Three challenges of TKA – one force-torque-based solution: the genALIGN system

ZIMMERMANN F¹, ASSELM M¹, RATH B², RADERMACHER K¹

¹Chair of Medical Engineering, Helmholtz-Institute for Biomedical Engineering, RWTH Aachen University, Germany
²Department for Orthopaedics, Aachen University Clinic, RWTH Aachen University, Germany

zimmermann@hia.rwth-aachen.de

Introduction: TKA is one of the most frequently performed orthopedic surgeries in Germany (> 158,000) and the USA (> 719,000) [1, 2]. Even though prosthetic design and surgical techniques improved over the years, revision rates are still high (about 16% in Germany) and patient satisfaction with primary TKA ranges only between 82% and 89% [1, 3]. In order to prevent TKA failure, the surgeon tries to meet three challenges: (I) the preservation and/or recovery of the mechanical leg axis, (II) correct rotational alignment of the prosthesis components and (III) well-balanced ligaments.

Intramedullary guiding systems and image-based/image-free navigation systems support axial alignment, while ligament balancing can be facilitated by using tension jigs, laminar spreaders or spacing blocks and by quantifying the tibiofemoral gap with navigation methods. Rotational alignment is either based on anatomical landmarks palpated with purely mechanical guides or tracked probes, or on the balanced-gap technique, similar to the ligament balancing methods. Apart from method-specific disadvantages (for further information see [4]) all techniques are primarily based on geometrical dimensions: axial alignment on joint centers, ligament balancing and rotational alignment on the tibiofemoral gap under tension or on anatomical landmarks.

However, TKA failures mainly depend on unphysiological forces and torques in the joint, resulting from malpositioned prostheses components or insufficient ligamentous guidance. Therefore, the genALIGN approach is purely based on intra-operative force-torque measurement in order to detect unphysiological joint loading at an early stage. Using this system, optical or magnetic position tracking as well as any fixation of invasive rigid bodies are no longer necessary.

Basic Principles: For axial alignment, the mechanical femoral axis is determined by using a simple, rod-shaped instrument attached to the center of the distal femur. The surgeon applies an axial load to the instrument in the approximate direction of the hip center, simulating the natural loadbearing situation. As the rod can freely rotate about all axes at the knee center, the whole system can only be in an instable equilibrium, if both rod and mechanical femoral axis are coaxial. In this case, the forces and torques applied by the surgeon to stabilize the system should be zero. These are measured by the instrument and displayed on a graphical user interface (GUI) for feedback. The genALIGN approach has been recently patented under US8308730B2.

For ligament balancing, a sensor integrated tibial trial inlay measures the resultant forces transferred on the medial and lateral condyles as well as the force application points. This information is displayed on a GUI. Thereby the surgeon can objectively assess the effectiveness of the balancing procedure and, if necessary, adjust the ligament tensions.

For rotational alignment of the femoral component, the knee is flexed to 90° after ligament balancing in extension. By measuring the condylar forces, the distal femoral cut can be planned using the correlation between the condylar forces and the amount of bone to be resected. The plausibility of the planned rotational alignment can be checked by comparison to the anatomical landmarks before cutting.
Implementation: The current laboratory prototypes for axial alignment and intra-articular force measurement are based on low cost force sensors. Sensors used before (see below) required large read-out electronics and a laptop which were difficult to apply in clinical settings. For mechanical axis alignment and intra-articular load measurement, function specific housings were developed to measure forces and torques. Beside the force-torque sensor unit, the tool for axial alignment (see figure) comprises a ball and socket joint (A) at the knee center and a handle at the distal end (B). In order to be able to fixate the tool axis in the correctly aligned position, a blocking mechanism is incorporated into the device. This mechanism blocking the ball and socket joint can be released by pushing the integrated trigger (C). The sensor unit for ligament balancing is small enough to be integrated into standard tibial trial inlays. Both sensor units can be read-out by the same microcontroller-based electronics integrated in a small graphical display proximal to the sensor (D).

Feasibility Studies: Feasibility studies have been performed using a commercial force-torque sensor in the axial alignment tool and a customized sensor-integrated tibial inlay [4, 5]. The axial alignment tool was initially evaluated in a phantom study using an optical tracking system as reference. Subsequently, the clinical application has been simulated in a cadaver test (n = 2) with an OrthoPilot navigation system (B. Braun Aesculap, Germany) as reference. The sensor-integrated tibial inlay was tested under linearly increasing compression load on a universal materials testing machine under approximated physiological loading conditions on a knee simulator [4]. Using the axial alignment tool, the mechanical femoral axis was determined with an angular deviation of 0.1° ± 1.8° (mean ± std. dev.) varus, 0.1° ± 1.4° anterior slope in the phantom study, 2.9° ± 1.5° valgus and 0.3° ± 2.4° anterior slope in the cadaver test. The sensor-integrated tibial inlay was able to measure the increasing compression load correctly and the knee simulator study showed that joint load measurements resulted in plausible values over the whole range of motion. Based on the results of the feasibility study, the genALIGN system has been optimized resulting in the new microprocessor based instruments with an integrated display (figure 1) without any need for an additional computer system.

Acknowledgment: This work has been funded in part by the German Ministry for Education and Research (BMBF) in the framework of the OrthoMIT project under grant nos. 01EQ0402 and 16SV2019 and by the Ministry of Innovation, Science, Research and Technology of the State of North Rhine-Westphalia and EFRE under grant no. 280155401 (genALIGN M).

References
[2] National Hospital Discharge Survey: ICD-9-CM codes 81.54, 0.80-0.84, 2010