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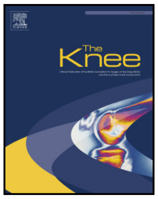

What are the bias, imprecision, and limits of agreement for finding the flexion–extension plane of the knee with five tibial reference lines?

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ABSTRACT

Background: Internal–external (I–E) malrotation of the tibial component is associated with poor function after total knee arthroplasty (TKA). Kinematically aligned (KA) TKA uses a functionally defined flexion–extension (F–E) tibial reference line, which is parallel to the F–E plane of the extended knee, to set I–E rotation of the tibial component.
Methods: Sixty-two, three-dimensional bone models of normal knees were analyzed. We computed the bias (mean), imprecision (±standard deviation), and limits of agreement (mean ± 2 standard deviations) of the angle between five anatomically defined tibial reference lines used in mechanically aligned (MA) TKA and the F–E tibial reference line (+external).
Results: The following are the bias, imprecision, and limits of agreement of the angle between the F–E tibial reference line and 1) the tibial reference lines connecting the medial border (−2° ± 6°, −14° to 10°), medial 1/3 (6° ± 6°, −6° to 18°), and the most anterior point of the tibial tubercle (9° ± 4°, −1° to 17°) with the center of the posterior cruciate ligament, and 2) the tibial reference lines perpendicular to the posterior condylar axis of the tibia (−3° ± 4°, −11° to 5°), and a line connecting the centers of the tibial condyles (1° ± 4°, −7° to 9°).
Clinical relevance: Based on these in vitro findings, it might be prudent to reconsider setting the I–E rotation of the tibial component to tibial reference lines that have bias, imprecision, and limits of agreement that fall outside the −7° to 10° range associated with high function after KA TKA.

1. Introduction

Mechanically aligned total knee arthroplasty (MA TKA) is one of the most successful operations for restoring patient function, however 15% to 25% patients report dissatisfaction and 10% require revision surgery by 10 years [1–4]. One cause is internal and external (I–E) malrotation of femoral and tibial components, which is associated with poor function after MA TKA [5,6].

In MA TKA the surgeon uses one of five anatomically defined tibial reference lines for setting the I–E rotation of the tibial component which include: 1) the line connecting the medial border of the tibial tubercle with the center of the posterior cruciate ligament (PCL) fossa, 2) the line connecting the medial 1/3 of the tibial tubercle with the center of the PCL fossa, 3) the line connecting the most anterior point of the tibial tubercle with the center of the PCL fossa, 4) the line perpendicular to the posterior condylar axis of the tibia, and 5) the line perpendicular to the line connecting the centers of the medial and lateral tibial condyles (Cobb's method) [7,8] (Figure 1).

An inaccurate selection of the orientation of the tibial reference line has been proposed as an etiology for patient dissatisfaction and aseptic failure [9]. The accuracy of the selection of the orientation of a tibial reference line for setting the I–E rotation of the tibial component can be quantified by the bias and imprecision. A measurement, such as the angle between a tibial reference line and a target reference line, is biased when both the mean and the standard deviation (SD) respectively of the measurements of this angle in a sample of subjects are different from zero. Hence, an accurate tibial reference line is one that forms an angle with the target reference line in a sample of subjects with a mean and a SD that is not different from zero.

Kinematically aligned (KA) TKA is a new method that has gained interest because two studies showed that patients with a reported better pain relief, better function, better flexion, and a “more normal feeling knee” than patients with a MA TKA [10,11]. In KA TKA the target reference line for setting the I–E rotation of the anterior-posterior (A-P) axis of the tibial component is the flexion–extension (F–E) tibial reference line. The F–E tibial reference line is a functionally defined rather than anatomically defined tibial reference line because it is oriented parallel to the F–E plane of the extended knee rather than to lines connecting anatomic landmarks on the tibia. The F–E tibial reference line is aligned perpendicular to the transverse axis in the femur about which the tibia flexes and extends, and is drawn perpendicular to lines tangent to the distal and posterior

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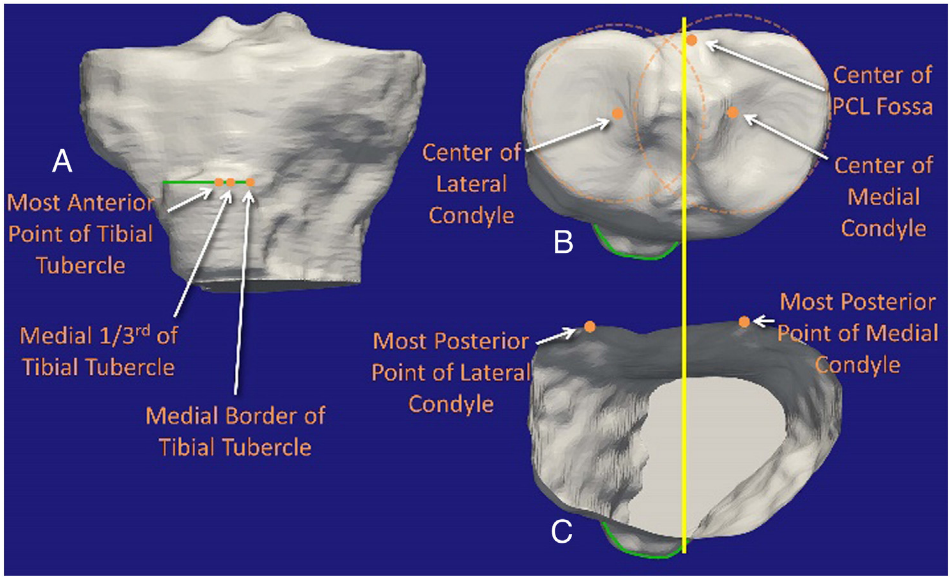

Figure 1. A composite of three views of a right tibia shows the eight tibial landmarks for constructing the five tibial reference lines. (A) The most anterior point, medial border, and medial 1/3 of the tibial tubercle (green arc), were identified on the projection of the tibia in the coronal plane. (B) The center of the PCL fossa and the center of the medial and lateral tibial condyles were identified on the projection of the proximal tibia in the tibial resection plane. (C) The most posterior points on the medial and lateral condyles were identified on the resected tibia. The F–E tibial reference line (yellow) on the proximal surface of the tibia is parallel to the F–E plane. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

joint lines of the femur at 0° and 90° of flexion (Figure 2) [12–17]. One study reported that setting the angle of I–E rotation of the A–P axis of the tibial component with the F–E plane of the knee with a limit of agreement of −7° to 10° (i.e. mean ± 2 SDs) is acceptable because these patients reported high satisfaction and function as measured by the Oxford Knee Score (mean 42 of 48 (best)) [18].

Because an inaccurate selection of the orientation of the target reference line has been proposed as an etiology for patient dissatisfaction

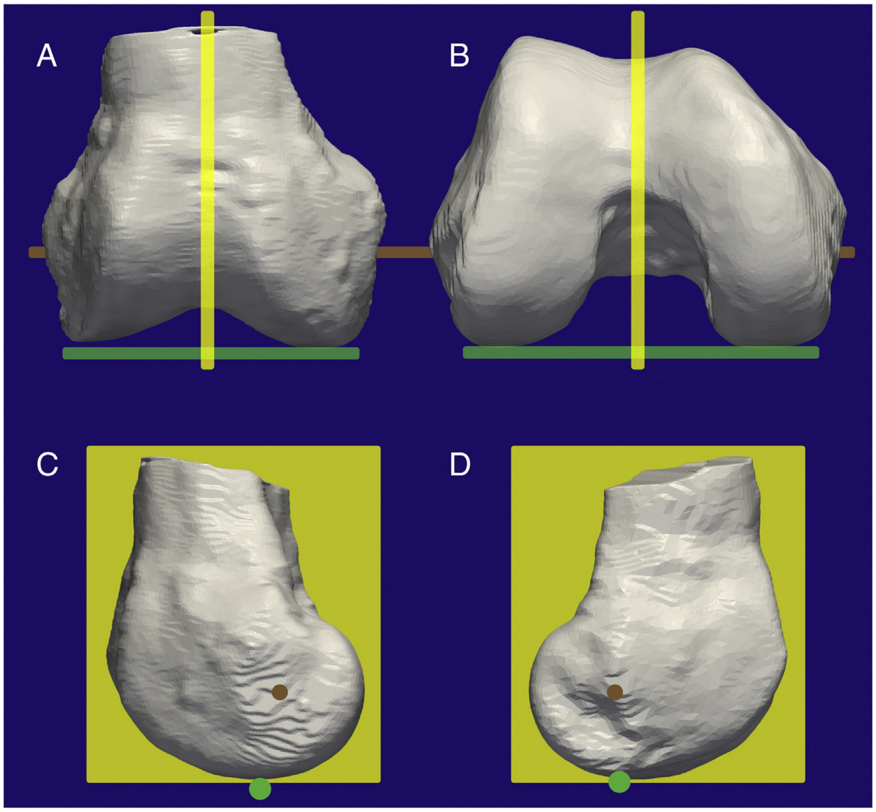

Figure 2. The composite shows a three-dimensional model of a right femur in an (A) anterior, (B) distal, (C) medial, and (D) lateral view. The F–E plane (yellow) is perpendicular to the transverse axis in the femur about which the tibia flexes and extends (brown) and approximately perpendicular to lines tangent to the distal and posterior joint lines of the femur at 0° and 90° of flexion (green). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

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and aseptic failure, and because the target tibial reference line is constructed functionally in KA TKA and anatomically in MA TKA, the present study analyzed three-dimensional bone models of 62 normal knees and determined the bias, imprecision, and limits of agreement between the five anatomically defined tibial reference lines used in MA TKA and the functionally defined F–E tibial reference line used in KA TKA. If the bias and imprecision are small (i.e. 0), and if the limits of agreement are within −7° to 10°, then an anatomical tibial reference line might be useful for setting the I–E rotation of the A–P axis of the tibial component parallel to the F–E plane in KA TKA.

2. Materials and methods

2.1. Models

We analyzed 62, three-dimensional bone models of normal knees constructed from thin slice (0.7 mm) 3.0 Tesla magnetic resonance images (MRI) randomly selected from the Osteoarthritis Initiative database (www.oai.ucsf.edu). Because these MRIs were deidentified and publicly available, their use was not subject to institutional review board approval. The MRIs were obtained as described in the Osteoarthritis Initiative protocol using the SAG 3D DESS WE series, which uses near anisotropic voxels (0.7 mm slice thickness × 0.37 mm × 0.46 mm) to maximize in-plane sagittal spatial resolution in a reasonable acquisition time (10.5 min) [19]. Before segmentation, each MRI was reviewed to verify that the knee was normal without meniscal or ligament tears, arthritis, fracture, or internal fixation hardware. Segmentation was performed with proprietary software developed to make models for patient-specific instrumentation (TechMah, LLC, Knoxville, TN, www.techmah.com).

2.2. Orientation of models

The following steps determined the orientation of F–E tibial reference line with the knee in extension, the level and orientation of the tibial resection plane, and the orientation of the coronal plane on each bone model. The bone model was imported into free, open-source, three-dimensional visualization software (Version 4.1.0 64-bit, Paraview, Kitware Inc., www.paraview.org) (Figure 3). Superimposition of the distal and posterior femoral condyles with the knee in extension orients the femur and tibia in a sagittal plane that is parallel to the F–E plane of the knee. The F–E plane is perpendicular to the distal and posterior condylar axes of the femur (lines tangent to the distal and posterior femoral condyles respectively) [12–17]. The F–E tibial reference line is drawn parallel to the F–E plane and propagated to the tibia with the knee in full extension because there is minimal passive I–E rotation of the tibia on the femur in the extended position [20,21]. The selection of the proximal–distal level of the tibial resection plane was 10 mm distal from the deepest portion of the medial tibial condyle to simulate the

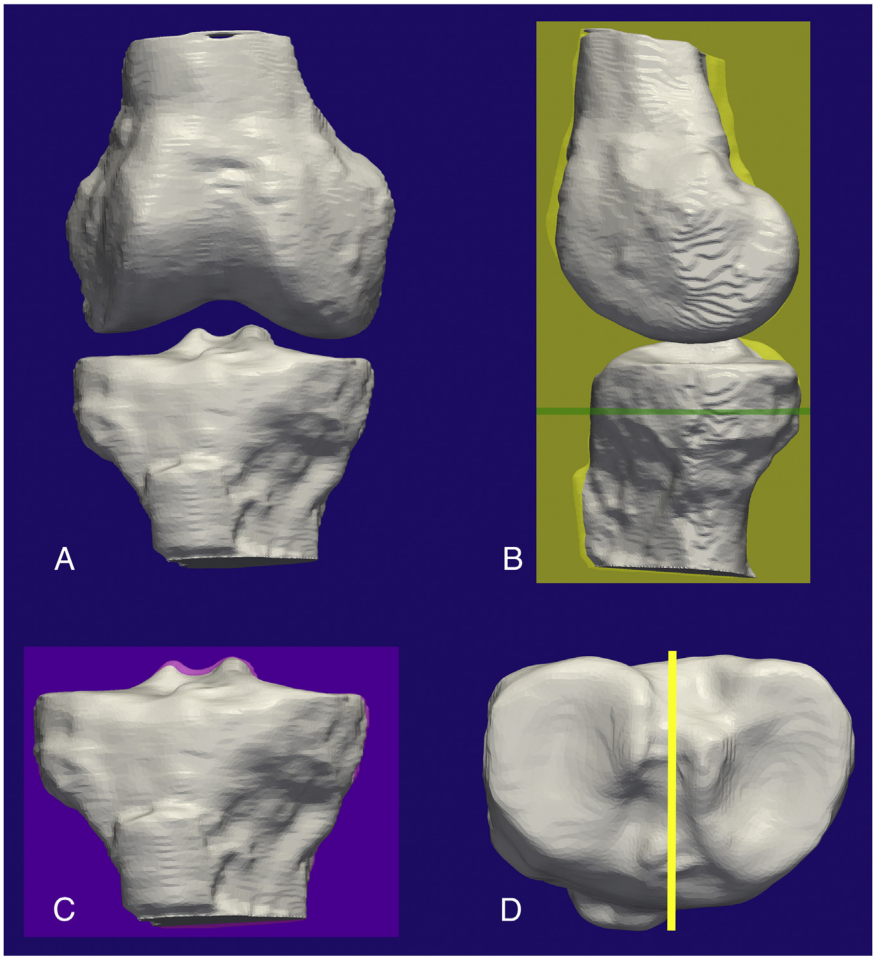

Figure 3. The composite shows a three-dimensional model of a right knee in extension and the steps for orienting the knee in the F–E plane, selecting the plane and level of the tibial resection, and orienting the knee in the coronal plane. (A) The bone model was imported into software. (B) With the knee extended, the medial and lateral femoral condyles were superimposed, which projected the femur and tibia in the F–E plane (yellow). The tibial resection plane (green) was positioned 10 mm distally from the deepest portion of the medial tibial condyle and oriented perpendicular to the F–E plane and parallel to the medial articular surface of the tibial plateau. (C) The coronal plane (purple) was oriented perpendicular to both the F–E plane and the tibial resection plane. (D) The F–E tibial reference line (yellow) on the proximal surface of the tibia is parallel to the F–E plane. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

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thickness of the resection needed to insert a 10 mm thick tibial liner and component. The tibial resection plane was oriented perpendicular to the F–E plane and parallel to the medial articular surface of the tibial plateau. The coronal plane was oriented perpendicular to both the F–E plane and the tibial resection plane.

2.3. Identification of tibial reference lines

The following series of steps identified eight anatomical tibial landmarks from which the five tibial reference lines were constructed (Figure 1). The most anterior point of the tibial tubercle was identified on the projection of the tibia in the coronal plane by translating the coronal plane anteriorly until tangent to a single point on the tibial tubercle. The medial border and medial 1/3 of the tibial tubercle were identified at the proximal–distal level of the most anterior point of the tibial tubercle. The center of the PCL fossa and the center of the medial and lateral tibial condyles were identified on the projection of the proximal tibia in the tibial resection plane. The center of each tibial condyle was the center of a circle that best fit at least ten points on the periphery of each condyle as described by Cobb et al. [7]. A virtual resection was performed parallel to and at the level of the tibial resection plane. The most posterior points on the medial and lateral condyles were identified on the projection of the resected tibia in the coronal plane by translating the coronal plane posteriorly until tangent to a single point on each condyle [7]. Three tibial reference lines were constructed by drawing a line connecting the medial border [8], the medial 1/3 [8,22], or the most anterior point [8] of the tibial tubercle with the center of the PCL fossa. Two tibial reference lines were constructed by drawing a line perpendicular to either the line connecting the most posterior points on the tibial condyles (reference line perpendicular to posterior condylar axis of tibia) or the line connecting the centers of the medial and lateral tibial condyles (Cobb's method) [7]. The angle between each MA TKA tibial reference line and F–E tibial reference line (reference value) quantified internal (−) and external (+) malrotation (Figure 4).

2.4. Reproducibility

To quantify reproducibility, the intraclass correlation coefficient (ICC) was computed from measurements of the angle between each MA TKA tibial reference line and the F–E tibial reference line made by three trained observers on ten randomly selected bone models. For each tibial reference line, a two-factor analysis of variance (ANOVA) with mixed effects was used to compute the intraclass correlation coefficient. The first factor had three levels (observer 1, observer 2, and observer 3) and was the fixed effect. The second factor had ten levels (bone models 1 to 10) and was the random effect. An ICC value of >0.9 indicates excellent agreement and 0.75 to 0.90 indicates good agreement [23]. The ICCs were 0.87, 0.87, and 0.83 for the tibial reference lines connecting the medial border, medial 1/3, and most anterior point of the tibial tubercle with the center of the PCL fossa, respectively. The ICC was 1.00 for the tibial reference line perpendicular to the posterior condylar axis of the tibia. The ICC was 0.80 for Cobb's method.

2.5. Statistical analyses

The bias (expressed as the mean), the imprecision (expressed as the SD), the limit of agreement (expressed as the mean ± 2 SDs), the 95% confidence interval (CI) of the mean, and the range of the angle between each anatomical tibial reference line and the functional F–E tibial reference line were computed from measurements made on 62 knee models by one observer (+external/−internal). A Student's t-test determined whether there was bias when the mean angle was significantly different from zero. Significance was $p < 0.05$. Software performed the statistical analyses (Version 12.0.1, JMP; SAS Institute Inc., Cary, NC; www.jmp.com).

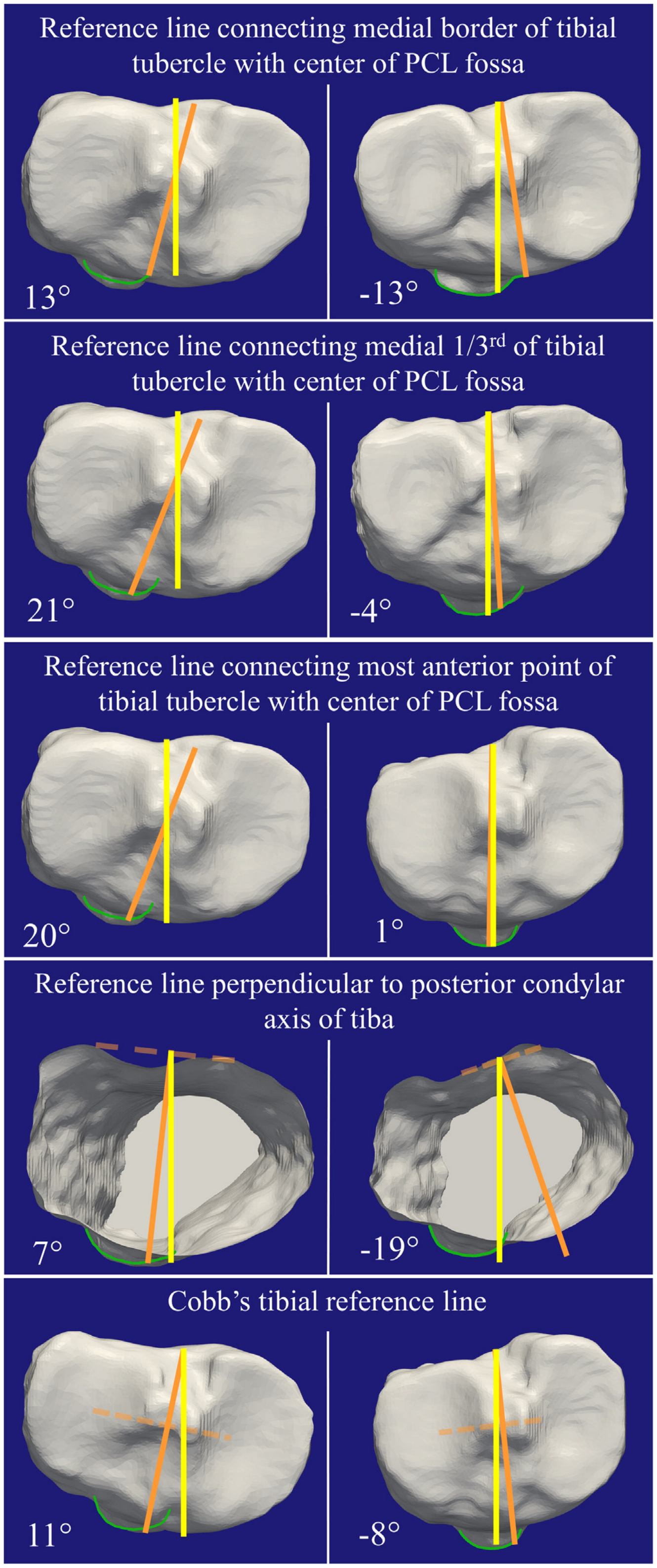

Figure 4. The composite of the axial projection of ten tibias shows the greatest external (+) and internal (−) malrotation of each tibial reference line (orange line) from the F–E tibial reference line (yellow line) (each tibia is viewed as right). The angle between each tibial reference line and the F–E tibial reference line was computed. The medial–lateral location of the tibial tubercle (green arc) varies widely with respect to the medial border of the tibia. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

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3. Results

The following are the bias, imprecision, limits of agreement, and the significance of the bias of the angle between the F–E tibial reference line and 1) the tibial reference lines connecting the medial border (−2° ± 6°, −14° to 10°, $p < 0.005$), medial 1/3 (6° ± 6°, −6° to 18°, $p < 0.001$), and the most anterior point of the tibial tubercle (9° ± 4°, −1° to 17°, $p < 0.001$) with the center of the PCL, and 2) the tibial reference lines perpendicular to the posterior condylar axis of the tibia (−3° ± 4°, −11° to 5°, $p < 0.001$), and a line connecting the centers of the tibial condyles (1° ± 4°, −7° to 9°, $p = 0.173$) (Figure 5).

4. Discussion

Because I–E malrotation of the tibial component is associated with poor function in MA TKA and because the target tibial reference lines are defined anatomically in MA TKA and functionally in KA TKA, the present study determined the bias and imprecision between the five anatomically defined tibial reference lines used in MA TKA and the functionally defined F–E tibial reference line used in KA TKA. The key findings were that four of five anatomically defined tibial reference lines were biased with an absolute mean malrotation from 2° to 9° from the F–E tibial reference line, five tibial reference lines were imprecise with a SD of the malrotation ranging from 4° to 6° from the F–E tibial reference line, and four of five had a limit of agreement that falls outside the −7° to 10° range associated with high Oxford Knee scores after KA TKA [18].

Two limitations that might affect the generalization of the findings of the present study should be discussed. One limitation is that the use of knee models in flexion rather than extension might have changed the position of the F–E tibial reference line because the tibia internally rotates approximately 10° when the knee flexes [24]. A different position for the F–E tibial reference line might have changed the bias and imprecision of the angle between the five anatomically defined tibial reference lines. Accordingly, we constructed the F–E tibial reference line on the extended knee because there is little passive I–E rotation of the tibia on the femur [20,21]. A second limitation is that the orientations of each of the anatomically defined tibial reference lines used in mechanically aligned TKA were set more reproducibly on the bone models with software than when set intraoperatively where osteophytes, deformities, articular wear, and soft-tissues may obfuscate the identification of anatomic tibial landmarks. This obfuscation might explain the large bias and large imprecision of the angle between the tibial reference line selected by 11 arthroplasty surgeons each working with 10 cadaveric knees from the target tibial reference line, which measured −27° internal ± 28° for the line connecting the medial border of the tibial tubercle with the center of the PCL fossa, −15° internal ± 27° for the line connecting the medial 1/3 of the tibial tubercle with the center of the PCL fossa, 0° ± 11° for the line connecting the most anterior point of the tibial tubercle with the center of the PCL fossa, and −5° internal ± 10° for the line connecting the most medial and most lateral points of the plateau [8].

The most important clinical application of the findings of the present study for surgeons that perform KA TKA and MA TKA is that the use of functionally defined or anatomically defined tibial reference lines set the I–E rotation of the A–P axis of the tibial component quite differently. The goal of KA TKA is to correct the arthritic deformity of the limb to the constitutional alignment of the patient with the intent of aligning the rotational axes of the femoral and tibial components with the goal of restoring the natural tibial–femoral articular surfaces, alignment, and laxities of the knee [10,25]. This is accomplished in part by setting the A–P axis of the tibial component parallel to the F–E tibial reference line [12–17]. Because of the inherent bias of four of the five anatomically defined tibial reference lines from the F–E plane and imprecision of all five, those surgeons performing KA TKA might consider the use of a different method for setting I–E rotation of the tibial component.

Because KA TKA is a new technique, we are aware of only one clinical study that has determined the association between I–E malrotation of the A–P axis of the tibial component from the F–E plane of the knee and patient satisfaction and function. The limit of agreement of the angle between I–E rotation of the A–P axis of the tibial component and the F–E plane of the knee of −7° to 10° (i.e. mean ± 2 SDs) was considered 'acceptable' because these patients reported high satisfaction and function as measured by the Oxford Knee Score (mean 42 of 48 (best)) [18]. In the present study, the limits of agreement between the F–E tibial reference line and the tibial reference lines connecting the medial border (−14° to 10°), medial 1/3 (−6° to 18°), and the most anterior point of the tibial tubercle (−1° to 17°) with the center of the PCL, and the tibial reference line perpendicular to the posterior condylar axis of the tibia (−11° to 5°) fell outside the acceptable limit of agreement of −7° to 10°. Until a clinical study determines whether these broader limits of I–E malrotation of the A–P axis of the tibial component from the F–E plane are associated with high patient reported satisfaction and function, it might be prudent to reexamine the use of these anatomically defined tibial reference lines used in MA TKA when performing KA TKA.

Accordingly, we have used a method that sets the I–E rotation of the A–P axis of the tibial component parallel to a tibial reference line that

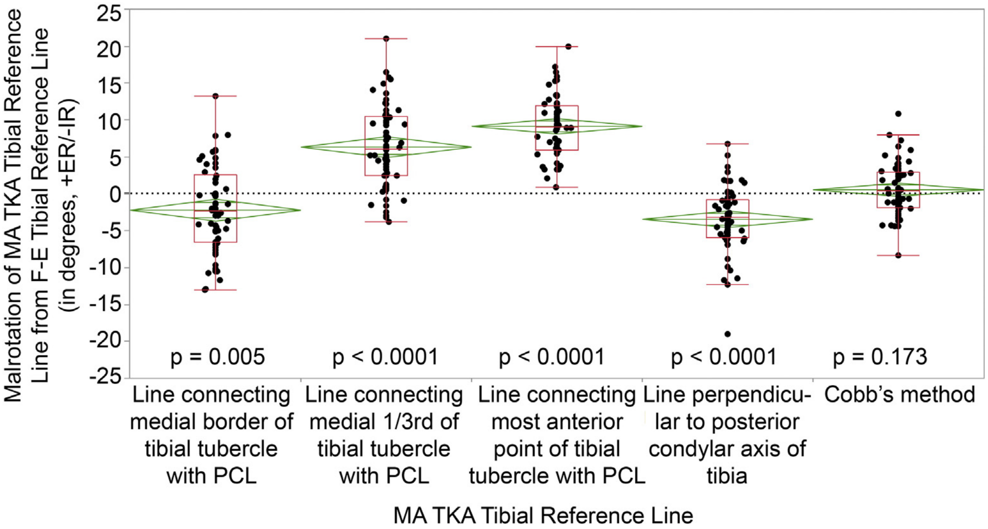

Figure 5. The graph displays the diamond (green), which illustrates the mean and 95% confidence interval, and an outlier quartile box plot (red) which shows the imprecision in I–E malrotation of each MA TKA tibial reference line from the F–E tibial reference line. The p-values are the results of a Student's t-test that determined whether the mean I–E rotation of a MA TKA tibial reference line was significantly biased from the F–E tibial reference line. Only Cobb's method did not have a significant bias from the F–E tibial reference line.

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bisects the oval boundary of the lateral tibial condyle with the goal of being parallel to the F–E tibial reference line [18,26,27]. A study of 71 consecutive KA TKAs treated with this method determined whether the tibial component was aligned parallel to the F–E tibial reference line by analyzing the angles between reference lines drawn on synchronized axial preoperative MRI and post-operative computer tomographic scans. The intraoperative bias was −1° internal and the imprecision was ±5° for the angle between the A–P axis of the tibial component and the F–E tibial reference line. These values are lower than the intraoperative bias that ranged from 0° to −27° internal and the imprecision that ranged from ±10° to 28° for the angles between anatomically defined tibial reference lines positioned by 11 arthroplasty surgeons and the target reference line [8]. Two other studies showed that this method limits the I–E rotational mismatch of the tibial component on the femoral component within 0 ± 10° in 97% percent of patients. This range of rotational mismatch is relatively narrow because it was shown to be compatible with high function as determined by self-reported Oxford Knee Scores and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Scores at 6 months [11,18,26].

5. Conclusions

Based on these in vitro findings, surgeons who perform KA TKA might be prudent to reconsider setting the I–E rotation of the tibial component to tibial reference lines that have bias, imprecision, and limits of agreement that fall outside the −7° to 10° range associated with high function after KA TKA. When performing KA TKA, we prefer to set the I–E rotation of the tibial component parallel to a line that bisects the oval boundary of the lateral tibial condyle. The intraoperative use of this method sets the tibial component parallel to the F–E plane with no bias, low imprecision, and an acceptable limit of agreement each of which are associated with high patient reported satisfaction and function as measured by the Oxford Knee Score [18,26,27].

Conflict of interest statement

The authors list the following disclosures: S. Howell is a board member of the American Academy of Orthopaedic Surgeons and the American Journal of Sports Medicine, a paid consultant for THINK Surgical and Zimmer-Biomet, and received royalties from Zimmer-Biomet. M. Hull is a board member of the Journal of Biomechanics, received research support from Zimmer-Biomet and THINK Surgical, and received in-kind support from Zimmer-Biomet.

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