CT-based patient-specific instrumentation is accurate for TKA: a single-surgeon prospective trial

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Introduction: The goals of total knee replacement are well defined. Restoration of a neutral mechanical alignment with correction of preoperative deformities has been shown to improve the outcome and longevity of the prosthesis. Recently, multiple companies have produced Patient-Specific knee Instrumentation (PSI) to perform this procedure. These technologies utilize CT, MRI, and/or X-rays preoperatively to recreate the patient’s anatomy. The TKA implantation is planned and rapid prototyping technology is used to create a block, or instrument, that is used by the surgeon to perform the bony resections during TKA. The present study evaluates the success of 100 CT-based TKAs using this technology (MyKnee®, Medacta International, SA, Castel San Pietro, Switzerland).IRB approval was obtained.

Materials and Methods: 100 consecutive eligible knees (93 patients) of the senior author underwent TKA using the PSI technology. All patients received the same implant (GMK, Medacta International). Utilization of PSI begins preoperatively. A CT scan of the lower extremity is obtained utilizing a proprietary protocol including the hip, knee, and ankle. From these images, the knee can be reconstructed 3Dimensionally alignment. Surgical planning is performed according the surgeon’s preferences for mechanical axis, femoral rotation, tibial rotation and posterior slope of the tibia. Furthermore, implant is approved by the surgeon and made using rapid-prototyping technology. This process requires 3 weeks. All surgeries were performed via a medial-parapatellar or subvastus arthrotomy. No osteophytes are removed as the blocks use the positive topography of the osteophytes for registration. The PSI cutting block is placed on the femur first, and secured with smooth pins. Pilot holes are drilled in the distal femur setting the femoral rotation and AP placement of the implant. The distal resection is performed through a cutting slot on the block. The remaining resections are performed as is standard to all surgical techniques. Outcomes measured for the present study include: pre-operative and post-operative long-standing radiographs, tourniquet time (TT) as a measure of surgical efficiency of surgery, and estimated blood loss (EBL). Intraoperative and postoperative complications were also recorded. Furthermore, the actual intraoperative bony resection thicknesses were measured and compared to the planned resections from the CT scan.

Results: There were 50 Left and 50 Right TKAs performed in 61 females and 39 males. All patients had diagnosis of osteoarthritis. The average BMI was 31.1 and average age was 64.5 (range 41-90). Average
follow-up is 51.3 weeks (range 31.1-72.9). 79 patients had pre-operative varus deformities with HKA average of 174.7° (range 167°-179.5°). 19 patients had pre-operative valgus deformities averaging 184.4° (range 180.5°-190°). Three patients were neutral. Post-operative alignment was 179.36° (range 175°-186°) for all patients. Alignment was neutral, within 3° in 94% of patients. There were only 6 outliers with maximal post-operative angulation of 6°. No intraoperative complications occurred. Average TT was 31.2 minutes (range 21-51 minutes). Femoral bony resections were complete an average of 11.6 minutes, while tibial resections were completed at 16.6 minutes following tourniquet inflation. With regard to the bony resections, the Actual vs. Planned resections for the Distal Medial Femoral resection was 8.7 mm vs. 8.9 mm respectively. Further Actual vs. Planned Femoral resections include Distal Lateral Femoral 7.2 vs. 6.7 mm; Posterior Medial Femoral 8.3 vs. 8.9 mm; and Posterior Lateral Femoral 6.2 vs. 6.8 mm. The Actual vs. Planned Tibial resections recorded include Medial 6.4 vs. 6.3 mm and Lateral 8.3 vs. 8.2 mm. The planned vs. actual bony cuts are strongly correlated, and highly predictive for all 6 measured cuts (p<=.001). Two patients had a post-operative infection requiring surgical intervention. There were no thromboembolic complications. Average Knee Society Score (KSS) improved from 45.9 to 81.4, and KSS Function Score improved from 57.7 to 73.5 at 6 weeks postoperative visit. There were no revisions in the present population.

Discussion: Many techniques exist for performance of TKA. PSI technology allows the surgeon to preoperatively determine resection depths, rotations, alignment, and sizing prior to the operative procedure itself. The present study shows definitively that CT-based PSI can accurately predict the bony resections prior to the surgery. Furthermore, neutral post-operative alignment can be accurately achieved, regardless of preoperative deformity. Disadvantages of CT-based PSI include increased radiation exposure prior to surgery. Furthermore, costs of the CT and production of the blocks requires additional costs of the procedure. How these compare to the capital investment of a Conventional Instrumentation set for TKA remains to be seen. Intraoperative efficiency of surgery is important to all participants in TKA: surgeon, hospital, and patient. Accuracy should not be sacrificed for speed so it is important for any new technology introduced to the market to accelerate surgery not compromise results. Surgical efficiency was demonstrated by the rapid tourniquet times. Furthermore, accuracy of the procedure is reflected in the 94% post-operative alignment within 3° of goal. The technology is safe as well as no intra-operative complications occurred as a result of the utilization of PSI. Strengths of the current study are its single-surgeon design and therefore uniformity of surgery, outcome goals, and peri-operative care. Furthermore, the data was gathered in a prospective fashion and all data was gathered and evaluated by an independent third party, blinded to the technique itself. In conclusion, early results using CT-based PSI is safe, quick, and accurate in performance of TKA. These results offer promise of improving speed of surgery, and reduction of case complexity, without compromising clinical outcomes.