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Evaluation of implant position and knee alignment after patient-specific unicompartmental knee arthroplasty

Franz Xaver Koeck [a,*], Johannes Beckmann [a], Christian Luring [a], Bjoern Rath [a], Joachim Grifka [a], Erhan Basad [b]

[a] Orthopaedic Surgery, University of Regensburg, Germany
[b] Orthopaedic Surgery, University of Giessen, Germany

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ABSTRACT

Implant positioning and knee alignment are two primary goals of successful unicompartmental knee arthroplasty. This prospective study outlines the radiographic results following 32 patient-specific unicompartmental medial resurfacing knee arthroplasties. By means of standardized pre- and postoperative radiographs of the knee in strictly AP and lateral view, AP weight bearing long leg images as well as preoperative CT-based planning drawings an analysis of implant positioning and leg axis correction was performed.The mean preoperative coronal femoro-tibial angle was corrected from 7° to 1° ($p<0.001$). The preoperative medial proximal tibial angle of 87° was corrected to 89° ($p<0.001$). The preoperative tibial slope of 5° could be maintained. The extent of the dorsal femoral cut was equivalent to the desired value of 5 mm given by the CT-based planning guide. The mean accuracy of the tibial component fit was 0 mm in antero-posterior and +1 mm in medio-lateral projection. Patient-specific fixed bearing unicompartmental knee arthroplasty can restore leg axis reliably, obtain a medial proximal tibial angle of 90°, avoid an implant mal-positioning and ensure maximal tibial coverage.

1. Introduction

Compared to the number of total knee arthroplasties (TKA), unicompartmental knee arthroplasties (UCA) are only a small share of the total number of knee replacements. Against the background of a high growth rate in knee arthroplasty over the past 10 years, the number of UCA in the US in 2005 accounted for less than 8% [1], however, at least 25% of patients with osteoarthritis of the knee are estimated to suffer from isolated medial and 5% of patients of isolated lateral compartment disease [2]. Early results of UCA reported in the 1970s and 1980s were discouraging [3,4], but 10 to 20 years later advancements in patient selection, surgical technique, and implant design have improved the clinical outcome even in younger and more active patients [5,6]. Recently several studies reported excellent 10-year survivorships of UCA [7,8]. Patients treated with UCA have a better range of motion [9] and their knee feels more normal when compared to TKA patients [10]. However, UCA remains a highly demanding surgical procedure.

Especially in UCA, durability of component fixation is dependent on good bone stock as well as on precise alignment and component orientation [11,12]. To improve the precision of implantation, computer-assisted navigations systems have been used in UCA for almost ten years [13]. The navigation systems were reported to have an immediate positive effect on implant orientation and leg axis [14,15]. The positive implications on long-term results can be extrapolated [16]. Currently reported use of elaborate robotic-arm assisted UCA also addresses the accuracy of implant orientation and leg axis restoration [17]. Another problem relates to current implant designs, which do not match the anatomy precisely [18]. The use of personalized, patient-specific instruments and implants is a newly developed suitable solution to address above-mentioned problems of off-the-shelf implants and current surgical techniques.

The aim of this study was to evaluate the precision of implant positioning and accuracy of leg alignment using novel CT-based, patient-specific instruments and fixed bearing implants in UCA. We hypothesized that the patient-specific UCA solution would result in a precise component orientation and leg axis restoration, and thereby may improve patient long-term outcome.

2. Patients and methods

A prospective study with 31 patients (32 knees) with isolated unicompartmental medial osteoarthritis of the knee was conducted from May 2008 to November 2009 in two German university orthopaedic departments. The study was conducted according to the directives of the Regensburg University IRB. In this study, two surgeons (FXK and EB) implanted a total of 32 individualized iUni™ (ConforMIS, Burlington, Massachusetts) unicompartmental medial knee arthroplasties (17 right, 15 left). This implant has been cleared under the

* Corresponding author. Department of Orthopaedic Surgery, University of Regensburg, Kaiser-Karl-V.-Allee 3, 93077, Bad Abbach, Germany. Tel.: +49 9405 180; fax: +49 9405 182925.
E-mail address: franz.koeck@klinik.uni-regensburg.de (F.X. Koeck).

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510(k) process (i.e., pre-market notification) by the United States Food and Drug Administration (FDA) and was CE Mark approved for both the iUni™ unicompartmental resurfacing device and the iJig™ instrument system for use with the iUni™ in 2007. All sequential cases were included. The average age of the patients (15 women and 16 men) at the time of surgery was 58.8 years (43 to 73 years).

Pre-surgery CT-examination of the affected knee and additionally the centre of the femoral head and the centre of the talus is performed according to the prescribed protocol to obtain data of the knee joint surfaces as well as the mechanical and anatomical axes.

The patient-specific fixed bearing UCA, which is available for the medial compartment as well as the lateral compartment, is designed from this CT-scan using a proprietary software algorithm (iFit™-Technology), which maps the articular surface of the joint, defines the area of disease and the extent of malalignment present in the knee, and creates an implant design that is precisely matched to the patient's anatomy. After implant design, this technology generates a computer aided design file (CAD/CAM) with individualized implant components. The implants are manufactured in Cobalt–Chromium–Molybdenum using direct digital manufacturing and standard metal working techniques. Because of its patient-specific conformity to the subchondral bone, the femoral component is a true resurfacing product, completely covering the condyle (Fig. 1a and b) and requiring only cartilage removal and one small posterior bone cut. The geometry of the tibial implant is specified to provide full cortical rim coverage on the tibia (Fig. 2).

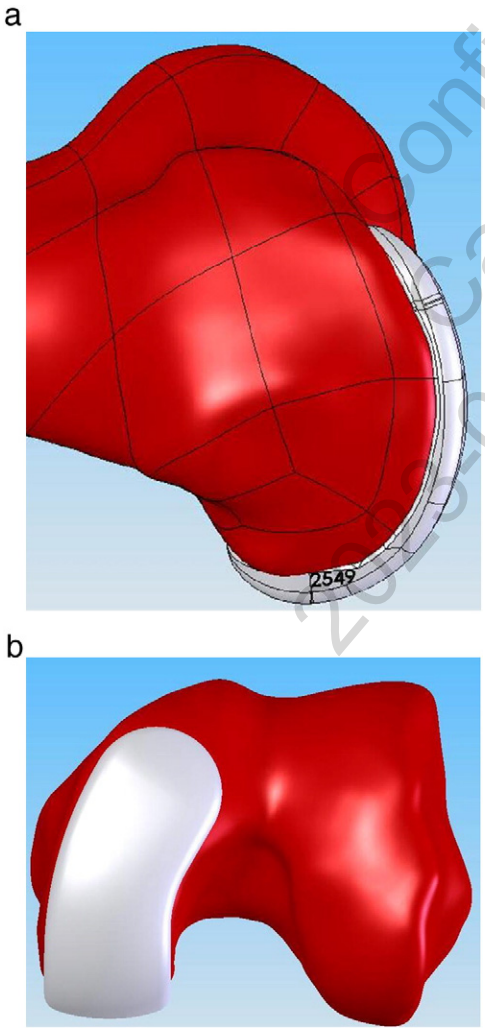

Fig. 1. a, b. Design drawing of femoral component indicating an anatomical fit and a complete coverage of the condyle in two planes.

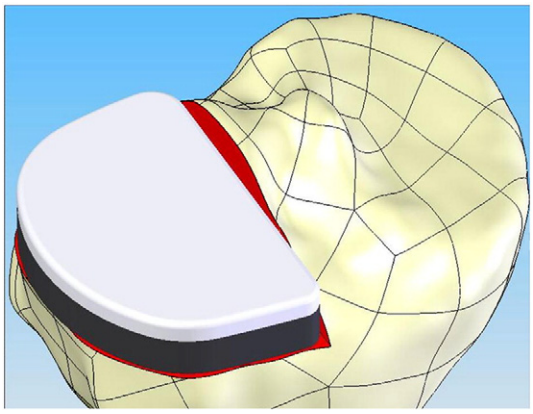

Fig. 2. Design drawing of tibial component indicating a full coverage of the cortical rim.

The implants are provided in a sterile box in combination with patient-specific, single-use instruments (iJigs™), which are produced of nylon by 3D rapid prototype printer based on the same CT-scan and using the same software technology. The cutting jigs match the bony joint surfaces and utilize all essential information about joint geometry, mechanical and anatomical axes and planned cutting planes. Therefore the device can by labeled as pre-navigated.

2.1. Surgical procedure

The joint is opened through a midline skin incision and a short medial parapatellar arthrotomy. In full knee extension, the linea terminalis is marked. Subsequently, meniscectomy and resection of all osteophytes are done. Using a curette all remaining cartilage below the linea terminalis at the affected femoral condyle is removed and the femoral jig is brought in place. Next, the remaining tibial cartilage is removed and one of the tibial navigation chips, which are provided in four thicknesses, is placed while the knee is kept in slight flexion of about 20°. This enables proper tensioning of the affected collateral ligament until the ideal laxity is determined (joint space opening of 1 mm medially and 1 to 2 mm laterally). The tibial cutting block is then mounted to the proper navigation chip and fixed with one or two tibial pins and can additionally be belayed by an additional external alignment guide. The sagittal and horizontal tibial cuts are completed (Fig. 3).

Using the femoral jig, two peg holes are drilled, the femoral jig is fixed with pins, and the dorsal femoral cut is made. The amount of resection should be the same as that indicated by the preoperative drawing. Using a high speed burr, an anterior recess at the femoral condyle is made for plunge of the anterior tip of the femoral component and creates a smooth implant–cartilage transition. To provide better

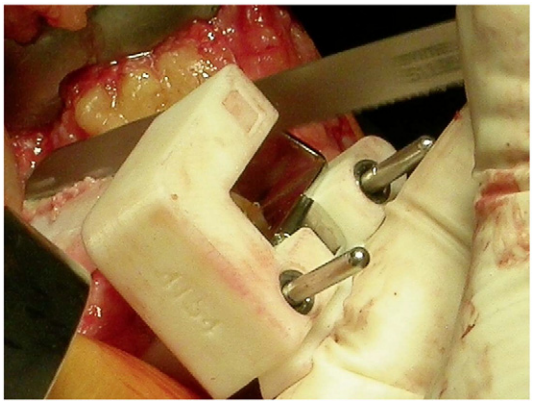

Fig. 3. Sagittal tibial cut with pin-fixed cutting block mounted to tibial navigation chip.

cement penetration, multiple 2 mm holes are drilled femorally. Tibial preparation is completed by drilling two peg holes and creating a pin inset using the tibial preparation template. The implant fit and ligament tension can then be tested using trial components and the original implant with a trial insert. After cleaning the bone surfaces with a pulsatile jet-lavage, first the tibial and then the femoral component are cemented in a standard technique before inserting the original polyethylene insert.

Our surgical procedure in both centres was according to the technique first described in detail by Fitz [19].

2.2. Radiographic analysis

The radiological examination was performed before surgery and 1 week postoperatively with standardized pre- and postoperative radiographs of the knee in strictly antero-posterior (AP) and lateral view with an additional scale. Furthermore, AP weight bearing long leg images were taken. Great care was taken to ensure that the femoral condyles were parallel to the frontal plane, which corresponded to the centre of the film. This was achieved by frontally aligning the patella while neutrally extending both knee joints. The X-ray technicians received special training in this technique in preparation of the study.

Lateral view images and preoperative CT-based planning drawings were used to determine the amount of dorsal condyle resection. The fit of the tibial component was determined with pre- and postoperative AP and lateral view images (Fig. 4), respectively, and the fit of the tray to the medial or lateral tibial border.

An exact matching of the tibial and prosthetical border was targeted. The pre- and postoperative tibial slope was determined by the preoperative planning drawings (Fig. 5) compared to the postoperative lateral radiographs. The slope was targeted to be individually restored or rather kept.

The pre- and postoperative medial proximal tibial angel (MTPA) according to Paley [20], as well as the deviation from the load axis of the surgically treated knee joint under stress, was determined with the pre- and postoperative AP weight bearing long leg images (Fig. 6). All measurements were done twice by two independent orthopedic surgeons in separate readings on different days.

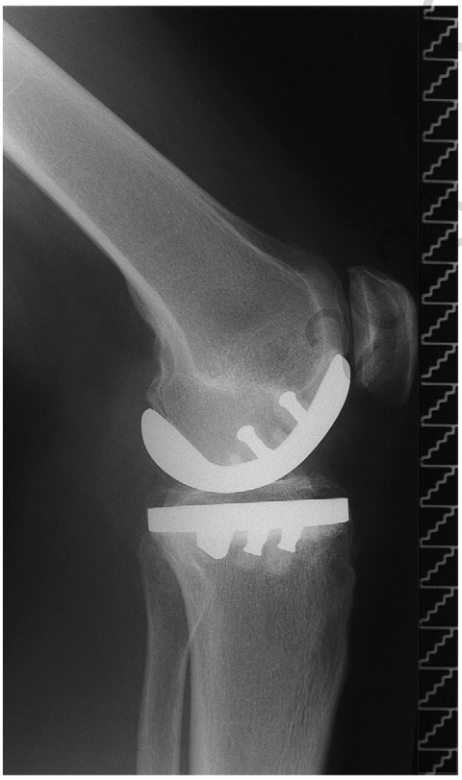

Fig. 4. Lateral view with the scale of the knee joint after iUni™ implantation.

2.3. Statistical analysis

The Kolmogorov–Smirnov test was used to evaluate whether the distribution of the particular results followed a normal distribution (Gaussian distribution). This analysis demonstrated that none of the examiners produced results that represented a significant deviation from a normal distribution. Paired *t*-test was used to compare values of means for determined parameters pre- and postoperatively. A level of $p<0.05$ was considered to be of statistical significance. The standard deviation for the achieved correction in regard to each parameter was determined.

3. Results

3.1. Mechanical leg axis

The objective was to correct the leg axis to 0° and/or to undercorrect up to 2° of remaining varus. This could be reached in 25 of 32 cases. In two cases, we found a slight undercorrection of maximum 3°, in five cases there was a slight overcorrection of maximum 2° (Fig. 7). The mean preoperative coronal femoro-tibial angle was corrected from 7° (SD 3.3) to 1° (SD 0.9). The average extent of the correction was 6°. The results were statistically significant ($p<0.001$). This represents a slight undercorrection of varus alignment with a remaining mean varus of 1°.

3.2. Implant positioning

An angle of 90° was aimed for the coronal orientation of the tibial component (MPTA, medial proximal tibial angle). We found a mean preoperative MPTA of 87° (SD 2.4) which was corrected to 89° (SD 1.2) postoperatively which was statistically significant ($p<0.001$). For the tibial tray we targeted an adjustment to the natural slope. The mean preoperative tibial slope of 5° (SD 2.5) was reproduced reliably, reaching a mean slope of the tibial component of 5° (SD 2.5) ($p<0.001$) postoperatively.

The amount of dorsal condyle resection of 5 mm (SD 1.2) postoperatively was equivalent to the desired value of 5 mm (SD 1.2) ($p<0.001$). The accuracy of the tibial component fit from the desired exact cortex match of therefore 0 mm was 0 mm (SD 0.6) in the sagittal plane ($p<0.001$) and was +1 mm (SD 0.9) in the coronal plane ($p=0.003$).

4. Discussion

According to the demographic development, the numbers of implanted TKA and UCA grow steadily [1]. However, particularly in UCA, precise knee alignment and implant orientation can not always be achieved due to the demanding surgical technique and the lack of individualized implants by means of off-the-shelf implants[13].

To our best knowledge, this is the first study that evaluates the precision of implant positioning and leg axis restoration using CT-based personalized instruments and implants in UCA.

In patients with medial unicompartmental arthritis, the best results are obtained when the postoperative mechanical axis is neutral or slightly medial to the centre of the knee. Overcorrection as well as undercorrection have been associated with early failure [8,11,21]; particularly overcorrection might result in medio-lateral subluxation of the femoro-tibial articulation and in excessive force on the unresurfaced compartment with early secondary degeneration [22,23]. However, the effect of alignment is smaller than often reported and seems to be a poor predictor for expected joint space narrowing in the opposite compartment [24]. Our study demonstrated that a sufficient leg axis correction with individualized UCA slightly below neutral axis (1.1°) with an average extent of the correction of 5.7° can be achieved. This represents a slight undercorrection with a remaining mean varus of 0.7°, which is clinically very satisfying. Furthermore, the frontal plane alignment of tibial implant is meant to influence long-term results in UCA, with increased varus position resulting in higher failure rates [25–27]. In our study we could increase the preoperative MPTA and by

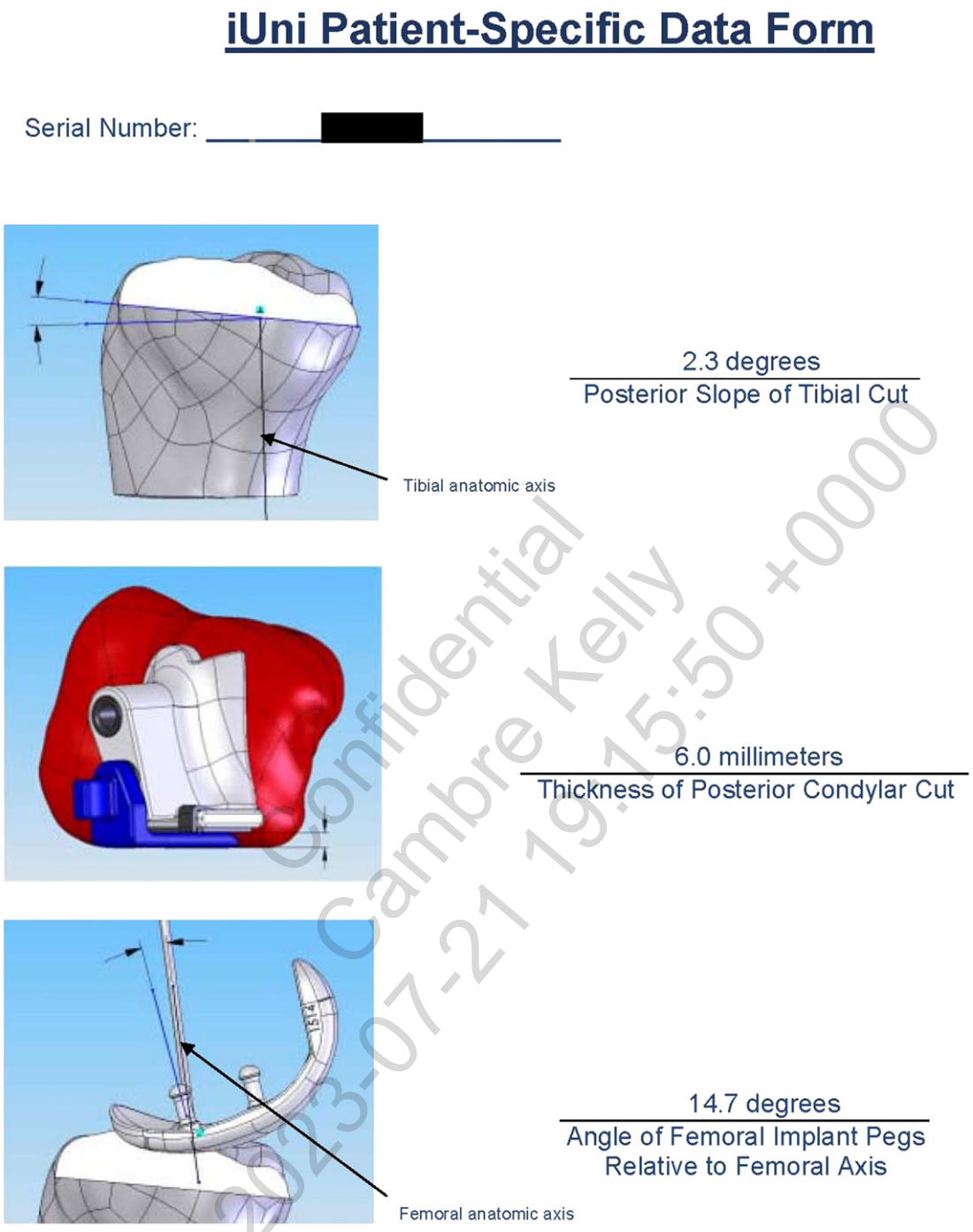

Fig. 5. Preoperative planning drawing provided for each implant.

association the frontal tibial component orientation from 87.0° to 89.3°. However, a recently published study showed that after Oxford UKR, about 25% of patients have varus alignment, but that this does not compromise their clinical or radiological outcomes [28].

Even the importance of the posterior tibial slope in UCA was demonstrated. There is a linear relationship between anterior tibial translation and posterior tibial slope and, by association, a higher risk of tibial component loosening with a posterior tibial implant slope of >7° [29]. Using the patient-specific UCA system, the mean preoperative tibial slope of 4.6° for the tibial component orientation in sagittal plane could be reproduced reliably.

The reliability of the measured extent of dorsal femoral resection compared to preoperative planning outlines high precision for femoral component positioning, which is designed as a true resurfacing implant and covers the condyle completely. Moreover, the anatomic femoral design may avoid edge-loading and, in combination with individual tibial slope, restore the patient-specific knee kinematic [19].

Compared to computer-assisted implantation of unicompartmental knee prosthesis, the presented technique using CT-based personalized instruments and implants demonstrates comparable positive results with regard to limb alignment and tibial component orientation [13,14,30,31]. However, as a limitation of this study, we

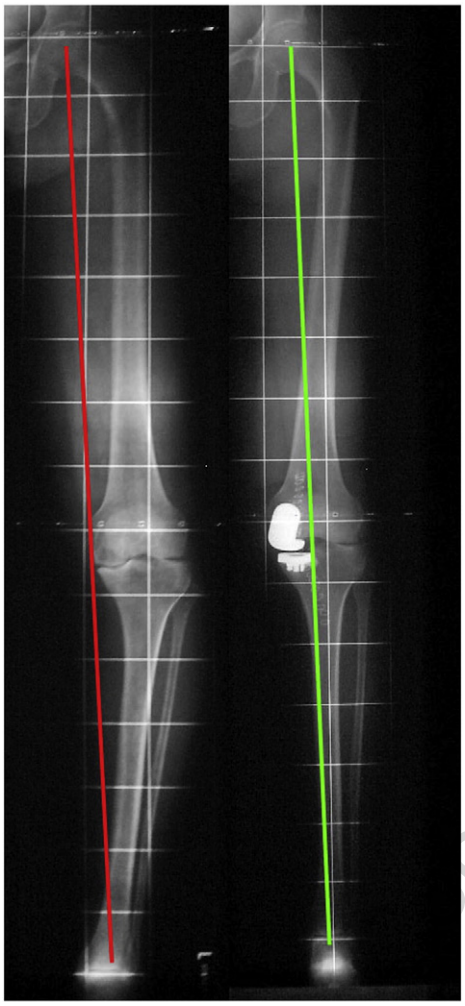

Fig. 6. Pre- and postoperative long leg standing view with correction of the leg axis.

cannot present a control group using off-the-shelf implants and cannot present long-term clinical results so far.

As shown by Fitzpatrick [18] as well as by Servien [32], most available unicompartmental implants cover the tibial cortex insufficiently. This problem worsens in lateral UCA: in addition to the poor accuracy of femoral component fit on the smaller lateral condyle, off-the-shelf tibial components do not match the more round anatomical tibial geometry in both dimensions [19]. Hence using navigation systems or robotic guidance even with an optimized off-the-shelf design the maximum tibial coverage would be only 75% [18]. Also, viewing the tibial cortex in two planes indicated a high accuracy of the implant's fit with no significant over- or underhang, which is known to increase failure rates particularly in obese patients [33]. However only postoperative multiparameter computer-assisted tomography assessment as described by Campbell [34] could prove a 100% tibial and femoral coverage as well as proper femoral component orientation.

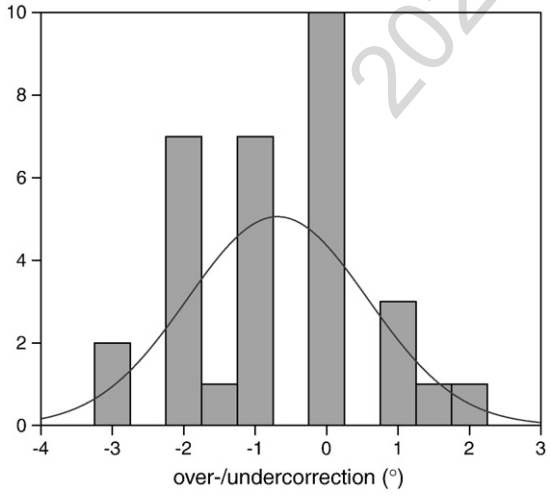

Fig. 7. Over- and undercorrection of the leg axis, negative sign therefore representing a remaining varus.

5. Conclusion

Besides the primary goal of restoration of the arthritic joint surface, CT-based customized fixed bearing unicompartmental knee arthroplasty reliably achieves a targeted leg axis correction, a near optimal implant positioning and an anatomical component orientation as well as a full coverage of tibial cortex. From experience, these advantages may result in improved clinical results; however this has to be further explored in long-term clinical follow up trials.

6. Conflict of interest statement

There was no sponsored research involving the implant or design company with regard to this study. Furthermore the authors have full control of all primary data and will agree to allow the journal to review the data if requested.

Acknowledgment

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