be exact as long as no other bone would show up in the CT volume of a particular bone. The CT volume was then transferred to the video card, and by setting the camera geometry according to the information from fluoroscope calibration, a DRR of a given pose could be rendered as if a fluoroscopic image was taken. For the purpose of registration, soft-tissue is not rendered in the DRR. This can be done easily by changing the colour transfer function with a suitable threshold according to the Hounsfield units given in the CT volume. For the intensity-based registration, a single fluoroscopic image was used as in the point-based registration. We used gradient correlation [2] for the similarity measure, which is a cost function measuring how similar a fluoroscopic image is to a DRR. The registration is to find a pose that minimizes the cost function. As gradient information of the similarity function cannot be efficiently calculated, we avoided such calculation by using the downhill simplex method for the minimization. To avoid being trapped in local minima, the initial guess was perturbed a number of times to try registering with a smaller (128 _ 128) image, and the best one was used to register with the full image.
**Results:** With a 512_512_160 CT volume, a DRR of size 128_128, 512_512, and 980_980 (size of the fluoroscopic image) took an average of 0.009, 0.110, and 0.378 seconds, respectively, to generate. A registration took about 5 minutes to complete on a 2.4 GHz PC. Absolute error was calculated by determining the difference of the position between the point-based method and the intensity-based method. For knee 1, there were 32 images, and the mean absolute error (standard deviation) for rotation and translation were 0.70 (0.31) degrees, and 2.08 (1.69) mm. There were 23 images for knee 2, and the errors were 1.78 (1.60) degrees, and 3.00 (2.40) mm. The point-based method has an error of about 1 degrees and 2 mm [3].

**Discussion:** A full-size DRR generated by ray-casting takes close to 10 seconds to compute. The hardware generation is about 25 times faster, and in terms of image quality, there is no noticeable difference between software and hardware generation. Its main advantage over other fast DRR-generation methods is that it does not require any precomputation while image quality is maintained. The errors in the intensity-based registration were comparable to those reported in literature; they were slightly higher because our method used only a single fluoroscopic image for registration, while others use at least two or more different views. However, we found that the errors were higher under certain views, for example, the AP view of the knee. This might be because under the AP view, some characteristic features such as the posterior of the condyles cannot be seen clearly, hence a slight change of position along the sagittal plane may have minimal difference in the resulting images. A number of improvements can be made. For example, the registration took relatively long to complete, as calculating the gradient correlation is an expensive process. We chose it because other similarity measures did not perform as well for the data we had. It is generally believed that there is no single measure that is suitable for all cases, therefore one could try combining other measures to make it more versatile. A better searching algorithm would also help in this aspect, especially in overcoming the problem that there are many local non-global minima.

**Conclusion:** Generating DRRs using hardware is an effective way of speeding up this process. With no degradation in image quality, they can be used in intensity-based registration. Results in here showed that our intensity-based registration method using a single DRR has accuracy comparable to those reported in literature. Future works will focus in exploring more efficient search algorithms and similarity measures.

**References:**

THE INFLUENCE OF IMAGE DATA OF CONVENTIONAL CT, CT TRAUMASCAN AND ISO-C-3D TO ACCURACY DURING PEDICLE SCREW PLACEMENT – AN EXPERIMENTAL STUDY

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Introduction: The full potential of CT based navigation dependent on the registration. Pair point landmarks must be determined preoperative on the CT images. For surface registration landmarks are not necessary. Due to the introduction of multi slice CT scanner this investigation become quickly. In polytrauma patients a so called traumascan including the whole body is possible within minutes [1]. This scan use higher slice distances. The question is if these CT data are as precise for navigation as CT data for normal scanned spines. The Iso-C-3D (Siemens AG, Erlangen, Germany) is connectable to a navigation system to navigate in these images. One advantage of this technique is that no registration process is necessary. The aim of this study was to evaluate: 1. the influence of the CT scan protocol to the accuracy. 2. the influence of different placement of the surface registration points to the accuracy within CT based navigation. 3. Comparison of CT based vs. Iso-C-3D based navigation within the spine.

Methods: The Surgigate system (Medvision, Switzerland) was used. A model (Synbone, Switzerland) of the spine were marked at level T4, T8, T12, L2, L4 with titanium markers. Furthermore pedicle screws were placed and removed so the canal is visible. A CT scan (Volume Zoom, Siemens, Germany) of the spine was performed. Two scan protocols were used: 1. a spine protocol including one vertebra above and one vertebra below. 2. a CT scan of the whole model using the traumascan protocol. Pair-Point-registration was performed using five anatomical landmarks at the posterior vertebra. Surface registration was performed using symmetric and asymmetric protocols at the posterior vertebra. The Surgigate system enables to verify the accuracy of the registration. In our experiments we used a “reversed verification”. A special holder was used allowing a three dimensional manipulation until the displayed pointer hit a selected point on the navigation monitor. The holder was fixed and the distance in reality was measured with a calliper (Mitutoyo Inc, Aurora, Illinois, USA). As landmarks the titanium pin marked points at the vertebra were used. Afterwards trajectories were planned within the pedicle screw holes.
pedicle awl was placed into the canal and a screen shot was performed and a print out was done. The difference of the planned trajectory and the visualisation of the pedicle awl were measured.

**Results:** Comparing the overall accuracy the deviation at the marked points was 0.9 mm (0-4.09) using the normal dataset vs. 1.16 (0-8.23) using the traumascan. The difference comparing the planned trajectories with the image of the pedicle awl revealed a deviation of 0.3 mm (-4.1.5) with conventional CT vs. 0.1 mm (-2.4) with the traumascan. A negative value means a medial deviation. The craniocaudal deviation was 1 mm (-3.5) for conventional CT vs. 0.7 mm (-2.3) with the traumascan. A positive value means a cranial deviation. Medial and lateral deviation of the angle between the planned trajectory and the image of the pedicle awl was 0.1° (-4.2) in conventional CT and 0.2° (-1.5-5) with the traumascan. The craniocaudal deviation was 1.2° (-2.6) in normal CT and 0.8° (-4.5) with the traumascan. The different registration methods did not have an influence for the accuracy. The accuracy using Iso-C-3D images showed an accuracy of 0.5 mm (0-1.9) within the reversed verification. The difference comparing the trajectories with the image of the pedicle awl revealed a deviation to medial or lateral of 0 mm (-4.1.5) and a craniocaudal deviation of 0.2 mm (-2.3). Medial and lateral deviation of the angle between the planned trajectory and the image of the pedicle awl was 0° (-1.1) in and 0.7° (-2.3) for craniocaudal deviation.

**Discussion:** Pedicle screws should be placed within the axis of a pedicle and should use the whole diameter [3]. The pedicular canal should be in a trajectory straight through the pedicle. Pitfalls during navigation might occur during registration. The surface of the vertebra might not be calculated correctly due to an osteoporotic bone or other artifacts. With an incorrect surface calculation the registration will not be correct and the position of the instruments might be calculated incorrect. Within this study a spine model was used so this mistake can be excluded. In a prospective randomized study Laine [2] showed significant reduced misplacements with computer navigated pedicle screw placement. There is no doubt that the pedicle screw placement with the use of computer assisted navigation is more precise than the placement in conventional manner. Our study showed that CT based registration might be inaccurate and there is still the need for intraoperative fluoroscopy control. Iso-C-3D based navigation is more accurate than CT based navigation. The reason therefore might be that no registration is needed. One disadvantage might be the limited image quality. Further clinical studies have to show the supposed benefit of the intraoperative three-dimensional navigation with ISO-C-3D in spinal pedicle screw placement.

**References:**

A CUTTING GUIDE POSITIONER
ROBOT TO IMPROVE BONE-
CUTTING PRECISION IN KNEE
OSTEOTOMY

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Objectives: The main objective of this project was to develop a robot device to provide mechanical guidance for a saw or a drill in a range of orthopaedic applications. This paper describes a study aiming at assessing the performances of this robot device – called BRIGIT – in knee osteotomy procedures.

Background: A knee osteotomy is a procedure in which a section of bone is removed from either the upper tibia or distal femur in order to change the loading conditions at the knee or to remove a tumour. One of the major difficulties with knee osteotomies arises from the fact that the result is not always predictable. The major suspected reason for this unpredictability is that it is difficult to attain the desired correction angle. Numerous long-term clinical studies have shown that significant errors in the angle of correction after operation could be observed. Recent results have suggested that more precise execution of the osteotomy could greatly contribute to produce longer-lasting knee osteotomies\cite{1,2}.

Design/Methods: BRIGIT (Bone Resection Instrument Guidance by Intelligent Telemanipulator), is a surgical robot used for optimal positioning of a guide providing mechanical support for a saw or a drill. BRIGIT is a compact 6 degree-of-freedom robot system mounted onto a wheeled trolley, together with its control software. Adequate position of the guide is derived from three-dimensional calculations performed from desired surgical planning parameters and spatial positions of anatomical landmarks. Pinpoint collection of anatomical landmarks is carried out with BRIGIT surgical robot and its pointing end effector device. Indeed, while offering ultimate rigidity indispensable for accurate and steady support of the guide, BRIGIT surgical robot can also be shifted into a “cooperative mode” where the surgeon can manually move the arm anywhere in the operating field by simply grabbing the tip. The study presented in this paper is carried out with dry bones and a prototype version of BRIGIT.

Using BRIGIT robot in a “cooperative mode” and its pointing device, the first step consists in locating a series of anatomical landmarks (to determine the anatomical axis of the tibia) and the level of the upper resection plane parallel to the plateau.
Then, the surgeon inputs the desired correction angle thanks to a user-friendly graphic interface. The cutting guide now replaces the pointing device. BRIGIT surgical robot precisely positions this cutting guide where the upper resection should be done. Once the saw cutting completed, BRIGIT now moves the cutting guide to the position where the second resection should be done. The bone wedge is removed, measured and compared with the desired correction input to the system.

**Results:** This paper presents an in vitro study of robot assisted high tibial osteotomy without addressing any surgical navigation issue: the planning is done the conventional way without support of any kind of image-guided system. The study focuses uniquely on assisting surgeons optimising the actual bone cut. Although not fully available, the results obtained so far are very encouraging.

**Conclusions:** We have developed a robot assistant to provide mechanical support for a saw or a drill in a variety of orthopaedic applications. The bone-cutting accuracy outlined with this dry-bone study needs to find confirmation at the occasion of a cadaver study before being tested in clinical trials.

**References:**

DETECTION OF THE FUNCTIONAL KNEE CENTER USING THE MEAN HELICAL AXIS : APPLICATION IN HTO

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Introduction: HTO (High Tibial osteotomy) is an efficient treatment of osteoarthritis in minor cases, and for young patient. The main goal of this procedure is to align, in the frontal plane, the center of the hip (H), the center of the knee (K) and the center of the ankle (K). In order to achieve a good long term clinical result, one must be able to obtain a post-operative HKA angle in between 183° to 186° [2]. However these results are very difficult to obtain since the surgeon has no control on the location of center of the joints when he is performing the correction. In order to increase the accuracy of such procedure we developed a computer assisted surgical protocol (CASP). In this application one is able to plan the needed correction in 3D and to guide the surgeon intra-operatively to perform the planning. The key issue of the software relies on the ability to provide an accurate 3D location of the hip, knee and ankle centers. Since the surgery is performed without opening the joint itself, the center of the knee can not be digitized directly onto the bone. One had therefore to implement a kinematics approach and to asses its accuracy.

Material and Methods: All data, experimental, as well as surgical data, have been acquired with the help of a passive optical tracking device POLARIS (NDI©) integrated into the SURGETICS© system from PRAXIM©. Definition of the reference system: We performed our first test on two plastic models of the leg. T and F trackers have been set up on the femur and tibia. Several anatomical landmarks have been acquired: the morphological ankle center “MAC”, the tibia center “MTC”, the internal condyle “IC”, the external condyle ”EC” and the femoral center “MFC” using the P tracker. The functional hip center “FHC” was obtained thanks to a kinematic approach. The position sequence of FTRS was used to compute the less moving point in the femoral reference system; this point was used as the FHC. The IC, EC, MFC and FHC were used to build the femoral reference system “FRS”, which was referenced to FTRS. The IC, EC, MTC and MAC were used to construct the tibia reference system “TRS”, which was referenced to TTRS. Acquisition of morphologic data: To obtain a three-dimensional shape of tibia and femur we used a method based on the registration of sparse point data with a 3D statistical deformable model “Bone Morphing” [1]. The points used for the registration were obtained using the P tracker and projected on TRS and FRS. Acquisition of kinematics data and localization of the knee center: During two flexion-extension movements of the knee
joint, the sequence values of FTRS “FTRS_i” and TTRS “TTRS_i” have been recorded. Each TTRS_i was projected on FTRS_i. The result was a system sequence referenced to FTRS (“PRS_i”, Projected Reference System). The PRS_i’s sequence was then divided into 4 groups (2 flexions and 2 extensions). In each group, an instantaneous helical axis sequence “ISAS” was computed using the method developed by SOMMER [3]. For each sequence the mean helical axis “MHA” was computed. The mean of all MHA was used as the functional knee axis FKA. Then, the intersection between the femoral model and the FKA was computed. The mean external intersection “MEI” was used as the functional knee center “FKC”.

**Assessment based on clinical data:** Description of patient data: Morphologic and kinematics data acquired during computer assisted ACL reconstructions in 27 patients were used to assess the accuracy of the proposed method.

**Results:** To assess the accuracy of FKC and FKA, we have computed the relationship between the axis FKC-MAC (Empirical Tibia Axis “ETA”) and MTA. The angle MKA-FKA allows computing the influence of a HTO performed using the Empirical Tibia Plane “ETP”, on the morphological tibia plane “MTP”. We obtained the mean following values for sawbones: MTA-ETA 0.57° - MKA-FKA 2.36° and for clinical cases MTA-ETA 0.94° MKA-FKA 3.77°.

**Discussion:** In the saw bone test we found a highly concordance between ETA and MTA. According to these results, the ETA is a valid approximation of morphological tibia axis. The concordance found in the clinical test is not the same as the one computed in the saw bone. However, it is acceptable to use the ETA like an approximation of MTA, since the final consequences on the HKA clinical axis are very low. The maximum angle between the ETP and MTP for the clinical test performed is 7.74°, and we demonstrated that with such a difference the final error on the mechanical axis is as low as 0.5°. Therefore one can say that this kinematics approach can be used to provide robust data on the knee center location.

**References:**

SURGICAL PLANNING OF
BIPLANAR OSTEOTOMY USING
STEREORADIOGRAPHY AND
COMPUTED TOMOGRAPHY: A
CASE STUDY

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Introduction: We present hereafter a computer simulation to blueprint biplanar osteotomy, by combining 3D-reconstruction obtained from two modalities.

A 17 years old girl, with a severe congenital scoliosis (hemivertebra of L1), suffering from low back pain, was planned for surgery. There was an important kyphosis of 72° at L1 level with a slight imbalance in the coronal plan. A biplanar osteotomy was decided at this level in order to correct the deformity. However, due to the important 3D-deformation of the spine, a classical surgical planning was believed as misfit.

The surgeons had two matters: First of all, is-it possible to tune the osteotomy parameters using computer simulation, based on 3D reconstruction of the spine? Secondly, how will be the patient post-operatively, i.e. will she be able to recover an acceptable spine balance?

In order to set osteotomy’s angle and orientation, a computer simulation was decided, mainly based on a stereoradiography exam. Stereoradiography is a method from which 3D reconstruction of the bones shape can be obtained with a good accuracy [1,2] from two radiographs (frontal-lateral), in free standing position. However, as the vertebral deformation was difficult to assess at the hemivertebra location from stereoradiography, we used computed tomography to obtain complementary information at this location. Preliminary results are presented hereafter.

Materials and Methods:

Data acquisition:

Pre-operatively, four exams were collected from the patient:

A stereoradiographic acquisition (from head to knees, free standing position), realized on a low dose digital imaging device (EOS™, Biospace, Paris France), in the Saint-Vincent de Paul Hospital (Paris, France),
A millimeter CT-scan imaging of the thoracolumbar region (supine position),

Right and left lateral bending (supine position),

MRI of the intervertebral disc to assess their degenerative grade.

Post-operatively, a stereoradiography was realized in Pellegrin Hospital (Bordeaux France).

Data processing:

A highly detailed reconstruction of the T11–L3 segment was realized (Slice’O’Matic, Tomovision, Montréal, Canada) using the CT-scans cuts.

Detailed 3D-reconstruction of the spine and the pelvis were obtained in free standing position from stereoradiography (@sterX software, Biospace-LBM-LIO, Paris, France).

The 3D models resulting from the CT-scan reconstruction were superimposed on the 3D-reconstruction in standing position obtained from the stereoradiography.

Surgeons evaluated intervertebral disc degenerative grade from MRI. Vertebral mobility’s were calculated from pre-operative lateral bending using SpineBalance software (Surgiview-LBM-LIO, Paris, France). These values will be used to set maximum compensation angle thresholds in the last simulation step.

Computer simulation:

A graphical interface using Matlab (The MathWorks, USA) was created in order to plan surgery. 3D-reconstructions were displayed on the screen, and could be manipulated by the surgeon in order to examine the spine of the patient in free standing position. Simulation was realized using the following steps:

The surgeons interactively defined (using the positioning of the 3D camera on the reconstructions and mouse clicks) the superior osteotomy plane. Intersection of the superior osteotomy plane and the vertebral body defined a contour from which is extracted a 3D-point, which will be used to define the pivot osteotomy axis in the following step.

The surgeons adjusted the orientation of the axis of the osteotomy.

The angle of the osteotomy was then defined. A real time graphic display showed the positioning of the superior part of the spine (i.e. the vertebrae above the osteotomy level), considering the osteotomy’s angle and orientation (Figure 1, left image). Osteotomy parameters could be adjusted until the surgeon validates them.

Finally, post-operative compensation possibilities of the spine were estimated. Considering the positioning of the spine after osteotomy, the surgeons could interactively define for each vertebral segment the intervertebral compensation rotations, in
the sagittal and frontal planes. Compensations were defined to be within preset range values obtained from pre-operative bending in the frontal plane. For the sagittal plane, the surgeons estimate from MRI the quality of the intervertebral discs and fixed acceptable angle thresholds. This procedure allowed the surgeons to validate the osteotomy parameters.

The surgeons visualized the two planes of the osteotomy on the virtual 3D-models (figure 1, middle images), and memorized anatomical landmarks, in order to retrieve them during surgery. Moreover, a stereolithography model of the T12-L2 vertebral segment was created and gave to the surgeons.

**Results:** The graphical interface was created and allowed the surgeon to test several osteotomy solutions within minutes. Finally, a 50° osteotomy was planed for surgery, using simulation. Per operatively, the surgeons had no difficulties to reproduce osteotomy parameters (i.e. position and orientation of the osteotomy planes), as they could easily retrieve anatomical landmarks they memorized before surgery. Correction was obtained without major problems in the sagittal plane, but was incomplete in the coronal one. In post operative course, thoracolumbar curves were similar to those obtained with the computed simulation (including compensation simulation), with good restoration of the sagittal balance. Figure 1 (right image) shows a sagittal view of the spine before and after surgery, where 3D reconstructions were superimposed using the pelvis reconstruction.

**Discussion:** In such a severe congenital scoliosis case, computer simulation revealed to be appropriate to plan biplanar osteotomy. The surgeons could visualize the 3D-spine model in free standing position obtained from stereoradiography where the highly accurate scanner reconstructions were replaced. They could evaluate in real time the influence of the osteotomy parameters, and therefore realize a fine tuning of those.

The T12-L2 angle (superior endplate of T12 to inferior endplate of L2) was underestimate when measured on radiographies (72°) compared to the 3D-reconstruction (85°), because maximum deformation was not in the radiological plane. One could think that if surgery was directly planed on radiographs, underestimation of the osteotomy angle would have lead to unsatisfying clinical results.

Per operatively, the surgeons could not achieve complete correction in the coronal plane, because of the stiffness of the spine. Post operatively, we understood the possible reason: As the pivot axis was defined as the intersection of the two osteotomy planes intersection (figure 1, middle images), the part of the tissue beyond this axis were distracted during osteotomy reduction. Figure 1 show the area distracted during this reduction (middle-bottom image, stripped area). One solution would have been to keep the plane orientations, but to cut slightly above (resp. bellow) the superior (resp. inferior) plane, thus translating the pivot axis behind the vertebral body. In such case, the tissues would not have been distracted, and the surgeons would have achieved the complete correction.

**Conclusion:** We believed that biplanar osteotomy can be efficaciously blueprint from 3D reconstruction obtained from stereoradiography, as it is possible to evaluate
the patient capacity to recover an acceptable balance after surgery. Combining 3D reconstruction from stereoradiography and CT-scan allowed the surgeons to precisely memorized anatomical landmarks, in order to faithfully reproduce what was planed.

In conclusion we think that this computer assisted surgery planning is useful, to avoid errors in the correction of the spine balance, and to optimize the surgical procedure, by choosing the most appropriate plans for osteotomy, in order to reach the most satisfying correction.

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**References:**

Figure 1. **Left:** Graphical display of the spine before and after osteotomy (but without compensation). **Middle:** T12-L2 vertebral segment before (up) and after (bottom) osteotomy; the striped zone correspond to the anatomical area distracted during the reduction of the osteotomy. **Right:** Lateral view of the spine after surgery (red, or dark gray) compared to before surgery (green or light gray), when superimposed using the pelvis.
A NEW APPROACH FOR PLANNING SURFACE REPLACEMENT PROSTHESIS SURGERY ON THE HIP

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Introduction: To avoid the implantation of total hip prostheses in younger patients or at least postpone the procedure, the implantation of a surface prostheses is used as an alternative. Preserving bone structure this type of primary intervention provides an additional option for revision.

Background: During conventional surgical planning a standardized radiograph of the entire hip in frontal view is used, often supplemented by Lauenstein view. Computer tomography (CT) is usually not needed. The desired size and position of the implants are determined by means of a x-ray template. Much attention is paid to the bio-mechanically correct adjustment of the central drilling. For a long life time of the prosthesis as well as a good mobility of the hip joint this must be optimized to the physiological conditions. For the preparation of the femur and the adjustment of the prosthesis, a mechanical aiming instrument is attached on the femur, which defines the planned prosthesis axis on the basis of two values: the distance measured on the radiograph from the trochanter major to the point of hanging up the mechanical instrument at the lateral femur and the centre of the femur neck. The center of the femoral neck is determined by a probe cirumscring the femoral neck. This procedure is time-consuming due to the complicated application of the device, limits the accuracy and does not guarantee a central placement of the drilling in the bone. To exclude possible corticalis damage intraoperative fluoroscopic control is used. However, 2D-Xray control as such does not guarantee the central position of the drilling in the femoral neck [2].

Method: Depending on the operation-specific boundary conditions a planning and navigation system was developed, which uses intraoperative calibrated X-ray images as data basis and an optical tracking system. After analysis of the conventional procedure including the boundary conditions of the operation planning the following points were identified: 1. The shaft of the prosthesis must run completely in the femoral neck and has to be the bone surface only up to a biomechanical minimum distance 2. Within the prosthesis head, sufficient healthy bone substance must be present, in order to provide a stable anchorage of the femoral head coverage 3. A slight valgus position is generally recommended, where the rotation center of the
prosthesis is situated above the top point of the trochanter major 4. Impingement must be prevented. Underlying geometrical dependencies can be identified using a sphere model for the femoral head and an attached cylinder model for the femoral neck (see illustration). From the conditions specified above and the cylinder-sphere-model an information management can be derived, which leads to a successful positioning or identifies incorrect user input conditions. The graphical user interface based on these realizations and visualizes a cylinder sphere model on the intraoperative x-ray images. The surgeon can manipulate the model using a touch-screen, although not all degrees of freedom are permitted. In the master picture a shift and a rotation of the model parallel to the x-ray projection are allowed. In the other pictures the positioning can only be shifted on the virtual x-ray of the master picture. Additional functions such as transparency alternation and scaling of the model help the surgeon when approximating the anatomical structure of the proximal femur. The position of the prosthesis is controlled by an overlayed model. The information about the size of the prostheses is colour coded according to the surgical instrument set. The planning system is organized sequentially and guides the user from the picture acquisition over the planning of the drilling up to the navigated execution.

**Results:** The accuracy of the planning system was validated in a laboratory study. As potential sources of error the calibration of the intraoperative x-ray images, the planning procedure with the limited resolution of the images as well as the navigation procedure including the calibration of the tools were identified. The investigation should include those sources of error. As in the conventional medical planning procedure with the help of the cylinder sphere model a drilling was planned in X-ray images. A test body was used consisting of PUR foam with a size of 18x8x10cm_. The test specimen was surrounded by wooden plates with 26 iron spheres (1mm diameter). After the image acquisition of the test specimen the plates with the sphere were removed from the building foam and replaced with the plates without markers. For the trials with test users drilling with 3mm diameter was supported by the navigation system. Afterwards the distance between the steel sphere positions and the start and end points of the drilling as well as the angle deviation of the drilling and of the planned direction were compared. The deviation between the position of steel spheres and start/end points of drilling averages 2,5mm and the angle deviation 2,0°. The use of a 6mm drill reduced the average deviation to approx. 2mm.

**Conclusion:** The integration of simplified deformable 3D models for the approximation of the individual anatomy in intraoperative 2,5D radiographs allows an accurate positioning of the surface prostheses. Due to additional information based on the model such as the outer bone surface, user errors during the planning can be prevented. Better accuracy can be achieved by the use of a drilling sleeve. The system proved its suitability in the laboratory. The evaluation on anatomical specimens is the subject of current work, in order to prepare clinical studies. Results will be presented.

**References:**

AUTOMATED PREOPERATIVE 3D PLANNING OF ACETABULAR CUP POSITIONING AND SIZE SELECTION IN TOTAL HIP ARTHROPLASTY USING CT DATA

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Introduction: Conventional preoperative planning for total hip arthroplasty (THA) has been typically performed by superimposing implant templates onto a scale-normalized 2D X-ray image. While manual operation of 3D implants models on 3D CT images is useful for intuitive understanding of spatial relations between implants and bones, it is still difficult to objectively evaluate the suitability of implant size and pose based on various factors from 3D visualizations of the spatial relations. To address the above problems, we have developed an automated THA planning system based on 3D CT data, in which objective criteria are defined and implemented as a computer algorithm to determine the optimal size and pose of implants [1]. In this paper, we describe an acetabular cup placement subsystem in automated THA planning. An improved method is presented for the determination of size and position of the acetabular cup. The center-edge angle and the thickness of the medial wall are newly incorporated into the optimal determination procedure of the cup position.

Methods: We assumed that a segmented 3D model of the pelvis reconstructed from CT data was available, and the pelvic coordinate system was determined on its 3D models using the methods described in [2]. In addition, the acetabular rim contour of the pelvis model was assumed to be extracted. The pelvis segmentation was performed by a semi-automated method, and the rim contour was manually extracted in the experiments. The abduction and anteversion angle of the acetabular cup were fixed to 40 and 20 degrees, respectively, which are considered to minimize the risk of dislocation. It was assumed that the cup shape was hemisphere and its size was from 40 to 60 mm with 2-mm pitch. To evaluate the fixation strength of the cup, two parameters were considered. One is the cup coverage ratio, which is defined as the ratio of cup surface covered by pelvic bone tissue to the whole cup surface. The other is the cup CE angle, indicating the coverage of upper portion of the cup where the stress concentrates. We also measure thickness of the medial wall so as not to break the inner cortex of the pelvis. Considering these factors under the above assumptions, the position of the cup were determined. The cup size is given by the distance between two intersection points of the acetabulum rim contour.
**Results:** We used four preoperative CT data sets of the dysplastic hip patients. The cases of prominent osteophyte were not included in these data sets. To evaluate the method, we compared the final solutions of cup size and position determined by the proposed method with those determined by an experienced surgeon. The surgeon used a 3D interactive THA planning system to determine the cup size and position. It took around one minute to obtain the final solution of cup size and position by the computer program implemented on Windows XP, Pentium4 2.4 GHz. The average (maximum) difference in cup position was 1.7 mm (2.0 mm). In the determination of cup size, the size was the same between the automated method and the surgeon in two cases, and the maximum difference was 2 size.

**Discussion:** The surgeon evaluated that the final solutions of the automated method were acceptable except one case, which showed a potential usefulness of the automated method. In the one failure case, the cup position determined by the automated method was close to that of surgeon. However, the cup size was two-size larger, and perforation of the anterior wall of the acetabulum was observed, based on which the surgeon judged it as failure. In the failure case, a large osteophyte existed, and the surgeon extracted it as the acetabulum rim contour. This problem may be potentially avoided by incorporating thickness measurement of the anterior and posterior walls and violation detection of them in the cup size selection procedure. Although the automated method has not been clinically applied yet, we consider the method to be applicable for clinical use since it only required around 10 minutes for the manual operation to extract the acetabular rim contour. Further, the reproducibility of the manual extraction of the acetabular rim contour is expected to be high since it is a distinctive anatomical feature.

**Conclusions:** We have described an automated planning method in acetabular cup placement and size selection in THA. The method was evaluated by comparison with an experienced surgeon planning results. We confirmed that the method could be applied to secondary osteoarthritis due to hip dysplasia. Future work will include the validation of the method using more cases and its clinical application.

**References:**

COMPUTER MODEL-BASED STUDY FOR MINIMALLY INVASIVE THR FEMORAL CAVITY PREPARATION USING THE ROBODOC SYSTEM

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Background and Objectives: Minimally invasive Total Hip Replacement (THR) surgery has been shown to result in less pain and more rapid recovery [2]. For THR surgery, there is some minimum access volume required for the instruments, manual or robotic, to prepare the cavity, and for the prosthesis to be inserted. This access volume is important for determining surgical exposure and incision size. The smaller the required access volume, the smaller the requirement for the incision size and vice-versa. However, smaller incision sizes result in additional challenges for manual surgery since the surgical area directly exposed to the surgeon is smaller. The ROBODOC system, that has been shown to provide improved fit and reduced complications such as intra-operative fractures [1, 3], uses pre-operative CT imaging data to determine the cavity preparation position in the femur. Following intra-operative registration of bone surface data to CT image data, the ROBODOC system knows the femur location, and once directed close to the start of the femoral preparation area, completes the cavity preparation on its own. Therefore, we believe that application of the ROBODOC system for minimally invasive surgery has the best potential for improved clinical outcomes by providing the combined benefits of precise cavity placement and preparation, and reduced incision size, while avoiding some of the visualization challenges of manual minimally invasive THR surgery. The aim of this study is 1) to compare the ROBODOC cutting access volume required, to the access volume necessary for manual cavity preparation and 2) to model the minimally invasive incision size required for THR femoral preparation using the ROBODOC system.

Materials and Methods: Fifteen computer models, five each for three different “straight” cementless press-fit implant shapes were used. Proprietary ISS software algorithms were used to determine the minimally invasive cutting access volume required for the ROBODOC instruments to prepare the femoral cavity. The inputs for these software algorithms were the three-dimensional model of the femoral cavity to be prepared for the implant, and the models of the robot instruments, such as cutters etc., used for femoral cavity preparation. These algorithms were designed to keep the cutting access volume medial to the greater trochanter and to minimize the cutting access volume at the modeled surgical incision site. The incision site was modeled to be 75mm superior to the tip of the greater trochanter in a direction along the femoral shaft axis (or the distal implant axis). Also, the femoral shaft axis was assumed to
intersect the incision site within 20 – 40 degrees of the tangent surface at the incision site. Similarly, the implant insertion access volume was defined as the volume swept out by the prosthesis traveling along the most medial insertion path. For these studied implant shapes, the rasp geometry is not significantly different from the implant geometry. Therefore, it is reasonable to use the implant insertion volumes as equivalent to the manual cavity preparation volume. To compute the lateral limit of the two access volumes at the location of the greater trochanter tip, both, the cutting access volume and the implant insertion access volume were intersected with an axial plane perpendicular to the implant (or femoral shaft) axis at that location. The lateral limits of these intersecting contours were then measured and compared. Statistical analysis using one-way ANOVA for three independent samples was also completed. To compute the incision size for ROBODOC femoral preparation, the cutting access volume was intersected with the tangent surface at the modeled incision site, and the cross-sectional circumferential length computed for the resulting intersection contour.

**Results/Discussion:** For the studied implant shapes, at the greater trochanter tip area, where the abductor muscles attach to the bone, the ROBODOC cutting access volume lateral limit was more medial and therefore less invasive than the manual cavity preparation access volume. The average number by which the ROBODOC cavity preparation access volume was less invasive for different implant shapes was 2.36 mm, 8.36 mm and 3.9mm respectively. Statistical analysis results (p < 0.002) showed that the average depended on implant design.

The primary implant geometry design parameters that appear to affect both, the cutting access volume and the implant insertion access volume, are the implant length, the shape of the medial side, and the extent, if any, of a lateral “flare.” However, we have not carried out a separate analysis to quantify the affect of the different implant geometry design parameters on the implant insertion volume and the ROBODOC cutting access volume. Typically, though, longer implants require both the volumes to be straighter and less medialized.

For all implant shapes, the computed cross-sectional circumferential length was less than 50 mm (or 5 cm) at the incision site for the minimally invasive ROBODOC cutting access volume. Therefore, an incision of half that size or 25 mm, is sufficient for the ROBODOC system to prepare the femoral cavities for the studied implant shapes. The incision size does not appear to depend on implant design, rather it appears to depend on the ROBODOC femoral cavity preparation instruments.

**Conclusions:** For the studied implant shapes, the access volume required for ROBODOC cavity preparation is always less invasive than that for manual preparation at the site of the attachment of the abductor muscles. Additionally, with the ROBODOC system, this theoretical study has shown that it is possible to achieve incision sizes as small as 2.5 cm for the implants studied. Therefore, it appears that the ROBODOC instrumentation for cavity preparation may require a smaller incision size than that required by current manual instrumentation for minimally invasive femoral cavity preparation.
References:

CT-BASED-EVALUATION OF THE 3-DIMENSIONAL CUP POSITION AFTER NAVIGATION-ASSISTED THA

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Introduction: Several navigation systems are now available for THA. We need CT-based navigation THA systems to treat Japanese osteoarthritic cases, because Japanese osteoarthritic hips often have severe pelvic deformities due to developmental acetabular dysplasia. It is impossible to evaluate the 3D cup position in the post-operative X-ray films after navigation THA and few are known about the post-operative 3-D cup position. In this study, we evaluated the 3D cup position of the patients underwent the navigation assisted THA using the post-operative pelvic CTs and the CT-based planning software, VectorVision Hip.

Methods: We evaluated 30 patients (28 females and 2 males, average operative age was 58.1 years old) who underwent the navigation assisted THA since October 2002 to December 2003. Preoperative diagnoses were all secondary osteoarthritis of hip joints. We used VectorVision® Hip version 2.0 (BrainLAB, Germany) for the preoperative planning, the navigation THA, and the post-operative evaluation using the post-operative CTs. Only cup navigation is available in Japan. We used Trilogy® cups, Versys Tivanium® TI-6AL-4V alloy stems, and Zirconia femoral heads (Zimmer) to minimize the metal haloation in the post-operative CTs. Preoperative planning: The pelvic CT data of 1.25mm slices were used to perform 3-dimensional preoperative planning THA using the VectorVision® 2.0. We used the anatomical pelvic plane defined by the bilateral anterior-superior iliac spines (ASIS) and the symphysis pubis to determine the cup inclination and anteversion. The cups were placed at 45° of inclination and 25° of anteversion based on this plane in the primary acetabulum. We chose the maximum cup size according to the anterior-posterior width of acetabulum. The depth of acetabular reaming was determined not to penetrate the inner wall of the acetabulum. Navigation THA: We performed navigation THA though direct lateral approach for cup replacement according to the pre-operative planning. The registered acetabulum was reamed to 2mm under size of the preoperative planning, and Trilogy® cup with cluster-holes were placed using an implant holder and a mallet. Postoperative evaluation: We took the post-operative CTs with the same condition as the pre-operative ones to simulate THA with these data. The cup inclination and anteversion were measured by adjusting the CAD cup on the real acetabular component in the software console. We compared the differences of cup position between the pre-operative planning and the post-operative cup position by measuring the 3-D hip center of the cup using a CAD software (Rhinoceros®, Robert.
McNeel Associate). We defined the coordination system as follows, the x-axis as a connecting line of the bilateral ASIS, the y-axis as a rectangular line of x-axis on the anatomical pelvic plane, and the z-axis as a perpendicular line against the x-y-plane for the following measurements. We defined the coordination (X, Y, Z) as the hip center and (ΔX, ΔY, ΔZ) as the difference of this coordination.

Results: The error range and average of the cup inclination were 0~13° and 4.3°, respectively. The error range and average of the cup anteversion were 0~26° and 9.1°, respectively. The error range and average of the hip center (ΔX, ΔY, ΔZ) were (1~9 mm, 1~11 mm, 0~11 mm) and (4.7 mm, 3.2 mm, 3.7 mm), respectively.

Discussion: This navigation system enables us to evaluate the post-operative 3-D cup inclination, as well as to simulate and navigate THAs. However, we cannot measure less than 1° in this system. In addition, we need the other CAD software to evaluate the 3-D position in this workstation. And the planning procedure was time consuming (over at least 20 min for each case). Our results showed that the deviations between the pre-operative planning and the measured position were < 9° and <5mm. DiGioia M, et al. performed 20 cases of navigation THA with the same Trilogy Cup and evaluated the cup position using 2-dimensional X-ray films in which the pelvic tilt was standardized. Their error ranges of the cup inclination were 3-9° (average 7.2°), and the cup anteversion were 1-11° (average 4.8°). Our data also support their hypothesis for possible mechanism for the change in acetabular cup alignment that a rounded impaction surface of an implant holder design may drive the guide off alignment when hit with the mallet. In addition, the final shape of the reamed acetabulum may force the cup orientation to conform to the reamed cavity and change the final alignment as impaction occurs or significant changes in pelvic orientation occur with each blow of the mallet. Appropriate devices should be newly developed instead of the present cup holder or the mallet. In some case, the references displaced during the THA procedures. The fixation tools for the references should be improved and we have to develop a monitoring tool to check the reference position during the surgery. We have to look at the monitor when we check the position of surgical tools during the navigation THA. To improve the accuracy of the navigation, the surgeon’s view should be fixed on the operative field. The alignment guide using laser beam developed by Dr. Sugano, or the special projector that is available in the field of neurosurgery to superimpose the operative field and navigation console will be options to fix the surgeon’s view on the operative filed. After all these feedback data will change and improve the navigation technology and spread it into clinical field.

References:

Introduction: The purpose of this research is to propose a compensation method using C-arm image to minimize the error, which occurs in the measurement of pelvic landmark percutaneously. Hip navigation systems are classified by their registration method; CT based and CT free navigation systems. In the former case, navigation system, either using pin based registration or geometry based registration, require 3D CT/MRI image of the patient’s pelvic bone. The latter systems use anatomical landmarks of the pelvis for the registration. Anatomical landmarks are measured percutaneously intra operation. Both anterior superior iliac spines and the pubic bone are used as anatomical landmarks. The anterior pelvic plane determines the orientation of the acetabular cup. Each of two systems have strength and weakness. CT free system can reduce dose of irradiation and charges for an operation, however it is less accurate than the CT based registration. The CT free registration uses palpable landmarks to obtain the pelvic reference system. However, due to existing soft tissue between the skin and the bone, it is difficult to secure the alignment of the implant. Primary source of error include the occurrence of offset caused by the soft tissue. The purpose of this study was to propose an improved CT free navigation system using the C-arm image, which will reduce error caused by the soft tissue. Also, a T-bar shaped gauge was used to improve the accuracy of CT free navigation system.

Methods: Experimental procedures of CT free hip navigation are as following:
1. Calibration measurement devices.
2. Insert DRB (dynamic reference base) to track the moving pelvic reference system into sawbone
3. Palpate anatomical landmarks on the skin of sawbone
4. Compensate offset of soft tissues by using C-arm images
5. Calculate the orientation of acetabular cup

We employed lateral C-arm image to measure the thickness of soft tissue. The offset caused by the soft tissue results an error in a Z-axis direction of anterior pelvic plane. The proposed method uses C-arm image of pelvis to compensate the offset. The large pelvis (saw bone 1301) for the test is covered with silicon gel to simulate the skin. We employed the local distortion calibration method to the C-arm for accurate distance measurement [3]. Custom-designed phantom, which has 49 steel balls, was used to calibrate the C-arm distortion. Evaluation by the same phantom showed accuracy of 0.2mm on C-arm image.
**Results:** The offsets were obtained by the lateral C-arm image of pelvis. Offsets in the ASIS and the pubic were 8mm and 20mm respectively. We compared the conventional method with proposed method using the pelvic reference system defined by positions of compensated landmarks. Accuracy and repeatability of both methods were evaluated as well. In landmarks based measurement, error about Z and X-direction were 1.44 and 0.93 degrees before applying the compensation algorithm. The registration method using the compensation algorithm produced smaller deviations: error about Z and X-direction in the anterior pelvic plane were 0.99 and 0.93 degrees respectively. Also, Errors of orientation in T-bar based measurement were obtained, error about Z and X-direction were 1.33 and 0.95 degrees before applying the compensation algorithm and 1.00 and 0.96 degrees after using compensation algorithm.

**Conclusions:** We analyzed causes of error to improve the accuracy of CT free navigation system. Palpating landmarks seemed to cause significant error. As a result of test, there are measurement deviations by an arbitrary measurement in the landmarks based registration while the T-bar based registration produced 40% smaller deviations(p<0.05). T-bar can reduce arbitrary measurements because probes of T-bar placed on all landmarks at the same time[2]. In addition, Compensation algorithm using the C-arm image reduced errors by palpating landmarks include offset of soft tissues. From our study, we concluded that the offset about the Z-axis on the anterior pelvic plane could be corrected through the proposed method. There exists a negligible difference between the compensated and the actual anterior pelvic plane. The proposed method also can be applied to the conventional system, which uses a method of percutaneous measurement in both hip and knee navigation systems. It can be concluded from our investigation that the compensation algorithm, compared to the conventional method, is more reliable and accurate.

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**References:**

FIRST CLINICAL EXPERIENCES IN STEM NAVIGATION WITH THE SURGEGATE SYSTEM

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Introduction: Early component loosening, excessive wear, leg length inequality, dislocation and subluxation in total hip replacement have been related to component positioning [1,2]. The use of navigation systems in cup placement in total hip replacement is an accepted method of increasing the accuracy of the surgical procedure. It was shown in several studies, that navigation leads to better results in cup positioning than the conventional approach [3]. To achieve an accurate position of the femoral stem as well, especially in relation to the cup position, navigation of the stem is the next step. A laboratory study of computer-assisted femoral stem placement demonstrated the high precision of the Surgigate® navigation system in THR [4]. In this pilot study we evaluated the clinical applicability of the Surgigate® System for stem navigation in total hip replacement.

Methods: The SurgiGATE® navigation system is a hybrid CT-free navigation system. For the pelvis the so-called anterior pelvic plane (APP) concept is used. For the femur the center of the femoral head, the posterior condylar tangential line, and the medullary canal axis of the proximal femur are used. Instrument actions are visualized to the surgeon by superposing virtual instrument representations onto the fluoroscopic images. For stem navigation several extra fluoroscopic images are necessary (proximal femur, distal femur and femoral shaft in anterior-posterior direction and in lateral-medial direction). First the cup is placed in the previous described manner. Following cup placement, a navigated rasp is used for preparing the femoral canal. During the procedure the systems gives online information about the varus/valgus position of the stem in relation to the femoral shaft, the change of leg length, lateralization of the hip joint, the antetorsion of the stem and the inclination and anteversion of the cup. All these values given by the system and the extra time used for the navigation process were calculated. The position of the rasp is given on the screen projected on the fluoroscopic images of the femur. The visualization of the rasp was compared intraoperatively with standard fluoroscopic control images to validate the visualization.

Results: Since August 2003 we implanted 20 stems using the Surgigate System for total hip replacement. The overall operation time was 120 ± 40 minutes, the extra time necessary for acquiring fluoroscopic images and other procedures according to the
navigation process were calculated with 29±5 Minuten. In 4 cases the navigation had to terminate before finishing the operation. In three of these cases the reason was, that it was not possible to get femoral and pelvic DRB in view for the camera at the same time because of decreased rotational movement of the hip. In only one case the values given by the system seemed to be senseless, so the navigation was stopped and the stem placement was continued in the conventional way. The reasons for this remained unclear. The other 16 cases were navigated without any problems. The visualization of the rasping process on the screen was accurate and helpful for the surgeon. Postoperative complications, especially complications related to the navigation procedure did not occur in any of the 20 cases. According to the data acquired from the navigation system the average position of the stem to the femoral shaft axis was 0,5° valgus. The mean antetorsion of the stem was 19°. The mean change of leg length was 6 mm. The cups were positioned with a mean inclination of 18° and a mean anteversion of 47°. The intraoperative visualization of the rasp compared with standard fluoroscopic control images was accurate in all 16 cases.

Conclusions: Stem navigation is an important supplement in total hip replacement. Compared to the standard procedure many parameters of the stem can be calculated and given online to the surgeon to optimize the implantation process. Suboptimal positioning of the stem in means of varus or valgus position in relation to the femoral shaft or antetorsion can be avoided. Our first experiences show that stem navigation is applicable in routine clinical care. Compared with cup navigation alone stem navigation is a technically more demanding procedure, 20 percent of the stem navigations did not work. Furthermore stem navigation is time consuming, even with an experienced team an extra 20 minutes are necessary compared to standard procedures. But in our view this time is well spent because of an increased accuracy and safety of the surgical process. The intraoperative visualization of the rasp is helpful especially in avoiding varus or valgus malpositioning of the stem. CT scans of all navigated stems are planned to validate the data given by the navigation system.

References:

FREEHAND NAVIGATION USING LONGSHAFT TOOLS – COMPARING A FORCE SENSOR BASED DEFLECTION COMPENSATION WITH AN INTRAMEDULLAR SUPPORTING DEVICE

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Introduction: In Revision Total Hip Replacement (RTHR), the removal of the distal femoral bone cement can be a time consuming and risky operation due to the weakened cortical wall and the difficulty in determining the 3D boundary of the cement. Within the MINARO project, funded by the German Research Foundation (DFG), we developed a new approach for fluoroscopic navigation in RTHR with the main focus on the computer guided removal of the femoral bone cement. Instead of navigating within the acquired two-dimensional x-ray images, free hand navigation has been realized providing cross-sections of the cement volume reconstructed on the basis of a three dimensional cement model [1]. A basic requirement for accurate navigation is a sufficient stiffness of the tool to be tracked. In RTHR instruments with a length of about 300 mm have to be used to reach the very distal part of the bone cement volume. Investigations of surgical long shaft milling devices showed that a radial application of common forces to the tool tip result in a deflection of up to 2 – 3 mm. For accurate navigation the position of the (distal) tool tip has to be known with respect to rigid body attached on the proximal part of the tool. Deflections of the tool will lead to incorrect positions shown on the navigation display. Fortunately, this wrong information is not a direct risk for the patient, as the system suggests to the surgeon that he removed more of the cement than he really did. However, measuring the forces and torques applied on the instrument would enable a compensation of the deflection. Based on a calibration of the tool concerning the force/deviation relationship, the correct position of the tool tip can be calculated. Moreover, by using intramedullar stabilization, the deformation of the milling tool could be reduced and handling should get significantly easier. Besides an optimal localization and manipulation of the tool, an adequate graphical user interface is crucial for a successful navigated cement removal [1].

Materials and Methods: To enable force measurement we developed a handle with an integrated 6D force-torque sensor. The tool shaft has been characterized by
applying radial forces from 0 - 20 Newton to the tool tip while determining the deviation with a laser distance sensor. Deflection was about 106 _m / N. We moreover developed a new intramedullar supporting device only slightly increasing the diameter of the tool and enabling an stabilization of the milling process in different levels within the femoral canal. For evaluation a group of test persons removed a predefined model of a distal cement plug with and without force based compensation, as well as using the intramedullar supporting device. The only feedback the test persons received during the process was the position of the tool tip within a two dimensional cross-section through the cement volume at the tool tips position. The measuring setup consisted of a proximal part of a sawbone femur with a cement cylinder (with a cavity of 10 mm diameter) located distally. As removal tool we used a pneumatic power milling device with a tool shaft lengths of 250 mm and a diameter of 8 mm. Finally, after the test persons had removed an elliptical volume of 16 x 12 mm with a length of 20 mm, the resulting cavity has been digitized with an optically tracked probe.

**Results:** Force compensation enables a precise navigation of a long shaft milling tool. The position shown on the computer display correlates with the real tool position with a max. deviation of 1 mm. With the help of the force-torque sensor based compensation the test persons reached an accuracy better than 0.7 mm (RMS) whereas without compensation the error was about 1.0 mm (RMS). Without compensation too few cement has been removed in most cases. The intramedullar supporting device significantly facilitated work and resulted in much better accuracies and efficiency. Even without force compensation the results were slightly better than the results achieved with force compensation only.

**Discussion:** In contrast to the compensation of the deflection of drills and needles, where unknown reaction forces are applied on the entire trajectory within bone, the force compensation in the case of cement removal is feasible on the basis of proximal sensor information due to the force application on the tool tip. However, if the tool collides with the proximal part of the femur compensation gets more complex. The error using the intramedullar supporting device has been that small, because it is better controllable and could be tracked with respect to the milling tool. Together with an ergonomic user interface guiding the user through an iterative processing with decreasing force application, the error due to the deflection becomes negligible. The current design of the intramedullar supporting device allows no processing of very distal parts because it reduces the tool length that can be inserted into the cavity. This problem will be solved by a redesign. In conclusion we can state that both approaches have shown an improvement compared to the conventional navigated tool. Force compensated machining should also be considered for a robot based cement removal.

**References:**

HOST BONE COVERAGE NEEDED FOR CEMENTLESS ACETABULAR CUP FIXATION. 3D-CT ANALYSIS

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Introduction: Press-fit fixation of cementless cups is one of the popular and secure initial fixation methods of total hip arthroplasty, in which a hemispherical cup is impacted into an underreamed acetabular cavity without additional screw fixation [1]. So the stability of the cup is influenced greatly by extent and distribution of host bone coverage. However, minimum extent of host bone coverage needed for press-fit cup fixation has not been reported in detail. To investigate host bone coverage needed for the fixation of press-fit cup, we evaluated host bone coverage of press-fit cup implanted to dysplastic hips with 3D-CT analysis and investigated a relationship between host bone coverage of the cups and their radiological results at final examination.

Materials and Methods: Fifty-five patients (63 hips) with osteoarthritis secondary to hip dysplasia are the subjects of this study. All patients underwent primary THA using hemispheric titanium porous-coated cups (Trilogy; Zimmer Inc., Warsaw, IN) without additional screw fixation. Radiological fixation of the cup was evaluated at final examination by a modification of the DeLee and Charnley classification, according to which cup fixation was classified into bone ingrowth fixation, stable fibrous fixation and unstable fibrous fixation. The average follow-up period was 2.8 years (2-6.1 years). Postoperative computed tomography images were obtained three months after surgery using a helical CT scanner. The slice thickness was 3 millimeters and matrix size was 512. The field of view was 200 millimeters. Two types of multiple plane reconstructed views through the acetabular cup center were made on 3D viewer software (Virtual Place-M; Medical Imaging Laboratory, Tokyo, Japan). First, a CT slice including the cup center was selected and oblique plane perpendicular to a diameter of cup semicircle was reconstructed to cancel anteverision cup angle. On this mid-coronal plane of the cup, to assess the bony coverage in the weight bearing portion, an angle of intersection between the vertical line through the cup center and the oblique line drawn from the cup center to the lateral edge of the host bone was measured and named cup center-edge (cup-CE) angle. Next, oblique plane parallel to a diameter of cup semicircle on the mid-coronal plane of the cup was reconstructed to cancel inclination cup angle. On this oblique plane in contact with the rim, a total of host bone coverage around the rim of was measured as a percentage of the total 360° of the rim. The size of each bone defect
was also measured as a percentage of the total 360° of the rim. The location of each bone defect was defined as an angle between a horizontal line through the cup center and an oblique line drawn from the cup center to the center of bone defect. Anterior rim on the horizontal line was defined as starting point and the location of the center of bone defect on the rim was measured clockwise on the direct lateral view onto the left acetabular cup or counterclockwise on the direct lateral view onto the right cup.

**Results:** All cups were judged to be bone ingrown stable. No acetabular cups have been revised during a minimum 2 year follow up. The mean cup-CE angle was 30.7 +/- 10.8° (SD) (6.7-50.8°). The total host bone coverage around the rim was 66.3 +/- 13.1 % (SD) (44.3-100 %). The mean size of each bone defect was 19.2 +/- 11.0 % (SD) of the rim (2.7-52.5 %). Bone defect was observed in 3 locations in 7 hips, 2 locations in 35 hips, one in 19 hips and none in 2 hips. The bone defects could be divided into an anterior group, posterosuperior group and inferior group. Anterior bone defect was observed in 13 hips, posterosuperior bone defect in 55 hips, and inferior bone defect in 42 hips. In anterior group, the mean angle of the center of bone defect was 10.4 +/- 12.0° (SD) and the mean size of bone defect was 8.1 +/- 3.9 % (SD) of the rim (2.7-17.4 %). In posterosuperior group, the mean angle of the center of bone defect was 130.4 +/- 18.0° (SD) and the mean size of bone defect was 28.4 +/- 7.8 % (SD) of the rim (9.6-52.5 %). In inferior group, the mean angle of the center of bone defect was -67.9 +/- 12.4° (SD) and the mean size of inferior bone defect was 10.6 +/- 3.0 % (SD) (2.8-17.1 %) of the rim.

**Conclusions:** Press-fit acetabular implantation aims to distribute compressive fixation forces to the periphery of the acetabulum to generate friction forces. So host bone coverage around the rim is important for its initial stability. In this study, stable fixation of the cup was obtained with average host bone coverage of 66.3 % of the rim, which might show complete bony coverage of the rim was not necessary for fixation of the press-fit cup. The bone defect was located mainly on an anterior, posterosuperior and inferior portion of the rim, which corresponded to anterior acetabular edge, posterior acetabular edge and acetabular fovea, respectively. There were no defects around an anterosuperior, posteroinferior and anteroinferior portion, which corresponded to iliac facet, ischial facet and pubic facet, respectively. So the distribution of the host bone around the rim was considered more important for press-fit fixation than the extent of bone coverage. Stable fixation of an acetabular cup might be achieved by a 3-point like bony support at iliac, ischial, and pubic bone. The Superior region of the bone-cup interface is a portion where weight bearing force concentrates and it is reported that good superior bone-cup contact is required for stability in finite element analysis. In this study, the cup-CE angle was measured to represent the bony coverage in this superior portion. Stable cup fixation was obtained with a cup-CE angle more than 6.7°, which is considered large enough to resist superior directed loads.

**References:**

LOAD OPTIMIZED THERAPY PLANNING IN THA

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Introduction: Hip joint loading exhibits a complex dependency on joint geometry and plays an important role in the aseptic loosening of hip joint prostheses. Forces in the hip are known to be well in excess of body weight (BW) due to the action of the surrounding muscles, with forces of over 3 BW observed during normal daily activities in vivo [1]. Unnecessarily large joint forces in THA patients, however, can lead to additional component degradation and wear debris, possibly resulting in biological reaction and ultimate failure of the joint [3]. Whilst it is generally accepted that the musculoskeletal loading conditions play an important role for the success of THR, information regarding the joint loading for specific reconstructions is not available to support the surgical planning and execution process. It would seem possible that a combination of the surgeon’s expertise and knowledge of the patient’s musculoskeletal loading conditions could help surgeons to consider each case individually to avoid increased joint contact forces and thus increased wear and loosening risks. The goal of this study therefore, was to develop a therapy planning tool that supports the surgeon decisions and helps to minimize joint contact forces based on the musculoskeletal load analysis.

Materials and Methods: A musculoskeletal model of the human lower extremity was developed [2] based on CT-data from the Visible Human (NLM, USA). Instrumented femoral prostheses were used to measure the in vivo hip contact forces in four patients as described in a previous study [1]. Clinical gait analysis was conducted for six trials of both walking and stair climbing, with in vivo hip contact forces measured simultaneously. An optical system (Vicon, UK) consisting of six infrared cameras was used to determine the movement of the lower limbs. The complete musculoskeletal model was scaled to each patient anatomy using bony landmarks positions and then further individualised by modelling each specific joint reconstruction including e.g. femoral offset, CCD angle, neck-stem angle, femoral anteversion, and position of the cup. Intersegmental resultant forces, muscle forces and finally joint contact forces were then calculated for all trials. Measured and calculated hip contact forces revealed good agreement in both pattern and magnitude for all activities in all patients [2]. Based on these validated analyses of the muscle and joint contact forces in the human lower limb, a platform-independent software tool has been developed for the therapy planning of THA. The software package, composed of both a musculoskeletal analysis module and a dedicated pre-op planning module, was developed in Java using Java Swing, JDBC and the Java 2D API. The software is capable of interactively computing and visualizing the joint contact forces at the hip as a function of the each individual’s calibrated radiographs, including the femoral offset, CCD angle, femoral anteversion, leg length discrepancy and cup position.
To evaluate the capabilities of the THA planning software, a retrospective analysis of 100 THAs is currently being performed. All patients had received an uncemented stem (Zweymüller, Endoplus) and a threaded cup (Bicon, Endoplus). In all cases, an experienced surgeon (J.S.) first assessed each patient’s pre-op anatomy and their associated musculoskeletal loading conditions, and then planned each hip reconstruction individually using the software. Changes in hip anatomy and resulting forces for the pre-, planned and post-op conditions were then compared. From the ongoing clinical evaluation, results of the first 16 hips are presented here.

**Results:** The comparison of pre-op to both planned and actual reconstructed hip geometry revealed a general tendency towards increased femoral offsets: values were increased from an average pre-op value of 35.6mm to 40.1mm using the new planning tool. Evaluation of the achieved reconstructions revealed an offset modification to an ave. value of 39.8mm. CCD angles were decreased from an average pre-op value of 137.7° to the shaft’s CCD angle of 131.0°. The joint centre was generally medialised, with the planned cases resulting in an average medialisation of 13.0mm compared to an average of 11.2mm in the achieved reconstructions. These modifications resulted in a general decrease of joint contact forces when the planned (ave. 2.79BW) and achieved (ave. 2.81BW) reconstructions were compared against the pre-op values (ave. 3.06BW). When individual patients were analysed, it appeared that the interactive display of musculoskeletal loading promoted the planning of biomechanically more favourable joint reconstructions: whilst in 3 of the 16 patients (19%), the actually achieved reconstructions resulted in joint contact forces that were larger than the patient’s pre-op values, the joint contact forces were always lower than each patient’s corresponding pre-op values when planned using the new therapy planning tool.

**Discussion and Conclusion:** This study presents a new software package for THA planning in musculoskeletal surgery. Whilst a larger study including 100 patients is currently under way to fully evaluate the capabilities of the software, preliminary data presented here suggests that with support of the new software, an optimisation of joint loading e.g. minimum hip contact force after THA might indeed be achievable. Through a combination of the interactive musculoskeletal analysis module with e.g. intra-operative data from surgical navigation systems, an intra-surgical estimation of the current or proposed biomechanical situation of the selected joint reconstruction may even be within reach. This could help to achieve an optimal outcome of THA for each individual patient and reduce the risk of early wear and loosening.

**References:**

MINIMAL INVASIVE SURGERY AND NAVIGATION IN TOTAL HIP PROTHESIS

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Introduction: Two years ago we have started a comparative study on cup positioning with and without navigation using the Ortho-pilot system. The goal was to evaluate if navigation gives a better precision on inclination and anteversion of the cup.

Material and Method: We have used the Ortho-pilot system of navigation with a classical pre operative planning with templates. The patient is lying dorsally on an orthopaedic table. We use an anterior minimally invasive approach of six centimeters long going directly to the capsulae between tensor fascia latae and sartorius without severing any muscle or tendon.

The position of the leg, as directed by the manipulation of the orthopaedic table, allows accessible exposure of the acetabulum and of the femoral canal. At the end of the procedure we just have to close the aponevrosis of the fascia latae. For navigation, we register the pelvic plane through three landmarks: the two anterior iliac crests and the pubis.

The reaming and the final positioning of the cup will be appreciated according to that plan guided by the computer controlling. We do not navigate the stem for the moment but after reduction of the prosthesis with the trial stem; the computer can check the leg length and the offset compared to the initial position.

Results: We have been able to study 78 cups, 38 with conventional positioning and 40 navigated by the same surgeon. By using the same technique and the same prosthesis, the study was prospective. The post op positioning of the cup was controlled by C.T. scans for inclination; the figures given by the computer pre op and the C.T. scan post op are:

For anteversion the figures are quite different (mean 6° navigated, 16° conventional because of the variation of the reference plan)

In unilateral cases, there no significant difference between the operated and the control side, navigated or not, just a little reduced anteversion in the navigated (mean 6° for 16° control)

Finally, there is no significant difference between the navigated and none navigated for inclination (mean 45°) and anteversion (mean 17°).
**Discussion:** We have not found significant differences between the navigated and conventionally positioned cup. In the first case the position is reproducible as in the second case it is operator dependent.

The problem with checking the true anteversion is to find a reliable plan because of the difference of orientation in lying or standing position. This plan needs to appreciate the lumbar lordosis and its compliance. We also have to evaluate the accuracy of the post op C. T. scan to control the position of the cup.

What is actually of great value is the control of the leg length and the offset at the end of the procedure. Finally we are looking in a very short time to navigate the stem which will really permit a total hip navigation.

**Conclusion:** Navigation seems a valuable way to position the cup in a reproducible way and to appreciate leg length and offset. The evolution towards stem navigation will really permit a total hip navigation. The technique can be performed with a minimally invasive approach using an anatomical anterior incision without any muscle or tendon disruption, with the help of an orthopaedic table.
MINIMALLY INVASIVE COMPUTER ASSISTED VS CONVENTIONAL THR: A PROSPECTIVE ASSESSMENT OF SAFETY AND RECOVERY

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**Introduction:** Computer assisted, minimally invasive THR has the potential to speed recovery while simultaneously improving component position. Yet, minimally invasive techniques have been reported to increase perioperative complication rates. The current study prospectively measures recovery and complications of conventional vs minimally invasive, computer-assisted techniques.

**Methods:** 123 ceramic-ceramic THA using conventional open surgery without computer assistance were compared to 66 ceramic ceramic THA using minimally invasive, computer-assisted techniques. The procedures were all performed by the same surgeon and using the same implants. The conventional procedures were all performed using a modified direct lateral exposure. The minimally invasive, computer assisted hips were all performed through a superior capsulotomy, anterior to the piriformis, posterior to the gluteus minimus. All cases were performed using CT-based navigation (BrainLAB). Length of stay and use of walking aids at 1st followup, and surgical complications were assessed.

**Results:**

<table>
<thead>
<tr>
<th></th>
<th>Conventional THR</th>
<th>Minimally Invasive, Computer Assisted THR</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>123</td>
<td>64</td>
</tr>
<tr>
<td>age (SD)</td>
<td>49.6 (13.4)</td>
<td>55.7 (11.0)</td>
</tr>
<tr>
<td>sex</td>
<td>51% male, 49% female</td>
<td>63% male, 37% female</td>
</tr>
<tr>
<td>length of stay (SD)</td>
<td>4.3 (1.6)</td>
<td>3.8 (0.9)</td>
</tr>
<tr>
<td>walking aides at 6 weeks (Harris hip scale)</td>
<td>1.86 (2.96)</td>
<td>6.23 (4.23)</td>
</tr>
</tbody>
</table>
Surgical complications for the conventional arthroplasties included one postoperative greater trochanteric fracture requiring fixation, two cases of failure of abductor healing, requiring repair. Surgical complications for the superior capsulotomy group included one intraoperative greater trochanteric fracture which was internally fixed and one acetabular component that was displaced during reduction, recognized in the PACU, and acutely corrected. There were no dislocations in either group.

The results show that, despite the patients being older, the patients who had THR performed using minimally invasive, computer-assisted techniques left the hospital sooner and recovered the ability to walk dramatically more rapidly than those patients who had THR performed with conventional surgical techniques. Contrary to prior reports of increased risks with less invasive techniques, based on the surgical complications, less invasive techniques appear to be as safe or safer than conventional THR.
NAVIGATED NON IMAGE BASED REGISTRATION OF THE POSITION OF THE PELVIS DURING TOTAL HIP REPLACEMENT - AN ACCURACY AND REPRODUCIBILITY STUDY

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Introduction: The precise recording of the position of the pelvis is a prerequisite during total hip replacement (THR) implantation. It has been demonstrated that the conventional, non navigated measurements are less than optimal [1]. CT based navigation systems have been demonstrated to improve the accuracy of the recording of the pelvic position [1, 2, 3]. However, pre-operative CT-scan is not considered as a routine examination and involves additional costs. Non image based navigation system might allow the same accuracy at lower costs [4].

The anterior pelvic plane, considered as the plane containing both anterior iliac spines and the pubic symphysis, is an accepted reference to determine the 3D pelvic orientation [1]. The authors hypothesized that the cutaneous palpation of these three relevant anatomical landmarks was accurate and reproducible.

Methods: The authors studied 10 consecutive navigated implantations of a THR with the OrthoPilot ® system (Aesculap, FRG). Study was approved by the institutional board, and all patients gave a written informed consent.

One infrared localizer was fixed with a screw on the anterior iliac crest on the operated side. The first author performed four palpations of three anatomical landmarks with a navigated stylus: both anterior iliac spines and pubic symphysis. The first palpation was made on actual bone contours through a skin punction, the three others were made over the intact skin. The 3D positions of the localizer and of the stylus was recorded by the infrared Polaris ® camera (Northern Digital, Canada). The 3D pelvic orientation was calculated, and the variations between the three cutaneous registrations, and between the cutaneous and the mean transcutaneous position were studied.

Results: There was no significant difference between the calculated 3D pelvic orientation measured by the three cutaneous palpations, with less than 5° variation in all three reference planes. There was no significant difference between the calculated 3D pelvic orientation measured by the transcutaneous palpation and the mean cutaneous palpation, with less than 5° variation in all three reference planes.
**Discussion:** Proper cup placement is critical for the short-term risk of prosthesis luxation and for the long-term survival of a THR. Conventional, visual instruments involve an unacceptable rate of non optimal placements. Computer assistance have proved to be helpful in total knee replacement implantation, and led to a more accurate and more reproducible prosthesis placement. The same systems can be adapted for THR implantation. CT-based systems have proven to be effective during THR implantation, but involve an additional pre-operative examination which is not routinely used. Non image based systems, which can be based on cinematic, anatomic or echographic registrations, might be more cost-effective. However, the accuracy and reproducibility of such systems remains questionable.

The OrthoPilot ® system relies on an anatomic registration of the anterior pelvic plane for the definition of the pelvic orientation. We observed that the intra-operative palpation of this plane by a cutaneous technique was reproducible, with a variation of less than 5° between different registrations. We also observed that there was no significant difference between this palpation and the palpation of the actual bone contours by a transcutaneous technique. The cutaneous palpation can be considered as a reliable technique for the definition of the pelvic orientation during THR implantation.

**Conclusion:** Cutaneous pelvic palpation is an accurate and reliable way to determine the pelvic position during navigated non image based THR implantation.

**References:**

NAVIGATION ASSISTED TWO INCISION MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY, PRELIMINARY RESULTS

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Introduction: The two-incision minimally invasive (MIS) total hip arthroplasty (THA) technique is a new technique that minimizes surgical trauma, reduces pain and allows faster recovery. No muscle or tendon transection is involved and with the use of specially constructed instruments the acetabulum can be reamed and partially viewed, while the femur is prepared and reamed under fluoroscopic control. This technique was recently described [1], and was performed until now using conventional fluoroscopy only. The use of a guidance system for THA can improve the accuracy of components placement, especially in the mini invasive approach, since it enables the precise placement of implants without directly observing the bony landmark [2]. It is more than possible that long term result can be improved by the precise component’s alignment, especially regarding dislocation rates, aseptic loosening and leg length discrepancies. Until recently, only CT based navigation systems for cup and stem placement were available. The main disadvantage was the preoperative time needed for registration outside the operating room, increased radiation for the patient, as well as the cumbersome and problematic intraoperative matching process [3]. CT-free guidance platforms for the performance of THA are new and rely on algorithms for calculating coordinate systems for the pelvis and the femur, applying them to intraoperative fluoroscopic images. Described herein is our preliminary experience combining these two innovative techniques – 2-Incision MIS THA and CT-free fluoroscopic navigation.

Methods and Surgical Technique: We utilized the MIS two-incision surgical technique as described by Berger [1] using the anterior approach for the acetabulum and a posterolateral approach for the femur. The Medtronic Surgical Navigation Technologies (Louisville, Colorado USA) Fluoronav® StealthStation® System, equipped with the Zimmer MIS 2-Incision Hip software was used as a guidance system platform. The procedure employs specially designed MIS surgical instruments equipped with passive infrared reflecting optical trackers. The workstation is composed of a central computer, a position sensor (infrared optical camera), and a calibration target containing infrared transmitting diodes (IREDs) attached to the C-arm fluoroscope. While the patient is being anesthetized and prepped, all tracked instrumented are verified using a special calibration block. Two bone trackers are attached to the patient - one into the iliac crest and the second to the distal femur. Several fluoroscopic images for the registration of the coordinate system and navigation are acquired while the team
is within a safe distance from the radiation source (C-arm). A coordinate system is built in the computer for both pelvis and femur using an algorithm described elsewhere [3]. After this process a coordinate system is built by the computer for the determination of 3-D anatomy. At this stage the anterior incision is marked using a tracked pointer using virtual fluoroscopy. The anterior approach is carried out as described by Berger [1]. A tracked osteotomy guide is placed on the femoral neck so the exact place and angle of neck osteotomy can be determined. Specially designed low-profile (with cut sides) tracked reamers are used to ream the acetabulum. The surgeon can observe the anteversion and abduction angles of the reamer and can navigate without the use of fluoroscopy towards the desired values (45° of abduction and 20° of anteversion). After reaming, the cup is impacted with a specially designed optically tracked cup inserter, being constantly monitored on the computer screen. The femur is approached in a posterolateral 4 cm incision collinear with the piriformis fossa as previously described. In facilitating the location of the incision a tracker probe is approximated to the femur while the screen displays its relation to the bone. An optically tracked femoral awl is used to penetrate the femoral canal, being monitored in both views for centralization on all views. Specially designed lateralized side-cutting reamers equipped with optical tracking are used to enlarge the starting point and ream the femoral canal. Using the navigation system, their position is constantly monitored. After reaming, optically tracked rasps are introduced sequentially and seated. After the final rasp is well seated the femoral stem can be inserted.

Results: We used this entirely new system in 6 patients achieving maximal accuracy in placing the implants with abduction angles of 45-50 of cup abduction, 20-25 degrees of cup anteversion, and neutral axis placement of the femoral stems.

Discussion: Minimally invasive surgery has the potential to minimize soft tissue trauma while accelerating the recovery of patient undergoing THA, thus significantly reducing hospital stay and markedly improving short-term results [2,4,5]. Several studies had published the results of a single incision modified posterior approach for THA including the use of computerized navigation. However, the two-incision approach is unique by not severing muscles or tendons and relying on imaging for the placement of implants. The use of computerized fluoroscopy based computerized navigation system for the MIS 2-Incision THA technique can greatly improve some of its technical pitfalls, mainly concerning implant placement and the risk of femoral fractures. In contrast to open or posterior mini-incision technique, the use of navigation is not an extra-addition of surgical time to the procedure, but has the potential of reducing both surgical time and radiation by avoiding the constant need for fluoroscopy. The use of CT free system and the intraoperative registration of data eliminate the need of additional imaging studies involving the spending of extra time, cost and radiation. Its preliminary design seems promising.

References:

NAVIgATIoN IN TOTAl HIP ARTHROPLASTY

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Introduction: Total hip replacement (THR) has been well accepted in the treatment of the advanced disorders of hip joints. The continuous efforts have been made in the designs of the implants, fixation methods, materials and refined surgical technique, yet little has been made to improve the accurate implantation of the prosthesis in a reliable and reproducible way. The acetabular alignment guide has been developed to help surgeon achieve the optimal placements of the acetabular cup, yet the guides have been proved to be inaccurate. The postoperative cup orientations have been variable. In recent years, the computer-aided navigation systems have been introduced into arthroplasty surgery. It intends to improve the accuracy of the surgery. The purpose of this study is to determine whether the navigation system can improve the surgical accuracy for acetabular cup implantation during THR procedure or not.

Methods: From February to December 2003, a consecutive series of 19 patients (mean age 63.7 years; 8 males and 11 females; 7 left and 12 right hip joints) underwent CT-based navigation total hip arthroplasty. All patients received preoperative CT. A preoperative planning was undertaken one day before surgery. All patients were operated in a lateral decubitus position under general anesthesia. An anterolateral approach was used to precede the THR. The AML prostheses were implanted with or without cement fixation. The BrainLAB system (Munich, German) was adopted to assist the operation. During surgical procedure, the navigation system allows the surgeons to implant the proper acetabular cup according to the preoperative planning. The radiographic evaluations were performed after surgery. During these operations, the angular orientation of the inserted implants was recorded. The following clinical parameters were measured at different times during and after surgery: cup inclination and anteversion, varus/valgus sitting of the stem, and changes in leg length after THA.

Results: The mean and anteversion and inclination of the cup were 11.2± 2.3 and 45.3 ± 3.7 degrees each separately. The treated leg length is longer than health side with an average 1.3 ± 0.6 mm. No serious complications were present. The mean operation time is 2.4 hours (range 1.6 to 4.8 hours). The mean blood loss is 563 cc (range 320 to 1350 cc). The mean hospital stay is 5.6 days (range 5 to 8 days).

Conclusion: The consecutive series of 19 THAs acquired the satisfactory orientation of acetabular cup implantation on a radiographic assessment after surgery. And proper lengthening of the operative limb resulting in approximation of both lower legs. Thus, CT-based navigation can be a useful assistant tool in THA interventions.
References:

THE INTEGRATION OF NAVIGATION AND ROBOTICS IN MINIMALLY INVASIVE SURGERY (MIS)

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Objectives: Two centers that have used computer-assisted techniques in THA and TKA for many years have started using minimally-invasive surgery for THA.

A kinematic, non-image based Navigation System (Stryker Navigation System®) in combination with a surgical robot (ROBODOC®) are used on a routine basis.

The presentation intends to show that minimally-invasive surgery has the potential to achieve equal and better results than conventional techniques by using computer-assisted procedures in addition with a specially designed new implant. Thus, a very consistent level of safety and benefit for the patient can be guaranteed.

Background: The ultimate goal in THA and TKA is a long lifetime of the implant combined with the greatest possible kinematic function of the joint.

MIS presently does contribute to better long-term results or increased lifetime of the implant. It will allow reduced blood loss, a skin incision below 7cm, maximum soft-tissue saving (muscle sparing), immediate mobilization and minimum pain of the patient as well as an impressive early ROM. The dangers of MIS in THA are the possibility of a higher dislocation rate due to malpositionings of the cup, sub-optimal choice of stem size, increased risk of intra-operative fractures and fissures as well as malpositionings of the stem in rotation and anteversion.

Design / Methods: After starting MIS for THA at those two centers in 2003, beginning with the two-incision technique on a trial basis we experienced these pitfalls after the first number of cases that were done manually with the aid of fluoroscopy.

Due to our learning curve OR-time was increased, we did experience femoral fractures and, in spite of the use of fluoroscopy, there were quite a few malpositionings or at least sub-optimal positionings of the cup and the stem which only became apparent on the post-OP conventional x-ray and which could not be detected with the fluoroscope.

At this point we realized that major changes had to be made for the patient’s benefit and for an improved outcome.
We realized that we had to change our technique from two-incision to one-incision. For the much smaller skin incision it did not make sense to use conventional instruments that were not designed for that purpose – the implant manufacturer had to provide a new design for the instruments used in MIS. This came along with using an implant that was also designed for that purpose. Finally, we decided that pre-operative planning was essential for a good outcome of MIS – and we replaced the fluoroscope by a combination of the Stryker Navigation System® and a surgical robot.

The following cases were performed by either navigating the cup and stem OR navigating the cup and using the robot for the femoral component.

When the robot was used a pre-OP CT-scan and pre-OP 3-D-planning was performed.

Whenever possible the new implant (Life Quality Hip®, Stryker Howmedica) was used.

We used the one-incision technique combined with the antero-lateral approach.

**Results / Conclusions:** As we are in a very early stage of using this new technique in combination with computer-assisted technology and a new, less-invasive implant we can only show trends, not final results.

We had to realize that, at the beginning, adding all that technology again added some OR-time although it was not significant as we had been well trained in the use of these systems after years of experience.

We were able to achieve constant precision even with low or zero visibility. Precise navigation with minimal trauma was possible, without losing the correct path. In spite of a minimal skin incision malpositionings of the cup and stem could be avoided. Using the new, less-invasive implant and the specially designed instruments we were able to use a smaller incision that was much more soft-tissue-saving and muscle sparing than before.

The major advantage seems to be that we did not have to rely on mere visibility anymore but were safely guided by using computer-assisted technologies. The combination of a kinematic navigation system and a robot seems to be a great step forward in MIS.

**References:**

COMPUTER-ASSISTED TOTAL KNEE ARTHROPLASTY IN COMBINATION WITH THREE-DIMENSIONAL LEG ALIGNMENT ASSESSMENT SYSTEM

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Introduction: Recently, many computer-assisted surgery systems for total knee arthroplasty (TKA) have been developed to perform precise bone cutting and to obtain ideal leg alignment, and many published data showed optimal implantation results. But no other systems can evaluate three-dimensional component positions relative to bones of each subject.

We have developed the three-dimensional lower extremity alignment assessment system using biplanar (simultaneous, AP and 60-degrees oblique) computed radiography in standing position. We used this system to evaluate the three-dimensional component position for TKA. Previous study demonstrated that the error of component position adopted to three-dimensional bone model was controlled within 1mm or 1 degree. And this time, we applied this system to control whole steps from preoperative planning to surgical procedure and postoperative evaluation of position of the components. The objective of this study is to assess accuracy of controlling component placement and efficacy of this system for clinical application of computer-assisted TKA.

Materials and Methods: According to the steps described below, 5 consecutive TKAs were performed for osteoarthritic knees by one surgeon. The mean age at the surgery was 71.4 years. There were all women. And the type of the prosthesis was the ADVANCE® medial-pivot knee system_Wright Medical Technology_USA for all cases.

Three-dimensional leg alignment assessment system: A biplanar (A-P and 60-degrees oblique) long leg (from femoral head to ankle joint) (CR) images are simultaneously taken in standing position by use of the special cassette holder. The holder has a mobile cover for simultaneous projection. Using the camera calibration technique, the three-dimensional position of each X-ray film can be calculated by digitizing the markers of the calibration frame. The three-dimensional position of each X-ray film can be calculated by digitizing the markers of the calibration frame. The CR image is transferred to the personal computer, and the reference points are digitized, femoral side: femoral head, outer shape of femoral neck, and bilateral posterior condyles of femur as a spherical shape, and the tibial side: tip of medial and lateral eminence, medial and lateral edge of proximal joint surface, and medial and lateral edge of talar
dome, and proximal and distal tip of fibula. By this digitizing, the anatomical coordinate systems are established in a biplanar x-ray images. Then the surface of femoral and tibial shaft are digitizing at each 10 percent intervals. The projection matrix of the three-dimensional computed tomography (CT) model, which has been constructed from CT images of each subject in advance, is superimposed in the biplanar X-ray images. By this technique, the approximation of three-dimensional shape and position of the subject are determined.

Pre-operative planning for TKA: Three-dimensional component models of various different sizes, which are obtained from their CAD data, can be superimposed in X-ray images. By translating and rotating the component models to fit the shadow of the component models to the femoral and tibial joint geometry, surgeons can determine a suitable size and can assess three-dimensional position of both femoral and tibial components to anatomical coordinate systems in the personal computer.

Intra-operative registration and bone cutting: For intra-operative registration, intramedullary rod is used for femoral side and extra-medullary guide is used for tibial side. X-ray markers are attached to both femoral rod and tibial guide. The fluoroscope is used to take simultaneous A-P and lateral images of the knee joint. The images are downloaded to the computer immediately to fit the intra-operative images to that of pre-operative planning. Then osteotomy levels of the pre-operative planning related to X-ray marker of the femoral rod or tibial guide are calculated, and the special osteotomy jigs that consist of a small rod connected to universal joint are attached to the femoral rod or tibial guide. The direction and distance of the small rod is set to control flexion or extension, valgus or varus, internal- or external rotation, anterior or posterior and proximal or distal translation of the osteotomy surface of both distal femur and proximal tibia. Finally, cutting blocks are attached with the osteotomy jigs and both femoral and tibial cutting are completed.

Postoperative evaluation of component position: Biplanar long leg CR images are taken again by similar manner. And they are downloaded to the computer and the reference points are digitized again. The projection matrix of the CT bone models which has been saved pre-operatively are superimposed in the postoperative biplanar CR image so that the surface shape and reference points of the models and postoperative images are matched. Then the projection matrix of the three-dimensional model of femoral and tibial components are superimposed in the component position in the CR images so that the surface contour of the models and component images in the CR are matched. The positions of the component relative to femur or tibia are calculated from the relationship between the anatomical coordinate systems and the component coordinate systems that are previously installed in the component model.

Results: The extra-time for the intra-operative registration was less than 10 minutes in all cases. And the error of the position of both femoral and tibial component compared with pre-operative positions were 1.6 ± 0.3 degrees in varus-valgus alignment, 2.2 ± 0.4 mm in antero-posterior translation, and 1.2 ± 0.3 degrees in rotatory alignment in femoral component and 1.8 ± 0.3 degrees in varus-valgus alignment, 2.6 ± 0.5 mm in antero-posterior alignment, and 2.0 ± 1.2 degrees in rotatory alignment in tibial component.
Discussion: Nowadays, computer assisted surgery and navigation of positioning of TKA has become popular, but an evaluation of positioning of TKA is still routinely done in two-dimensional method, usually is done by plain radiographs such as the Knee Society’s system. In this study, we could control the three-dimensional component position for total knee arthroplasty.

We have developed three-dimensional leg alignment assessment system using biplanar long leg CR in standing position. And we have reported more reproducible evaluation for the position of components after TKA by the application of image fitting technique of deformed bone model and component model to this system.

In this study, two modifications were added. First, CT bone model of each subject was used to minimize the error during preoperative planning and intra-operative registration. Second, a fluoroscopy was applied to create better environment for the registration. These modifications also helped to reduce total extra-time for the registration. And the accuracy of three-dimensional component position after TKA, comparing with preoperative planning was thought to be good enough for clinical application.

Recently, three-dimensional knee kinematics after TKA has been focused by some studies. These studies mainly evaluated and analyzed the relative motion between femoral component and tibial component. However, in order to evaluate the knee motion after TKA accurately, three-dimensional component position relative to the bone should be evaluated because knee kinematics is essentially the relative motion between femur and tibia. This system also enables to evaluate the knee kinematics with prosthesis under weight-bearing condition by applying fluoroscopic analysis. And it may be able to evaluate the correlation between preoperative leg alignment, the position of the components, and postoperative kinematics of the knee, and the clinical results. We believe it is one of the great advantages of this system. In conclusion, three-dimensional evaluation of component position after TKA with the system we developed may be useful for the intra-operative management of total knee arthroplasty.
TOTAL HIP ARTHROPLASTY USING CT-BASED HIP NAVIGATION FOR JAPANESE DYSPLASTIC HIP JOINTS

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Introduction: Most of the Japanese osteoarthritic hips are sequels of developmental acetabular dysplasia and have complex pelvic deformities. In such cases, it is difficult to place acetabular cups in the proper position. CT-based images are crucial to obtain the 3-D geometry of the deformed pelvis. We used a CT-based VectorVision Hip navigation system (BrainLAB) for Japanese osteoarthritic hips and analyze short-term clinical results of patients treated with CT-based navigation system and the accuracy of the cup position. Problems during the simulation and navigation THA were also discussed.

Patients and Methods: We analyzed 29 joints (25 cases, 23 females and 2 males, the average age was 58.9 y.o.) underwent the navigation assisted THAs. Eight joints (8 cases, 7 females and 1 males, the average age was 69.0 y.o.) underwent the conventional THAs were also evaluated as a control. The operative time, the intra- and post-operative blood loss, the value of CRP on day 7 post-operatively, and length of hospital stay were compared between the patients underwent the navigation and the conventional THAs. In the pre-operative simulation THA, the acetabular cup was placed at the level of the primary acetabulum. The anatomical pelvic plane, defined by the bilateral anterior superior iliac spines and the symphysis pubis, was used to determine the cup inclination and anteversion. The cup inclination was set to be 45°. The anteversion was set to be 15° or 25°, depending on cases. Trilogy acetabular cups and Versys stems (Zimmer) were used. The intraoperative cup position was evaluated by the verification procedure in the navigation system and compared with the pre-operative planning. The paired t-test and the Mann-Whitney U-test were used for statistical analysis. Differences were considered significant when P < 0.05.

Results: Pre-operative simulation THA: To separate the femoral elements from the pelvis was difficult in cases with severe pelvic deformities during the pre-operative simulation. When the joint space disappeared, the virtual bony surface in the 3-D graphics was not identical to the true surface of the patient’s pelvis. Such bony surfaces could not be used as the reference points during the intra-operative surface matching registration. Intra-operative navigation THA: The operative time for the navigation THA was over 60 min longer than that of the conventional THA. The femoral registration was time consuming. It was not easy to ream the acetabulum or place the implants according to the planned position by using of conventional opera-
tive tools such as an acetabular reamer, a cup holder, an oscillating bone saw, and a mallet. **Post-operative evaluation:** The short-term post-operative clinical results showed no differences between the navigation and conventional THAs. The differences between the pre- and post-operative cup position were 2.3±2.4 mm in medial shift, 3.4±3.0 mm in anterior shift, 3.0±2.3 mm in cranial shift, 3.6±2.2 mm in depth, 4.5±3.2° in cup anteversion, and 2.6±2.9° in cup inclination. When cup anteversion was set to be 15° in the pre-operative simulation, the post-operative X-ray films showed that the cup anteversion was smaller than those of the conventional THAs.

**Discussions:** **Pre-operative planning:** Severe bony deformation led the VectorVision Hip system stuck during the separation procedure. The software for the segmentation procedure should be improved. **Surgical Invasions:** There were no differences in the short clinical outcomes between the navigation and the conventional THAs, except for operative time. Recently, the surgical time has been reduced less than 2.5 hours by using of new version (version 2.1). **Accuracy of the cup position:** The differences between the pre- and post-operative cup position were around 3 mm in our cases. Bassini F and Pozzi-Mucelli M performed navigation THAs using the VectorVision Hip for 60 patients and reported that the measured deviation between treatment plan and achieved results amounted to < ±5° in 81.3% of performed cases for the inclination and in 78.2% for the anteversion [1]. In our study, the measured deviation amounted to < ±5° in 96.3% for the inclination and in 66.7% for the anteversion. **Cup anteversion to the anatomical plane:** When the cup anteversion was 15°, the radiographic cup anteversion were smaller than expected. As Zheng G et al. mentioned, the cup anteversion in the postoperative X-ray films seemed to be smaller than the anteversion to the anatomical pelvic plane in the preoperative planning [3]. Therefore, we now set the cups anteversion at 25°, except for the cases with posterior inclination of pelvis. **Surgical tools:** The acetabular reamer and the cup holder were not appropriate to place the cup at the precise position according to the pre-operative planning [2]. Now, we have developed a cannulated acetabular reamer to fix the reaming center of the acetabular reamer. In conclusion, the CT-based VectorVision Hip navigation system was useful for Japanese OA hips, especially with severe pelvic deformities. The segmentation and registration procedures should be improved, as well as the surgical tools.

**References:**

UPDATE ON THE SECOND ROBODOC MULTICENTER TRIAL

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Introduction: Robodoc was developed in the late 1980’s to address the relatively poor results of the first generation cementless femoral components (1). The device consists of two parts. A computer workstation is used to pre-operatively plan the size and type of implant and to position it in the bone as depicted by CT-scan images. A surgical 5-axis robotic arm is used in surgery to machine the cavity in the femur for the implant as planned on the workstation. Prior studies (2) have verified its accuracy and repeatability.

The Original USFDA Robodoc multicenter trial began in 1994 and ended in 1998. The findings of that study (2) showed superior implant fit and alignment, but no clinical differences at 2 years. Although there were no device-related complications, the Robodoc procedure took significantly longer and resulted in more blood loss. A second multi-center study was begun in 2001. This study was designed to evaluate the DigiMatch software that eliminates the need for placement of locator pins (i.e. “pinless” technique) for registration. In addition, improvements in cutting times and fixator placement allow for less time and a more efficient procedure.

Method: This interim report reviews the first 88 consecutive cases (68 Robodoc, 20 Control) with 6-month follow-up. Longer-term follow-up is planned, but was not part of this study. This is an uneven randomized study with a 3:1 ratio of study cases to controls. The implant used in all cases was the HA-coated VerSys Fiber Metal Taper (Zimmer, Warsaw, IN). There were 48 males and 20 females in the Robodoc Group, and 12 males and 8 females in the Control Group. The average age was 60.1 years in the Robodoc Group and 60.3 years in the Control Group. The average weight was 190 pounds in the Robodoc Group and 195.3 in the Control Group (BMI: 24.4 vs. 25.3). There were no statistically significant differences between the groups for any of the demographic variables.

Results: The average Surgery Time was 120.6 min. in the Robodoc Group versus 82.7 min. in the Control Group (p< .001). The average Blood Loss was 463.4 cc for the Robodoc Group and was 415.8 cc for the Control Group (NSD). The Total Harris Hip Scores improved from a mean baseline of 51.5 to 85.5 at 6 months for the Robodoc Group. For the Control Group, these scores went from a mean baseline of 50.4 to 88.0 at 6 months. There was no statistical difference between the groups for the final Harris Hip Scores. One case required revision in the Robodoc group for a traumatic post-operative peri-prosthetic fracture. There were no device related complications. Radiographic analysis showed all hips to be stable and ingrown at 6 months.
Conclusions: From this interim analysis of the second FDA study, the DigiMatch software for the “pinless” Robodoc technique appears to be just as safe and effective as the original technique. Improvements in speed and efficiency have reduced the added surgical time to 38 minutes as compared to controls with no significant difference in blood loss. These data show significant improvement compared to time and blood loss reported in the first study (136 min. longer and 718cc more).

Robodoc has been used extensively outside the United States. Over 10,000 cases have been performed worldwide, mostly in Europe, but more recently in Japan and Asia. Although most reports have been positive, a recent study (3) reported an unacceptably high incidence of hip instability and need for revision for Robodoc cases compared to controls. This is in contra-distinction to the findings of the first U.S. multi-center study (2), which found no difference in the rates of dislocation or instability between the groups. This is also true to date of the second study. In addition, analysis of the data from the first study has been reported (4) to show no difference in the incidence of limp or the use of ambulatory aides for the Robodoc or control groups. A careful review of the study in question seems to show that the cause of the instability was damage to the abductor muscles. This appears to be due to improper implant selection and failure to protect the soft tissues at the time of the surgery. When planning a case on the workstation, if there is excessive overhang of the trochanter over the projected cut path of the robot, the case should be excluded. Indeed when these cases are excluded from the study in question the Harris Hip Scores, prosthesis alignment and limb length were actually better for Robodoc group at 6 and 12 months.

The surgeon has certain responsibilities when using Robodoc. Among these are:

Select the appropriate design of implant
Plan the appropriate fit and position of the implant
Exclude patients with anatomy that is not appropriate
Protect the soft tissues

If these responsibilities are accomplished, Robodoc seems to be a safe and effective device.

References:

COMPUTERIZED KINEMATIC ANALYSIS OF ROTATOR CUFF BEHAVIOUR DURING PASSIVE MOTION

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Introduction: Rotator cuff pathology is the most common cause of shoulder pain and dysfunction in adults and in overhead sport activities. The knowledge of pathophysiology of these disorders is fundamental to determine the cause of these problems but mainly to define a precise and effective treatment to correct defects already present or prevent the mechanisms that determine the formation of such pathology. In particular an accurate knowledge of the intrinsic kinematics of the shoulder and the relation between different structures inside the joint are fundamental to achieve an overall comprehension of the mechanism of failure or inflammation of the rotator cuff muscle during specific sport activity or during the early degenerative phase of such district. In particular our study concerns the supraspinatus and infraspinatus muscles, that are important active and passive stabilizers of the glenohumeral joint. The study was developed to describe accurately, utilizing a computer-assisted method, the anatomic features of a shoulder joint including center of rotation, articular joint surface of the humerus and glenoid, the coracoid process and the acromion as well as the supraspinatus and infraspinatus insertion area on the humerus and scapula and coracoacromial ligament.

Materials and Methods: We recorded motion and articular surfaces with the Faro Arm digitizer, a 6-degrees-of-freedom electrogoniometer, that allows a computer elaboration of anatomical and kinematic data with submillimetric accuracy, as described in detail in [1]. We examined three normal shoulders randomly chosen. All specimens had full range of motion, no evidence of rotator cuff tears, arthritis or bone deformity. The scapula was fixed to the experimental desktop, while the humerus was left intact up to the elbow and mobile. Passive motions were recorded with the intact joint and repeated without deltoid and teres minor. The relative position of humerus and scapula was recorded thrice at different range of passive motion (ROM), that is in elevation, in abduction and in internal and external (IE) rotation at 0° and 90° of the humerus. Then the coraco-acromial ligament and the supraspinatus and infraspinatus muscles were isolated and their insertion area on humerus and scapula was digitized. We also identified four main fibers on the mentioned muscles, digitizing couples of corresponding insertion points on humerus and scapula.
**Results:** The humerus head of our joints had a diameter of 43.3 ± 0.8 mm and resulted conformal with glenoid cavity with millimetric accuracy. The infra-spinatus insertion area was $171 \pm 28 \text{ mm}^2$ and was $33.4 \pm 2.1$ mm far from the humerus center. The supra-spinatus insertion area was $170 \pm 24 \text{ mm}^2$ and was $30.8 \pm 1.8$ mm far from the humerus center. The distance of center of the supraspinatus and infraspinatus insertion from coracoids, acromion and ligament coraco-acromial was similar and the standard deviation due to repeated motions overcomes the difference between the two tendons. The distance of supra and infra-spinatus from these points decreased during abduction up to 35% and during flexion up to 25%, even if the absolute values depended on the specimen. The different fibers of the same muscle showed different length by 50-60 mm and we measured some differences also among different specimens, therefore fibers’ length at 0° varied globally from 95 to 165 mm. However all fibers showed the same elongation pattern during passive elevation and abduction and extreme positions of internal and external rotation: they decreased their length in a variable way from 5% to 25%. Although in most cases the supraspinatus fibers are slightly shorter than corresponding infra-spinatus ones, the variability of the fibers was more statistically significant than the difference between the two muscles.

**Conclusions:** We have used a new method to perform the analysis of the shoulder biomechanics. This method was validated on the knee in previous studies [1] and has provided anatomical measurements on the shoulder comparable with recent morphological studies of the gleno-humeral joints [2,3]. This study showed no significant differences between the supraspinatus and infraspinatus behaviour with respect to the acromion, coracoid and the coraco-acromial ligament. Examining the distance of their humeral insertion areas from the acromion and coracoid in the different range of passive motion we concluded that the most critical positions are near the maximum passive abduction and elevation in neutral rotation. The internal and external rotation at 0° and 90° of the humerus confirmed that extreme positions are the most critical of the range of motion, but the behaviour of the three specimens during this test were less comparable than during elevation and abduction. We also examined the distance of the humeral insertion areas of supraspinatus and infraspinatus from the center of the rotation of the gleno-humeral joint, which was computed as the center of the glenoid cavity, and the fibers’ elongation of during passive motions.

**References:**

ACCURACY OF ISO-C$^{3D}$ NAVIGATION – IS IT ADEQUATE FOR SPINAL SURGERY?

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Objectives: For surgeons as clinical users of direct, registration-free ISO-C$^{3D}$ navigation, the effective navigation accuracy of their system is of main importance. Thereby neither a technical evaluation of the conformity of physical dimensions of the volumetric reconstruction, nor the error distribution of the inherent volume registration is crucial, but as final consequence the accuracy with which a surgical instrument is represented in the virtual projection. Surgeons want to know how accurate the position and orientation of a surgical tool is visualized by the navigation system in respect to the patient’s anatomy. Especially for instrumentations in the thoracic spine the requirements for navigation accuracy are extremely high. At some levels screw diameters are of the same size as the width of the pedicle.

Methods and Material: In this study, the effective navigation accuracy of our ISO-C$^{3D}$ navigation system was evaluated and represented. The actual instrument position has to be measured for a defined number of instrument positions, which have to be well distributed within the reconstructed and registered ISO-C$^{3D}$ volume, and then compared to the position calculated by the inherent registration process of the navigation system.

A high precision measurement instrument has been manufactured in the machine shop of the MEM (Research Centre for Orthopaedic Surgery Institute for Surgical Technology and Biomechanics, University of Bern). This measurement tool consists of radio translucent plastic (PEEK) with embedded fiducial markers. Each marker has a diameter of 1mm.

To know the spatial position of each marker sphere in this measurement phantom, an optical IRED marker carrier was mounted on the cube, which can be traced by an optical tracking system (Optotrak 3020, Northern Digital Inc., Canada). This so called dynamic reference base (DRB) carries 4 IRED markers. The relationship between this DRB, which spawns a fixed coordinate system, and the actual marker sphere positions, was registered in a further calibration step. The spatial position of those markers can be measured by the optical tracking system with a high precision pointer and using a pivoting algorithm, whereby the location of the spheres can be transformed into the cube’s reference coordinate system.

The spheres in the measurement phantom represent individual instrument tips, as for example the tip of a drill. Therefore 8 regularly distributed “drill positions” can be
evaluated in a single ISO-C3D scan.

The Siremobil ISO-C3D was inherently registered for navigation by the navigation company.

To determine the navigation accuracy of the system, 10 verification scans of the measurement phantom were conducted, whereas it was always positioned in an optimal field of view.

The exact virtual position of each sphere in those 10 reconstructed volumes was evaluated by a manually sphere detection. The precision and reproducibility of the sphere detection was validated in an intraobserver analysis with 10 repetitions and 8 different spheres.

The real sphere positions, measured by the optical tracking system, are then transformed into the same coordinate space as the detected spheres by the following formula:

\[
R_{\text{ISO}} = T_{\text{AMP-ISO}} \cdot T_{\text{REF-AMP}} \cdot R_{\text{REF}}
\]

Whereas \( R_{\text{REF}} \) are the coordinates measured in the reference coordinate system of the measurement phantom, \( T_{\text{REF-AMP}} \) is the position of the Siremobil ISO-C3D at image acquisition time in respect to the measurement phantom and \( T_{\text{AMP-ISO}} \) is the transformation given by the intrinsic calibration of the system described in which is the performed matching procedure.

\[
T_{\text{AMP-ISO}} = T_{\text{CAL-ISO}} \cdot T_{\text{AMP-CAL}}
\]

In the ISO coordinate system the transformed measured sphere coordinates and the detected sphere positions can directly be compared and statistical analysis can be performed.

In a second step, different influence parameters on navigation accuracy were analyzed. The whole setup was placed in the very far edge of the field of view (FOV) of the camera (250cm) and at the very narrow edge of the FOV. The position of the marker shield of the accuracy phantom was tilted just before becoming invisible for the camera and the marker shield of the camera was partially hidden. Studies were performed with single parameters and combinations of parameters. Navigation accuracy was recorded and statistically analyzed. In an additional test the phantom was moved with a regular amplitude of 10mm during registration and acquisition of the isoc image data, simulating the patients breathing.

Results: The results of the intraobserver study have shown that the center of the 1mm fiducial marker in a 3D dataset can be defined very precisely. In 88 measurements the maximum deviation was 0.112mm with an average of 0.056 (Std. Dev: 0.002). In a cluster analysis no preferred direction for the deviation could be detected.

The results of the accuracy study with optimal parameters and 10 repetitions (8 measurements each repetition) have shown an average navigation accuracy of 0.40mm
The modification of the parameters affected the navigation accuracy differently. Going to the far edge of the FOV had no influence on the overall accuracy (mean 0,41; Std. Dev. 0,13; max 0,68). A slight decrease of accuracy was observed during the closest camera position possible (mean 0,48; Std. Dev. 0,16; max 0,83). Tilting the marker shield of the phantom also affected the accuracy negatively (mean 0,51; Std. Dev. 0,15; max 0,83). The worst results were observed in a combination of maximum accepted distance between camera and phantom, minimum required LEDs visible at the isoc and tilting the phantom marker shield (mean 1,53; Std. Dev. 0,46; max 2,08).

We observed extremely bad accuracy results in the movement analysis (mean 5,53; Std. Dev. 1,46; max 7,81).

**Conclusions:** We recommend to the responsible industrial or clinical system maintenance to perform such an accuracy verification measurement at regular system verification intervals to make sure there is no decrease in the accuracy over time. A decrease of the system accuracy was observed for the device used in daily clinical routine. Possible influence parameters to the system accuracy have to be respected implicitly. We successfully used the inherent navigation in the Iso-C3D images in 63 patients with spinal instrumentations. A total of 308 instrumentations were placed in these patients. All instrumentations were performed in regard to our precision study, especially to the influence of different parameters. The camera was placed in an optimal distance and orientation to the dynamic reference frame and the marker shield of the isoc during all navigations. The isoc scan was performed in all cases during breath arrest after sufficient preoxygenisation and continuous monitoring of oxygen saturation. Breath arrest was always performed in expiration to prevent relative movement of the vertebra. All patients had a postoperative CT together with an analysis of the screw placements by means of axial reconstructions. Only 3 screws were classified with a misplacement of 2 or more mm (0.97%).
Figure 1: Intraoperative visualisation of guided ISO-C3D guided Pedicle screw placement in Th 12 level. The red line is representing the planned screw position, the green line is visualizing the actual implant position (5mm Schanz screw, USS, Synthes, inserted by use of a T-Handle)
AUGMENTED REALITY AND IN-SITU-VISUALIZATION IN THORACOSCOPIC SPINE SURGERY

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Introduction: While using surgical navigation and intraoperative imaging systems the authors experienced the need for more intuitive user interfaces in the operation room in order to facilitate the workflow. Pre- and intraoperative 3D images, endoscopic camera view, visualization of instrument position and planning of procedures offer an amount of data the surgeon has to deal with during the course of an intervention.

Augmented Reality (AR) promises one solution towards a more intuitive approach. Looking for a technically especially demanding image-guided surgical procedure endoscopic spine surgery for several reasons seemed to be an ideal model for a test-setup:

Thoracoscopic spine surgery in most cases is a planned surgical procedure. Following emergency surgery and dorsal stabilization it is the second stage of dorso-ventral fusion in unstable spine fractures. Thus new technology can be established under safe conditions.

Thoracoscopic spine surgery is minimally invasive and image-guided: The surgeon has 3D information about the patients anatomy using the preoperative CT-scan; intraoperatively 3D-flouroscopy can update these data. The surgery is than performed mainly under 2D vision through an endoscopic camera without actual 3D control.

Using augmented reality these different imaging modalities can be visualized in-situ, i.e. in their actual location, overlaid onto a stereoscopic video view.

Materials and Methods: We combined an existing augmented reality-system that was developed for augmented reality of medical images with an additional external real-time optical tracking system. The user wears a custom video-see-through head-mounted display (HMD). Two color video cameras attached to the head-mounted display provide a stereo view of the scene. A third head-mounted video camera is added for inside-out tracking. A set of optical markers (“frame”) is attached to the phantom. Other sets of optical markers (“clusters”) are attached to standard surgical instruments. The “frame” and “cluster” marker sets provide the pose of both the observer’s viewpoint and the tracked tool, respectively. The system
runs on a single PC and achieves real-time performance (i.e., 30 frames per second) with latency of about 0.1 sec, generating a stable augmentation with no apparent jitter visible in the composite images. The principle of the system is shown in Fig. 1.

An operation phantom for thoracoscopic spine surgery was constructed and a CT-scan performed (Siemens MSCT). After segmentation of the CT-data different visualization options were obtained: bone as a grid model, semi-transparent, vascular structures, neural structures, implants and embedded targets. Graphic models of several standard surgical instruments for thoracoscopic surgery were built. A simple calibration procedure for the instruments and the environment had to be established.

During the course of the experiment surgeons with different levels of experience in endoscopic and image-guided surgery had to perform simple operation tasks. We tested different visualization options in order to find an optimal workflow with maximum information avoiding redundancy.

**Discussion:** In this experiment an augmented reality workplace simulating operation room conditions in thoracoscopic spinal surgery was setup. The different components of the system, e.g., optical tracking, head-mounted display, visualization, that had been developed apart, had to proof their joint capabilities under real-time conditions.

The system proofed to be robust regarding real-time tracking of long thoracoscopic instruments (35cm) in a large workspace (OR-table environment). Number and positions of tracking cameras was varied: we used 2 - 4 cameras in different geometrical positions in order to enable optimum workflow. Thus a precision of 2mm could be reached without any "dark spots". Also size and position of mounted targets was varied to minimize overlaps.

Size and weight of the head-mounted display are unfavourable regarding intraoperative use. However smaller technology will be available in the near future. The visualization system offered robust real-time augmentation without any jitter visible thus making it comfortable for longer work.

Image fusion of preoperative and intraoperative radiographic data and the actual operation situs offers a unique vision for the surgeon. The surgical approach gets intuitive and surgical procedures like placing implants are enhanced with 3D information. Overlay of actual 2D endoscopic images enabled direct control of instrument position. Combination of 3D and 2D view can be challenging for the user demanding good stereoscopic vision.

We performed a series of operation tasks, using tracked standard instruments:

Orientation in the phantom was intuitive and simple. Identification of the correct level of intervention was simple, avoiding extra radiation in the operation room.

We embedded targets in the phantom, identification was controlled by endoscopic camera, by haptic-feedback and by motion analysis. All tasks were accomplished intuitively be the test-users.
**Conclusion:** Augmented reality seems to offer a unique and intuitive way of visualization in the operation room. Different types of data like 2D vision, 3D radiographic data and real-time measurement tools offered by navigation systems can be fused for the ease of the user.

In the presented system the user wears a video-see-through head-mounted display to observe 2D and 3D radiographical data in-situ, i.e. in their actual location, overlaid onto a stereoscopic video view.

The required hardware is economic using a single PC for visualization and head-mounted display. Smaller versions of the head-mounted display will be available in the near future. The development of a intuitive user interface remains a demanding task and further investigations have to be done.

**References:**


Fig. 1: Principle of video-see-through
COMPUTER ASSISTED SPINE SURGERY. ERGONOMICS ASPECTS AND FIRST CLINICAL CASES (2003)

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Introduction: The purpose of this study was to evaluate the accuracy and reliability of a new Computer Assisted System, for pedicle screw insertion. The CT-based navigation technique is currently used in spinal surgery but very few studies were done yet, to try to evaluate the accuracy and reliability of this new system, with also ergonomics and efficiency aspects.

Material and Method: Between january 1st and december 31st 2003, 8 patients were instrumented for different pathologies (scoliosis, fractures, spondylolisthesis and degenerative instabilities). There were inserted 28 pedicle screws, on different vertebral levels, from T12 to L5. The CT-based navigation system was used for every patients (28 pedicle screws). The screw placement, was evaluated on plain X rays and on postoperative CT scans, by an independent observer. In order to increase ergonomics and efficiency of Computer-Assisted Spine Surgery, new devices and technologies have been developed. For the operating field, new passive wireless surgical tools (reference frame, pointer, drill guide, screwdriver …) have replaced the active (with cumbersome electrical wires) surgical tools. On the workstation, keyboard and mouse have been removed and replaced by a simple footswitch and cumbersome computer screen has been replaced by a flat panel touch screen.

Results: In clinical papers are reported results ranging from 15 to 40 % of misplaced pedicle screws, for the conventional technique, varying by pathology, type of post-operative evaluation (CT or X ray only) and authors. The screws were considered misplaced, when the cortical penetration (on CT) was superior or equal to two (2) mm. Only one screw was not exactly placed into the pedicle (L3), but in this specific clinical case the surgery was performed to correct a severe double curve scoliosis in a 34 years old woman who suffered an osteogenesis imperfecta. There were no neurological complications following surgery. The CT-based technique reported here offered much better results, than the conventional techniques.

Conclusions: The general purpose of CAS technology is to increase accuracy, to reduce morbidity, to offer the possibility of performing minimally-invasive surgery with ease and safety, to reduce x-ray radiation doses, and to improve surgical proto-
cols by allowing consistent post-operative studies. Looking back on their experience in Computer-Assisted Spine Surgery, the authors demonstrated the importance of ergonomics and efficiency with the new generation of CAS systems. The biggest advantage of this technique is the possibility to navigate, having real three dimensional information, that is extremely important for deformed pedicles such as in scoliosis. The registration step between the preoperative and intraoperative datas is no longer than the conventional procedure, because the computer is equipped with a faster data collection process. From a surgical point of view, the use of new passive wireless surgical tools is very simple. Simple footswitch for computer assistance, flat panel touch screens and simplified menus are really the best tools for a user-friendly user interface.

References:


CT-BASED, NAVIGATION-ASSISTED PEDICLE SCREW INSERTION IN THORACIC AND LUMBAR SPINE FRACTURES

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Introduction: The biomechanical advantages of transpedicular screw fixation for spinal fractures include three-column control of vertebral segments, and fixation of a vertebral segment in the absence of intact posterior elements. The position of the pedicle screw is important in the reduction and fixation of thoracic and other spinal fractures. Incorrect placement of pedicle screws may adversely affect reduction of the spinal fracture. This in turn could lead to neurovascular injury. CT-based image-guided surgery has been promoted as a means of theoretically improving the accuracy of pedicle screw placement. We reviewed radiographic and post-operative computed tomography images with a view to evaluating the accuracy of pedicle screw placement in thoracic and lumbar fracture cases treated using a CT-based navigation system.

Methods: A BrainLAB CT-based image-guided system was used for pedicle screw insertion in patients with thoracic and lumbar spine fractures from August 2003 to January 2004. The criteria for inclusion in the study were an unstable vertebral body burst fracture, fracture dislocation or an unstable pathologic fracture with neurological symptoms. In order to treat these conditions, CT-based image-guided navigation was used to facilitate posterior spine fusion and pedicle screw insertion. The accuracy of the pedicle screw placement within the pedicle and vertebral body were assessed. Cobb’s angle was measured from the inferior endplate (below the lowest fractured vertebrae) to the superior endplate (above the highest fractured vertebrae), both preoperatively and postoperatively, using sagittal radiography. Kyphosis correction was determined by subtracting the postoperative Cobb’s angle from the preoperative Cobb’s angle. The sagittal screw angle was determined based on a line parallel to the inferior vertebral endplate and a line through the center of the screw. Pedicle perforations were classified as either medial or lateral, and categorized into one of four groups: 0–2.0mm, 2.1–4.0mm, 4.1–6.0mm, or 6.1–8.0mm. Penetration of the anterior vertebral cortex was also determined using postoperative CT scans.

Results: 14 patients were included in the study during this period. The causes of injury were as follows: fall from a height (4 cases), motor vehicle accident (5 cases) and pathologic fracture (5 cases). The pathologic fractures were further divided into 2 cases of lung cancer metastasis, 1 osteoporotic fracture, 1 case of tuberculosis of the spine and 1 case of ankylosing spondylitis. 102 screws were inserted from level
T1 to level L5 under the guidance of the CT-based navigation system. The kyphosis correction averaged 15 degrees. The average sagittal screw angle was 5 degrees. In 90.2% of cases (92 screws), the sagittal screw angle was less than 10 degrees. In a postoperative CT study it was determined that the pedicle penetrated the cortex laterally in only 3.9% of cases (4 screws). Three of the lateral pedicle perforations were measured at 0-2.0mm. The fourth perforation was measured at 2.1–4.0 mm. Neither penetration of the medial pedicle cortex, nor penetration of the anterior vertebral cortex were observed. There were no cases of iatrogenic neurological injury. One case was complicated by deep wound infection, however this was resolved by debridement and implant removal.

**Conclusions:** The advancement of transpedicular screw fixation has revolutionized the treatment of thoracic and lumbar fractures. The biomechanical advantages of transpedicular screw fixation for spinal fractures include three-column control of vertebral segments and fixation of a vertebral segment in the absence of intact posterior elements. However, the overall complication rate documented for the use of pedicle screws ranges from between 21% to 27%. Intraoperative complications, occurring in approximately 10% of all cases, are divided into neurological impairment due to nerve root injury, pedicle fracture, dural tear with cerebrospinal fluid leak, vascular injury, visceral injury resulting from screw overpenetration, and incorrect screw placement. Thoracolumbar pedicle screw insertion is a technically demanding procedure.

Accuracy of pedicle screw placement in thoracic and lumbar spine fractures is important for fracture reduction and fixation. Using CT-based image-guided surgery, we can improve screw insertion parallel to the endplate and reduce the risk of penetration of the pedicle and vertebral cortex. Furthermore, the need for intraoperative fluoroscopy is minimized and both radiologic exposure and operative time may be reduced.

**References:**

PERCUTANEOUS BONE BIOPSY. A NEW INDICATION OF ISO C³D NAVIGATION

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Introduction: The histological examination has remained indispensable for a definitively diagnosis of ambiguous bone lesions although imaging modalities for diagnostics make great strides [1]. The removal of tissue samples for histopathological analysis percutaneous bone biopsies plays a prominent role in addition to surgical excision. CT-navigated percutaneous bone biopsies have become a generally accepted standard method for non-surgical extraction of histological and cytological material. A percutaneous bone biopsy should only be considered, if singly the histological examination could give information about dignity and diagnosis of a radiological and sczintigrafical conspicuous lesion and therapeutical consequences result from this information [2]. In numerous studies it could be shown that almost 90% of CT-navigated percutaneous bone biopsies afford the classification of osteolytical lesions. The high level of x-ray exposure for the patient as well as the examiner is still a disadvantage as well as important CT capacities are occupied. Computer-assisted methods could lead to significant and qualitative improvements of results of surgical treatment. For many surgeries it could be demonstrated that the use of navigation systems can lead to a reduction of radiation dose and increase of precision [3]. The registration in Iso-C-3D navigation results self-acting at the moment of data acquisition, so the source of error of pair-point registration on anatomic landmarks does not occur and a second surgery for the fixation of fiducials is not necessary. The aim of this study was to develop a navigated sleeve for the Jamshidi nail so percutaneous bone biopsies could be taken navigated with the help of Iso-C-3D. The examination was analysed relating to precision, total operating time and level of contamination.

Methods: Navigated by Iso-C-3D, 30 percutaneous bone biopsies were taken from cadaver specimen (10 Femura, 10 Tibiae und 10 Humeri). In advance, artificial bone lesions were prepared with a mixture of methylene blue and radiopaque material. The dynamic reference base was placed at a safe distance of approximately 130 mm to the lesion. To avoid artefacts in data acquisition with the ISO-C-3D-C-bow Siremobil® The biopsy on tibiae and femura took place in dorsal position. To guarantee a rotation of 190° around the isocentre at proximal humerus biopsy, the cadaver had to be placed in 45° oblique position. The 3D data was generated by the Iso-C-3D Siremobil® (Siemens AG) and transferred to the navigation system in the mode of
Iso-C-Navigation. A conventional Jamshidi needle 15.3 cm x 3.1 mm was used by the surgeon. For each biopsy a separate needle connected to a special holder including a reference was used. The biopsy was considered to be successful when the bioptical sample contained methylene blue. To each biopsy total operating time, including the placement of the dynamic reference base, as well as radiation time was taken in consideration. The results were compared to retrospective data of CT-based bone biopsies from the last 3 years.

**Results:** In comparison to CT navigated biopsies Iso-C-3D navigated percutaneous bone biopsies could be taken significantly faster. By using the Iso-C-3D the total operation time could be reduced to 11.7 min (8-14.3) in relation to 40 min (30-110) by using the CT. Radiation time was at 0.3 min (Iso-C-navigated) and 1.6 (CT-navigated). In Iso-C-3D navigated biopsies 30 of 30 (100%) lesions were definitely hit by the surgeon. Concerning hit rate, information could not be worked out from the retrospective collected data.

**Discussion:** The CT-navigated percutaneous bone biopsy became established as a minimal-invasive standard method for the fast removal of material from non-specific bone lesions for histological examination. Within the literature an overall accuracy of 90% is declared. In the past, Computer assisted methods could lead to significant and qualitative improvements of results of surgical treatment. A great barrier of CT-based navigation was the necessary of registration. The anatomic-based registration was technically difficult to realize. The implantation of the fiducials included a second surgery so that this indication was rarely given. This workflow was improved by Iso-C-3D navigation. The registration in Iso-C-3D navigation results self-acting at the moment of data acquisition, and manual registration is not required. Since this study was designed under laboratory conditions and the patients collective was not really corresponding to the retrospective analysed patients, only an indirect comparison is possible. With this study it could be demonstrated that Iso-C-3D-navigated percutaneous bone biopsies could be gained faster and with less radiation dose. The overall accuracy was up to 100%. However the histological overall accuracy is not possible to explore in an invitro study. At the moment the feasibility of Iso-C-3D navigated bone biopsies is limited by the fixation of the dynamic reference base (DRB). Therefore further experiments concerning this problem are in process. Whether or not the radiation dose and total operating time can be reduced and how exact histological overall accuracy must be evaluated in following clinical studies.

**References:**

SURGICAL SIMULATION USING CUSTOM PLASTER MODELS FOR TRANSARTICULAR C1–2 SCREW FIXATION

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Introduction: Posterior transarticular C1–2 screw fixation (Magerl technique) is a commonly performed surgical procedure for treatment of atlantoaxial (AA) instability. This procedure required spatial orientation and techniques for accurate placement of transarticular screws. To improve the accuracy of transarticular screw placement, we attempted a new method to assist this surgical procedure. From computed tomography (CT) image information, plaster models of the craniovertebral junction of this patient were created with rapid prototyping equipment and used for preoperative simulation of the screw insertion. Here we report this methods and discuss its feasibility for clinical application.

Methods: Serial CT images taken with 1 mm thickness, in the Digital Imaging and Communications in Medicine (DICOM) format, were processed with the following three software packages to make a plaster model. The 3D Slicer (Brigham & Women’s Hospital, Harvard University) was used to adjust the threshold of a volume and separate the image data of the occipital bone/atlas and vertebral artery from those of C2 and below. The Forge (Ver. 2.00, Studio PON Japan) was used to convert the image data into the standard triangulation language (STL), a standard file format for rapid prototyping (RP). The Magics RP (Materialise N.V. Belgium) was used to simulate the repositioning of atlantoaxial articulation on a computer monitor. Plaster models were then created with the aid of RP technology using a 3D printer (Model Z406, Zcorporation, USA).

Results: A 52-year old male patient with chronic atlantoaxial instability due to rheumatoid arthritis, who was scheduled for the posterior transarticular C1–2 screw fixation, underwent preoperative spiral contrast CT scans (W3000AD, Hitachi Japan). In neutral positioning, the sagittal atlas/axis angle was 7 degrees and the atlantodens interval (ADI) was 2mm. In computer simulation using MagicsRP, our target alignments of the AA complex were set at that the sagittal atlas/axis angle of 20 degrees and the ADI of 0 mm. To achieve targeted positioning, the separated occipital bone/atlas complex was rotated 13 degrees backward relative to the inferior baseline of the axis body. And then it was shifted 2 mm posteriorly to terminate ADI. From image information of repositioned occipital bone/atlas, bilateral vertebral arteries and the rest of cervical component, two plaster models were made using 3D
printer. One was plaster model of the atlantoaxial complex in the reduced position, and another was included colored vertebral artery components. Preoperative simulation of the surgical procedure was conducted by placing transarticular screws into the plaster models, which provided actual 3D visualization of the procedure. It was revealed that safe trajectory for screw insertion was very narrow at the left side. The optimal positioning of the screws was confirmed by taking X-ray images of the models in three directions. The adequate atlantoaxial joint alignment and a point and angle of screw insertion were verified by usual intraoperative fluoroscopy, as well as by observation of the plaster models inserted transarticular screws. Postoperative plain radiography and CT demonstrated satisfactory placement of the inserted screws and the fixation angle of C1-2 was approximately 20 degrees.

**Discussion:** Transarticular screw fixation of Magerl technique is used to stabilize the cervical bodies C1 and C2. According to previous reports, the sagittal alignment of the cervical spine after various sorts of surgery may affect long-term clinical results. Yoshimoto et al reported the importance of C1-C2 fixation angle in patients with AA subluxation. To fix C1-C2 joint in an appropriate angle during surgery, surgeons should evaluate the C1-C2 angle by image-intensifier after general anesthesia is settled. A plaster model of reduced position allows direct visualization of the atlantoaxial anatomy after a computer-simulated reduction procedure, as well as visualization of the optimal positioning of transarticular screws.

There are several reports concerning anatomic variation of the vertebral artery groove of the axis. In a survey of 1318 patients treated with the Magerl technique, Wright and Lauryssen reported the risk of vertebral artery injury to be 4.1%. Surgeons have no way to confirm the position of arteries intraoperatively. A plaster model with colored vertebral artery components allows surgeons understand the personal trajectories avoided the vertebral artery groove of the axis before surgery.

**Conclusions:** A new method of surgical support was attempted to improve the accuracy of transarticular C1–2 screw fixation in two ways. These methods may improve the accuracy and safety of the surgical technique by facilitating the understanding of the anatomical relationships of craniovertebral complex by surgeons.

**References:**

THE BENEFIT OF COMPUTER-ASSISTED KYPHOPLASTY

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Introduction: With a population rapidly getting older, degenerative disease increases in numbers. Especially osteoporotic compression fractures gain socio-economic importance with costs for conservative treatment and disablement being predominant factors. Not only severe pain requires adequate therapy but also hyper-kyphotic deformities deteriorate the spinal function and amplify the risk of further damage due to unphysiological load distribution [1,2]. By the percutaneous augmentation of fractured vertebra with polymethymethacrylate it can be stabilized and pain sufficiently be treated [1-3]. Modifications of vertebroplasty led to kyphoplasty, that additionally offers the opportunity to restore the height of the crushed body and thereby to lead back biomechanical imbalance [1-4].

The minimal-invasive approach is transpedicular. A canulated bone cutting needle must be placed close to the center of the respective vertebra from both sides. Cement of low viscosity is filled with pressure directly into the spongy bone structure for vertebroplasty. For kyphoplasty a balloon catheter is placed first. By inflating the balloon the depressed endplate is elevated and a cavity is created in which PMMA can be filled to stabilize the result. The whole procedure requires permanent x-ray control, as affection of blood vessels, nerves and spinal cord are an immanent risk. The cement may not only distribute within the vertebral body, but in the spinal canal with severe neurological deficiency as a consequence and instruments can hurt delicate structures directly. Particularly, at the thoracic spine and in cases of vast deformity the orientation becomes difficult and complications impend.

To reduce the significant amount of radiation exposure and to ensure utmost accuracy to a popular and potent procedure like kyphoplasty a CAS system was to be implemented [4].

Material and Methods: A new method of computer-assisted navigation for percutaneous procedures was developed, experimentally tested, evaluated and finally established in the clinical routine. Invasive fixation of a dynamic reference base with clamps or screws used to be a standard in spinal CAOS. Hence, early research focussed on the development of a new epicutaneous DRB that can percutaneously be fixed with K-wires and nevertheless provides enough stability for surgical use (figure 1). Besides, it leaves more room for instrumentation, allows simultaneous registration
of several vertebral bodies and helps in segmental orientation. Experimental trials were undertaken to compare the new to the conventional DRB and to scrutinize the accuracy of needle placement in soft-tissue and in bone. Fluoroscopic navigation of a bioptic needle settled with a rigid body was compared to the conventional method.

For the preclinical trial a spherical defect defined to a diameter of 7 mm was cut in the ventral aspect of the vertebral bodies of a cadaver spine as a target. The lesions were filled with equivalent standardized globules of BaSO4-augmented plaster. The typical approach for kyphoplasty was navigated with computer-assistance in one pedicle, while the control was performed in conventional fashion in the other, defining the centre of the artificial target as the desired position for the tip of the canula. The accuracy of both procedures was controlled by comparative calculations based on a CT-generated 3-D-model of each vertebra and macroscopic sections. Total operating time, total radiation-exposure and criteria of general expenditure were analysed before the new application was first used for operation. Computer-assisted kyphoplasty was subsequently compared to conventional proceeding.

**Results:** Mathematic and macroscopic evaluation of the cadaver study showed that planning of the transpedicular insertion trajectory was easy feasible in two perpendicular planes. Navigation was performed without difficulty and could be executed with a mean deviation less than 2mm or 3°. Spinal cord and nerves were circumnavigated with high accuracy and the needle tip reached the target in all specimen. With computer-assistance the needle generally was navigated following an ideal trajectory, whereas the conventional technique often led to peripheral or parapedicular positions. Using fluoroscopic navigation the radiation exposure was reduced to 25% and operation time was up to 40% shorter in the experimental set-up.

The clinical application of the new method indicates, that total operation time due to the installation of the system and a certain learning curve is still slightly prolonged. Radiation time, however, is reduced to the expected extend, if the surgeon trusts and does not double-check the system. Post-operative x-ray and CT-control did not allow depiction of significant differences between the results of both groups. The clinical out-come is similar, as well.

**Discussion:** Although the clinical results of both groups do not differ a lot, the introduction of computer-assistance is significant step towards an optimised therapeutic concept. Not only radiation exposure can significantly be reduced to the patient and to the OR-staff. But, a highly accurate navigation system is in reserve for demanding cases such as asymmetric or even comminuted fractures. Anatomic peculiarity may strongly complicate the correct needle placement in the middle of the fracture gap. Especially at the thoracic spine the pedicles limit the introduction angle and make precise placement of its tip a demanding task, if the vertebra is extensively damaged. Once a needle is placed in the wrong position, it leaves a canal, that hinders the diversion into a new better position. With navigation, multiple attempts become rare and the procedure not only becomes more accurate, but minimal-traumatic, as the imminent risk for delicate structures is proportionally reduced. Furthermore, if the canula is placed too much laterally, precocious contact of the balloon with the cortical wall will lead to incomplete inflation, to insufficient repositioning effect and to inadequately small PMMA depots. With navigation such unpleasant results may be
avoided as the whole procedure can far better be controlled in two or more plains simultaneously, than in just one sporadically with the necessity to interrupt the operative work-flow to put into action the C-arm.

**Conclusions:** Computer-assisted fluoroscopic navigation enables the surgeon to realise intraoperative planning and placement of the needle with high accuracy in a comfortable fashion and thereby assures highest safety for the technically demanding procedure. Fewer x-ray-images are required, therefore the radiation exposure can be reduced. The total operation time is equal if not shorter. By avoiding recurrent interruptions for positioning of the C-arm during canula placement, the intervention becomes more ergonomic and efficient. In special cases of anatomical or technical pit-falls computer-assisted fluoroscopic navigation can be recommended for kyphoplasty and similar procedures. As the epiDRB does not require significant additional trauma and the navigation system is based on the standard C-arm technique, use on demand is possible, if the conventional method fails.

**References:**
Figure 1 – epiDRB (epicutaneous dynamic reference bas with a low center of gravity design and variable pin-fixation)
VALIDATION OF ROBOTICALLY-ASSISTED SYSTEM FOR SPINAL PROCEDURES

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Introduction: Successful application of robotic assisted surgery in active or semi-active modes requires an accurate execution of a long list of steps, such as: pre-operative 3D image handling, pre-operative planning, 2D to 3D registration, robot calibration and correct surgical tool positioning.

All the above steps should be accomplished with high accuracy and simplicity so that, for example, in the common procedure of pedicle screw insertion used in spinal fusion, the pedicle screw is positioned with greater accuracy than is achieved by the free hand of the surgeon.

This paper presents a validation process of a miniature (dimensions are 60mm height and 250 grams weight) robotically-assisted pedicle screw positioning system conducted on a carefully instrumented dry bones spine. Proposed routine verifies the overall chain starting by pre-operative planning, proceeding through intra-operative X-ray imaging and computer-based registration and finalized by guiding the robot to the predicted position and inserting the K-wire through the guiding sleeve. Numerous papers dealt with the surgical robots and the associated registration problem e.g. [1,2], but to the best of the authors’ knowledge there is no standard for validation of robotically-assisted orthopedic procedures before in-vivo clinical trials. We believe that the method suggested here is one way to approach this issue.

Materials and Methods: In this investigation, we applied a miniature robotic system to perform pedicle screw positioning in a series of dry bones experiments. Pre-operatively the surgeon plans the surgery on a CT data by manipulating the screws to the preferred locations. Intra-operatively, a clamp is mounted onto the bone (spinous process). Then special X-ray opaque passive targets are attached to the clamp and fluoroscopic images, containing both the targets and the vertebra, are taken from one or several directions. These 2D images are processed and registered to each other and to the pre-operative 3D model of vertebra derived from CT images, yielding the assessment of the desired drilling axes location respective to the clamp coordinate system. The passive target is then detached from the clamp and replaced by robot that performs targeting of the guiding sleeve to be co-axial with registered pre-planned drill line.
In order to verify the accuracy of this procedure, a special test was conducted in which the accuracy was assessed for each separate step and the overall procedure as a whole.

A special translucent “jig” was constructed that included an accurately machined frame to which dry lumbar spine was rigidly affixed. The frame was equipped with X-Ray opaque spheres implanted at known locations that can be detected by the imaging devices and constitute the jig’s coordinate system. In addition the jig was equipped with a moveable rigid beam, that can be positioned at several known accurate locations relative to the jig, and to which either a passive X-ray targets or miniature robot directing the guiding sleeve are fixed.

Special fiducial holes were drilled by an expert surgeon through the pedicles of the dry bones vertebrae. For better visualization on a CT images, these holes were filled with removable X-Ray opaque fiducial pins.

Then the following step-by-step validation process was conducted:

1. Two sets of CT data were acquired: one with and another without fiducial pins inserted. Special means were applied to ensure same position of jig relative to CT machine for both acquisitions.
2. Centers of the visible cross-sections of X-Ray opaque spheres attached to jig, and centers of the visible cross-sections of fiducial pins were accurately located on CT images and used to derive the location of fiducial drillings respective to jig coordinates.
3. In the planning phase the surgeon determined the drilling line along the axis of the clearly visible filled hole on three cross section views of the vertebra.
4. Passive targets were attached to the beam, and the jig was subjected to fluoroscopic imaging from two views.
5. Registration of the 2D fluoroscopic images containing both the target and the vertebra to the 3D CT model was performed. As a result, the coordinates of the planned drill axis were transformed into the coordinate system of the beam.
6. The robot was then attached to the beam and aligned its end-effector to the desired drill line resulted from registration process. To verify the position accuracy K-wire was inserted through the guiding sleeve in the attempt to hit the fiducial drills in the pedicle.

Validation of the planning module and registration module was performed separately and independently by comparing the numerical results delivered by each component, to the same parameters derived directly from the CT images upon stage 2 and the known geometry of the jig. Then, the overall accuracy was calculated assuming errors of each part statistically independent. Finally, the accuracy and robustness of the overall procedure was tested by measuring the discrepancy between the K-wire inserted through the robot’s sleeve and the actual axis of pre-drilled fiducial hole.

**Discussion:** Planning module was validated by pixel-based comparison of the planned screw axis overlaid on the CT data to the axis of fiducial pin inserted into the pre-drilled hole. It was found that this planning method resulted in an error of up to 0.3mm.
**Registration module** was validated by comparing parameters of the drilling axis in the beam coordinate system, assessed as a result of registration (validation step 5) with respect to the same parameters obtained upon validation of stage 2 with respect to the jig coordinates, and transformed into the beam coordinates utilizing its known position relative the jig. Deviations of the two lines within the pedicle were found to be within 0.9mm.

**Robot module:** The robot structure and performances are described in Shoham et al [3]. The accuracy was checked in the entire robot work volume by CMM machine and found to be better than 0.5mm.

**Beam assembly:** In the experiments we used a sufficiently rigid construction to support the robot relative to the bone. However, in actual operation one should account also for the actual clamp-bone rigidity. Numerous experiments have been conducted to identify the bone-clamp attachment strength and rigidity. Some of these results reported in Wolf et al [4] and other experiments with insertion forces applied to K-wire resulted in deviation at the entry point of up to 0.2mm.

**Derived Overall Accuracy:** Assuming independent sources of error, the total error resulted from planning, registration, robot and clamp stability calculated to be 1.1mm.

**Direct Measurement of the Overall Accuracy** was performed by attaching small plastic pipes to the entrance of pre-drilled fiducial holes and attempting to hit the inner gap of the pipe with the 2.5mm K-wire guided by the robotic system. By moving the supporting beam into different fixed positions machined on the jig and targeting the robot to different fiducial holes we managed to carry 25 independent tests. When the inner diameter of the pipe was set to 5mm the insertion was successful in all 25 cases thus achieving an overall accuracy of better than +/- 1.25 mm.

**Conclusions:** In this paper we presented a validation method applied to the robotic-assisted pedicle screw insertion procedures.

Utilizing a dedicated jig and fiducial inserts, we have assessed and learned both the error contribution of each component of the chain – from planning through registration to robot positioning, as well as the overall system accuracy.

It was proven by 25 independent tests that the robotic system had achieved an overall accuracy better than +/-1.25mm at tool tip which is consistent with the evaluation of the overall accuracy calculated by the accuracy of each separate component.

The proposed method, applied here for validation of the pedicle screw guiding system, can be extended, as well to similar robot-assisted orthopedic surgery.

**Acknowledgement:** The help of Prof. Leo Joskowicz, of The Hebrew University of Jerusalem is acknowledged.
References:


Mazor’s SpineAssist miniature robot guides a K-wire into a pipe located along the axis of a drilled-hole in a pedicle.
A NEW APPROACH FOR COMPUTER-AIDED LONG BONE FRACTURE REDUCTION USING UNILATERAL EXTERNAL FIXATOR

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Introduction: Accurate anatomic reduction is a prerequisite for operative treatment of displaced long bone fracture. In current clinical practice, closed reduction and external fixation of long bone fracture can be regarded as a trial and error process. Based on the two-dimensional images provided by a single C-arm view, surgeon has to manipulate the fracture site so that the proximal and distal fragments are aligned. This approach would predispose the surgeon and patient to excessive amount of radiation. This abstract presents an innovative computer-aided method to plan and execute long bone fracture reduction using unilateral external fixator (EF). Success of this method would allow the surgeon to perform fracture reduction more efficiently and accurately yet minimize the use of image intensifier during the operation.

Theoretical Consideration: A bone-fixator system can be regarded as an open kinematic chain system allowing rotation and translation at the fracture site through fixator joint adjustments. The Dynafix® unilateral external fixator (EBI L.P., NJ) was selected in the current study mainly because each Dynafix® joint possesses only one degree of freedom, which makes the adjustment plan readily applicable to the EF. It consists of 6 body components, 2 pin clamps, a pair of pins that connect the proximal pin clamp with the proximal bone fragment, and another pair of pins that connect the distal pin clamp with the distal bone fragment. Each of the EF parts and bone fragments can be regarded as a rigid body that linked together by 2 telescopic joints, 4 revolute joints, 1 central rotary joint, 4 pin-bone interfaces and 4 pin-pin clamp interfaces. Since the distal (proximal) tibial fragment, the distal (proximal) pins and the distal (proximal) pin clamp are rigidly linked together by distal (proximal) pin-pin clamp and pin-bone interfaces, both the distal and proximal assembly (i.e. pin clamp + pins + bone fragment) can also be considered as a rigid body. By defining a local coordinate system on each assembly and body component, the matrix equation: \( \mathbf{T}_{i+1} = \mathbf{T}_i \cdot \mathbf{T}_{i+1} \cdot \mathbf{T}_{i+2} \cdot \mathbf{T}_{i+3} \cdot \mathbf{T}_{i+4} \cdot \mathbf{T}_{i+5} \cdot \mathbf{T}_{i+6} \) which represents a sequential transformation from proximal to distal ends, can be solved for the amount of rotation and translation required at each joint of the EF to correct for a displaced fracture using a non-linear least square optimization method if \( \mathbf{T}_{A} \) can be estimated pre-operatively. Superscript A stands for “after reduction”, 1 and 8 represent the distal and proximal assembly respectively, and 2 – 7 represent the six EF body components from distal to proximal.
ends respectively. Each matrix within the equation is a 4 x 4 homogeneous transformation matrix, which represents the relative position and orientation of the subscript component with respect to the superscript component.

**Laboratory Validation:** Laboratory test was conducted on six polyurethane-foam tibia models. Osteotomy was performed at the mid-shift of each polyurethane-foam tibia model to form either a transverse or oblique fracture. A fracture deformity was arbitrarily introduced to each model so that the six models covered a wide range of misalignment at the fracture site. Initial configuration of each EF was set to its neutral position before reduction. The distal fragment was fixed by a jig so that only the proximal fragment was allowed to move during the EF joint adjustment process. To validate the theoretical correctness of our method, we manually aligned the distal and proximal fragments and digitize three markers marked on the surface of the distal and proximal fragments respectively using an OPTOTRAK (Northern Digital Inc., Canada) and used their 3D coordinates to determine the ideal transformation matrix of the proximal assembly with respect to the distal assembly. This ideal transformation matrix was then used as an input to the program to calculate the EF joint adjustment requirement, which was then applied to the Dynafix® EF joints to reduce the fracture site. During the EF joint adjustment process, both the distal and proximal fragments were covered to eliminate any visual hint. Upon completion of the adjustment, the cover was removed and the actual transformation matrix of the proximal assembly with respect to the distal assembly was determined by digitizing the markers again. The reduction accuracy of our method was then quantified by calculating the residual displacement in the x-, y-, z- directions and the residual angulations $\alpha$, $\beta$, $\gamma$ based on the Bryant Eulerian angle convention [1].

**Results:** The absolute values of the residual displacement and angulation of our computer-aided long bone fracture reduction technique as well as the total residual displacement ($d = \sqrt{x^2 + y^2 + z^2}$) and angulation ($\theta = \sqrt{\alpha^2 + \beta^2 + \gamma^2}$) were calculated. The mean $\pm$ SD of $\alpha$, $\beta$, $\gamma$, x, y, and z of the six models were $1.6^\circ \pm 1.1^\circ$, $1.3^\circ \pm 0.9^\circ$, $0.7^\circ \pm 0.7^\circ$, $1.0 \pm 1.9$ mm, $0.8 \pm 0.7$ mm, and $0.3 \pm 0.3$ mm respectively and the mean $\pm$ SD of $\theta$ and $d$ were $2.3^\circ \pm 1.5^\circ$ and $1.5 \pm 1.8$ mm respectively, which demonstrated the reduction accuracy of our method.

**Discussion:** Although substantial effort has been employed to position the fixator joints as closely as possible to the positions suggested by the solutions computed by our model, the actual joint positions applied to the revolute and central rotary joints can only be set to nearest $\pm 2^\circ$ with respect to the calculated solutions due to the limitation of the Dynafix® joint design. This may affect the accuracy of our laboratory validation. Moreover, errors in measurement of the fixator dimensions may also affect the accuracy of our laboratory validation. Anyway, we have demonstrated the theoretical correctness of our method to reduce long bone displaced fracture. The same technique and device can also be applied to other orthopaedic applications such as high tibia osteotomy and limb lengthening to benefit a wide range of subject groups.

**References:**

A NOVEL FLUOROSCOPY-GUIDED AUTO-FRAME NAVIGATION SYSTEM FOR DISTAL LOCKING OF INTRAMEDULLARY NAILS

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Introduction: Distal locking of intramedullary nails is a major challenge in long bone fracture therapies. The early free hand trial-and-error procedure heavily depends on the operator’s long term clinical experiences and undertakes too much X-ray exposure. The widely applied mechanism-assisted devices, however, can not compensate for nail’s deformation during insertion procedure [1]. In optoelectronic navigating system, no obstacles can be existed between position sensors and localizers. Besides, the other surgical navigating systems still keep either the high cost, or the complicated operation. With the binocular vision based biplane imaging principle, this paper proposes a novel X-ray fluoroscopy-guided auto-frame navigation system for distal locking of long bone intramedullary nails. The error distribution and the system performance are also evaluated after structure analysis and model experiments.

System Description: This system is designed for accurately modeling the space axis of the target hole, and optimally planning and positioning the surgical path. The functionality based modular design is convenient for system extension in future. The image acquiring and processing module uses an video framegrabber board equiped on a notebook through a USB2.0 protocol to import real time video from the output port of a C-arm system into compter for remotely monitoring surgical procedure simultaneously. Two snapshots from lateral and AP views of fracture anatomy can be easily acquired after several mouse clicks and be preprocessed to identify all fiducial markers and the target points. The path planning module which is programmed in three layers structure with OOP style, utilizes these information to calculate and interactively plan out the optimal surgical path. The motion control module which consists of master control program, PLC, encoder, etc, tranfers the navigating signals from the master PC to PLC through asynchronous serial communication and triggers PLC program sending out pulse signals to drive four stepping motors’ motions. Eventually, the navigating mechanism, the essential part of the system which consists of a cubic mechanical frame, two sets of movable positioning unit, four stepping motors, and other accessories, is used for implementing all navigating motions. The frame is the main body of the mechanism and installation base of other parts. It should be noticed that there are 4 sets of steel ball markers (3 markers in each set) embedded in 4 X-ray radiolucent planes on front, rear, top, bottom sides of the frame respectively to form two biplanar groups from lateral and AP views. According to computer vision theory, the real surgical path can be determined using two pos-
tioning units driven by four motors horizontally or vertically as the two intersections of the axis of distal hole with the front and the rear reference planes of the frame. Consequently, the distal locking procedure after screwing the proximal end can be described as following: 1) bind the fractured leg with the frame tightly. 2) acquire and archive two valid 2D X-ray images which contain the targeting hole and all six markers from lateral and AP views respectively. 3) plan out the optimal drilling path of distal hole by simple mouse interaction. 4) move the positioning units which attached a guided hole to the desired positions driven by four stepping motors and fix the path using a guided bar. Then the operator can drill the screw hole and lock the distal end of intramedullary nail easily.

**Simulation and Experiments:** Firstly, the Monte Carlo simulation is adopted for error analysis because many independent variables existed in the mathematical model. The same standard deviation \( \sigma \) is assumed to each variable for the consistent picking errors of screen points[2]. Then the \( \sigma \)-curves of 12 typical lateral images influenced by each variable with the sample size 50,000 are drawn out. Experiments with two far distal screwing of each nail are applied to 10 plastic tibia models and 20 plastic thighbone ones (Sawbone, Swiss) of the same specifications by the same staff. Experimental results show that the successful locking rate is 100%, the mean operating time is 4.4 min, and the mean X-ray expose time is 1.2 min, which are dramatically decreased compared to the traditional free hand operation.

**Discussion:** Once the mechanical frame is assembled, the system errors are mainly from picking errors of image points, the angular deviation of the nail axis compared to the two parallel planes in lateral side of cubic frame, and the inherent image distortion of C-arm imaging system, etc. Monte Carlo simulation has shown three

**Conclusions:** 1) The synthesized error is approximately linear to each original variable. 2) The error in Y-direction is more sensitive than that in X-direction which should be further investaged in future. 3) If the error of each variable is less than 0.3 mm, the synthesized error of system can not exceed 0.5 mm which is enough for clinical need and has been validated by model experiments. For further study, the problems existing in the mechanical structure should be revised. The more accurately quantitative analysis and tests about the error distribution should be carefully studied. The image distortion correcting method and more reasonable interaction operation should be deeply researched so as to optimize the performance of system globally.

**Conclusions:** This system has enough motion precision and repeated positioning precision with a compact and rigid structure. Invalidated drilling procedures have been eliminated and the surgical time has been obviously reduced. The minimal invasion and less X-ray exposure time are helpful for patient’s rehabilitation. Above analysis has validated the stability, reliability and cost-effectiveness of this system.

**References:**

CLINICAL RESULTS OF DYNAMIC HIP SCREW (DHS) INSERTION USING COMPUTER ASSISTED ORTHOPAEDIC SURGICAL SYSTEM (CAOSS)

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Introduction: Accurate insertion of guide wire is the most vital surgical step in Dynamic Hip Screw (DHS) insertion for fracture neck of femur fixation. The positioning of the guide wire is technically challenging and usually a trial and error approach. This is undesirable as it prolongs the operation time, increases tissue damage, increases radiation exposure to both patients and staff and greatly relies on surgical expertise. Non-optimal placement of the implant may also affect the mechanical stability of the femur [4]. The failure of fixation was found to be a significant complication of the treatment of unstable inter-trochanteric fractures [2]. A computer assisted orthopaedic surgery (CAOS) approach offers the opportunity to address these shortfalls. The Computer Assisted Orthopaedic Surgical System (CAOSS) has been developed collaboratively by the University of Hull and the East Yorkshire Hospitals NHS Trust. It uses intra-operative fluoroscopic images for surgical planning. The CAOSS creates a 3D surgical plan by reconstructing the information from a pair of 2D fluoroscopic images [3]. This paper presents the early clinical results of CAOS system to assist in insertion guide wire in DHS fixation operation.

Methods: The CAOSS equipment comprises a CAOSS trolley, an optically tracked end-effector (spider) attached to a lockable passive arm, a registration phantom and various guiding cannulas. The optical tracking system uses a two camera array that tracks the position of seven Infra-Red Emitting Diodes (IREDs) of the end-effector in 3D space. The end-effector is used to position the registration phantom and various guiding cannulas. The calibration of fluoroscopic image is obtained once a month by using a calibration plate containing a grid of 64x64 radio-opaque balls that attaches to the x-ray receptor tube. A distortion-undistortion map is created and saved. A registration phantom containing H arrangement of 21 metal balls is held in the end-effector and placed in image space of C-arm. This allows accurate determination of the position of the x-ray source and the virtual plane of C-arm. The CAOSS creates a 3D surgical plan by reconstructing information from a pair of 2D fluoroscopic images. The head, neck and shaft of femur are identified on two fluoroscopic images in operation theatre (AP and Lateral). The CAOSS determines the centre of head and
centre of neck as well as shaft axis. It calculates the entry point and the trajectory for
the guide wire of DHS at an angle similar to the DHS implant to be used (115° to
150°). The depth of the drill hole is also calculated. The trajectory is then shown on
both AP and lateral images on the screen. The surgeon can modify the trajectory if
necessary. The computer guides the surgeon by a quantitative graphical display of the
cannula movements required. The rest of the operation is performed as standard. All
the components of CAOSS are sterilisable to requisite EC standards. The positional
accuracy was shown to be within 0.7mm and angular accuracy to be within 0.2°. The
clinical trial has been approved by Ethics Committee and by Medical Devices
Agency for single centred clinical trial. The outcome was measured in terms of posi-
tional accuracy of implant (tip apex distance), time needed to place the guide wire,
number of fluoroscopic images needed, and need of blood transfusion.

**Results:** The CAOSS was used on 10 patients for extra-capsular fracture of femoral
neck. Eight were female and two were male patients. Mean age was 85 (75 to 93)
years. Mean follow up was 11.5 (9 to 21) months. Mean drop in haemoglobin level
was 2.1 g/dl. One patient needed blood transfusion. Six fluoroscopic images were
used on average. Average time taken to insert the guide wire was 17.2 (8 to 23)
minutes. Mean tip apex distance (TAD) was 17.7 (6 to 31) mm. No implant failures
were found on follow up in the entire series.

**Conclusions:** In all 10 cases, CAOSS was found to be successful without any tech-
nical problems. The TAD was well within acceptable limit of 25 mm [1].
Theoretically, only four x-ray images should be needed with CAOSS, two (AP and
lateral) images for initial registration process and two images after insertion of guide
wire. But in our series, an average of six images were needed. Although, this number
is still considerably low compared to a standard procedure without CAOSS. The
CAOSS was found to be safe, user friendly, accurate, and reliable for the guide wire
placement for DHS insertion in its early clinical application. More importantly, the
surgeon is in-charge of decision-making and control throughout the operation.
CAOSS for these operations has the following potential benefits: improved patient
outcome, improved delivery of treatment, development of new improved surgical
procedures and reduction in required surgical skill level for these operations.

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Introduction: The exact anatomic reduction and correct implant placement is directly related with the result and long term outcome of surgical treated tibial plateau fractures. Especially during minimal invasive procedures intraoperative imaging provides important result informations for the surgeon and is consequently indirect responsible for the result. Twodimensional intraoperative c-arm images are limited in some informations and usually postoperative computer tomography (CT) necessary for a final decision about anatomic reduction and hardware placement. It has been shown that multiplanar reconstructions in different planes allow more precisely the indentification and interpretation of tibial plateau and other articular fractures. The use of a introperative CT is rare and intial costs extremly high. So far a low number of spezialized clinics were able to achieve such an introperative imaging device. Alternatively the new Iso-C 3D allows a mobile intraoperative three-dimensional imaging device. The accuracy and introperative value has been already shown in previous studies. The Iso-C3 D provides intraoperative multiplanar reconstructions, ennabling control of remaining tibial articular steps and screw or k-wire placement. An immediate result control and operative correction during the same procedure become possible. We report about our first clinical experience and value of the intraoperative Iso-C3D imaging at tibial plateau fractures.

Material and Method: During January to November 2003, 19 intraarticular tibia plateau fractures were introperatively scanned with the Iso-C3D (Siemens, Germany). All patients were positioned on full-carbon tables and according to an internal standard the positioning of the Iso-C 3D was done. The cases were randomly scanned and the operating surgeon and patient asked about acceptance. In 14 cases a open reduction was done, combined wih an internal fixation, in 5 other cases a minimal invasive, arthroscopy based, procedure was performed. After initial reduction, fixation and result acceptance of the surgeon a conventioanal twodimensional c-arm based imaging was done for first result control. Anterior-posterior and lateral imaging was done in all cases. Following an Iso-C3 D scan was performed. Before a secondary complete sterile draping of the whole situs was done. The Iso-C3 D calculates multiplanar reconstructions out of 100 c-arm images, registered during one automated rotating scanning procedure. Evaluation of the multiplanar reconstructions was done by the operating surgeon and concerning about intraarticular steps and implant misplacements compared to the conventional c-arm images. Identified remaining articular steps or hardware misplacements were corrected in same operative procedure. Post operative CT scans were done in all cases.
**Results:** Two (10%) Iso-C3D scans had to be repeated caused by insufficient positioning during the scan. Direct scanning procedure took always two minutes. Intraoperative positioning and set up of the system needed 187 seconds (140-480). Examination and analysis of the multiplanar reconstructions by the surgeon was measured with an average of 247 seconds (135-450). In four cases (21%) a direct intraoperative corrections resulted, in two cases correction of the reduction and a implant correction in two other cases. Three of those cases did not reveal significant articular steps (>2mm) or screw misplacement in the conventional c-arm imaging and were only detected in the Iso-C 3D images. Another exact subchondral k-wire placement was confirmed with the Iso-C 3D. All postoperative CT scans confirmed the intraoperative Iso-C 3D imaging, no further steps or misplacements were identified.

**Discussion:** Exact reposition of tibial plateau fractures is essential for the operative outcome and consequently responsible for early arthritis. Three-dimensional imaging is more accurate in the interpretation of intraarticular tibial plateau fractures. The Iso-C3D allows a reliable intraoperative control of reduction and hardware placement and provides significant more information compared to the usual twodimensional c-arm based imaging. Tibial revision surgery based on the knowledge of threedimensional postoperative CT scans might be avoided. The use of postoperative CT imaging as a result control is widespread and mostly intrarticular steps of >2mm usually operatively revised. As shown in other studies the ISO-C 3D enables a identification of articular steps >1mm in different anatomic regions. Potentially further postoperative CT scans are not necessary if the surgeon is satisfied with the Iso-C3D imaging, additionally the system can be used as a regular c-arm image amplifier during the rest of operation. Controversary high initial costs, extra intraoperative time for positioning and scanning and additional personell at the imaging device is needed. These disadvantages have to be compared with safed reoperations and safed postoperative CT scans to provide the economic advantages of this new imaging technique. Further clinical studies need to evaluate the value and usefullness at other anatomic regions.
COMPUTER ASSISTED ORTHOPAEDIC SURGICAL SYSTEM FOR INSERTION OF DISTAL LOCKING SCREWS IN INTRAMEDULLARY NAILS: LABORATORY BASED VALIDATION

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Introduction: The majority of femur and tibia fractures and some of the humerus fractures are treated with intramedullary (IM) nails. The difficult part of the operation is to insert distal locking screws to achieve axial and rotational stability. The current technique to insert these screws uses numerous fluoroscopic images and depends on skills and expertise of the surgeon. A free hand technique or radiolucent drill is used to drill a hole in the bone that passes through the nail hole. The problems encountered with this technique include length of time required for distal locking, radiation risk to patient and theatre staff and misplacement of the screw. The placement of distal screws usually takes half of the total operation time and is responsible for 30-50% of total radiation exposure [1,2]. It is clearly desirable to improve the surgical technique to avoid these shortfalls. A computer assisted orthopaedic surgery (CAOS) approach offers the opportunity to address these shortfalls. Our Computer Assisted Orthopaedic Surgical System (CAOSS) uses intra-operative fluoroscopic images for surgical planning. CAOSS creates a 3D surgical plan by reconstructing information from a pair of fluoroscopic images for distal locking of IM nail [3]. This paper presents a CAOS system to assist in insertion of distal locking screws in IM nails. Laboratory based test results for IM nail procedure are presented and discussed in terms of accuracy and as part of the validation process to introduce new CAOS procedures into clinical use.

Methods: The CAOSS equipment comprises a CAOSS trolley, an optically tracked end-effector (spider) attached to a lockable passive arm, a registration phantom and various guiding cannulas. The optical tracking system uses a two camera array that tracks the position of seven Infra-Red Emitting Diodes (IREDS) of the end-effector in 3D space. The end-effector is used to position the registration phantom and various guiding cannulas. The calibration of fluoroscopic image is obtained once a month by using a calibration plate containing a grid of 64x64 radio-opaque balls that attaches to the x-ray receptor tube. A distortion-undistortion map is created and saved. A registration phantom containing H arrangement of 21 metal balls is held in the end-effector and placed in image space of C-arm. This allows accurate determination of
the position of the x-ray source and the virtual plane of C-arm. The CAOSS creates a 3D surgical plan by reconstructing information from a pair of 2D fluoroscopic images. The IM nail, the shaft of long bone and both distal holes are identified on two fluoroscopic images (AP and Lateral). CAOSS software determines the nail axis and recovers the geometry of both the distal holes from these images [4]. CAOSS then displays the drilling axis of both holes in 3D as well as the length of screw needed for locking. The computer guides the surgeon by a quantitative graphical display of the cannula movements required. Laboratory tests were performed on a 14mm diameter hollow metal tube representing a standard IM nail. A screw-guide was designed which when inserted in distal hole, represents the true trajectory of the hole. The CAOSS calculated trajectory was compared with the true trajectory obtained by the screw guide to determine various distance and angle error metrics of surgical plan. The Mathcad software (Mathsoft Engineering & Education, Inc. USA) was used to analyse data from the laboratory tests. Assuming a 3.2mm drill, the analysis also determined whether the CAOSS calculated plan is successful, i.e. the drill, if implemented perfectly, would pass through the hole.

**Results:** Ninety-eight laboratory tests were done using a Philips BV25 Gold image intensifier. Calibration of all the components was checked using a coordinate measurement machine (CMM). The first 12 tests showed a fixed error of 0.9 mm in one direction. The next 76 tests were done to locate this error. The error was corrected and the final 10 tests showed the positional accuracy of 0.26 mm and 0.19 mm for two distal holes. The angular accuracy was 0.15° and 0.18° for two distal holes. All CAOSS plans for the above tests were successful. Thus, the CAOSS planning accuracy is shown to be within 0.3 mm for distance and 0.2° for angle. This study shows that CAOSS in IM nailing is robust and reliable.

**Conclusions:** The study has validated by laboratory tests that CAOSS is able to assist surgeons in drilling holes in the bone, rapidly and with the required accuracy for distal locking screws in intramedullary nailing operations. CAOSS for these operations has the following potential benefits: improved patient outcome, improved delivery of treatment, development of new improved surgical procedures and reduction in required surgical skill level for these operations.

**References:**

COMPUTERIZED NAVIGATION FOR CLOSED REDUCTION DURING FEMORAL INTRAMEDULLARY NAILING

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Introduction: Intramedullary nailing is the most commonly used technique for fixing long bone fractures. The use of fluoroscopy based computerized navigation system can improve nailing technique with markedly reduced radiation exposure [2]. However, the task of fracture reduction has not been addressed yet by computerized navigation systems, since dynamic imaging of two separate anatomic sites, such as fracture fragments, is not feasible yet. Several techniques have been suggested to accomplish closed reduction, including the use of the femoral distractor, percutaneous Schanz screws to manipulate the fragments and tourniquet [5]. We present here a new technique for closed reduction in intramedullary nailing utilizing fluoroscopy based computerized navigation system.

Methods and Surgical Technique: The ION Fluoronav StealthStation workstation (Medtronic SNT Inc, Louisville Colorado USA) is a dedicated fluoroscopic computerized navigation unit. It includes a central computer, a position sensor, and trackers attached to bone, to the surgical instruments and to the C-arm machines. The process of navigation involves the fixation of a bone tracker to the skeleton with constant relation to the operated site. In the next step a few radiographic images are taken while the surgical team is within a safe distance from the radiation source. The position sensor must be triangulated with both C arm and bone tracker, both equipped with active infrared emitting diodes, in order to acquire the fluoroscopic images. The images are then processed by the computer, displayed virtually on the screen and navigation can commence. In the navigation process, a tracked instrument is manipulated and its image is depicted simultaneously on all the images taken previously representing the patient’s anatomy. The SureTrak 2 system (Medtronic SNT Inc, Colorado USA) is a modular infrared emitting active instrument tracker that can be attached to any surgical instrument and enables its spatial recognition in relation to the patient’s anatomy by the computer. A straight nail or a guide-wire can be defined on real-time and displayed on previously acquired images. In order to achieve fracture reduction, the tracker is mounted on a cannulated intramedullary fracture aligning device and its configuration is registered by the computer. The patient is positioned supine on a radiolucent table with a traction unit. A skeletal traction pin is placed in the proximal tibia thus maintaining length, and later on simplifies closed reduction. The preparation of nailing and location of the entry point can be done conventionally or with the use of computerized navigation as already described [3].
After locating the entry point, the proximal fragment is reamed, up to the diameter of the tracked intramedullary fracture alignment device, which is then inserted into the proximal fragment’s medullary canal, advanced to the fracture site, and will later be used as a “joystick” for fracture reduction. A bone tracker is inserted to the distal segment of the fracture. Two fluoroscopic images (AP and Lateral) of the distal fragment are now taken and stored in the computer. The fluoroscope is now removed from the surgical field and will not be used throughout the reduction process. At this time, the position sensor (infrared camera) is tracking the intramedullary fracture alignment device and the distal fragment. Since the intramedullary device is located inside the proximal fragment, its image represents both the device and the proximal fragment as a single unit. This eliminates the need to fix a reference frame to the proximal fragment. Now the actual fracture reduction is carried out by manipulating the proximal fragment using the tracked intramedullary alignment device, directing its virtual image on the computer screen it towards the medullary canal of the distal fragment. During the reduction process, the image seen on the computer screen, while navigating, is of the device and the distal fragment. The fracture is reduced when the virtual images of the device and the distal fragment are aligned on both AP and Lateral views previously taken. It is stressed that the above procedure is done entirely without the use of fluoroscopy. At this point the reduction has been achieved and a reaming guide wire is passed through the intramedullary alignment device into the medullary canal of the distal segment. A verification fluoroscopy is taken (fig 4). From this point onwards, nailing continues in the standard fashion.

**Discussion:** An innovative technique for long bone fracture reduction, based on computer assisted surgery, with minimal exposure to radiation is presented here. Several authors have suggested techniques to overcome the obstacles of closed reduction. The maneuvering of the proximal fragment by a small diameter nail or a customized tool designed for this application was previously described [5]. The main disadvantage of these techniques is that they rely heavily on conventional fluoroscopy and its hazardous implications [2]. It should be kept in mind that significant amount of radiation is delivered both to the patient and to the surgical team while reduction attempts are taking place, especially to the surgeons’ hands [2]. The technique presented here is accurate and based on minimal number of fluoroscopic images. Existing computerized fluoroscopic based navigation platforms can be used as an “augmented fluoroscopy” with increased precision and reduced exposure to radiation [2]. They do not allow, however, dynamic imaging of two separate anatomical structures, and thus fracture reduction by means of computerized fluoroscopic based navigation has not been feasible yet. The manner to overcome the drawbacks of the existing computer navigation systems is described here. This technique is based on tracking standard available equipment for fracture reduction, eliminating the need for two different bone trackers on both fracture fragments. In conclusion, we find this technique useful in the reduction of femoral shaft fractures, reducing exposure to radiation and creating new concepts for future techniques in orthopedic traumatology.

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DYNAMIC HIP SCREW: A COMPARISON BETWEEN NAVIGATION AND CONVENTIONAL TECHNIQUE

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Introduction: The incidence of hip fractures is expected to almost quadruple in the next sixty years. Operative treatment is generally indicated and leads to good results in the majority of cases. The failure of fixation is however a troublesome complication resulting in major costs for the patient and the health-care system. The most important predictive factor for mechanical failure in peritrochanteric fractures is the position of the screw in the femoral head [3]. Screw insertion into the femoral head is classically performed under fluoroscopic control and must be checked in two planes leading to scattered radiation to patient and surgical staff, which is proportional to operation time [1]. Computer-assisted surgery could be an alternative concerning accurate screw insertion with low radiation dose. In this way, experiments have shown the accuracy of navigated target drilling in femoral head [2,4,5]. Up to our knowledge, however, these studies had not considered the insertion of implants used in management of proximal femur fractures. We designed an accuracy laboratory trial where precision of screw insertion into femoral head was analyzed regarding two different control methods – conventional fluoroscopy and computer-assisted surgery (CAS) – as well as surgeon’s experience – resident and senior. The aim was to determine if CAS is able to produce as accurate hip screw placements as fluoroscopy. Furthermore, we were interested to screen the interaction between surgeon experience and CAS concerning precision of screw placement in the femoral head.

Materials and Methods:

Artificial bones:

40 intact artificial proximal femora (Synbone®, Malans, Switzerland) were involved in cylindrical foam, aiming to difficult surgeon’s direct optical control during experiments. The femora were then fixed to the operation table by a radiolucent support.

Groups:

Two different methods were used to control screws insertion: conventional fluoroscopy and CAS. Two surgeons performed all experiments. The senior one has an
experience of more than ten years treating proximal femoral fractures. The resident surgeon has assisted operative procedures and performed few operations in this area. Before starting the experiment, a workshop was done with the resident addressing his technical doubts. Each surgical step was carefully discussed and trained with him.

**Fluoroscopic Set-up:**

Two C-arms (Ziehm®, Nuremberg, Germany) were disposed orthogonally in relation to the proximal artificial femur enabling simultaneous control of anterior-posterior and lateral planes during the experiment. Following AO technique a dynamic hip screw (DHS) and an anti-rotational (ARS) 6.5mm screw (Synthes®, Bochum, Germany) were inserted into the femoral head oriented 135° in relation to femoral shaft. A radiographic control in anterior-posterior and lateral views documented the final position of implants.

**CAS Set-up:**

A commercially available navigation system (Surgigate®, Medivision, Oberdorf, Switzerland) including an Ultra 10 Workstation (SUN Microsystems, Palo Alto, CA) and an Optotrack 3020 optoelectronic localizer (Northern Digital Inc, Waterloo, Ontario, Canada) were used for the navigated groups. The localizer is assembled from three charge coupled device cameras that trace infrared light emitting diodes in space with an accuracy of 0.1mm translation and 0.1° rotation according to producer. The light emitting diodes are present in navigated tools as drill machine, screwdriver, C-arm and dynamic reference base (DRB). The DRB was fixed about 20 cm distal to the tip of greater trocanther on the lateral femoral cortical. Thanks to its specific coordinates, the DRB informs CAS system the position of our region of surgical interest in the operation room. The next step is the acquisition of femoral head views in two planes – anterior-posterior and lateral – with navigated C-arm (Ziehm 8000®, Nuremberg, Germany). The images are transferred to CAS system where they will be used as a navigation map. The traceable C-Arm enables simultaneous correlation between image and patient anatomy, precluding the needing of registration techniques. Although navigated drill machine is traceable by CAS drill bending is not even precisely detected. Factors such as drill diameter, drill length, machine’s weight, and bone density can affect the accuracy of navigating drillings. Because of these evidences, we changed the conventional dynamic hip screw technique. Instead of using the classical 2.5mm threaded guide wire 230mm in length, we favored a 3.2mm drill bit 195mm in length performing the guiding hole. No mechanical angle guide was used to achieve a desirable 135° insertion angle of screw, since virtual control of such angle was deductible on CAS monitor. The next operative steps followed the conventional technique, but assisted exclusively by CAS system. A navigated screwdriver was used to insert the hip screw. An anti-rotational 6.5mm screw was additionally inserted proximally to the hip screw, according to AO technique and under CAS guidance. The software module “C-Arm” was used as platform for all navigation procedures. Anterior-posterior and lateral radiographs were taken to document the end position of implants.
Predictor Variables and Statistics:

Five predictor variables were considered. Total operation time (OT), total radiation time (RT), Tip-Apex Index (TAD) [3], and insertion angles on anterior-posterior radiograph views of dynamic hip screw (DHS) and anti-rotational screw (ARS). The desirable angle for screw insertion was set on 135°. TAD was considered acceptable if up to 25. OT was recorded in minutes including the while of operative procedure and image acquisition. RT was recorded in seconds and included all uses of fluoroscopy. The data obtained was evaluated by a professional statistician using SPSS (Version 11.5, SPSS Inc., Chicago, IL). Each predictor variable was tested by One-Way ANOVA, assuming both methods and surgeons as its categories. Statistical significance was set at p<0.05. Considering that the parallelism of DHS and ARS can be an important technical step assuring the well function of DHS sliding mechanism, we aimed to insert the screws as parallel as possible in two planes. We defined as standard on anterior-posterior view a 135° screw angle in relation to the shaft. After screw insertion DHS and ARS angles were measured as well as their standard deviation to the predetermined angle. For each surgeon and control method a t-paired test was applied comparing DHS and ARS angles with the significance set on p<0.05. The screws were considered parallel on anterior-posterior plane if no statistical significance between them were detected. On lateral plane the orientation of screws were considered acceptable if the screws were parallel to the femoral neck axis. To check the performance of a single surgeon in relation to conventional fluoroscopy and CAS, the two methods were compared using a t-paired test for each predictor variable.

Results: CAS control enabled a significant reduction of radiation exposure time as high as 94% if compared with conventional fluoroscopy (p<0.001). There were no significant differences between methods and surgeons regarding Tip-Apex Index (p=0.092), DHS insertion angle (p=0.245), the ARS insertion angle (p=0.243), and the operation time (p=0.735). The TAD was greater than 25 in only one case, performed by junior surgeon. The comparison between DHS angle and ARS angle revealed significant differences in fluoro groups (junior p=0.014; senior p=0.007) and no differences in CAS groups (junior p=0.08; senior p=0.25).

Conclusion: Fluoroscopy has been the standard assistive method to control insertion of implants in fracture management. Its use is however associated with radiation exposure to the patient and surgical staff. This problem can be easily magnified if we consider that surgical staff must be exposed to fluoroscopy many times a week while performing multiple operations. Considering TAD index as a precision parameter, CAS achieved results as precise as fluoroscopy, but with drastic reduction of radiation time. These finds are according to the literature were CAS has been used to assist precise drilling and screw insertion. CAS is related with increase in operative time. We believe that most of this additional time is related to equipments set-up in Operation Theater, training of operative room personal, and institution of routine schedules. Before starting our laboratory study, we planned carefully a reproducible set-up, where the navigated tools were always traceable by camera. It should at least partially explain why in our series no significant differences in operative time between CAS and fluoroscopy were observed. The role of surgical experience was also investigated in this study. Although factors as surgical approach, bleeding, frac-
ture reduction, and operative stress were excluded, this laboratory study shows that regarding drilling precision, CAS is a reproducible technique leading to accurate results independent of surgeon experience.

References:
EXPERIMENTAL EVALUATION OF A FLUOROSCOPY-GUIDED AUTOMATIC NAVIGATION SYSTEM FOR DISTAL LOCKING OF INTRAMEDULLARY NAILS

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Introduction: Although the therapy of long bone fractures with the interlocked intramedullary nailing has made a great progress, the distal locking of nails is still one of the challenges in the internal fixation [1]. The unsuccessful placed screws rate still keeps a high level (some reported 29% [2]) even utilizing the modern mechanical positioning devices. In this paper, a stereotactic-frame assisted distal locking system of intramedullary nails under C-arm based fluoroscopy was briefly introduced. The initial experiments of this system have been carried out with the lower limb’s bone model of plastics and cadavers.

Materials and Methods: Reference frame and software: The system uses a cubic mechanical frame with known dimension-size as a reference coordinate system to implement surgical navigation. The frame has two paralleled reference planes in the front and rear side. Two units which can move horizontally and vertically in the range of each reference plane were mounted on the frame so as to locating and locking the two intersections of the axis of screw hole with reference planes after path planning intraoperatively. Then the surgeon can screw the nail along the path line determined by these two points. The software system has two main functionalities of determining the axis of screw hole based on the X-ray image and obtaining the necessary data.

The operating procedure: (1) Implant intramedullary nail into the marrow cavity with proximal screw locked as usual. (2) Acquire two X-ray images on which markers and distal hole of intramedullary nails. (3) Based on the image, calculate nail position by front and rear reference planes. (4) Using the coordinate values of two section centers of distal holes in the reference frame coordinates system, calculate the offset values of the font and rear positioning blocks along the vertical and horizontal axis in the frame respectively. (5) Adjust the positioning blocks such that the center axis of guiding holes coincide with the axis of the screw holes. Then finish drilling of distal hole and screws locking.

Experimental: Ten plastic tibia models and twenty plastic femur models with the same kind of type and the same specifications were partitioned into two groups. And
the left and right side lower limbs from six fresh young men's cadaver were assigned into the above two groups. The experimental group used computer assisted distal locking system, control group used mechanical aiming device.

**Methods:** Implant the intramedullary nail into plastic bone marrow cavities in each samples group. Distal locking of the intramedullary nails must be done by the computer assisted distal locking system of intramedullary nails and the traditional mechanical aiming device respectively. The operating time of distal locking, the expose time under X-ray, and the successfully locking rate of screws of both group were obtained and recorded for further studies.

**Result:** For procedure in the experimental group, the mean operating time is 4.44±2.99 min, the mean X-ray exposure time is 1.16±0.38 min, the successfully locking rate is 100±0.00%. For procedure in the control group, the corresponding result are 10.42±4.18 min, 4.71±3.86 min and 94.44% respectively. It is obviously that the time is dramatically decreased (P<0.05), and successful rate has no obvious difference.

**Discussion:** The deviation of drilling path or error locking occurs frequently [3], nail will be deformed when implanted into the marrow cavity. Although the optical positioning systems used in the computer assisted navigation systems can avoid the above problems, they need large-scale computer hardware and software for image processing [4, 5] and are hardly to be adopted widely in primary hospitals of China.

The single functional we developed with spatial target position calculated according to two X-ray pieces and the entrance of the locking nail was indicated and the reading of moving block was shown. Make surgeons positing the guide canula and lock the distal nail. Besides, the system can also calculate the length of locking screw. The unsuccessfully locking rate of screws is satisfied in this experiment and it is no essential to take X-ray pieces after previous two pieces were taken.

**Conclusions:** The strategy of computer assisted positioning combined with free-hand adjustment not only improved the accuracy and successful rate of positioning during the surgical procedure.

**References:**

FLUOROSCOPY BASED CAS GUIDED CORRECTION OF POSTTRAUMATIC ANKLE AND HINDFOOT DEFORMITIES – NEW INDICATION AND FIRST CLINICAL CASES

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Introduction: Posttraumatic ankle and hindfoot deformities are not uncommon after complex trauma of the ankle and hindfoot. The biomechanical consequences of these deformities frequently lead to clinical symptoms like pain and gait disturbances. The correction of the deformities is challenging. The preoperative diagnostic with radiographs and CT allows accurate planning of the correction. However, during the operative procedure the realization of the planned correction is difficult, because the correction process performed by the surgeon without guidance. However, there is no commercially available tool for navigated foot surgery. A Computer Assisted Surgery Based (CAS) guided correction was developed using a commercial available navigation system for reduction of fractures. In this feasibility study, the first clinical experiences were analyzed.

Methods: Patients with posttraumatic deformities of the ankle or subtalar joint with deformity were included. C-arm based CAS guided arthrodeses with correction of the deformity were performed. During the procedure time spent, accuracy, problems were analysed. Furthermore the surgeons’ ratings [Visual Analogue Scale (VAS, 0-10 scale) judging the usefulness, accuracy and clinical benefit of the device were recorded. The accuracy of the drillings were assessed by ISO-C 3D. A conventional navigation system (VectorVision, Brainlab, Kirchheim-Heimstetten, Germany) was used for the navigated fusion operation. The system support independent tracking and manipulation of fragments in fluoroscopic images. One DRB was fixed to each of the two bones or fragments that had been planned for correction in relation to each other. The both fragments can be segmented within the x-ray image. Therefore the outline of the bone has to be marked manually. During the correction, the angle motion and translational motion between the bones or fragments in all degrees of freedom were displayed on the screen of the navigation system. Furthermore, virtual radiographs with the moving bones or fragments were displayed on the screen. C-arm use was not used during the correction process. After correction, retention was performed with 3.0 mm K-wires. Then the accuracy of the correction was checked with c-arm and intraoperative three-dimensional imaging with ISO-C-3D (Siemens Inc., Germany).
Finally screw fixation followed. The insertion of the screws was also c-arm based CAS guided. Therefore the system provides planning of trajectories.

**Results:** Patients. Two patients were included. Patient 1 with posttraumatic arthritis of the ankle with deformity showing a hindfoot varus of $3^\circ$ and lack of motion in the ankle with the talus fixed in $10^\circ$ plantarflexion in the ankle. Patient 2 had a posttraumatic arthritis of the subtalar joint with deformity. Preoperative analysis showed a flattening of the longitudinal arch, Boehler’s angle of $0^\circ$, calcaneus inclination of $5^\circ$ and hindfoot angle of $10^\circ$ varus. Furthermore the foot had a shortening of the calcaneus of 60mm and a shortening of the lateral column with forefoot abduction. Patient 1 was treated with screw arthrodesis of the ankle with correction of the hindfoot angle ($0^\circ$) and the talus axis (neutral position in the ankle). In patient 2, a screw arthrodesis of the subtalar joint with correction of the deformities was performed. The tuber calcanei-fragment and the talus were equipped with DRBs, and the tuber was corrected CAS guided in relation to the talus. In both patients the required screws for fusion were placed with navigated control. Therefore the trajectories were planned within the x-rays performed for accuracy analysis of the reduction. Time spent. The time for preparation, including the placement of the two DRBs, scanning time and preparation on the screen for the correction was 550 s in patient 1 and 580 s in patient 2. The correction process took 35 s in patient 1 and 50 s in patient 2. Accuracy. The postoperative evaluation using the Iso-C-3D revealed that all angles and translations were exactly achieved as planned before. The screw positioning was accurate as planned and showed no misplacement. Problems. During the navigated operation no problem occurred. Surgeons’ rating. In both operation one surgeon was involved. He rated the feasibility as 9.5 (patient 1, 9; patient 2, 10), accuracy 10 (10, 10) and the clinical benefit 9 (8, 10) according to the Visual Analogue Scale.

**Conclusions:** The feasibility of the introduced method is favourable. The time spent is less than 10 minutes for preparation. The correction process is very fast and extreme accurate, especially regarding the problems with the conventional c-arm based correction. In our experience, the correction without CAS guidance needs more time because the necessary frequent c-arm controlling. Furthermore, it is much more difficult, not only because of the difficult visualization but also because the very demanding correction process with three-dimensional motion of two different fragments in relation to each other. This is one reason that during ankle fusion high x-ray exposure is common. With CAS based fusion operation x-ray exposure will decrease due to virtual correction. In our study just two fluoroscope images were needed for the correction process and two for judgment of the accuracy afterwards. In conclusion CAS guided correction of posttraumatic deformities of the ankle and hindfoot region is feasible and provides very high accuracy and a faster correction process. The significance of the introduced method is high in those cases, because the improved accuracy may lead to an improved clinical outcome. Further studies will show if the patient will profit from this novel method.
ISO-C 3D CONTROLLED REDUCTION AND IMPLANT POSITION IN WEBER-C-FRACTURES

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Introduction: Isolated fractures of the distal fibula of type weber C are treated with closed reduction and placement of a syndesmosis screw if there is a diastasis. Within the literature there are different width witch are acceptable ranging from 1 to 2 mm [3]. Furthermore a syndesmosis screw should be used in fractures more than 3.5 cm above the syndesmosis [2]. The assessment of rotational malalignment, persistent diastasis or anteroposterior shift of the distal fibula in the distal tibiofibular joint during operative treatment of Weber-C-fractures with two-dimensional imaging, either fluoroscopy or plain x-rays is problematic. If no anatomical result is achieved during the operation the long term result might be altert with an increased rate of osteoarthritis. This may require a fusion operation for the patient. The aim of the study was to assess the feasibility and benefit of intraoperative three-dimensional imaging with ISO-C-3D within operative treatment of isolated distal fibula of type weber C.

Methods: The ISO-C-3D was used intraoperatively in all patients with isolated unilateral Weber-C fracture after 06/2003 in a level one trauma centre. Those patients had to be treated operatively using a syndesmosis screw. The device was used after the reduction and positioning of implants were judged by the surgeon to be correct using conventional C-arm images. For the scanning procedure draping of the situs with a sterile towel was performed. The time needed for the different steps of the procedure including preparing time of the ISO-C-3D in the operating room, scanning time and calculating time of the ISO-C-3D device were recorded. Furthermore the evaluation time i.e. time for choosing the views and planes on the screen and analysing the reduction and implant position performed by the surgeon were take down. The interruption time of procedure due to the use of the ISO-C-3D and problems with the device during use were recorded. The consequences of the ISO-C-3D-scan for the procedure meaning changing of reduction or implant position were analyzed. Furthermore the surgeons rating according to a Visual Analogue Scale (VAS, 0-10 scale) judging the usefulness, accuracy and clinical benefit of the device were recorded and analyzed.

Results: Seven patients could be included in the study. Three different surgeons were involved in the procedures. The patients were placed either on normal operation tables with metal bars at the side in 2 cases and on a carbon fiber table in 3 cases. No
influence was found on the surgeons evaluation due to artifacts. However image quality was reduced due to metal artifacts using normal operation tables. In every case a 190° rotation with 100 images were used. The preparation time including sterile covering of the Iso-C-3D was 190 (155-245) s. Evaluating the calculating time of the computer an average time of 300 (285-330) s was found. The time for surgeons’ evaluation was 180 (140-210)s. The operative procedure was interrupted for 300 (200-420) s during scanning and evaluation. Preparing and calculation was performed parallel to the operation. Assessing the accuracy of the c-arm in one case (14%) an incorrect syndesmosis screw position, and in two cases (28%) an incorrect reduction were recognized by ICO-C-3D. Prior the operative result was judged as correct by the surgeon. The implant position or reduction were corrected in the same procedure and then confirmed by a second ISO-C-3D scan. No problem of the hard- or software occurred. The surgeons rating for feasibility was VAS 9 (7.3-10) and for the intraoperative helpfulness of the described technique 9.3 (7.5-10). The clinical benefit was rated 8.5 (5.5-10).

**Conclusions:** The intraoperative assessment with two-dimensional imaging using either fluoroscopy or plain x-rays of rotational malalignment, persistent diastasis or anteroposterior shift of the distal fibula in the distal tibiofibular joint during operative treatment of Weber-C-fractures is problematic. If those operative results are not recognized osteoarthrosis may occur during follow up which may require a fusion operation for the patient [4]. However a second operation for the patient is necessary if the malalignment is recognized after performing the first operation. Grass recommends performing a postoperative CT for evaluation of the distal fibulotibial joint [3]. The intraoperative three-dimensional visualisation with ISO-C-3D can provide important information during the operative treatment of Weber-C-fractures which cannot be obtained from plain films or c-arm use alone. The ISO-C-3D is extremely useful in evaluating reduction and implant position intraoperatively. Artefacts within the images due to placement on normal operation tables did not seem to have an influence for evaluation. However, placement of the patient on carbon tables is recommended for better image quality. The ISO-C-3D showed an incorrect implant position and reduction that needed to be corrected in three out of seven cases. In those cases, reduction and implant position was judged to be correct by the surgeon using c-arm images before. A revision could be avoided in three of seven (42%) cases. The ISO-C-3D is extremely useful in evaluating reduction and implant position intraoperatively and can replace a postoperative CT scan.

**References:**

MEASUREMENT OF FEMORAL NECK SHAFT ANGLE USING COMPUTER ASSISTED ORTHOPAEDIC SURGICAL SYSTEM (CAOSS)

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Introduction: The extra-capsular fractures are usually treated with the insertion of dynamic hip screw (DHS) implant. The 135° DHS implant is most commonly used to fix these fractures. Ideally, the screw should be placed in the centre of neck and the centre of head of femur. Non-optimal placement of the fixation implant may affect the mechanical stability of the fracture [3]. Thus, the DHS implant angle should be similar to the neck-shaft angle of femur. But the neck-shaft angle varies significantly in different individuals. The Computer Assisted Orthopaedic Surgical System (CAOSS) has been developed collaboratively by the University of Hull and the East Yorkshire Hospitals NHS Trust. The CAOSS creates a 3D surgical plan by reconstructing the information from a pair of 2D fluoroscopic images [2]. The aim of our study was to determine an accurate neck-shaft angle of human femur using CAOSS and to discuss the potential problems of using 135° DHS implant in neck of femur fracture.

Methods: The CAOSS equipment comprises a CAOSS trolley, an optically tracked end-effector (spider) attached to a lockable passive arm, a registration phantom and various guiding cannulas. The optical tracking system uses a two camera array that tracks the position of seven Infra-Red Emitting Diodes (IREDs) of the end-effector in 3D space. The end-effector is used to position the registration phantom and various guiding cannulas. The calibration of fluoroscopic image is obtained once a month by using a calibration plate containing a grid of 64x64 radio-opaque balls that attaches to the x-ray receptor tube. A distortion-undistortaiton map is created and saved. A registration phantom containing H arrangement of 21 metal balls is held in the end-effector and placed in image space of C-arm. This allows accurate determination of the position of the x-ray source and the virtual plane of C-arm. The CAOSS creates a 3D surgical plan by reconstructing information from a pair of 2D fluoroscopic images. The positional accuracy of CAOSS is shown to be within 0.7mm and angular accuracy is within 0.2°. Laboratory tests were done on 18 cadaveric dry femurs. Two fluoroscopic images (AP and Lateral) were taken and processed using CAOSS. On AP image, the proximal shaft of femur was identified with 7 points, the neck with 6 points and the head with 6 points using a mouse on computer screen. Similar point marking was done on lateral image of proximal femur. CAOSS calculated the centre
of head and neck of femur as well as the axis of the shaft of proximal femur in 3D space. A vector (head-neck axis) was determined by joining the two points of centre of head and centre of neck mathematically. The angle between the shaft axis and head-neck axis was calculated using the dot-product calculation. Three tests were done on each femur and average reading for each femur was used for analysis. SPSS 11.5 software (SPSS Inc., Chicago, USA) was used for statistical analysis.

Results: The mean (standard deviation) neck-shaft angle was 124.4 (4.9)°. The range was 117.1° - 133.4°. The standard error of mean was 0.7° and the 95% confidence interval of mean was 123.0° to 125.7°. Only three femurs had neck-shaft angle of more than 130°. No femur had neck shaft angle of 135°.

Conclusions: It has been shown that the failure of implant/ fixation is a significant complication of unstable inter-trochanteric neck of femur fractures [1]. Moreover, non-optimal placement of the fixation implant may affect the mechanical stability of the fracture [3]. None of the femurs, we studied, had neck-shaft angle of 135°. Only three femurs had neck-shaft angle of more than 130° (17%). The mean neck-shaft angle was 10° less than the standard DHS implant of 135° used for the neck of femur fracture fixation. Thus, a 135° dynamic hip screw-plate implant cannot achieve the optimal position that should ideally go through the centre of head and the centre of neck. This alteration in angle may create additional stress on the implant and may cause implant failure. To position a 135° implant in these femurs, one need to drill very low in the neck and this often damages the strong calcar bone. By damaging this calcar bone, additional weakness is created in the neck of femur that in turn, may cause implant failure and non-union of the fracture. Preoperative knowledge of geometry of a particular bone is very useful in planning a surgical approach. The study shows that CAOSS is useful in determining the 3D anatomical features and the geometry of bones based on the 2D x-ray images. A closer integration and standardisation between CAOSS and fluoroscopic imaging can be very useful. For example, an image intensifier or x-ray machine with integrated CAOSS can provide all the computing facilities to derive the required geometry of a bone right from the first x-ray of the patient. These details can then be made available to the surgeon along with the x-ray images using PACS system.

References:

NAVIGATED PERCUTANEOUS PELVIC SCREW FIXATION – COMPARISON OF PRECISION AND CLINICAL PROBLEMATIC BETWEEN CT-, FLUOROSKOPY - UND ISO-C-3D NAVIGATION

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Introduction: In the treatment of instable pelvic injuries with disruption of the iliosacral joint, the osteosynthesis with iliosacral screws can be an elegant possibility to stabilise the posterior pelvic ring. Condition is a fixation of the anterior pelvic ring with plates or external fixation [2]. By using conventional technique the drilling can only be performed in one projection, the position of screws must be followed and altered under radioscopy in inlet-outlet and a lateral projection afterwards. This can lead to a high radiation dose for the surgeon and the patient. Injuries of nerve roots and the gluteal vessels are described with the use of this method. This is among other things due to the reduced imaging. In the last years, navigation systems were used increasingly for traumatological indications, especially in the field of spine- and pelvic surgery. Particularly in spine surgery the CT based navigation could proof its importance by placing the pedicular screws. The aim of this study was to evaluate the precision and the special problematic of conventional navigation possibilities (CT-, fluoroscopy- und Iso-C-3D navigation).

Material and Methods: Altogether 60 holes were drilled navigated on synthetic pelvis models (Synbone) with standardized methods. The reference base was placed at the same side as the drilling with the help of a rotation stable screw. In each examination group the dates were collected with CT, fluoroscopy or ISO-C-3D. As navigation system the Surgigate, Medivision, Oberdorf, Switzerland and an Optotrack 3020 optoelectronic localizer (Northern Digital Inc) was used. Set-up for the fluoroscopy-based navigated drillings: The module “C-arm” was used. Following, 4 projections (a.p., lateral, inlet and outlet) were acquired with the navigated C-arm (Exposkop 8000®, Ziehm, Nürnberg). The images were imported in the system and the trajectories defined corresponding to the course of S1 resp. S2 screw. Set-up for the CT- based navigated drillings: A spiral-CT of 5. generation was used. After the data set was loaded to the navigation system module “spine”, the segmentation, anatomic-based landmarks and trajectories were planned in the preoperative mode.
The drillings were performed with only a mean error of registration of <1mm. Set-up for the ISO C 3D - based navigated drillings: The Iso-C3D Siremobil® was used. to plan the drillings. After the planning of the multiplane layers the navigated drilling was started. For every method of navigation five pelvises were used, the drillings were performed on S1 and S2, any two right and left. For the drilling the pelvis was covered and fixed in a special holding fixture. As tool a 4.5 mm drill with the length 145 mm (Mathys, Bochum) was used. The drillings were performed after a training curve. Considering a postoperative CT, the evaluation was taken with a score: 0= no perforation, 1= minimal perforation, without clinical relevance, 2= obvious perforation. The postoperative data set was analysed in the DICOM viewer eFilm Workstation™ (Merge eFilm, Milwaukee, WI, USA).

**Results:** By using CT based navigation 14 screws (70%) could be placed without perforation., 4 screws (20%) perforated the cortex grade 1, and 2 screws (10%) grade 2. Concerning the distribution of S1 and S2 it yielded the result, that all S1 screw connections could be placed correctly, all incorrect placements were seen at S2. With all Iso-C-3D navigated drillings, no perforation was seen.

**Discussion:** Percutaneous screw fixation in the field of pelvic surgery is technical demanding. The treatment under fluoroscopic control demands partly a long radiation time, since drilling is only possible in one projection and the result must be controlled in the other projections. For other applications it was already shown that the use of navigation systems could reduce the radiation exposure. The results show that CT navigated drillings are in an inferior position to Iso-C-3D. An important source of error could be the registration. The intraoperative calibration of anatomic landmarks is even more difficult than on models as they must be dissected accesso- rily. The registration under fluoroscopy and Iso-C-3D navigation results self-acting, so the source of error of pair-point registration does not apply. Another serious advantage is the intraoperative availability collection of data after the reduction. A possible disadvantage of fluoroscopy could be the picture quality with obese patients. Additionally no real three-dimensionality is given. This does not apply with Iso-C-3D but there a disadvantage follows from the small volume, which is restricted to a cube of ca. 12cm length (119mm³). Because of the great formation of artefacts a carbon table is necessary for the data collection. Before the placement of the patient it should be paid attention to remove the side rails and radial setting clamps of the surgery table from the optic path as far as possible. Additionally all tools that can result artefacts should be also removed of the scan area. Corresponding to an intern standard all necessary instruments are placed before surgery and the realization of the scan checked. Furthermore the alignment of the isocentre is aggravated with obese patients. In following clinical studies the clinical precision of the three mentioned navigation systems should be evaluated.

**Reference:**
NAVIGATION AND LOWER LIMB FRACTURES: ADVANTAGES AND SIGNIFICANCE

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Introduction: Fluoroscopy is used in traumatologic surgery to reduce the fractures and to fix them with intramedullary nails or percutaneous screws; in this way, both the patient and surgeon are exposed to significant radiation dose. The application of fluoroscopy-based surgical navigation to traumatological surgery provides to improve the surgical results but also to reduce the radiation exposure. The fluoroscopy-based surgical navigation is terrifically useful to find the entry point for internal device, to perform the distal locking of intramedullary implants and to fix the fracture by cannulated screws reducing the x-ray exposition for patient and surgeon.

The purpose of the study is to evaluate the utility to apply the fluoroscopy-based surgical navigation to nailing of femur and tibial fractures.

Materials and Methods: The navigation device used is the iON Surgical Navigation System from Medtronic with a standard C-arm. Intra-operative imaging data is collected using a conventional C-arm technique and transferred and stored to the iON computer workstation. Infrared cameras tracks special surgical instruments via reflective spheres or light emitting diodes (LED’s) relative to stored imaging data, informing the surgeon about the position of instruments and implants. In femoral and tibial nailing, LED’s is positioning on bone fragment with a closed technique near the entry point before than in distal fragment near the distal holes of nails.

10 fractures of lower limb have been treated from 2002 with fluoroscopy-based surgical navigation system. Two subcapital femoral neck fractures, 5 femoral shaft fractures, 3 tibial shaft fractures , 1 calcaneus fracture have been treated. Navigated Trauma Instrument Set has been used in all cases. Subcapital femoral neck fractures have been fixed with three or four percutaneous cannulated screws. In femoral shaft fractures, M/DN femoral locking nail (Zimmer) has been used; the intramedullary nail used has special instruments for less invasive surgery (Zimmer). Trigen locking nail (Smith & Nephew) has been used for tibial fractures. Calcaneous fracture has been fixed with plate and screws. Time of surgery, accuracy of nails o screws position studied with x-ray and per or postoperative complications have been evaluated.

Results: All fractures were healed, no delayed consolidation or non-union are reported. No intra or post-operative complications are reported. No complications referred to fluoroscopy-based navigation system are reported. In all case, the naviga-
tion system was used from starting until the end of operation without problems. Time of surgery is about 20 minutes longer than surgery without navigation. In all cases there are no differences between computer data recording and X-ray data. In all cases, the screw lengths chosen referred to data of fluoroscopy-based navigation system.

**Conclusions:** Navigation system applied to traumatology surgery started few years ago with CT based system but the applications of this technology in fracture care were very limited because the data were obtained before the surgical fracture reduction. CT based surgical navigation was applied only for acetabular or pelvic ring fractures minimally displaced or if a closed reduction could be obtained and maintained with an external fixator prior to obtaining the preoperative CT scan. It could not be applied to long bone where bone fragments are reducted after the CT scan was performed. Fluoroscopy-based surgical navigation has expanded the applications of navigation system in all cases where intraoperative fluoroscopy is required like management of long bone fractures with intramedullary nails or percutaneous screws fixation. Starting application of fluoroscopy-based surgical navigation was distal locking of intramedullary nails [3]. Suhm et al. [2] applied this to 42 interlocking procedures in 27 patients with pertrochanteric femoral fractures and reported only one misplaced interlocking screw and concluded that fluoroscopy image processing with submillimetric accuracy is practically feasible on clinical images. In our clinical experience we applied the navigation system also to choose the entry point in femoral and tibial nailing and to perform the percutaneous fixation with cannulated screws. All the procedures were performed by surgical navigation: entry point, positioning of internal device, screw length, distal locking for intramedullary nails. In all cases, there are no differences between navigation system imaging and post-operative X-ray and all osteosynthesis were satisfactory. By fluoroscopy-based surgical navigation it is possible to choose the length of screws of distal locking or for internal fixation.

According to Shep et al.[1], the system is not accurate enough to prevent malrotation of femur or tibia. At the moment, we are performing the navigation of fracture so could be possible to avoid the use of fluoroscopy after the reduction of fracture and use the fluoroscopy-based navigation system during all steps of osteosynthesis. Our results are preliminary but very promising.

Medtronic navigation system for trauma is very accurate and safe; our results are very promising so we think that in the next future the use of navigation system will be routinely reducing the time of surgery. The best utilization is with surgical techniques and devices for less invasive surgery so it’s possible to obtain excellent results with very low radiation dose.

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PRECISE IDENTIFICATION OF BONE FRAGMENT BOUNDARIES TO ASSIST IN REDUCTION OF HIGHLY COMMINUTED FRACTURES

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Introduction: Bone and joint injuries with comminution (multiple bone fragments) present a significant surgical management challenge, especially when they extend into an articular joint. There is a lack of consensus in grading of injury severity among these fractures.⁴ We have developed a new objective injury severity schema, of import because injury severity gradings currently rely on subjective clinician opinion. The new schema exploits relationships between the amount of mechanical energy required to fracture a brittle solid (bone) and the quantity of de novo surface area.¹ In the present investigation, a series of patients with comminuted tibial pilon fractures were studied. Their bone boundaries were identified, and individual fragments were segmented from CT scans to assess the energy of injury in each case. To provide an initial proof of concept, the results were compared to experienced clinician independent subjective ranking of the injury severity.

Materials and Methods: Bone free surface areas were measured from CT studies obtained during standard clinical care in order to quantify injury severity in a series of eleven tibial pilon fracture cases seen between 8/2001 and 5/2003. The patients (9 male, 2 female) ranged in age from 20 to 64 years. The fractures ranged from minimal to extensive comminution. In-plane CT scan resolution averaged 0.25 mm, with 0.5 mm reconstructed slice spacing. Contralateral limb scans provided intact endosteal and periosteal bone surfaces over a comparable distal segment of the patient’s tibia, for taring purposes. Bone free surface areas were extracted slice by slice from all datasets, using validated digital image analysis routines on a personal computer,² implemented in the MATLAB Image Processing Toolbox (Mathworks, Inc., Natick, MA). Fracture energy calculations based on this complete dataset incorporated local bone density extrapolated from CT-based Hounsfield units.³ With boundaries extracted, a second routine was written to complete the segmentation for visualization purposes, restricting itself to fragments greater than 10,000 voxels (a volume of roughly 315 mm³) in size. A final decimation step reduced the number of patches to 4% of those originally identified. The clinical cases were also rank ordered by an experienced orthopaedic traumatologist in terms of lowest to highest injury severity, based on subjective appearance of AP and lateral radiographs of the cases. The results of the fracture energy analyses were compared, using a Spearman rank-order correlation, to the experienced clinician rank ordering of the same eleven cases.
Results and Discussion: The segmentations produced accurate renderings of the fractured fragments, with clear boundaries and matching surface features across neighboring boundaries of adjacent fragments. Total bone free surface areas measured in the intact tibias ranged from 8577 to 25,059 mm$^2$. Of note, between matched intact tibias in two publicly available CT datasets, there was a less than 1.2% side-to-side variation in measured surface area. Among fractured tibias, surface areas ranged from 8722 to 30,826 mm$^2$, yielding net liberated surface areas ranging from 2 to 75% of the intact side. When plotted alongside images of the distal tibia, these differences in measured bone surface areas show variation in the degree of proximal to distal fragmentation, and they reflect the proximity of a given fracture to the distal tibia articular surface. The Spearman correlation analysis comparing clinical rank ordering with the fracture-liberated surface area ranking yielded an R value of 0.72, showing good agreement. Including local bone densities into a fracture energy measure increased the correlation to an R value of 0.90. Of potential future interest, these bone fragment boundaries provide a high fidelity dataset defining the independent pieces to be re-approximated in surgical reduction and fixation, with accuracy heretofore unavailable. We aim to couple these methodologies with existing technologies to produce a computer-assisted fracture reduction tool enabling minimally invasive surgical management of these complex fracture cases. Segmented bone fragments would be shown intra-operatively to the surgeon, tracked during reduction maneuvers, and feedback provided as to the favorability of a current pose of reduction.

Conclusions: We have developed estimates of the liberated bone surface area associated with a series of clinical pilon fractures. Our previous work has shown that this parameter correlates closely with fragmentation energy in the laboratory setting. Now, for the first time, it is possible to quantify the mechanical insult associated with a clinical fracture, previously an immeasurable confounding factor in fracture studies. Because biomechanical fracture toughness is bone density-dependent, the surface area measurements incorporate local material variability, available in the form of CT Hounsfield densities. The energy measures here calculated agree favorably with the clinical impression of the treating surgeon, in terms of a rank ordering of injury severity.

References:
ANALYSIS OF PRECISION OF ISO-C-VS. FLUOROSCOPY BASED NAVIGATED RETROGRADE DRILLING OF OSTEOCHONDRAL LESIONS


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Introduction: Osteochondral lesions on the talus are described as detachment of a cartilage fragment with or without participation of subchondral bone. The aim of the operative treatment of osteochondral lesions of talus stage I and II is the revascularisation of the defect [1]. The difficulty of the operative treatment is the localisation of the lesion. Anterolateral lesions are accessible by arthroscopy treatment, but the handling of the dorsomedial lesions is much more difficult and often only reachable by an osteotomy of the medial malleolus. The direct anterograde drilling of dorsolateral located osteochondral lesions is much more difficult. A disadvantage of all anterograde drilling techniques is the fact, that the intact cartilage is drilled and so injured. Also the malleolar joint cartilage is injured [2]. Incorrect drillings and perforation of the joint cartilage can often happen although an x-ray image amplifier is used. In these cases navigation can be a useful tool and could often be used in clinics [3]. On the basis of a cadaver study the precision, radiation exposure and the operative set-up of Iso-C-3D- and fluoroscopy-based navigation was evaluated in this study.

Material and Methods: On 14 anatomic specimen posteromedial lesions were created via medial malleolus osteotomy. Therefore a special sleeve of 4 mm diameter was created. The dynamic reference base (DRB) was placed at the collum of the talus with a new developed screw. It provides stable rotation for both navigation methods. By the use of this screw with only 4mm diameter the artefacts in radiation can be reduced. 7 retrograde drillings were performed with the help of Iso-C-3D- and 7 with the help of fluoroscopy based navigation. As navigation system the Surgigate, Medivision, Oberdorf, Switzerland and an Optotrack 3020 optoelectronic localizer (Northern Digital Inc) was used. The precision of the optoelectronic localizer is declared with/as 0.1mm in translation and 0.1° rotation. Set-up for the fluoroscopy-based navigated drillings: The module “C-arm” was utilised. Following 3 projections (a.p., lateral, oblique) were acquired with the navigated C-arm (Exposkop 8000®, Fa. Ziehm, Nurnberg). The images were imported in the system and the trajectories defining the entrance and ending point were planned. After verification the drilling was started. Set-
up for the ISO C 3D - based navigated drillings: The Iso-C3D-C Siremobil® was utilised. With the help of the laser the talocalanean joint was placed in the isocentre. With a rotation of 190° around the isocentre 100 single images were generated. This data set was transferred via Navi-Link®-interface (Fa. Siemens) to the navigation system in the mode of Iso-C-3D- navigation. The trajectories defining the entrance and ending point were planned in the corresponding multiplane layers. As tool a 3.2 mm drill with a length 110 mm (Fa. Mathys, Bochum) was used. To analyse the precision after the navigated drilling an Iso-C3D was obtained as well as a CT scan. Beyond it, the result was controlled macroscopically via medial malleolus osteotomy. The post-operative data set of ISO-C-3D and the CT was analysed in the DICOM viewer eFilm Workstation™ (Merge eFilm, Milwaukee, WI, USA). Both groups were compared with regard to operation time (min), radiation time (s) and precision.

**Results:** The radiation time of Iso-C-based navigation was significantly higher (ISO C 3D = 23 sec. (22-24 sec.) than of fluoroscopy 14 sec. (11-17 sec.). It was possible to hit the lesion in 7 of 7 cases (100%) with the use of the Iso-C-3D on the contrary of fluoroscopy-based navigation, where only 5 of 7 (72%) lesions could be hit exactly. No difference was noticed relating to the methods of evaluation. Loosening of the reference base with the fixation pin could not be observed in any case.

**Discussion:** The usage of retrograde drillings as a minimal-invasiv treatment of osteochondral lesions of the talus is described as effective and sparing. The intraoperative identification of the lesion is quite difficult because of the anatomic shape of the talus and a narrow jointspace. Especially the frequently affected posteromedial lesion is hard to localise, so that incorrect drillings can often occure. The images generated by fluoroscope turned out to be insufficient. The localisation of the lesion was complicated. With the dataset of the Iso-C-3D Siremobil® (Siemens, Germany) the lesion was adjusted in multiplane layers and the trajectory planned without any problems. Specific problems arise out of the intraossear metallic fixation of the DRB. This problem was solved by the development of a new fixation pin. This pin provides a stable plancement so no rotation occurs and causes only minimal artefacts. The intraoperative usage of Iso-C-3D imaging for the immediate control after drilling is another advantage of this method. The use of conventional CT-based navigated drillings is limited by the necessary intraoperative registration. The option with preoperative fixed markers (fiducials) includes a second operation and the registration with joint immobilising plasters requires a major effort for material resources. It is a moot question whether or not higher success rates can be attained with the use of Iso-C-3D based navigation compared to conventional methods. This will be evaluated in following clinical studies.

**References:**

PREOPERATIVE PLANNING FOR PROXIMAL FEMUR FRACTURE REDUCTION BASED ON VOLUME REGISTRATION OF CONTRALATERAL FEMUR USING 3D CT DATA

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Introduction: In femur fracture reduction, the reduction of the surgeon’s exposure to X-ray radiation and hard labor of traction and rotation as well as the improvement of the reposition accuracy of bone fragments are important issues. We focus on proximal femur fractures (such as intertrochanteric fractures) unlike previous works in which femoral shaft fractures are dealt with [1,2]. Reposition planning in proximal femur fractures often becomes unstable and inaccurate due to its complex shape and large inter-patient variation compared with femoral shaft. Thus, a stable and accurate reposition planning method is required. The use of contralateral healthy femur is regarded as effective for stable and accurate planning without depending on complexity of the shape of the proximal femur. In this paper, we propose a method based on intensity-based volume registration of fractured bone fragments with the mirror-reflected contralateral femur using preoperative CT data. The accuracy of reposition planning is evaluated in comparison with the previous methods.

Method: The reposition planning is defined as determining the relative pose of proximal and distal fragments after properly repositioning. The reposition planning procedure is as follows. Firstly, preoperative CT data is divided into fracture side and contralateral. Secondly, a reflected and segmented image of the contralateral of CT data is generated. For each of proximal and distal fragments of the fractured femur, volumes of interest (VOIs) is specified so as not to include fracture surface which may cause volume registration error. Finally, intensity-based volume registration between each of fragments and reflected contralateral healthy femur is performed. The result of reposition planning is provided as the relative pose of proximal and distal fragments after registration. In accuracy validation, we used the CT data of
healthy femurs instead of fractured femur. Using CT data of healthy left and right femurs, one-half of femurs was assumed to be a fractured femur, and the reposition planning method is applied. The relative pose between proximal and distal fragment regions was acquired by assuming imaginary fracture surfaces of typical intertrochanteric fractures in the femur assumed to be fractured.

**Results:** We used four CT data sets in which healthy left and right femurs were imaged. The reposition planning results were evaluated by using estimated translation and rotation parameters of the relative pose between the two fragments as well as the antetorsion angle and leg length by comparison with the ground truth of them. In the reposition planning experiments, the reposition accuracy was evaluated by bias and precision. The bias (precision) in rotation and translation were 4.4 degrees (0.5 degrees) and 2.3 mm (0.1 mm), respectively, in the proposed method. The bias (precision) in the antetorsion angle and leg length were 2.2 degrees (0.4 degrees) and 2.5 mm (0.2 mm), respectively, in the proposed method.

**Discussion:** The bias in the rotation and antetorsion angle of the proposed method was significantly smaller than the previous methods. In the previous method using X-ray images, manual specifications of landmark points were essentially inaccurate. In the previous method using CT data, the estimated axis was largely affected by differences in left and right bone surface points. Further, the available surface points were appeared insufficient for the proximal fragment in proximal femur fractures. The bias observed in the proposed method was considered to come from the inherent asymmetry of the left and right femur since the image registration itself appeared successful in the sense that registered two images were highly matched. The precision in the proposed method was quite small, which showed the high stability of the method using intensity-based volume registration. In order to reduce the inherent bias due to the use of contralateral femur, post-processing would be required in which performs matching of the fracture surfaces of the two fragments. The proposed method will provide an initial estimate for the post-processing.

**Conclusion:** In this paper, we have proposed the reposition planning by volume registration using contralateral bone for proximal femur fractures. Accuracy was evaluated by well-designed validation procedures based on the ground truth using CT data of healthy femurs. We evaluated antetorsion angle and leg length for the validity of using contralateral bone. In our experiment, the proposed method was able to obtain more accurate reposition planning than previous methods. As future work, we are planning that the reposition planning results are used in an intraoperative guidance system by using 2D-3D registration system, and finally executed by a robotic-system.

**References:**

THE USE OF COMPUTERIZED NAVIGATION IN THE TREATMENT OF GUNSHOT AND SHRAPNEL INJURY

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Introduction: The recent global increased violence has created numerous situations where surgeons in major trauma centers are increasingly summoned to treat patients with penetrating injuries. The nature of the retained metals varies and includes shrapnel, nuts, bolts, screws, nails, and other improvised metals. Many of these bullets or shrapnel do not cause overt fracture or neurovascular injury but are mostly retained within soft tissues, muscles, bones or joints. In general, missiles retained in the soft tissues or muscles of the axial and appendicular skeleton become inert and are shielded from their host. It has been demonstrated that excellent long-term results can therefore be achieved without applying a routine removal of these missiles. The risk of infection is low and the risk of local or systemic lead toxicity is extremely rare \cite{1,2,4}. In contrast, missiles causing infection, pain and discomfort, or those retained within joints, bursae, and other strategic sites must be removed. The most serious complications resulting from retained intra-articular or intra-bursal missiles are destructive arthritis and rarely systemic lead toxicity. The mechanical action of joint movement can be compromised in some of these injuries and requires the removal of missiles. The removal of missiles retained in an inaccessible location poses a major problem for the trauma surgeon, since it can be hazardous to the integrity of the nervous system and blood vessels. In these cases the computerized navigation system, based on intra-operative fluoroscopy has proved its effectiveness in solving this major problem easily, even during urgent stages of the treatment.

Materials and Methods: The ION Fluronav “Stealth-Station” Treatment Guidance Platform System by Medtronic (Surgical Navigation Technologies, Louisville, Colorado, USA) is used, enabling surgical navigation based on real time acquirement of fluoroscopic data. A calibration target with affixed infra-red-emitting diodes (IREDs) is attached to a C-arm fluoroscope. The Stealth-Station guidance platform system is used to track the fluoroscope as well as a bone tracker (rigidly attached to the patient’s adjacent bone) and an instrument tracker. Several fluoroscopic images of the required anatomical site are obtained and are saved in the Stealth-Station System computer. The spatial accurate location of the foreign object can be seen on the images (2-4) displayed on the computer’s screen. It should be noted that the preliminary fluoroscopic views are taken while the operating team stands at a distance of more than 2 meters from the radiation source. No further fluo-
roscopic radiation is necessary. A Modular instrument tracker (SureTrak 2, Medtronic SNT, Louisville, Colorado USA) is attached to a cement grabber used for revision hip arthroplasty. This tracker enables immediate registration of the grabber’s ends on real time. After a short calibration process, the grabber’s position is spatially recognized in space so it can be displayed on all previously acquired anatomy images without the use of further fluoroscopy. Once the position of the instrument is navigated to the missile’s position, the foreign body can be easily grasped and removed. An alternative method is to use a sharp tracked pointer instead of the grabber for location of the missile and then grasping it by ordinary forceps or clamps. 12 patients with retained metals in their limbs or in the axial skeleton underwent navigation guided removal of these metals. In all cases the bone tracker which was used for the registration of the acquired images was attached to an adjacent bone. In all cases the navigation system led us to the exact anatomical site of the retained metal and enabled minimal invasive surgery in order to remove it. The approximate duration of removal of each foreign body, after the installation of the system, was less than 10 minutes, in which no fluoroscopic imaging was needed. No infection or neurovascular damage were recorded.

**Discussion:** Removal of symptomatic missiles causing infection, pain and discomfort, or located in strategic sites is imperative. The problem exists when the missile is retained in a crowded anatomical zone with susceptible structures. The current approach of minimal invasive computerized surgery is time-consuming and requires pre-operative imaging, by means of CT or MRI. This method is usually unavailable for cases of acute trauma, including penetrating injuries. Unlike the CT or MRI based computerized surgery, the fluoroscopic assisted navigational system requires very short pre-operative preparation. Due to the high accuracy of this system, its utilization in complex and dangerous situations where the foreign body is located in the proximity of blood vessels, nerves and narrow “Safe-Zones”, is promising. Although other methods have been proposed, such as arthroscopy, they involve soft-tissue dissection or the introduction of fluid into closed cavities and are not devoid of hazardous complications. In comparison to other techniques the use of fluoroscopic based navigation has allowed us to minimize soft-tissue dissection [3,5]. After a relatively short learning period we were able to acquire confidence in the system and the removal of missiles was performed in a “one-shot” quick procedure. This innovative technique saves surgical time and radiation exposure, whereas in the conventional method multiple repeated fluoroscopic images, several trials and gradual controlled advancement of the guiding probe towards the foreign body are required. The approximate duration of removal of each foreign body, after the installation of the system, was less than 10-15 minutes, in which no fluoroscopic imaging was needed. In using conventional techniques the time of the procedure may be within the same limits, but the amount of radiation to both patient and surgeon is significantly higher. This is of significant importance when considering removal of foreign bodies from areas such as the hip and pelvis in young patients.

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3-D PET-CT WITH DIGITAL SUBTRACTION ENHANCES BONE TUMOUR SURGERY

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Introduction: PET-CT is a novel technology that allows co-registration of two imaging modalities: one biological, and the other anatomical. Their use in combination is attractive but as yet has had little real impact on decision making or therapeutics. Pelvic sarcomas are extremely challenging for the surgeon, who has to rely on his understanding of 3-D space to interpret the 2-D images and plan his resections and reconstructions around them. At present the surgeon has to rely on local cues to orient himself in the operating theatre, and so will make simple bone resection plans such as a transverse cut in the coronal plane to excise a tumour, as this is a surgical plan that he can hope to achieve with some degree of accuracy. With the advent of computer assisted orthopaedic surgery, the surgeon should be able to plan and perform much more sophisticated operations, with more complex planes of resection and reconstruction. Until now, these plans are limited by a lack of 3-D imaging to enable the definition of the tumour boundaries. This project is designed to enable the surgeon to use real 3-D models of the tumour to plan excisions that are safe and more conservative and reconstructions that may have superior function owing to better osseo-mechanical integration of a sophisticated implant with a biologically advantageous resection.

Methods: Conventional CT scan with PET contrast FDG are acquired on a PET-CT scanner. Images are obtained sequentially on the same track, with the CT acquired before the PET images. Conventionally, the 2D PET-CT images are inspected on screen or on paper. Manual marking on a physical 3D model of a standard-shaped pelvis may be done by the surgeon: here the surgeon uses the 2D data to inform his choices on a 3D model. This calls for subjectivity, and inaccuracy. PET imaging using FDG is now established as a sensitive method of imaging sarcomas in bone. The margins of the tumour and the activity as shown by FDG PET are still being evaluated, but the modality looks promising in sensitivity and specificity. What we have done: we have taken the 3D reconstruction of the CT data and the PET data. This has been manipulated, and co-registered. The PET data has then undergone digital subtraction after image reversal, to generate a ‘normal’ and ‘abnormal’ PET outline overlaid by co-registration onto the patients’ own pelvis. The size, site and biological activity of the lesion is then available in 3D to enable the surgeon to plan a safe resection and optimal reconstruction.

Results: 1) The use of 3D reconstructions, with PET and digital subtraction of the
normal side has allowed elegant visualisation of the tumour, enabling detailed 3-D planning of treatment strategy. 2) Value: by improving visualisation, this technology allows the surgeon to plan treatment strategy, from modality, and approach, to resection and reconstruction options. It has greatly helped in decision making, where the precise way the tumour is located and will be delivered can be complex and technically demanding. When linked to computer assistance in theatre, this technology will realise its full potential.

**Conclusion:** This is an experimental procedure. The co-registration seems quite accurate, but not yet fully evaluated. The clinicians involved have been impressed with the visualisation and manipulation of PET-CT images in 3D. It has enabled the surgeons to plan limb salvage surgery with more sophistication while maintaining safe margins of excision. We expect to incorporate these imaging modalities with computer assistance in the operating theatre to improve outcome in bone tumour surgery.
INTEREST OF COMPUTER ASSISTED SURGERY (CAS) IN THE EXCISION OF OSTEOID OSTEOMA. CT-BASED AND FLUOROSCOPY-BASED NAVIGATION IN THREE PATIENTS

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Introduction: The surgical resection of the osteoid osteoma remains the technique of choice, for the treatment of this benign tumor. However, there are some anatomic localizations of the tumor (femoral neck, distal femur, spine), which are difficult to identify and to approach. The conventional techniques require a large surgical exposure and the risk to fragilise the bone segment involved, being also present. The minimal invasive image guided technique, can offer an improved tumor location and surgical safety, for both patient and surgeon. The goal of this study is to clinically evaluate the minimal invasive, computer assisted technique, in the osteoid osteoma resection.

Material and Methods: Three patients, a 13 years old male patient, a 14 years old female patient and a 48 years old female patient, diagnosed with osteoid osteoma, underwent surgical resection, using CAS methods. For the two first one, the tumor was located in the posteromedial region of the femoral neck. The lesion, invisible on X rays was put in evidence only after performing a CT scan. That’s why, the decision to use CT-based navigation, for surgery, was taken. The preoperative CT planning was followed by intraoperative location, navigation and complete tumor resection. For the third patient, with osteoid osteoma of the medial region of the lateral femoral condyle, virtual fluoroscopy was considered, to guide the resection. With two intraoperative X ray views (AP and lateral), the lesion was identified, allowing surgical navigation and minimal invasive, complete tumor resection.

Results: For the three patients, the tumors were completely removed, documented on postoperative CT scan and X rays. The clinical symptoms disapeared after surgery and the postoperative CT scan confirmed the complete resection, without bone fragilisation. Pain and limping, very important before surgery, practically disapeared after resection. The mean hospitalisation time was 72 hours. There are no clinical or radiological signs of tumor recurrence at 6 months.

Conclusions: The treatment of osteoid osteoma evoluated during the last decade, but surgical localization of the nidus is not always a simple task, even with intraop-
operative scintigraphy or CT. The minimal invasive resection technique is considerably improved, by using computer assistance. The image guidance, CT-based and fluoroscopy based, gave us real satisfaction, offering encouraging results, precise localisation, a safe and complete tumor excision.

References:

NAVIGATED ISO-C 3D BASED PERCUTAN OSTEOID OSTEOMA RESECTION -PRELIMINARY CLINICAL REPORT-

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Introduction: Computer tomography (CT) based osteoid osteoma resection showed good results [1]. Exact positioning of needles and hollow drills is technical demanding and drill failures occur [1,2]. Complications especially in anatomic demanding areas like femur neck or vertebrae bodies can appear. The steril conditions and total environment at the CT does not correspond to regular operations theater conditions and infections are described. If unsuccessful resection results by drill failures or inadequate visualisation of the lesion, a direct alternative in switching to an open procedure is not possible and revision surgery in the operation theater becomes necessary. Alternatively CT and fluoroscopic based navigation do not allow minimal invasive procedures with proper visualisation of the osteoid oestomas. Fluoroscopy based technique is limited by twodimesional imaging, CT based technique by necessary invasive matching procedures with preexcisting CT Data sets. Iso-C 3 D based navigation obtains intraoperative multiplanar reconstructions and allows good visualisation of osteal lesion under possible percutan resection technique. Implementations have already been described in pedicel screw placement, drilling of osteochondral lesions and acetabular screw placement. We report about our first two clinical cases of Iso-C 3D based navigated resection of osteoid osteomas.

Methods: Two symptomatic patients with osteoid osteoma lesions of the retropatellar surface and at the tibia edge were included this study. Both patients underwent preoperative MRI scans for diagnostics. Positioning was done on full-carbon Tables (VIWAS; Maquet). In general anaesthesia under regular steril OR conditions a Iso-C 3D (Siemens, Germany) scan of the region of interest was performed. The Iso-C3D provides 100 fluroscopic images by a motorized 190 degrees rotation about region of interest, calculating threedimensional data sets. Important for the Iso-C 3D scanning procedure is a check and definition of the isocentrum regarding to the operated extremity since the calculating area is limited by a cubus of 12 x 12 x 12 cm. The dynamic reference bases (DRB) were fixed to the patella and to the tibia shaft. Before scanning the region of interest a secundarily sterile draping was done, Following the data transfer of the multiplanar images to the

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navigation system (Surgigate, Medivision, Switzerland) was done. Osteoid osteoma lesions were adequate visible in all multiplanar reconstructions. Trajectories in all multiplanar reconstructions were planned on the navigation system. In percutan technique and under permanent navigated multiplanar image control first a 3.0 mm drill was placed direct in the nidus in both cases, along the planned trajectories. Following over a replaced k-wire a navigated 6.0 mm hollow drill was inserted to the nidus in the same technique. No other radiological imaging was done during these procedures. Bony cylinders from both patients were send to histology. With the control of the hollow drill in all planes the procedure was finished, still under steril conditions, a second intraoperative Iso-C 3D control scan was done. It approved exact resection of the lesions in both cases. Both patients left hospital the following day. Defined parameters like total operation time and total radiation time were compared to the last 12 conventional CT based cases at our clinic.

**Results:** Histology confirmed the diagnosis of an osteoid osteoma in both cases. One patient became pain free directly post operative and no further complications occured. The other patient became pain free after a total time of 7 weeks. After 5 weeks we decided to have another post operative control CT scan done in this case. The scan confirmed the exact drill canal into the former nidus of the lesion. It was congruently to the Iso-C 3 D scan. At the 5 month follow up both patients remained pain and complication free. The netto radiation time during one Iso-C 3D based procedure was 20 seconds (plus 20 seconds for the control scan). Contrasting 93 seconds (range: 56-402 seconds) at the CT based cases. The average operating time with navigation was 78 minutes, in the conventional method 60 minutes (range: 36-140 minutes).

**Discussion:** Techniqual guidance of hollow drills under percutan CT based technique is demanding and usually a direct control of surgical tools only inbetween control scans possible. Drill failures, repeated CT scans and sterility problems are associated. So far CT based navigation did not allow minimal invasive techniques since anatomic matching was required. The use of the Iso-C 3D as a diagnostic imaging tool intraoperatively has been well described before. Also the combination with a navigation system, especially in cases high accuracy with necessary three-dimensional imaging is needed, like in pedicle screw placement or iliosacral screw placement has been in use for a short time. The Iso-3 3D based navigation allows minimal invasive drilling under permanent multiplanar visual control. A stepwise drrllling without further radiation is possible. If necessary a intra operative Iso-C 3D control scan can be done. In our cases these were congruently to post op CT scans. Furthermore the collaboration with the radiologists and dependance on the CT suite is not longer necessary, compared to the conventional CT based technique. The implementation of Iso-C 3D to minimal invasive operating procedures offers new possibilities in the general use of navigation in orthopedic surgery.
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