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Inter-observer Precision and Physiologic Variability of MRI Landmarks Used to Determine Rotational Alignment in Conventional and Patient-Specific TKA

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Abstract

Preoperative planning for patient-specific guides (PSGs) in total knee arthroplasty (TKA) requires identification of anatomic landmarks on three-dimensional imaging studies. The aim of this study was to assess the accuracy and precision with which landmarks commonly used to determine rotational alignment in TKA can be identified on magnetic resonance imaging (MRI). Two orthopaedic surgeons and two musculoskeletal radiologists independently reviewed a sequential series of 114 MRIs of arthritic knees. The magnitude of interobserver variability was high, suggesting an inherent risk of inconsistency when these landmarks are used in PSG fabrication. Additionally, there was a high degree of physiologic variation among patients, indicating that assuming standard relationships among anatomic landmarks when placing TKA components may lead to rotational malalignment relative to each patient's native anatomy.

Keywords

Patient-specific TKA; rotational alignment

Introduction

Total knee arthroplasty (TKA) is one of the most commonly performed operations by orthopaedic surgeons, yet it has an overall dissatisfaction rate of almost 20% and a long term revision rate of 10% at 10 years [1, 2]. One possible etiology of poor functional outcome and aseptic failure is malalignment of components either relative to target ranges or to the

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patient's native anatomy. While Parratte et al. found no relationship between coronal alignment within 3° of neutral and survivorship of TKA at 15 years, numerous biomechanical, finite model analysis, and clinical studies have demonstrated an increased risk of failure and revision in cases of excessive varus or valgus malalignment [3-6]. Furthermore, malrotation of components in the axial plane has been implicated in patellar maltracking and anterior knee pain and may be a cause of poor functional outcome in patients with TKAs [7, 8].

Traditional TKA relies on standard intramedullary and extramedullary cutting guides to dictate placement of components. These guides have been associated with a high degree of inaccuracy, with numerous studies reporting that over 20% of TKAs performed with conventional cutting guides fail to restore coronal alignment to within 3° of neutral [9-11]. More accurate coronal alignment has been demonstrated with computer-assisted orthopaedic surgery (CAOS), which utilizes intraoperative navigation to guide cuts based on tracking markers that have been registered into a computer [12, 13]. However, CAOS has been associated with a high degree of rotational and sagittal plane malalignment [14-18]. Also, a recent systematic review of navigated TKA found no improvement in revision rates, survival, and functional outcomes in the short to medium term despite the additional cost and increased operative time[15].

Patient-specific guides (PSGs) were developed as a way to combine the ease of use of standard guides with the customization of computer-assisted techniques. Custom cutting guides are templated and fabricated based on preoperative computed tomography (CT) or magnetic resonance imaging (MRI) scans of the patient's knee, in essence moving navigation from the operating room to the preoperative period. This technology has been shown to reduce operative time and number of equipment trays needed and may enable the surgeon to customize implant placement in cases involving anatomic deformities [19]. Another theoretical benefit of PSGs is improved component alignment in all planes due to the ability to precisely determine component position preoperatively. However, studies evaluating whether PSG techniques improve either coronal or rotational alignment have been contradictory [9, 20-23]. Also, no clinical outcomes data have supported the use of PSGs over traditional instrumentation and justified the additional costs of the preoperative CT or MRI scans and PSG fabrication [19].

The achievement of consistent rotational alignment in TKA and PSG generation is dependent on two factors: (1) standard relationships among anatomic landmarks of the distal femur and proximal tibia and (2) accurate identification of those landmarks on three-dimensional imaging. We hypothesized that conventional assumptions of anatomic relationships may lead to rotational malalignment and that anatomic landmarks commonly used in TKA would not be identifiable on MRI with a high degree of reproducibility.

Materials and Methods

We performed a radiographic retrospective study to evaluate the physiologic variability of anatomic landmarks used in templating TKAs and the interobserver and intraobserver reliability of identifying those landmarks on MRI. One hundred fourteen patients obtained

knee MRIs at our institution as preoperative preparation for a patient-specific Biomet Signature TKA (Biomet, Warsaw, Indiana). This was a consecutive series of patients with osteoarthritis or inflammatory arthritis in a native knee evaluated by one of the two senior surgeons. These patients were part of a prospective cohort study performed to compare the radiographic clinical outcomes of the use of patient-specific cutting guides versus standard instrumentation at our institution. The option of PSG versus standard instrumentation was presented to the patients and selection was based on patient preference. Patients in the PSG cohort were willing to have a MRI and a six-week delay in their surgery for image processing. One hundred fourteen patients selected patient-specific cutting guides, while 134 selected standard instrumentation. One hundred fourteen was calculated as the minimum sample size based on the desired precision of ± 0.10 for a 95% confidence interval[24]. This cohort included 54 males and 60 females with an average age of 64 years old (range 46 to 90 years old). All patients were scanned in the supine position with the knee extended in a dedicated extremity transmit-receive coil. All study cases were scanned on 1.5T or 3.0T Siemens MRI scanners (Siemens Healthcare, Munich, Germany) with axial fast spin echo T2-weighted fat-saturated imaging. The scanning protocol included axial, sagittal and coronal images of the knee, as well as axial images of the ipsilateral ankle and femoral head and neck for the purpose of version evaluation. Only the axial imaging of the knee was considered for this study.

Four reviewers (two orthopaedic surgeons and two musculoskeletal radiologists) reviewed each MRI in duplicate, with two weeks between each review and in a fashion that blinded the reviewers to patient identifiers. For the distal femoral measurements, the TEA was drawn between the lateral epicondylar prominence and the medial sulcus of the medial epicondyle, as described by Berger[8]. If the two landmarks were not on the same slice, then the slice with the best-defined sulcus was selected and the position of the lateral epicondyle was extrapolated from adjacent slices. The slice number was recorded. The posterior condylar line was drawn between the posterior-most cartilage surfaces of the medial and lateral femoral condyles on the same slice as the TEA. The angle subtended by these lines, the posterior condylar angle (PCA), was measured with the Cobb angle tool, with positive numbers denoting external rotation of the TEA relative to the posterior condylar line and negative numbers denoting internal rotation (Fig. 1).

Two sets of measurements were obtained for the proximal tibia. For the first measurement, the slice with the best-defined tibial tubercle was identified and the medial third was marked (Fig. 2). This point was translated proximally to the most inferior slice containing the full PCL footprint, and the apex of the PCL sulcus was identified on this slice (Fig. 3). A line was drawn between these two points, and the angle between this line and the posterior border of the tibia (the line drawn between the most posterior medial and lateral aspects of the tibial plateau) was then measured (Fig. 4). For the second measurement, the tip or midpoint of the tibial tubercle was identified on the slice with the best-defined tibial tubercle (Fig. 2), then this point was translated proximally to the slice with the proximal tibial shaft just distal to the tibial plateau. The geometric center of the tibia was identified according to Berger's protocol [8], as the center of the best fit ellipse around the proximal tibial shaft (Fig. 5), and the angle subtended by a line between the tip of the tubercle and the geometric center and the posterior border of the tibia was measured (Fig. 6).

Statistical Analysis

Statistical analysis for reliability was performed by computing interobserver and intraobserver intraclass correlation coefficient (ICC) for each set of measurements. We computed ICC by comparing the variability of different ratings of the same subject to the total variation across all ratings and all subjects, using maximum likelihood estimation based on two-way mixed-effects ANOVA models[25, 26]. For interpretation of ICC, 1 was considered perfect reliability, 0.81-1 very good, 0.61-0.80 good, 0.41-0.60 moderate, and <0.4 poor [27].

Source of Funding

There was no external funding for the study.

Results

The average posterior condylar angle (PCA), or angle between the TEA and posterior condylar line, was 1.34° of external rotation (range 3.31° of internal rotation to 6.15° of external rotation). Thirteen percent of knees deviated from the mean by greater than 3° and none deviated from the mean by greater than 5° (Fig. 7). Interobserver ICC was good (0.66-0.67) and intraobserver ICC was good to very good (0.76-0.97) (Table 1). In terms of the absolute range of variability, for each knee the average range of measurements made by the four observers was 3.47° (SD = 1.19°). Seventy six percent of the PCA measurements were made on the same MRI slice by the various reviewers; 98% were made within 2 slices, or 8 mm, of the most frequently used slice.

The tip of the tubercle was externally rotated an average of 25.08° with relation to the geometric center of the tibia (range 4.20° to 42.55° of external rotation). Forty nine percent of knees deviated from the mean by greater than 5° (Fig. 8) and 15% of knees deviated by greater than 10°. Interobserver ICC was good (0.67-0.69) and intraobserver ICC was good to very good (0.75-0.92) (Table 1). For each knee, the average range of measurements made was 12.36° (SD = 4.31°).

The medial third of the tubercle was externally rotated an average of 12.38° with relation to the geometric center of the tibia (range 0.15° to 25.99° of external rotation) (Table 2). Thirty two percent of knees deviated from the mean by greater than 5° (Fig. 8) and 7% of knees deviated by greater than 10°. Interobserver ICC was moderate to good (0.53-0.64) and intraobserver ICC was good to very good (0.67-0.84) (Table 1). For each knee, the average range of measurements made was 10.18° (SD = 3.50°).

Discussion

Achieving rotational alignment of TKA components that optimizes knee kinematics (e.g. patellar tracking, collateral ligament and extensor mechanism tension, and flexion-extension gap balance) remains a key objective in TKA, yet it has proven difficult to consistently accomplish with either traditional or PSG TKA systems. Advocates of PSG TKA systems have noted that improved coronal and axial plane alignment could potentially improve patient satisfaction and long-term outcomes, yet to date reports with their use have been

contradictory [9, 20-23]. Both systems attempt to use anatomic landmarks to define femoral component rotation, but intraoperative identification of landmarks such as the femoral epicondyles has been shown to have high interobserver variability. Siston et al. compared the TEAs established by 11 orthopaedic surgeons to a reference axis established using a digitized model and found that fewer than 17% of the TEAs marked by the surgeons were rotated less than 5° from the reference axis [28]. Similarly, Yan reported interobserver variations of 4.2° for the TEA [29]. Jerosch found that when a group of orthopaedic surgeons marked the medial and lateral epicondyles of cadaver femurs with hypodermic needles, the markings covered footprints of 102 and 116 mm² respectively [30]. A similar study by Stoeckl using computer navigation to mark the epicondyles reported footprints of 278 mm² and 298 mm² [31]. Given such high variability in manual identification of the TEA, conventional instrumentation in TKA often references femoral rotation off the posterior femoral condyles and assumes that the TEA has a constant orientation of 3° of external rotation with relation to the posterior condylar line. This study demonstrates a high degree of physiologic variation among patients and suggests that assuming standard relationships among anatomic landmarks when placing TKA components may lead to rotational malalignment relative to each patient's native anatomy. Furthermore, the variability with which anatomic landmarks were identified on MRI between different observers suggests an inherent risk of inconsistency when these landmarks are used in the fabrication of PSGs.

Previous studies have evaluated the rotation of the TEA relative to the posterior condylar line. Berger studied 75 cadaveric specimens and reported an average posterior condylar angle (PCA) of $3.5 \pm 0.3^\circ$ in males and $0.4 \pm 1.2^\circ$ in females, with a statistically significant difference between males and females ($p < 0.0001$) [32]. Notably, this series specifically excluded all knees with arthritic changes. Pagnano measured the intraoperative PCA during 60 TKAs and reported an average PCA of 3.98° , with a range of 0 to 9° [33]. However, these studies were subject to the previously described limitations inherent with manual identification of the epicondyles. Griffin analyzed MRIs of 104 knees and found an average PCA of $3.11 \pm 1.75^\circ$, with no statistically significant difference between males ($2.75 \pm 1.61^\circ$) and females ($3.50 \pm 1.86^\circ$) [34]. Our study found an average PCA of $1.34 \pm 2.31^\circ$, with a statistically significant difference ($P < .0001$) between males ($0.94 \pm 2.25^\circ$) and females ($1.7 \pm 2.3^\circ$). While our measurement for the average PCA was less than Griffin's, the average age of patients in Griffin's study was 42 versus 64 years old in ours, and it may be possible that there is a relationship between posterior condylar wear and age. However, we could find no correlation between PCA and age in our data ($r = -0.057$) (Fig. 9). Additionally, Griffin's study included patients as young as 11 years old, as all 104 MRIs in his study were performed to rule out soft tissue pathology such as meniscus or anterior cruciate ligament tears [34]. Whether femoral component rotation should be established in relation to a patient's pre-arthritic or pathologic anatomy is currently subject to debate [35-37]. However, in practice, both traditional instrumentation and PSGs reference anatomic landmarks in the arthritic knee. Accordingly, we analyzed only MRIs performed for the fabrication of PSGs in patients undergoing TKA and therefore believe our results are more relevant and applicable in the assessment of anatomic variability of the arthritic knee. If our mean PCA of 1.34° were used as a target in TKA, 87% of knees in our sample would

be within 3° of the mean and 100% would be within 5° . However, if the conventionally assumed PCA of 3° were used, 73% of knees in our sample would be within 3° and 97% would be within 5° (Fig. 7). This indicates that assuming a PCA of 3° may be reasonable for many people but that there is a substantial minority of patients with arthritis for whom such an assumption could lead to malrotation relative to the TEA. While it is unknown whether the difference of 1.66° between our mean PCA and the conventional target of 3° constitutes a clinically significant difference, perhaps more important is the finding that neither 1.34° nor 3° describes a target that is optimal for all patients. In our cohort, the rotation of the TEA relative to the posterior condylar line ranged from 3.31° of internal rotation to 6.15° of external rotation. For the patient whose PCA was 3.31° of internal rotation, applying a standard PCA of either 1.34° or 3° of external rotation would lead to over 4° to 6° of femoral component malrotation relative to the TEA. Basing the rotation of the femoral component on a standard value may have clinically significant implications, as internal rotation of TKA components has been associated with anterior knee pain, patellar instability, patellar tilt, and lateral tracking[7, 8, 38]. Furthermore, Bédard et al. evaluated patients with stiff total knees and found that all 34 patients in their series had net combined internal rotation of the femoral and tibial components[39]. Each of these patients underwent revision TKA, and correction of malrotation alone resulted in improved range of motion and functional outcome scores. Rotational alignment is being increasingly recognized as a critical factor in the functional outcome of TKA, and the high dissatisfaction rate in TKA may be due in part to the inability of TKA systems to reproduce the native tibiofemoral relationship in the axial plane.

One purported benefit of PSG TKA is the ability to customize the position of components to each patient's unique anatomy. However, several authors have reported that intraoperative changes were required with a high degree of frequency when these “custom-fit” guides are used[40-42]. In addition, in a randomized-controlled trial of 48 TKAs performed using either PSGs or conventional instrumentation, Woolson et al. reported no statistically significant difference between the two cohorts for femoral component malrotation relative to the transepicondylar axis[43]. One potential obstacle with PSG design and implementation may be the requirement for precise identification of anatomic landmarks of the knee on three-dimensional imaging that are by definition non-discrete. For example, the tibial tubercle represents an oblong prominence that gradually arises from the tibial shaft. The “medial third”, while commonly used as a reference point in practice, may be inherently undefinable as a single point on either two-dimensional representations (e.g. axial MRI images) or three-dimensional reconstructions of the knee. Our data show that anatomic landmarks can generally be identified with relation to each other with a good to very good degree of interobserver and intraobserver reliability on MRI, but that the absolute magnitude of differences among reviewers was high for both the distal femur and especially the proximal tibia. In addition, the MRIs included in this study were those of arthritic knees specifically performed for the fabrication of PSGs, thus indicating that a large magnitude of difference can occur depending on the technician or observer who performs the digital landmarking. Given the conventional assumption that 3° represents the accepted tolerance for errors in alignment, our findings suggest that human error in identification of landmarks on MRI may lead to the creation of PSGs that result in clinically significant femoral and

tibial component malrotation. Moreover, we found a high degree of variability in anatomic landmarks among patients, calling into question the gold standards used to determine rotational alignment of TKA components [44].

A major limitation of our study was our lack of access to the proprietary algorithms that each company uses to design its PSGs. While the landmarks we used and the way in which we identified those landmarks may vary from specific manufacturers' design processes, we believe it is reasonable to assume that all PSGs represent finite approximations of an infinite number of anatomic points in space and that this many-to-one mapping process contributes to variability among observers. Furthermore, previously published images of pre-surgical plans delivered to surgeons during the fabrication process of PSGs demonstrate the use of anatomic landmarks for rotational referencing described and measured in our study[45, 46]. Another potential limitation was that we based our measurements on the cartilage border of the posterior femoral condyles and found that this border was often less distinctly defined on MRI than subchondral bone in the arthritic knee. However, posterior referencing systems use the cartilage border and not subchondral bone in TKA in practice, and studies have shown that plain x-ray and CT underestimate the true thickness of the posterior condyles by up to 5 mm[47, 48]. Finally, our study did not evaluate the in vivo implications of establishing the rotation of the femoral component based on the patient's native anatomy. We acknowledge that our study does not include rotational measurements of the PSG TKAs once created and implanted, nor do we present any intraoperative measurements that would potentially correlate with our MRI findings, but we feel that the current study lays the foundation for further biomechanical and clinical investigation as we continue to refine the optimal targets for rotational alignment in TKA.

In conclusion, this study demonstrates the wide range of physiologic variability of the TEA with relation to the posterior condylar line and indicates that basing the flexion-extension axis on the commonly held assumption of 3° of external rotation may lead to malrotation in many patients. Additionally, to date, ours is the first study to quantify the reliability with which anatomic landmarks of the knee can be identified on MRI in a cohort of arthritic knees undergoing TKA. Our data suggest that there is a high degree of variability with which custom PSGs can be made based on MRIs performed in the setting of arthritis and an even greater degree of variability in rotational anatomy of the distal femur and proximal tibia among patients undergoing TKA. These findings may explain why rotational alignment achieved with PSGs is better in theory than in practice. Given concerns regarding the physiologic anatomic variability noted in this study, in addition to the absence of proven clinical or radiological advantages, PSGs are no longer used at our institution.

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Figure 1.

The transepicondylar axis (TEA) was drawn between the lateral epicondylar prominence and medial epicondylar sulcus, and the posterior condylar angle (PCA), or angle between it and the posterior condylar line, was measured on this T2-weighted, fat-saturated axial MRI slice.

Figure 2.
Both the tip and the medial third of the tibial tubercle were marked on this image.

Figure 3.
Axial image of the tibial plateau containing the full PCL footprint.

Figure 4.

The medial third of the tubercle was transposed proximally to this image, then a line was drawn from it through the apex of the PCL sulcus. The angle between this line and a line bordering the posterior tibia was measured.

Figure 5. Axial image just distal to the tibial plateau. A best-fit ellipse was drawn around the tibia and the center of this ellipse was marked.

Figure 6.

The tip of the tibial tubercle was transposed proximally to this image, then a line between it and the geometric center was drawn. The angle between this line and a line bordering the posterior tibia was measured.

Figure 7.

Distribution of posterior condylar angles. A) Gray squares represent patients within 3° of the sample mean of 1.34° of external rotation and red squares represent patients outside of that range. B) Gray squares represent patients within 3° of the conventionally assumed PCA of 3° of external rotation.

Figure 8.

Distribution of proximal tibial measurements. Gray squares represent patients whose measurements were within 5° of the sample means and red squares represent patients outside of those ranges.

Figure 9.

No correlation was found between age and PCA ($r = -0.057$). However, a statistically significant difference was found between males and females ($P < 0.0001$).

Table 1

Intraclass Correlation Coefficient

	Femur	Tibia	
	Posterior condylar angle	Tip of tubercle and geometric center	Medial third and PCL sulcus
Interobserver			
Reading 1	0.66	0.69	0.64
Reading 2	0.67	0.67	0.53
Intraobserver			
Reviewer 1	0.78	0.84	0.82
Reviewer 2	0.76	0.75	0.67
Reviewer 3	0.86	0.83	0.84
Reviewer 4	0.97	0.92	0.81

1 = perfect reliability, 0.81-1 = very good, 0.61-0.80 = good, 0.41-0.60 = moderate, and <0.4 = poor²⁶.

Table 2

Physiologic Averages and Ranges

	Average	Min	Max
Posterior condylar angle	1.34°	−3.31°	6.15°
Tip of tubercle and geometric center	25.08°	4.20°	42.55°
Medial third of tubercle and PCL sulcus	12.38°	0.15°	25.99°