Accuracy of Individualized Custom Tibial Cutting Guides in UKA

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Abstract *Background:* Component malposition is one of the major reasons for early failure of unicompartmental knee arthroplasty (UKA). *Questions/Purposes:* It was investigated how reproducibly patient-specific instrumentation (PSI) achieved preoperatively planned placement of the tibial component in UKA specifically assessing coronal alignment, slope and flexion of the components and axial rotation. *Patients and Methods:* Based on computer tomography models of ten cadaver legs, PSI jigs were generated to guide cuts perpendicular to the tibial axis in the coronal and sagittal planes and in neutral axial rotation. Deviation $\geq 3^\circ$ from the designed orientation in a postoperative CT was defined as outside the range of acceptable alignment. *Results:* Mean coronal alignment was $0.4 \pm 3.2^\circ$ varus with two outliers. Mean slope was $2.8 \pm 3.9^\circ$ with six components in excessive flexion. It was noted that the implants were put in a mean of $1.7 \pm 8.0^\circ$ of external rotation with seven outliers. *Conclusions:* PSI helped achieve the planned coronal orientation of the component. The guides were less accurate in setting optimal tray rotation and slope.

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Introduction

Unicompartmental knee arthroplasty (UKA) has significantly increased its market share in the treatment of unicompartmental osteoarthritis in the USA over the last decade. Long-term survival of UKA in registries has, however, been reported to be inferior to that of total knee arthroplasty (TKA) [16, 29]. Experience with UKA contributes tremendously to successful outcome of this procedure [9]. As indications for UKA are less common, this experience is relatively hard to achieve in the average orthopedic practice.

Many of the early revisions of UKA seem to be due to implant-related problems, such as malpositioning, and this may at least in some cases relate to the experience level of the operating surgeon [16, 17]. Thus, an easy and affordable approach for reproducible implantation of UKA components would be highly desirable.

Patient-specific instrumentation (PSI) applying individualized custom cutting jigs have recently gained attention in TKA and are heavily marketed. They were introduced to improve the efficiency and accuracy of knee replacement [6]. With this technology, bone cuts are made using disposable cutting jigs individually designed from 3D images as obtained from either computed tomography (CT) or magnetic resonance imaging (MRI) [22].

Theoretically, precision of component orientation in all planes should be improved with the use of individualized custom cutting jigs. Data for TKA are partially contradictory, as some authors have shown improvement for the varus-valgus alignment with PSI [21, 22, 27] and rotation [10] while others have not [14, 23].

To date, several manufacturers have launched customized cutting jigs for facilitation of precise implantation of UKA. Since there is less surface contact area with PSI in UKA compared to TKA, concerns exist as to the precision and reproducibility of these tools. So far, there is however no

scientific data available that supports the efficacy of such cutting jigs in achieving better component alignment than with conventional techniques.

It was hypothesized that these cutting jigs would aid with orientation of the tibial components in all planes. The aim of this study was to investigate the ability of individualized tibial custom cutting jigs to help with the performance of bone cuts following a preoperative plan. We specifically assessed the ability of these jigs to achieve accurate placement of the components in the coronal and sagittal planes as well as in axial rotation and to document the need for recutting any of the planned steps in the UKA.

Methods

Using computed tomography (CT), 3D models of ten fresh frozen cadaver legs (Fig. 1, hip-to-toe, mean age 44.5 ± 13.7 years, six males, four females) were generated.

Fig. 1. Prepped cadaver with markers rigidly attached to femur and tibia. Hamstrings and quadriceps tendon were prepared and clamps were attached for application of muscle forces.

Functional ligaments and the absence of any major deformity were inclusion criteria.

The CT protocol included the entire lower extremity with submillimeter scan spacing and pixel size. The femur, tibia, and fibula were segmented from the scan using Mimics (Materialise, Leuven, Belgium) and exported as .stl files. The .stl files were imported into Computer-Aided Design (CAD) software (Pro/Engineer Wildfire, PTC, Needham, MA, USA) in order to design a specific customized cutting jig for each tibia.

The guide was designed to fit along the anteromedial aspect of the tibia (Fig. 2). In addition to the anteromedial aspect of the guide, a proximal portion was created that extended approximately to the midpoint of the articular surface of the medial condyle of the tibia.

A 1.4-mm slot was created to provide a surface for the horizontal bone cut. A vertical surface was included to assist in aligning the vertical cut. Lastly, two proximal and one distal hole were created in the guide in order to fix the guide to the tibia with pins (Figs. 2 and 3).

The contact surface of the guide was designed to match the surface of the tibia proximally to the distal end. This was accomplished by exporting the guide as an .stl file and imported the guide along with the tibia model into Geomagic Studio (3D Systems Corporation, Rock Hill, SC, USA). A Boolean operation was performed between the bone model and the guide to create the surface on the guide that matches the bone. Clearance was added proximal to the slot and between the proximal and distal screw holes to reduce the amount of soft tissue dissection.

The guide was designed to create a horizontal tibial resection perpendicular to the long axis of the tibia in the coronal and sagittal planes and in neutral axial rotation. The resection depth was measured from the most distal aspect of the medial femoral condyle and measured approximately 7 mm. The vertical cut was planned to be in neutral axial rotation using a tangent to the posterior tibial condyles as a reference (Fig. 2).

The knees thawed at room temperature the day before surgery. Cemented medial UKA was performed via a medial parapatellar approach. A Triathlon UKA (Stryker, Mahwah, NJ, USA) with a metal backed tibial tray in connection with the relatively flat polyethylene inlay and the single radius femoral component were implanted following the manufacturer's instructions. The tibial component was implanted using the patient specific cutting jig. Remaining cartilage had to be removed from the underlying bone allowing for perfect bony fit of the guide. The femoral component was done using the conventional instrumentation to allow for application of the balancing techniques as proposed by the manufacturer. For the case that the initial flexion space was too tight, a recutting guide allowed for additional resection of 1 or 2 mm proximal tibial bone (Fig. 4).

After surgery, the specimen were refrozen and scheduled for CT. Component orientation was verified by registering the pre- and postoperative CT reconstructions of the tibia and comparing the actual component orientation with the planned orientation (Fig. 5). A deviation $\geq 3^\circ$ from the designed orientation was defined as an outlier. Means and standard deviations were calculated for differences between plan and final orientation of the implant were calculated.

Fig. 2. Preoperative plan with CT based 3D images.

Results

Mean coronal alignment was $0.4 \pm 3.2^\circ$ of varus with one outlier in excessive varus (5.6°) and one in excessive valgus (6.7°). Mean slope was $2.8 \pm 3.9^\circ$ with six components in excessive flexion. Eight of the ten implants were within 4° deviation of the preoperative plan. Implants were put in a

mean of $1.7 \pm 8.0^\circ$ of external rotation with seven outliers (Fig. 6 and details for each specimen in Table 1).

Three tibias had no recut. Using the recutting jig, three tibias received a 1-mm recut, and in another three cases a 2-mm recut had to be done. Another specimen needed an additional manual recut, which was the tibia with 6.7° of excessive valgus (Table 1).

Fig. 3. Cutting jig in situ with knee mounted in robot.

Discussion

We observed that customized tibial cutting guides in UKA helped with coronal orientation of the tibial component. The guides were less accurate in setting optimal tray rotation and slope and possible underlying reasons for this need to be analyzed and discussed. A number of personalized jig systems are already available for clinical use for implantation of UKA. We are not aware of any scientific data yet published on this topic.

This study has several limitations. This is a pilot cadaver model and there can no correlations be made on component

Fig. 4. The recutting guide allows for an additional 1- or 2-mm bone cut.

orientation and long-term follow-up. The small sample size is another issue. We however believe it to be appropriate for a pilot study. This especially as most manufacturers have launched jig systems without a prior scientific prove of their effectiveness. Due to the limited resources in a cadaver project, this study lacks a control group using conventional techniques. A cutoff level $>3^\circ$ of deviation was applied to define outliers of optimal alignment, although there is hardly good data available to support the use of this level over others [2]. It should also be stated that other manufacturers with a different setup and different implants may come to

Fig. 5. Postoperative CT scan of UKA in situ with overlaying preoperative plan and differences between the two in degrees.

Fig. 6. Tibial tray positioning: mean values and standard deviations.

different findings as the complex algorithms for jig production and surgery will not be identical.

UKA preserves large parts of the anatomy of the knee and operations are usually performed through smaller incisions. Using tibial cutting jigs, the incision may eventually have to be extended a little more distally and more proximal tibia needs to be exposed than most surgeons would usually do. This allows for optimal fit of the jig as the available contact area for the jig eventually remains much smaller in comparison with TKA cutting guides. A higher contact surface will add to a better accuracy of a cutting jig. Nevertheless, the coronal alignment was very satisfactory in most cases, as the oscillating saw blade is very rigid in this plane and the cutting jig offers effective guidance. In the sagittal plane, the guide obviously is less effective to secure the oscillating blade and it is also more flexible in this dimension. This may explain the reported deviations with optimal slope.

The vertical cut determines the rotation of the tibial component in UKA to a large extent. This cut is usually made with a reciprocating saw that has a relatively flexible blade. The jigs used in this study only carefully directed the vertical cut rather than rigidly guide it. But more importantly, the bony anatomy of lateral aspect of the medial condyle may actually guide this cut more than any other structure and thus determine the

Table 1 Positive values for coronal alignment express relative varus. Positive values for the sagittal alignment stand for slope or flexion of the tibial tray. Positive values for the rotational alignment mean external rotation

Specimen	Coronal alignment varus/valgus (+var)	Sagittal alignment (slope)	Rotational alignment	Recuts
1	-1.3	9.5	2.4	No
2	0.3	1.3	13.4	2 mm
3	-0.7	-1.6	11.3	1 mm
4	1.2	3.2	9.1	No
5	5.7	-1.7	-10.4	2 mm
6	2	7.2	-0.4	2 mm
7	2.4	4.5	4.3	No
8	0.6	3.5	-0.6	No
9	-6.7	3.7	-4.8	Manual
10	0.7	-2.1	-7.7	1 mm

rotational alignment of the tibial component no matter what the configuration of the jig is in this plane.

The problem of optimal component alignment has been tackled with a number of different approaches. Coronal tibial component alignment has been described by Lonner et al. using a robotic technology. The average error was $2.7 \pm 2.1^\circ$ more varus using manual instruments compared with $0.2 \pm 1.8^\circ$ with robotic technology. The number of outliers was not reported [19]. Seon et al. gave their results for coronal tibial alignment using navigation in UKA [25]. The average error was $1.2 \pm 1.8^\circ$ with four outliers ($n=33$) with the conventional technique compared with $1.1 \pm 2.6^\circ$ with two outliers ($N=31$) in the navigated group. The value of patient-matched cutting jigs will have to be examined in clinical trials and ultimately has to be compared with other techniques such as robotics and navigation. Finally, the surgeon will still have to use his clinical judgment and possibly confirmation via conventional guides before performing the bone cuts and not solely rely on the technique designed for facilitation of component placement.

With all these novel techniques, the surgeon still has to be critical. As always, a surgeon should not rely only on the jigs but should use additional alignment tools available by most manufacturers to confirm appropriate positioning before the cuts are made.

Also, we must be aware that evidence based data to define a so-called optimal implant orientation allowing for best possible longevity of the UKA is to date scarce. Recommendations given by surgeons, manufacturers, and engineers are mainly based on empirical, anatomical, and kinematic considerations. There are hardly profound reports on radiological analysis of failures or biomechanical studies using these implants. High tibial slope was reported to promote ACL rupture in one study [7]. A high varus-mismatch between tibial and femoral components was reported to lead to peak stresses in another study [5].

When putting in the tibial tray, some surgeons recommend restoring the natural tibial varus of the tibial plateau [3, 9]. Most other surgeons aim for a tibial component being perpendicular to the mechanical axis of the tibia [1]. We followed the latter approach in this study. Significant deviations in component positioning using conventional techniques have been reported, e.g., for tibial tray rotation [26] without correlation to implant failure. It was decided to base the planned rotation neutrally to a tangent to the posterior tibial condyles as this seems to give the most reproducible measurements [8]. In absence of robust data for optimal slope of the tibial tray in UKA, we aimed for neutral slope.

Despite the lack of data to support actual values for optimal component alignment, a minimum of obvious orientation outliers from the preoperative plan is obviously desirable. Later studies will have to prove, if this leads to the ultimate goal with lower revision rates and better long-term survival of UKA.

Navigation is another promising technique, and it has been shown to improve postoperative alignment and reduces outliers in medial UKA [4, 11–13, 15, 20, 24, 25]. The clinical impact remains to be proven. Lim et al. reported poorer results evaluating navigated UKA with postoperative CT scans and concluded that navigation in UKA was less effective in reduction of outliers than in TKA [18].

A strength of this study is that analysis if precision was done via postoperative CT scans. It also underlines the importance of recutting jigs should the primary bone cuts not lead to the desired balancing of the knee.

There is some discussion whether to use MRI or CT for preoperative templating and planning of the cutting jigs. It has been claimed that MRI lacks accuracy in visualizing bone [30] but can account for femoral and tibial cartilage and osteophytes [28]. In this study, CT scans were used for 3D imaging and remaining cartilage had to be curetted before positioning of the tibial cutting jig. This needs to be done carefully as both remaining cartilage and excessive bone loss may influence the final position of the cutting jig.

As promising as individualized cutting jigs appear, they are not free of possible downsides. Preoperative imaging, jig production, and shipping will inevitably add costs to arthroplasty procedures unless they lead to a significant reduction in other surgical equipment and OR time. Eventually, OR setup and surgeon should be able to switch back to conventional technique at any given time during the intervention in case of incidents or a surgeon not willing to follow the suggested cuts.

Especially in the light of a growing debate with respect to the precision of patient specific cutting jigs in TKA, the introduction of these tools in UKA has to be considered with great care. Anatomic considerations and the rather small interface between exposed bone and the jig make this a challenging task.

In conclusion, customized tibial cutting guides in UKA help with coronal orientation of the component. The guides were less helpful in setting optimal tray rotation and slope. Further refinement of the customized tibia cutting guides is required to increase the precision of these guides with respect to these dimensions.

Disclosures

Conflict of Interest: Thomas J. Heyse, MD, PhD received grant funding from Marmor ARJR and research support from Stryker for the study; payment for lectures from Smith & Nephew and Biomet and other from Smith and Nephew, outside the work. Joseph D. Lipman, MS received Marmor ARJR Grant and research support from Stryker for the study; paid consultant for Ivy Sports Medicine; received royalties from Orthodevelopment Corporation and Mathys Medical, outside the work. Carl W. Imhauser, PhD received grant funding from Marmor ARJR for the study. Scott M. Tucker, MS received grant funding from Marmor ARJR and research support from Stryker for the study. Yogesh Rajak, received grant funding from Marmor ARJR and research support from Stryker for the study. Geoffrey H. Westrich, MD received grant funding from Marmor ARJR and research support from Stryker for the study; board member of Knee Society and EOA; paid consultant for Exactech, Stryker and DJO; grants from Exactech and Stryker; payments for lectures including service on speakers bureaus from Exactech, Stryker and DJO; royalties from Orthodevelopment Corporation and Mathys Medical, outside the work.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: N/A

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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