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THE VARIABILITY OF FEMORAL ROTATIONAL ALIGNMENT IN TOTAL KNEE ARTHROPLASTY

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Background: Several reference axes are used to establish femoral rotational alignment during total knee arthroplasty, but debate continues with regard to which axis is most accurately and easily identified during surgery. Computer-assisted navigation systems have been developed in an attempt to more accurately and consistently align implants during total knee arthroplasty, but it is unknown if navigation systems can improve the accuracy of femoral rotational alignment as compared with that achieved with more traditional techniques involving mechanical guides. The purposes of the present study were to characterize the variability associated with femoral rotational alignment techniques and to determine whether the use of a computer-assisted surgical navigation system reduced this variability.

Methods: Eleven orthopaedic surgeons used five alignment techniques (including one computer-assisted technique and four traditional techniques) to establish femoral rotational alignment axes on ten cadaveric specimens, and the orientation of these axes was recorded with use of a navigation system. These derived axes were compared against a reference transepicondylar axis on each femur that was established after complete dissection of all soft tissues.

Results: There was no difference between the mean errors of all five techniques (p > 0.11). Only 17% of the knees were rotated <5° from the reference transepicondylar axis, with alignment errors ranging from 13° of internal rotation to 16° of external rotation. There were significant differences among the surgeons with regard to their ability to accurately establish femoral rotational alignment axes (p < 0.001).

Conclusions: All techniques resulted in highly variable rotational alignment, with no technique being superior. This variability was primarily due to the particular surgeon who was performing the alignment procedure. A navigation system that relies on directly digitizing the femoral epicondyles to establish an alignment axis did not provide a more reliable means of establishing femoral rotational alignment than traditional techniques did.

everal studies of total knee arthroplasty have demonstrated long-term success in the treatment of osteoarthritis and other disabling disorders of the knee¹⁻³. This success depends, in part, on the proper alignment of the prosthetic components⁴. Abnormal varus or valgus alignment has been reported to be a cause of implant loosening⁵. Other investigators have concluded that femoral rotational malalignment is a major cause of patellofemoral complications^{1,6-8}.

Several reference axes have been proposed to establish proper rotational alignment of the femoral component, including the posterior condylar axis⁹, the anteroposterior axis (the so-called Whiteside's line)^{10,11}, and the transepicondylar axis⁴. Of these axes, the transepicondylar axis also has been shown to approximate the flexion-extension axis of the knee¹². Aligning the femoral component parallel to the transepicondylar axis also has been reported to optimize patellofemo-

ral tracking and to minimize tibiofemoral wear¹³. For these reasons, surgeons frequently try to align the femoral component along the transepicondylar axis, but the debate continues with regard to how accurately the transepicondylar axis can be located. Poilvache et al.¹⁴ reported that the transepicondylar axis was a reliable axis for establishing rotational alignment, but other studies have documented the difficulty of accurately establishing this axis^{15,16}.

Computer-assisted surgical navigation systems^{17,18} have been developed in an effort to align implants more accurately than is possible with use of traditional mechanical guides. Surgeons using these systems have reported more accurate alignment of implants in the frontal plane¹⁹⁻²². There are three types of computer-assisted navigation systems for total knee arthroplasty. Image-based systems use either intraoperative fluoroscopic images or preoperative computed tomography scans

to guide the placement of components. Image-free systems are based on anatomic landmarks that are located intraoperatively through direct identification or kinematic algorithms. Robotic systems use machines that either guide the surgeon or perform cuts during portions of the operation¹⁸. To our knowledge, only one study²³ has focused on the improvement in rotational alignment afforded by navigation systems. Furthermore, the advantages of navigation systems over traditional femoral rotational alignment techniques have not been critically examined.

The purposes of the present study were to characterize the variability associated with femoral rotational alignment techniques and to determine whether image-free computerassisted surgical navigation systems reduce this variability.

Materials and Methods

We conducted a series of experiments with ten embalmed cadaveric lower extremities. The specimens, containing all structures distal to the femoral head, were mounted on wooden platforms with the knee in approximately 90° of flexion. The capsule of each knee was opened to expose the distal part of the femur and the proximal part of the tibia, as is done for total knee arthroplasty, and the patellar tendon was resected proximal to the tibial tubercle to facilitate exposure. A member of the research team (N.J.G.) also cut the distal part of the femur and the proximal part of the tibia to simulate the initial steps of a typical total knee arthroplasty.

Eleven orthopaedic surgeons (including nine surgeons [eight of whom have a practice specializing in total joint arthroplasty] and two total joint arthroplasty fellows) participated in the present study. Each surgeon used one computer-assisted technique and four traditional (non-computer-assisted) techniques to establish rotational alignment axes on each specimen. The surgeons first established the transepicondylar axis with the computer-assisted technique (the "Digitized Epicondyles" technique) by directly digitizing the epicondyles¹⁸ with an opticallytracked stylus from an image-free navigation system. Mechanical tools (total knee arthroplasty instrumentation, straight-edges, and T-squares) were available to help the surgeons to establish the alignment axes with the four traditional techniques. For each technique, the surgeon used a mechanical tool as a visual aid in establishing an appropriate alignment axis and then digitized two points along the edge of the tool with the opticallytracked stylus to record the orientation of that alignment axis. Using this procedure, the surgeons established Whiteside's line (the "Whiteside's Line" technique), a transepicondylar axis projected onto the distal femoral cut surface (the "Projected Epicondyles" technique), a rotational alignment axis that is rotated 3° external to the posterior condylar axis (the "Posterior Referencing Guide" technique), and the individual surgeon's preferred method for establishing rotational alignment (the "Surgeon's Own Method"). With the last method, the surgeons were encouraged to establish the axis that, in their opinion, would result in the best postoperative outcome.

The alignment error was defined as the angle between the axis established by a surgeon and a reference axis on each specimen. The reference transepicondylar axis was established on each specimen by removing all soft tissues from the distal part of the femur and digitizing the prominence of the lateral epicondyle and the sulcus (or, when absent, the prominence) of the medial epicondyle on each bone⁴. We compared the rotational alignment established by each of the participating surgeons against the reference transepicondylar axes.

We used two-way analyses of variance to test for significant differences in the mean errors of the alignment techniques, to test for differences between the ability of the participating surgeons to accurately establish rotational alignment axes, and to investigate whether the interaction effect between surgeon and alignment technique was significant. We performed an a priori power analysis to determine the number of specimens to be tested. We calculated the effect size for this analysis by assuming a standard deviation of 7.0° for the techniques¹⁶ and by knowing that the minimal detectable difference between all techniques was 1.25° (due to the accuracy of our tracking equipment and the size of the specimens). Since eleven surgeons used five techniques on ten cadaveric knees, our study had an effect size of 0.178 and an a priori statistical power of 0.93 for the detection of differences between alignment techniques. Post hoc analysis revealed approximately equal variances between techniques and surgeons, and F tests were used to identify significant differences in the variability of the alignment techniques. One-way analysis of variance tests and the Tukey-Kramer method were performed to identify significant intraobserver differences in the mean errors with the techniques. In all cases, the level of significance was set at $\alpha = 0.05$.

Results

There was high variability in the femoral rotational alignment associated with all techniques (Fig. 1). The standard deviation across all techniques was estimated to be 6.5°. We found that only 17.3% (ninety-five) of the 550 axes identified in the present study were rotated <5° from the reference transepicondylar axis. The rotational alignment with respect to the reference transepicondylar axis ranged from 13° of internal rotation to 16° of external rotation. "Whiteside's Line" was the most variable technique, with a standard deviation of 7.6°. While F tests revealed that the standard deviation for "Whiteside's Line" was significantly different than that for the least variable technique at the 95% confidence level, the magnitude of this difference was only 1.3°.

There was no difference between the mean errors for the femoral alignment techniques investigated in this study (p > 0.11). All techniques resulted in a mean external rotation of the femoral component (see Appendix).

When we evaluated each surgeon's mean alignment for all techniques, we found a significant difference between surgeons with regard to their ability to align the implant along the epicondylar axis (p < 0.001). The interaction effect between surgeon and alignment technique also proved to be significant (p < 0.001). For eight of the surgeons, no significant intraobserver difference was seen with regard to their performance with the different alignment techniques (p > 0.05).

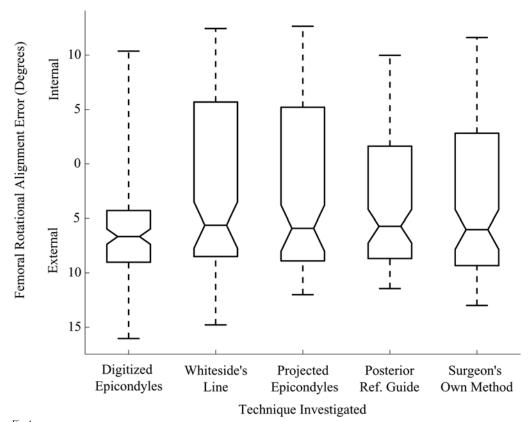


Fig. 1

Box plot showing the errors in rotational alignment for five alignment techniques. The horizontal lines across each box represent the median error, the upper and lower edges of each box represent the upper and lower quartiles of the data, and the error bars represent the total range of the data.

However, one surgeon (Surgeon 4) demonstrated significantly more accuracy with use of the "Whiteside's Line" technique as compared with the other techniques (p < 0.001), and two surgeons (Surgeons 8 and 10) displayed significant differences between the techniques by biasing some techniques toward internal rotation and others toward external rotation (p < 0.01) (see Appendix).

Discussion

The purposes of the present study were to assess the variability in techniques that are used for the establishment of femoral rotational alignment and to determine whether an image-free navigation system reduces this variability. Previous researchers have sought to identify the most accurate and repeatable axis for the establishment of femoral rotational alignment. Some investigators have reported difficulty in locating the transepicondylar axis and have found Whiteside's line to be a more accurate method for the establishment of rotational alignment^{11,24}. Other investigators have reported that the transepicondylar axis was located more easily and more consistently during surgery as compared with an anteroposterior axis^{14,25}. The present study demonstrated no differences in the mean errors associated with all of the techniques but indicated that all of the techniques were highly variable.

Because our two-way analysis of variance had three factors (the alignment technique, the participating surgeon, and the interaction effect between surgeon and technique), we could analyze how each of these factors contributed to the overall variability in alignment. First, the variability between surgeons was high, suggesting that some surgeons established the transepicondylar axis more accurately than other surgeons did. Second, the interaction effect between surgeon and alignment technique was significant (p < 0.001), indicating that certain surgeons implemented different alignment techniques with significantly different levels of performance. However, the intraobserver variability was low, indicating that most (eight) of the eleven surgeons implemented all of the alignment techniques with the same level of performance and that this interaction effect was due to the three surgeons who displayed high intraobserver variability with the technique. Third, there was no significant difference between the mean errors for the different alignment techniques. Hence, we concluded that establishing femoral rotational alignment is influenced by an individual surgeon's skill and preferences and not by the different techniques used to establish this alignment. To our knowledge, no other study has investigated how the abilities of an individual surgeon affect femoral rotational alignment.

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Our a priori power analysis suggested a 93% probability of detecting significant differences between alignment techniques given an assumed standard deviation of 7°. Our observed error variance was less than this predicted variance, so our assumption proved to be a reasonably conservative estimate. As the difference between alignment techniques was not significant and the power of the study was high, we are confident in stating that no difference between alignment techniques was present in this study.

Since we observed variability in femoral rotational alignment in this study, it is important to discuss the clinical importance of this variability. Little clinical information exists with regard to the relationship between the magnitude of femoral rotational malalignment and the rates of failure and revision following total knee arthroplasty. Berger et al.⁶ found that small amounts (1° to 4°) of combined femoral and tibial component internal rotation were associated with lateral tracking and tilting of the patella, whereas larger amounts (7° to 17°) of internal rotation were associated with early patellar dislocation and late patellar prosthesis failure. Patients with components that were aligned between 0° and 10° of external rotation did not present with patellofemoral complications. Cadaveric studies have indicated that aligning the femoral component in internal rotation with respect to the transepicondylar axis can cause complications such as knee instability, patellar maltracking, and increased patellar contact forces 13,26,27.

All of the femoral component alignment techniques that were evaluated in the present study resulted in a mean external rotational alignment, possibly indicating that, when given a choice to align a component, surgeons tend to bias the femoral component toward external rotation, a procedure that is known to avoid the undesirable outcomes associated with internal rotation and to improve patellar tracking^{26,28}. However, external rotation of the component with respect to the transepicondylar axis can introduce other problems. Excessive external rotation has been reported to increase the medial flexion gap and to lead to symptomatic flexion instability25, and external rotation of the femoral component by as little as 5° from the transepicondylar axis has been reported to increase shear forces on the patellar component¹³. Ultimately, it is unknown how much variability in femoral alignment can be tolerated. Future prospective studies on the relationship between rotational alignment and the rates of complication and failure are needed to address this question.

The present study has some limitations. The orientation of the cadaveric limbs may have presented difficulties for the participating surgeons as the cadaveric knees were approximately eye-level with respect to the surgeons and were positioned in 90° of flexion. This orientation resulted in a somewhat different view of the knee than the surgeons were accustomed to during surgery. In addition, the surgeons were novices in the use of this navigation system. Each surgeon was given a ten-minute orientation in the use of the system prior to the start of the experiment, but only one surgeon had more extensive experience with any navigation system. It is probable

that a learning curve is associated with the use of navigation systems and that the surgeons may have performed differently if they had had more experience with the equipment.

Given the large variability that was observed during the identification of the epicondyles, one might question whether this same variability would be observed during the establishment of the reference axes. Some authors have speculated that the difficulty of precisely locating the epicondyles may be due to soft-tissue coverage^{11,16}, and other authors^{4,29} have successfully characterized the shape of cadaveric femora that were stripped of soft tissue. While radiographic techniques^{6,30-32} have been used to gain valuable insights into femoral rotational alignment and could have been used in the present study, we chose direct observation of the epicondyles on bones that had been stripped of all soft tissues because it provided the best view of the anatomy for this study.

Our results illustrating the variability of a computerassisted femoral rotational alignment technique contrast with those reported by Stöckl et al.23, who found improved femoral rotational alignment in association with the use of a navigation system that established alignment by averaging the angles determined by Whiteside's line and the transepicondylar axis. To compare our results with theirs, we averaged our measurements that had been made with use of the "Digitized Epicondyles" and "Whiteside's Line" techniques and found that this averaged rotation axis (mean, 3.6° ± 6.1° of external rotation) was not different from the measurements associated with either the "Surgeon's Own Method" (p > 0.6), which would be comparable with the control method in the study by Stöckl et al.²³, or any of the other alignment axes in the present study (p = 0.15). Stöckl et al. found that the use of navigation provided a <1° reduction in the mean rotational alignment error and a 0.39° reduction in the standard deviation²³. We found that this averaged axis provided a 0.4° change in mean rotational alignment and a 0.4° reduction in the standard deviation in comparison with the "Surgeon's Own Method," but these improvements were not significant. It is debatable whether an improvement in the mean rotational alignment of <1° or a reduction in the standard deviation of a fraction of a degree is clinically important.

As navigation systems become more widely used, it is important to evaluate all aspects of their performance. We found that a navigation system that relies on digitization of the epicondyles to establish femoral rotational alignment did not provide a more reliable means of rotational alignment as compared with traditional techniques. Our findings should not diminish the demonstrated ability of navigation systems to achieve improved alignment in the frontal plane¹⁹⁻²². Rather, they emphasize the challenge of achieving accurate femoral rotational alignment and the need for further refinements in navigation technology.

Appendix

A table presenting the results for each surgeon is available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on

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"Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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