Biomed Tech 2012; 57:283–291 © 2012 by Walter de Gruyter • Berlin • Boston. DOI 10.1515/bmt-2011-0094

A new approach to implant alignment and ligament balancing in total knee arthroplasty focussing on joint loads

Frauke Zimmermann[1,*], Christoph Schwenninger[2], Ulrich Nolten[3], Franz Peter Firmbach[4], Robert Elfring[1] and Klaus Radermacher[1]

[1] Chair of Medical Engineering, Helmholtz-Institute for Biomedical Engineering, RWTH Aachen University, Aachen, Germany
[2] Department for Orthopaedics, Aachen University Clinic, RWTH Aachen University, Aachen, Germany
[3] Institute for Materials in Electrical Engineering 1, RWTH Aachen University, Aachen, Germany
[4] Aesculap AG, Tuttlingen, Germany

Abstract

Preservation and recovery of the mechanical leg axis as well as good rotational alignment of the prosthesis components and well-balanced ligaments are essential for the longevity of total knee arthroplasty (TKA). In the framework of the OrthoMIT project, the genALIGN system, a new navigated implantation approach based on intra-operative force-torque measurements, has been developed. With this system, optical or magnetic position tracking as well as any fixation of invasive rigid bodies are no longer necessary. For the alignment of the femoral component along the mechanical axis, a sensor-integrated instrument measures the torques resulting from the deviation between the instrument's axis and the mechanical axis under manually applied axial compression load. When both axes are coaxial, the resulting torques equal zero, and the tool axis can be fixed with respect to the bone. For ligament balancing and rotational alignment of the femoral component, the genALIGN system comprises a sensor-integrated tibial trial inlay measuring the amplitude and application points of the forces transferred between femur and tibia. Hereby, the impact of ligament tensions on knee joint loads can be determined over the whole range of motion. First studies with the genALIGN system, including a comparison with an imageless navigation system, show the feasibility of the concept.

Keywords: axial alignment; intra-articular force; intra-operative load measurement; ligament balancing; rotational alignment; total knee arthroplasty.

*Corresponding author: Frauke Zimmermann, Chair of Medical Engineering, Helmholtz-Institute for Biomedical Engineering, RWTH Aachen University, Pauwelsstr. 20, 52074 Aachen, Germany
Phone: +49 241 80-23869
Fax: +49 241 80-22870
E-mail: schmidt@hia.rwth-aachen.de

Introduction

Even though the longevity of total knee joint prostheses has improved over the years, in 2003 still 4% of the primary knee replacements had to be replaced within 5 years after surgery. Revision rates at 10, 15 and 20 years were 9%, 16% and 22%, respectively [58]. Currently, more than 23,900 revision surgeries are performed in Germany per annum [67]. Moreover, total knee arthroplasty (TKA) patients experience a significantly poorer functional outcome in comparison to total hip arthroplasty patients [20, 73].

The most common causes of TKA failure are instability, malalignment or malpositioning, polyethylene wear, implant loosening/migration, patellofemoral complications and infection [10, 23, 50, 66]. More than one indication was found in 32% and 64.4% of all cases, respectively [23, 50].

Three factors are associated with prevention of aseptic failures in TKA: (I) preservation and recovery of the mechanical knee joint axis (Mikulicz-line), (II) rotational alignment of the femoral component and (III) the ligamentous guidance of the knee joint movement. Several authors showed that an axial alignment within ±3° (in some publications ±2° or ±4°) of the mechanical axis, and well-balanced ligaments are prerequisites for the longevity of the prosthesis, whereas axial malalignment and inadequate ligament balancing are associated with instability, polyethylene wear and implant loosening/migration [4, 22, 26, 34, 38, 49, 54, 60]. With regard to the rotational alignment of the femoral component, internal rotation and also excessive external rotation were found to have a negative effect on the outcome of TKA causing, among others, flexion instability and patello-femoral complications [2, 6, 7, 27, 39, 44, 45, 55, 59].

Mechanical axis

With regard to the preservation and recovery of the mechanical axis, intramedullary guiding systems are conventionally used to align the femoral component. Generally, these systems are easy to use, and the number of operative steps is minimised [11]. However, even though the alignment using an intramedullary system is significantly better than using extramedullary alignment systems [8, 15, 62], about 10% to 26% of all surveyed cases have an angular deviation of more than ±3° [11, 19, 32, 51]. Further disadvantages of the use of intramedullary alignment guides include the creation of potentially fatal embolic debris caused by the displacement of bone marrow due to increased intramedullary pressure during rod insertion [9, 16, 48]. Moreover, the use of an intramedullary rod is impossible in patients with severe angular deformities [15]. Computer-based implantation systems, such as

image-based or image-free systems, significantly improve the femoral prostheses alignment [3, 5, 19, 32, 43, 51, 52, 70]. These systems are also qualified for minimally invasive interventions [17] and special cases with strong deformities [35]. However, the high costs for the instruments, the tracking system and necessary disposables [12, 36] are major drawbacks of these technical approaches. Furthermore, the operation time is extended by about 14 min (median value) compared to the conventional technique causing additional costs [12]. Nowak et al. [53] estimated the additional overall costs to be US$1500. For image-based systems, time and costs for additional imaging procedures and increased radiation exposure have to be considered. Furthermore, an increased fracture risk at the insertion side of the rigid body fixations has to be taken into account [51].

Rotational alignment

Currently, two different approaches to intraoperative rotational alignment are discussed in literature: (1) based on anatomical landmarks or (2) based on soft tissue-induced joint loading [69]. For the femoral component, the posterior condylar axis (PCA), both anatomical and surgical transepicondylar axes (TEA), and the Whiteside line (WL) can be used as anatomical references [30, 56, 69]. However, the use of these anatomical landmarks has to be critically discussed especially concerning their intra- and inter-observer reproducibility [31, 61, 74]. Greatest inter- and intraindividual variability was found for the Whiteside line, followed by the TEA [71]. Yan et al. [74] found the maximum potential errors for TEA and Whiteside line to be 13° (3° internal rotation to 10° external rotation) and 24° (16° internal rotation to 8° external rotation), respectively. Additionally, all landmark-based approaches for the rotational alignment of the femur do not consider the condition of the surrounding soft tissue and a potentially unbalanced flexion gap. This may have implications regarding polyethylene wear, range of motion and long-term clinical outcomes [21]. In contrast, the balanced gap technique is based on a controlled resection of the posterior femoral condyles, such that the flexion gap is rectangular [21]. However, this technique shows a larger variability with regard to the deviations from any anatomical reference axis [27, 29]. Up to now, there is no consensus about which of these methods is more appropriate to reach the best rotational alignment [30, 69].

Ligament balancing

Quantitative intraoperative assessment of soft tissue tension is regarded to be essential for an effective ligament-balancing procedure. During conventional and navigated TKA, soft tissue tension is estimated by evaluating the tibio-femoral gap (difference between medial and lateral gap distance or medial and lateral opening angle) under tension or varus/valgus stress. Both are applied manually. Generation of tension stress can be facilitated using tension jigs, laminar spreaders or spacing blocks inserted into the tibio-femoral gap. However, the applied effective load is very variable and to a high degree user-dependent. Laminar spreaders with integrated force control can enable reproducible load application [68]. Computer-assisted navigation systems support the assessment of soft tissue tension by measuring and displaying the tibio-femoral gap widths or angle. Direct verification of the impact of soft tissue releases is one advantage of these systems. However, both conventional and navigated techniques only estimate soft tissue-induced joint loads by applying unphysiological loads and thereby elevating the joint line during measurement. Additionally, these methods analyse soft tissue tension only in extension and 90° flexion, although knee joint laxity may also occur in other flexion angles.

More recently, sensor-integrated ligament-balancing instruments have been developed. By means of these measurement systems, loads transferred within the knee joint can be determined. Current systems for measuring forces or pressure distributions in the knee joint can be divided into three categories: pressure measuring foils [1, 24, 25, 28, 72], instrumented tibial plateaus or inlays [13, 14, 33, 46, 47] and instrumented spreader devices [40–42]. For detailed description and analysis, see Schmidt et al. [63]. However, none of these systems is optimally designed for the ligament-balancing procedure. Crinkling of the pressure-measuring foils on the contact surface, the need to calculate resultant forces from discrete pressure-measuring points [24] and mandatory recalibration after sterilisation [1] are the main disadvantages of pressure-measuring foils. Some of the instrumented tibial plateaus and inlays are designed for permanent implantation and cannot be used for “short time” ligament balancing. Other systems are less accurate [46, 47] or result in changed load transfer due to geometrical changes of the prosthesis components [13, 14]. Using instrumented spreader devices, the joint is loaded unphysiologically and the joint line is elevated during measurement as in the conventional procedure. Moreover, the measurement of intra-articular forces is not possible over the whole range of motion.

To conclude, several approaches to solve the three challenges of TKA have been proposed and partially established in clinical routine, however, each having specific disadvantages. In the framework of the OrthoMIT project, we developed and implemented a novel concept for an instrumentation system for ligament balancing as well as axial and rotational femoral prosthesis alignment by intraoperative and intra-articular force torque measurement.

Methods

Basic principle

Our concept combines two devices to address the three main issues described above: The genALIGN approach uses force/torque sensor (FTS) technology to determine the mechanical axis of the femur [18] as well as intra-articular load transfer.

The basic principle of the genALIGN system for the determination of the femoral mechanical axis considers the physiological loading condition of the lower limb: a simple, rod-shaped mechanical instrument is attached to the distal

femur. It is located in the centre of the knee joint, which can be easily determined according to Paley [57]. The surgeon applies a compression load F_Z to the instrument in the approximate direction of the hip centre simulating the natural load-bearing situation (see Figure 1).

As the connection between the femur and the tip of the instrument (in the following referred to as surrogate knee joint) allows free rotations about all axes, the system can only be in an instable equilibrium under compression load (F_Z>0), if both the mechanical axis of the femur and longitudinal axis of the instrument are coaxial, and the surgeon only applies an axial force: (F_Z, T_X, T_Y)=($F_{Z,min}$, 0 Nm, 0 Nm).

By measuring the internal forces and torques with a sensor S between the surrogate knee joint and the distal grip, the angular deviation of the instrument's axis from the mechanical femur axis can be quantified. If the torques measured equal zero, the axes are coaxial. The higher the applied force F_Z, the more sensitive is the measurement. Preliminary experiments have shown that an axial force F_Z of 40 N is sufficient for good measurement results and still manageable for the surgeon.

After determination of the femoral mechanical axis, ligament balancing and the femoral rotational alignment have to be performed. Based on a direct measurement of joint loads and on the balanced gap approach [29, 69], these problems can be addressed with the sensor-integrated tibial inlay. Optical or magnetic position tracking will no longer be necessary.

The basic principle of the genALIGN sensor-integrated tibial inlay is based on a simplified biomechanical model of the knee joint introduced by Crottet et al. in 2005 [13] (see Figure 2). This model specifies the correlation between the forces in the medial and lateral collateral ligaments ($F_{LC\,m}$, $F_{LC\,l}$) and the forces transferred between the femur and tibia at the medial and lateral condyles (F_m, F_l).

These condylar forces are directly associated with instability, polyethylene wear and subsequent implant loosening/migration: a too high overall condylar force may result in an increased polyethylene wear and subsequent implant loosening. If the overall condylar force is too low, the joint will be unstable after surgery. Unequal loading of the tibial condyles can yield joint instability as well as unilateral increased wear. By means of an intraoperative measurement of these forces, the surgeon can objectively assess the effectiveness of the balancing procedure and, if necessary, adjust the ligament tensions.

The genALIGN tibial inlay separately measures the amplitude and the application point of the forces for each condyle.

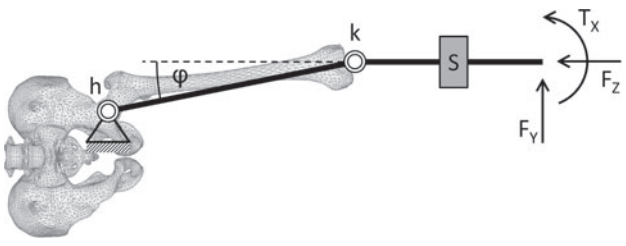

Figure 1 Basic principle of the genALIGN system illustrated using the simplified biomechanical model.

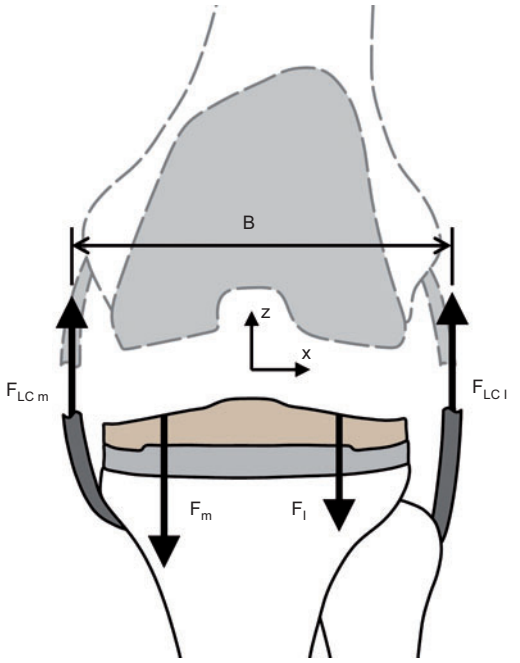

Figure 2 Simplified two-dimensional biomechanical model of the knee joint in frontal plane ($F_{LC\,m}$, $F_{LC\,l}$=forces in the medial and lateral collateral ligament; F_m, F_l=medial and lateral transferred joint forces) according to [13].

A graphical user interface displays the overall condylar force as well as the ratio between medial and lateral contact forces and the medial and lateral contact points over the whole range of motion.

After balancing the ligaments in extension, the knee is flexed to 90°, and the condylar forces are measured. The correlation between the condylar forces and the amount of bone to be resected in the distal femoral cut is used for planning the rotational alignment. The plausibility of the planned rotational alignment can be checked by comparison to the anatomical landmarks before cutting. If no significant discrepancies occur, bone cuts are performed corresponding to the conventional surgical procedure.

Implementation

The setup of the first version of the genALIGN tool (Figure 3) consists of: (A) a ball and socket joint, which can be fixed to the knee centre, (B) a 6 degree-of-freedom FTS (FT-MINI40 SI-100-5, Schunk GmbH & Co. KG, Lauffen, Germany) and (C) a handle at the distal end of the tool.

The ball and socket joint enables free pivoting of the device around the knee centre being the end point of the assumed mechanical axis. In order to be able to freeze the tool axis in the correctly aligned position, a blocking mechanism is incorporated into the device. The blocking mechanism of the joint can be released by pulling the integrated trigger.

The FTS measures the force and torques applied at the end of the device (F_Z, T_X, T_Y). The data is transmitted to a computer, providing a visual cross-hair feedback on the actual

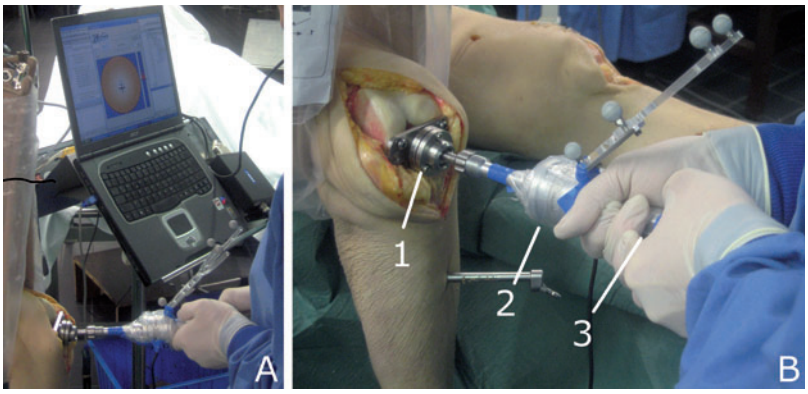

Figure 3 Overview (A) and close-up (B) of the first laboratory prototype of the genALIGN tool in an experimental setup of a cadaver study (note: the optical rigid body is only used in this experimental setup for comparison of the resulting axis with the OrthoPilot navigation system, B. Braun Aesculap, Tuttlingen, Germany).

forces and moments with respect to the reference values (F_Z, T_X, T_Y)=($F_{Z,min}$, 0 Nm, 0 Nm) for the compensation of resulting torques. The axial force F_Z is displayed as a coloured bar being red as long as the minimum force is not yet reached and changing to green when the threshold is exceeded. This user interface enables the surgeon to intuitively align the device.

Based on the above-mentioned concept, a first laboratory prototype of the genALIGN tibial inlay has been developed (see Figure 4). In order to ensure a physiological load transfer unaffected by geometrical differences between the measurement device and standard prosthesis components and a load measurement throughout the whole range of motion, a standard tibial trial component (Columbus T3, B. Braun Aesculap, Tuttlingen, Germany) was equipped with load measurement cells at the interface to the proximal plate of the tibial stem. The load measurement cells were specially designed and assembled for this application. Each load cell has a measurement range of 0–100 N. Medial and lateral sides of the inlay are mechanically decoupled to measure the axial force for each condyle separately. The anterolateral connection with microcables enables a measurement without everting the patella [14]. Before inserting the custom-made load cells into the tibial trial inlay, each load cell was calibrated using a spring-loaded piston with an integrated 6 degree-of-freedom FTS (FT-MINI40 SI-100-5, Schunk GmbH & Co. KG, Lauffen, Germany). In addition, the dynamic behaviour of the load cells was analysed.

Figure 4 Laboratory prototype of the sensorised genALIGN tibial inlay.

Feasibility studies

In order to prove the feasibility of our concept, the genALIGN system was tested in laboratory setups. Furthermore, the genALIGN mechanical leg axis alignment was evaluated in a cadaver study by an experienced surgeon.

The genALIGN system was initially evaluated in a phantom study with anatomical models (Sawbone AB, Malmö, Sweden). These leg models consisted of a pelvis, a femur and surrounding soft tissues. An optical tracking system (Polaris, NDI, Waterloo, Ontario, Canada) was used as reference. The reference of the mechanical axis of the femur was determined kinematically by pivoting the femur around the hip – corresponding to image-free navigation systems. Both mechanical axis of the femur (a) determined by the kinematic approach using the optical navigation system and (b) the genALIGN system were tracked, and the deviation was calculated.

Furthermore, the clinical setup has been simulated in a cadaver test. The mechanical axes of both legs of one fresh cadaver were repeatedly measured with the genALIGN system and compared to the axes determined with the OrthoPilot navigation system (B. Braun Aesculap, Tuttlingen, Germany). Therefore, both knee joints were opened according to classical TKA procedures. Subsequently, rigid bodies were fixed to the bones, and all landmarks and kinematic data needed for planning and navigation of the prosthesis components in the OrthoPilot system were recorded. Afterwards, the genALIGN system was attached to the centre of the knee joint, and several users determined the mechanical leg axis with this system. The instrument axis of the genALIGN system was optically tracked using an additional rigid body

to determine the difference between the OrthoPilot and the genALIGN system. For weight compensation, the thigh was supported by an elastically mounted strap such that the lower leg did not touch the table.

The sensor-integrated tibial inlay was tested following calibration (a) under linearly increasing compression load on a universal materials testing machine (Z020, Zwick GmbH & Co. KG, Ulm, Germany) and (b) under approximated physiological loading conditions on a knee simulator (EndoLab GmbH, Thansau/Rosenheim, Germany) [64, 65]. For linear compression load testing, the inlay was placed on a planar, polished tibial metal back component (Columbus T3, B. Braun Aesculap, Tuttlingen, Germany), and the load was applied using a femoral component of the corresponding implant. This prosthesis was connected to the movable cross head of the machine by a cardan joint to ensure uniform loading of the bicondylar inlay components. Additionally, each side of the inlay was tested separately using a sphere instead of the femoral prosthesis. For all tests, compression load was increased linearly with 100 N/min. The measurement range for the complete inlay was 0–500 N and 0–250 N for each side, respectively.

In contrast to the one-dimensional compression test with idealized loading conditions, the knee simulator tests were designed to represent physiological joint load. Mounting of the inlay on the tibial side was similar to the compression load test. In order to simulate an unbalanced knee, the femoral component used for load application was embedded into the standard clamping of the simulator with a slight lateral tilt. The same procedure is normally used in long-term tests of prosthesis components to create a load distribution of 60% medial and 40% lateral. After mounting the test inlay, different knee joint movements were applied varying axial load between 200 N and 500 N, flexion angle between 0° and 60° and torsion between 0° and 10°. All variations were conducted with a speed of 0.1 Hz.

Results and discussion

The laboratory studies have proven the feasibility of the genALIGN concept. The mechanical femoral axis could be determined with a deviation of 0.1°±1.8° (mean±std. dev.) varus and 0.1°±1.4° anterior slope compared to the optically tracked axis. The maximum deviation was 3.0° varus and 1.4° anterior slope, respectively. Cadaver tests resulted in an accuracy of 2.9°±1.5° valgus and 0.3°±2.4° anterior slope compared to the Mikulicz-line acquired by the optical navigation system. However, the maximum deviation was 5° varus and 11° anterior slope (due to deficiencies of the weight compensation mechanism). The results were not user-dependent. The system handling turned out to be very intuitive [18].

The results of the feasibility studies with the first prototype of the genALIGN demonstrate that, in general, the mechanical axis of the femur can be correctly determined under laboratory conditions. The results for the varus/valgus alignment and for the anterior slope under clinical conditions were promising. However, the outliers in the measurements, especially related to the anterior/posterior slope errors, showed that the first laboratory prototype had to be optimized prior to clinical trials. The most important issue for optimization is the compensation of the leg's weight (affecting the accuracy of the anterior slope). The leg's weight induces an additional torque around the medial/lateral axis thus influencing the anterior/posterior slope. For the laboratory study with the lightweight sawbones, the sensor was readjusted (tared) to account for the leg's weight. However, handling has proven impractical for a heavy real leg in the cadaver study, especially in case of high BMI, leading to inaccuracies. During the cadaver test, the leg was supported by an elastic sling, but the sterile handling of this support device might be too cumbersome for clinical routine use. Additionally, the elasticity of the sling might also be an issue, as it induces a path-dependent force, which cannot be fully compensated by readjusting the sensor. Therefore, a novel leg supporting system has been developed and will be evaluated soon.

Furthermore, the trigger mechanism and fixation of the ball and socket joint to freeze the mechanical axis position have been optimized. Additionally, the required computer equipment and cables for measuring and displaying the forces/torques (two boxes+laptop) have been eliminated. The new microcontroller-based version of the genALIGN device incorporates a new low-cost FTS and an integrated small display proximate to the sensor (see Figure 5). It will be evaluated in our upcoming cadaver studies.

Preliminary tests of the tibial inlay on the universal material testing machine (Figure 6A) showed that the increasing compression loads can be correctly measured. Slight deviations from the reference force may be caused by deformation of the PE housing (modified standard trial inlay). The load distribution between the three sensors of one inlay part indicated that the force application point in extension is very close to the line connecting the lateral and the posterior sensor. This involves the risk of anterior condylar liftoff especially as the contact point between femur and tibia moves posterior in flexion [37].

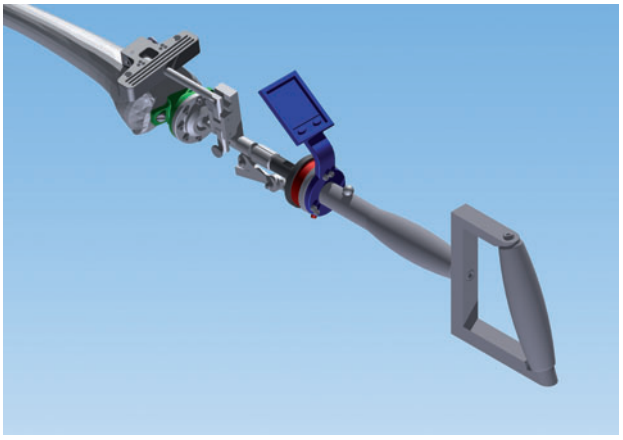

Figure 5 Design of the new microcontroller-based version of the genALIGN device.

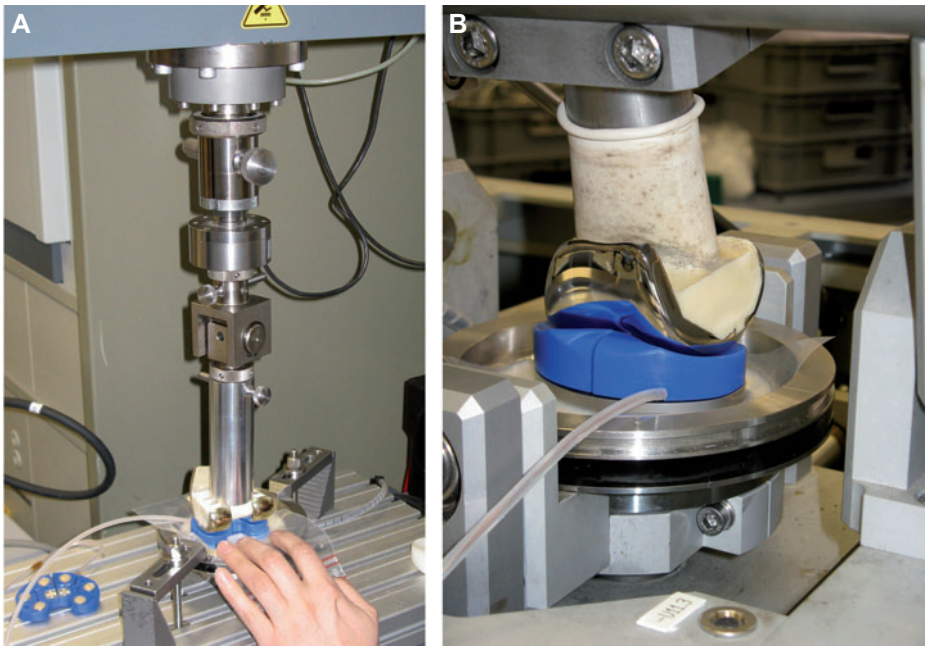

Figure 6 Experimental setup for the preliminary tests of the tibial inlay on the universal material testing machine (A) and on the knee simulator (B).

Based on the knee simulator study (Figure 6B), we could demonstrate that joint load measurement resulted in plausible values over the whole range of motion and for all applied load combinations. Figure 7 shows the load on the medial condyle for 200 N axial load, variation of flexion angle between 0° and 60° and constant torsion of 0° as one example. This record illustrates the main limitation of the current design: as indicated in the compression load test, a liftoff of the anterior and also the lateral sensor occurred during flexion (measured forces are close to zero). However, we could demonstrate in a finite element study that the implemented optimisation of the sensor positions can prevent this liftoff. The shift in knee joint loads from the anterior and lateral sensor to the posterior sensor, representing the movement of the tibial inlay on the tibial stem, is a consequence of the mobile bearing of the tibial inlay on the polished tibial stem plate and the slight lateral tilt of the femoral component. This shows that the genALIGN tibial inlay could provide additional information on intra-articular loading conditions. Moreover, the sensorised tibial inlay as such can replace the FTS for the determination of the mechanical leg axis, thus eliminating one sensor (and the related costs). The evaluation of this "streamlined" concept is one objective of our ongoing work.

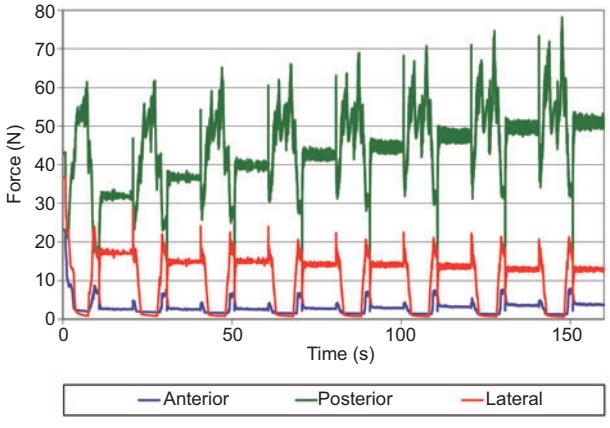

Figure 7 Force progression during knee simulator study (200 N axial load, variation of flexion angle between 0° and 60°, constant torsion of 0°).

Conclusion

In the framework of the OrthoMIT project, we developed a new navigated implantation approach based on intraoperative force-torque measurement. The genALIGN system potentially offers an accurate, simple and low-cost approach for mechanical alignment and ligament balancing in TKA, eliminating some of the drawbacks of conventional navigation systems (invasive rigid bodies, optical tracking system, computer equipment, costs). It directly addresses and measures the parameters of interest – forces and moments in the knee. First experimental studies have shown that the alignment of the femoral component can be performed without intramedullary devices and without the need for optical or magnetic tracking systems. The sensorised genALIGN tibial inlay enables objective measurement of intra-articular forces for ligament balancing and rotational alignment. Moreover, soft tissue-induced joint loads will be taken into account for rotational alignment. The laboratory and cadaver tests demonstrated the feasibility of the concept as well as the design principle of the current devices. We are confident that the evaluation of the improved new versions of the genALIGN system will confirm the positive results of the feasibility studies.

Acknowledgements

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 German State of North Rhine-Westphalia and EFRE under grant no. 280155401 (genALIGN™).

References

[1] Agins HJ, Harder VS, Lautenschlager EP, Kudrna JC. Effects of sterilization on the Tekscan digital pressure sensor. Med Eng Phys 2003; 25: 775–780.

[2] Akagi M, Matsusue Y, Mata T, et al. Effect of rotational alignment on patellar tracking in total knee arthroplasty. Clin Orthop Relat Res 1999; 366: 155–163.

[3] Amiot L-P, Poulin F. Computed tomography-based navigation for hip, knee, and spine surgery. Clin Orthop Relat Res 2004; 421: 77–86.

[4] Bargren JH, Blaha JD, Freeman MA. Alignment in total knee arthroplasty. Correlated biomechanical and clinical observations. Clin Orthop Relat Res 1983; 173: 178–183.

[5] Berger RA, Crossett LS, Jacobs JJ, Rubash HE. Malrotation causing patellofemoral complications after total knee arthroplasty. Clin Orthop Relat Res 1998; 356: 144–153.

[6] Berger RA, Rubash HE, Seel MJ, Thompson WH, Crossett LS. Determining the rotational alignment of the femoral component in total knee arthroplasty using the epicondylar axis. Clin Orthop Relat Res 1993; 286: 40–47.

[7] Brys DA, Lombardi AV, Mallory TH, Vaughn BK. A comparison of intramedullary and extramedullary alignment systems for tibial component placement in total knee arthroplasty. Clin Orthop Relat Res 1991; 263: 175–179.

[8] Bäthis H, Perlick L, Tingart M, Lüring C, Zurakowski D, Grifka J. Alignment in total knee arthroplasty. A comparison of computer-assisted surgery with the conventional technique. J Bone Joint Surg (Br) 2004; 86: 682–687.

[9] Caillouette JT, Anzel SH. Fat embolism syndrome following the intramedullary alignment guide in total knee arthroplasty. Clin Orthop Relat Res 1990; 251: 198–199.

[10] Cameron HU, Hunter GA. Failure in total knee arthroplasty: mechanisms, revisions, and results. Clin Orthop Relat Res 1982; 170: 141–146.

[11] Cates HE, Ritter MA, Keating EM, Faris PM. Intramedullary versus extramedullary femoral alignment systems in total knee replacement. Clin Orthop Relat Res 1993; 286: 32–39.

[12] Cerha O, Kirschner S, Günther K-P, Lützner J. Cost analysis for navigation in knee endoprosthetics. Orthopäde 2009; 38: 1235–1240.

[13] Crottet D, Maeder T, Fritschy D, Bleuler H, Nolte LP, Pappas IP. Development of a force amplitude- and location-sensing device designed to improve the ligament balancing procedure in TKA. IEEE Trans Biomed Eng 2005; 52: 1609–1611.

[14] Crottet D, Kowal J, Sarfert SA, et al. Ligament balancing in TKA: evaluation of a force-sensing device and the influence of patellar eversion and ligament release. J Biomech 2007; 40: 1709–1715.

[15] Dennis DA, Channer M, Susman MH, Stringer EA. Intramedullary versus extramedullary tibial alignment systems in total knee arthroplasty. J Arthroplasty 1993; 8: 43–47.

[16] Dorr LD, Merkel C, Mellman MF, Klein I. Fat emboli in bilateral total knee arthroplasty. Predictive factors for neurologic manifestations. Clin Orthop Relat Res 1989; 248: 112–118; discussion 118–119.

[17] Dutton AQ, Yeo S-J, Yang K-Y, Lo N-N, Chia K-U, Chong H-C. Computer-assisted minimally invasive total knee arthroplasty compared with standard total knee arthroplasty. A prospective, randomized study. J Bone Joint Surg (Am) 2008; 90: 2–9.

[18] Elfring R, de la Fuente M, Schmidt F, Niggemeyer M, Teske W, Radermacher K. A Novel system for the determination of the Mikulicz-line in TKA: a Cadver-Study. In: Davies B, Joskowicz L, Leung K-S, editors. Proceedings of the 8th annual meeting of CAOS International, Hong Kong: Department of Orthopaedics and Traumatology, The Chinese University of Hong Kong 2008; 8: 136–138.

[19] Ensini A, Catani F, Leardini A, Romagnoli M, Giannini S. Alignments and clinical results in conventional and navigated total knee arthroplasty. Clin Orthop Relat Res 2007; 457: 156–162.

[20] Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster J-Y. Health-related quality of life in total hip and total knee arthroplasty. A qualitative and systematic review of the literature. J Bone Joint Surg (Am) 2004; 86-A: 963–974.

[21] Fehring TK. Rotational malalignment of the femoral component in total knee arthroplasty. Clin Orthop Relat Res 2000; 380: 72–79.

[22] Fehring TK, Valadie AL. Knee instability after total knee arthroplasty. Clin Orthop Relat Res 1994; 299: 157–162.

[23] Fehring TK, Odum S, Griffin WL, Mason JB, Nadaud M. Early failures in total knee arthroplasty. Clin Orthop Relat Res 2001; 392: 315–318.

[24] Fregly BJ, Bei Y, Sylvester ME. Experimental evaluation of an elastic foundation model to predict contact pressures in knee replacements. J Biomech 2003; 36: 1659–1668.

[25] Fregly BJ, Sawyer WG, Harman MK, Banks SA. Computational wear prediction of a total knee replacement from in vivo kinematics. J Biomech 2005; 38: 305–314.

[26] Gonzalez MH, Mekhail AO. The failed total knee arthroplasty: evaluation and etiology. J Am Acad Orthop Surg 2004; 12: 436–446.

[27] Hanada H, Whiteside LA, Steiger J, Dyer P, Naito M. Bone landmarks are more reliable than tensioned gaps in TKA component alignment. Clin Orthop Relat Res 2007; 462: 137–142.

[28] Harris ML, Morberg P, Bruce WJ, Walsh WR. An improved method for measuring tibiofemoral contact areas in total knee arthroplasty: a comparison of K-scan sensor and Fuji film. J Biomech 1999; 32: 951–958.

[29] Heesterbeek PJC, Jacobs WCH, Wymenga AB. Effects of the balanced gap technique on femoral component rotation in TKA. Clin Orthop Relat Res 2009; 467: 1015–1022.

[30] Hofmann S, Romero J, Roth-Schiffl E, Albrecht T. Rotational malalignment of the components may cause chronic pain or early failure in total knee arthroplasty. Orthopäde 2003; 32: 469–476.

[31] Jenny J-Y, Boeri C. Low reproducibility of the intra-operative measurement of the transepicondylar axis during total knee replacement. Acta Orthop Scand 2004; 75: 74–77.

[32] Jenny J-Y, Clemens U, Kohler S, Kiefer H, Konermann W, Miehlke RK. Consistency of implantation of a total knee arthroplasty with a non-image-based navigation system: a case-control study of 235 cases compared with 235 conventionally implanted prostheses. J Arthroplasty 2005; 20: 832–839.

[33] Kaufman KR, Kovacevic N, Irby SE, Colwell CW. Instrumented implant for measuring tibiofemoral forces. J Biomech 1996; 29: 667–671.
[34] Kilgus DJ, Moreland JR, Finerman GA, Funahashi TT, Tipton JS. Catastrophic wear of tibial polyethylene inserts. Clin Orthop Relat Res 1991; 273: 223–231.
[35] Klein GR, Austin MS, Smith EB, Hozack WJ. Total knee arthroplasty using computer-assisted navigation in patients with deformities of the femur and tibia. J Arthroplasty 2006; 21: 284–288.
[36] Lavernia C, Hernandez VH, Hommen JP. Navigation and MIS in Orthopedic Surgery, chapter Cost Analysis of Navigation. Berlin: Springer Verlag 2006.
[37] Li G, Suggs J, Hanson G, Durbhakula S, Johnson T, Freiberg A. Three-dimensional tibiofemoral articular contact kinematics of a cruciate-retaining total knee arthroplasty. J Bone Joint Surg (Am) 2006; 88: 395–402.
[38] Lotke PA, Ecker ML. Influence of positioning of prosthesis in total knee replacement. J Bone Joint Surg (Am) 1977; 59: 77–79.
[39] Lüring C, Perlick L, Bäthis H, Tingart M, Grifka J. The effect of femoral component rotation on patellar tracking in total knee arthroplasty. Orthopedics 2007; 30: 965–967.
[40] Marmignon C, Leimnei A, Cinquin P. Knee prosthesis – a robotized distraction device helping the surgeon in ligament balancing. 3rd Annual Meeting of CAOS-International Proceedings, Marbella (Spanien), Darmstadt: SteinkopffVerlag 2003.
[41] Marmignon C, Leimnei A, Cinquin P. Robotized distraction device for ligament balance monitoring in total knee arthroplasty. 3rd Annual Meeting of CAOS-International Proceedings, Marbella (Spanien), Darmstadt: SteinkopffVerlag 2003.
[42] Marmignon C, Leimnei A, Lavallée S, Cinquin P, Hodgson AA. A computer-assisted controlled distraction device to guide ligament balancing during knee arthroplasty. 4th Annual Meeting of CAOS-International Proceedings, Chicago (USA), Berlin: Pro-Business 2004; 65–66.
[43] Mihalko WM, Krackow KA. Differences between extramedullary, intramedullary, and computer-aided surgery tibial alignment techniques for total knee arthroplasty. J Knee Surg 2006; 19: 33–36.
[44] Miller MC, Berger RA, Petrella AJ, Karmas A, Rubash HE. Optimizing femoral component rotation in total knee arthroplasty. Clin Orthop Relat Res 2001; 392: 38–45.
[45] Mochizuki RM, Schurman DJ. Patellar complications following total knee arthroplasty. J Bone Joint Surg (Am) 1979; 61: 879–883.
[46] Mohanty L, Tjin SC. Pressure mapping at orthopaedic joint interfaces with fiber Bragg gratings. Appl Phys Lett 2006; 88: 083901 1–3.
[47] Mohanty L, Tjin SC, Ngo NQ. Pressure mapping sensor with an array of chirped sampled fiber gratings. Sensors and Actuators, A: Physical 2005; 117: 217–221.
[48] Morawa LG, Manley MT, Edidin AA, Reilly DT. Transesophageal echocardiographic monitored events during total knee arthroplasty. Clin Orthop Relat Res 1996; 331: 192–198.
[49] Moreland JR. Mechanisms of failure in total knee arthroplasty. Clin Orthop Relat Res 1988; 226: 49–64.
[50] Mulhall KJ, Ghomrawi HM, Scully S, Callaghan JJ, Saleh KJ. Current etiologies and modes of failure in total knee arthroplasty revision. Clin Orthop Relat Res 2006; 446: 45–50.
[51] Mullaji A, Kanna R, Marawar S, Kohli A, Sharma A. Comparison of limb and component alignment using computer-assisted navigation versus image intensifier-guided conventional total knee arthroplasty: a prospective, randomized, single-surgeon study of 467 knees. J Arthroplasty 2007; 22: 953–959.
[52] Nabeyama R, Matsuda S, Miura H, Mawatari T, Kawano T, Iwamoto Y. The accuracy of image-guided knee replacement based on computed tomography. J Bone Joint Surg (Br) 2004; 86: 366–371.
[53] Novak EJ, Silverstein MD, Bozic KJ. The cost-effectiveness of computer-assisted navigation in total knee arthroplasty. J Bone Joint Surg (Am) 2007; 89: 2389–2397.
[54] Nowakowski A. Dynamische In-vitro-Kraft-, Bewegungs- und Druckanalyse an beweglichen Meniskallagern unterschiedlicher Konzeption nach alloplastischem Kniegelenkersatz. Hannover: Medizinische Hochschule 2001.
[55] Olcott CW, Scott RD. The Ranawat Award. Femoral component rotation during total knee arthroplasty. Clin Orthop Relat Res 1999; 367: 39–42.
[56] Olcott CW, Scott RD. A comparison of 4 intraoperative methods to determine femoral component rotation during total knee arthroplasty. J Arthroplasty 2000; 15: 22–26.
[57] Paley D. Normal lower limb alignment and joint orientation. In: Principles of Deformity Correction. Berlin: Springer 2002: 1–4.
[58] Rand JA, Trousdale RT, Ilstrup DM, Harmsen WS. Factors affecting the durability of primary total knee prostheses. J Bone Joint Surg (Am) 2003; 85-A: 259–265.
[59] Rhoads DD, Noble PC, Reuben JD, Mahoney OM, Tullos HS. The effect of femoral component position on patellar tracking after total knee arthroplasty. Clin Orthop Relat Res 1990; 260: 43–51.
[60] Ritter MA, Faris PM, Keating EM, Meding JB. Postoperative alignment of total knee replacement. Its effect on survival. Clin Orthop Relat Res 1994; 299: 153–156.
[61] Robinson M, Eckhoff DG, Reinig KD, Bagur MM, Bach JM. Variability of landmark identification in total knee arthroplasty. Clin Orthop Relat Res 2006; 442: 57–62.
[62] Rottman SJ, Dvorkin M, Gold D. Extramedullary versus intramedullary tibial alignment guides for total knee arthroplasty. Orthopedics 2005; 28: 1445–1448.
[63] Schmidt F, Lampe F, Elfring R, et al. Soft-tissue management in primary knee arthroplasty: common techniques, navigation and force-sensing devices. Z Orthop Unfall 2007; 145: 599–607.
[64] Schmidt F, Elfring R, Nolten U, Mokwa W, Radermacher K. A new force-based approach for prosthesis alignment and ligament balancing in TKA. In: Davies B, Joskowicz L, Murphy S, editors. Proceedings of the 9th Annual Meeting of CAOS International, Livermore: WingSpan Press 2009: 640–642.
[65] Schmidt F, Elfring R, Nolten U, Firmbach F-P, Mokwa W, Radermacher K. A new intra-articular load measuring device for ligament balancing and prosthesis alignment in total knee arthroplasty. In: Dössel O, Schlegel WC, editors. IFMBE Proceedings of 11th International World Congress on Medical Physics and Biomedical Engineering. Berlin: Springer 2009: 25/VI 331–332.
[66] Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM. Insall Award paper. Why are total knee arthroplasties failing today? Clin Orthop Relat Res 2002; 404: 7–13.
[67] Statistisches Bundesamt. Fallpauschalenbezogene Krankenhausstatistik (DRG-Statistik) – Operationen und Prozeduren der vollstationären Patientinnen und Patienten in Krankenhäusern 2009. Wiesbaden, Statistisches Bundesamt 2010. Artikelnummer: 5231401097015.
[68] Swank M, Romanowski IR, Korbee LL, Bignozzi S. Ligament balancing in computer-assisted total knee arthroplasty: improved clinical results with a spring-loaded tensioning device. Proc Inst Mech Eng [H] 2007; 221: 755–761.

[69] Victor J. Rotational alignment of the distal femur: a literature review. Orthop Traumatol Surg Res 2009; 95: 365–372.
[70] Victor J, Hoste D. Image-based computer-assisted total knee arthroplasty leads to lower variability in coronal alignment. Clin Orthop Relat Res 2004; 428: 131–139.
[71] Victor J, Van Doninck D, Labey L, Van Glabbeek F, Parizel P, Bellemans J. A common reference frame for describing rotation of the distal femur: a CT-based kinematic study using cadavers. J Bone Joint Surg (Br) 2009; 91: 683–690.
[72] Werner FW, Ayers DC, Maletsky LP, Rullkoetter PJ. The effect of valgus-varus malalignment on load distribution in total knee replacements. J Biomech 2005; 38: 349–355.
[73] Wylde V, Blom AW, Whitehouse SL, Taylor AH, Pattison GT, Bannister GC. Patient-reported outcomes after total hip and knee arthroplasty: comparison of midterm results. J Arthroplasty 2009; 24: 210–216.
[74] Yan CH, Yau WP, Ng TP, Lie WH, Chiu KY, Tang WM. Inter- and intra-observer errors in identifying the transepicondylar axis and Whiteside's line. J Orthop Surg (Hong Kong) 2008; 16: 316–320.

Received December 7, 2011; accepted March 21, 2012; online first May 6, 2012