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Can kinematic tibial templates assist the surgeon locating the flexion and extension plane of the knee?

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ABSTRACT

Purpose: We performed virtual feasibility and in-vivo validation studies to test whether the use of a kinematic tibial template (KTT) assists the surgeon in accurately locating the orientation of the F-E of the knee with low bias and high precision.
Methods: With use of 166 3-dimensional bone models of normal knees, we designed seven KTTs that located the orientation of the F-E plane of the knee when best-fit within the cortical edge of the tibial resection. The virtual feasibility study asked 11 evaluators with different levels of surgical experience to use software and select, orient, and best-fit the KTT within the tibial resection of each bone model. The in-vivo validation study analyzed tibial component rotation on postoperative CT scans of 118 consecutive patients after one surgeon set the I-E rotation of the tibial component with a KTT when performing kinematically-aligned TKA. Bias and precision were computed as the mean and standard deviation of the differences between the A-P axis of the KTT and the F-E plane of the knee.
Results: For the virtual feasibility study, the bias was 0.7° external and the precision was ±4.6° for 1826 KTT fittings, which were not affected by the level of surgical experience. For the in-vivo validation study, the bias was 0.1° external and the precision was ±3.9°.
Conclusions: The virtual feasibility and in-vivo validation studies suggest a KTT can assist the surgeon in accurately setting the I-E rotation of the tibial component parallel to the F-E plane of the knee when performing kinematically-aligned TKA.

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1. Introduction

Correct positioning of the femoral and tibial components is essential for a successful total knee arthroplasty (TKA). Malalignment of the femoral component alters both tibiofemoral and patellofemoral and is responsible for a certain proportion of TKA failure [1]. Malrotation of the tibial component of greater than 10° from the anteroposterior (A-P) axis of the femoral component is associated with persistent pain and poor patient reported satisfaction and functional outcome [2–4].

Current methods used in mechanically aligned TKA for setting the internal-external (I-E) rotation of the tibial component have some subjectivity and are prone to some inaccuracies which can be quantified by bias and precision. For example, a bias up to 25° internal and a precision (standard deviation) of ±10° to 28° from the intended target was reported when eleven arthroplasty surgeons selected the orientation of tibial reference lines connecting the medial border, medial 3rd and anterior crest with the center of the posterior cruciate ligament (PCL) to set I-E rotation of the tibial component [5]. Thus, a method that can assist the surgeon

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in setting I-E rotation of the tibial component with less bias and more precision (i.e. smaller standard deviation) might be of interest.

Kinematically aligned TKA is gaining interest because two level-one randomized trials and national multicenter study showed that patients treated with kinematically aligned TKA reported significantly better pain relief, function, flexion, and a more normal feeling knee than patients treated with a mechanically aligned TKA [6–8]. Kinematically aligned TKA has different targets for aligning a knee, which are to co-align the flexion-extension (F-E) axes of the tibia and patella in the femur and the longitudinal rotation axes in the tibia of the native knee with the axes of the implants [9–12]. Aligning the distal and posterior surface of the femoral component coincident to the native joint lines restores these kinematic axes. Varus-valgus deformities are corrected with a distal referencing guide with a 2 mm offset that compensates for the thickness of the worn cartilage that averages two millimeters on the distal medial and distal lateral femoral condyle in many knees with varus and valgus deformities, respectively [13–15]. Correction for cartilage wear posterior and femoral bone wear at 0 and 90 degrees of flexion is infrequent as most knees with Kellgren-Lawrence Grade 3 or 4 osteoarthritis have <1 mm of wear [15].

Restoring the native joint lines and alignments of the limb and knee to those of the pre-arthritic or native knee co-aligns the components with the kinematic axes (Figure 1) [6,7,13,14,16]. Unlike mechanically aligned TKA, the target for setting the I-E rotation of the tibial component in kinematically aligned TKA is parallel to the F-E plane of the knee. The F-E plane of the knee is oriented perpendicular to lines coincident with the distal and posterior joint lines of the native femur [14,17,18].

Kinematically aligned TKAs have high function when the I-E rotation of the tibial component is set between −11° internal to 12° external from the F-E plane of the knee [19]. Unfortunately the use of the medial border, medial 3rd, and anterior crest of the tibial tubercle is prone to error in locating the orientation of the F-E plane because of the high variability of the medial-lateral position of the tibial tubercle [20]. Therefore, we designed a kinematic tibial template (KTT) and developed a novel method to assist the surgeon in locating the orientation of the F-E plane of the extended knee (Figure 2).

The present study answered two questions: 1) Does a virtual feasibility study show that eleven observers with three different levels of training that select the best fit KTT within the cortical edge of the tibial resection accurately locate the F-E plane of the knee with low bias and high precision? 2) Does an intraoperative analysis show that the best fitting of a KTT by one surgeon accurately set the A-P axis of the tibial component parallel to the F-E plane of the knee with low bias and high precision?

2. Materials and methods

Two independent research settings were used to answer each question: a virtual feasibility study and an intra-operative validation study. All procedures performed in each research setting were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards and were approved by an institutional review board (IRB ID:801079-1, University of CA at Davis).

2.1. Virtual feasibility study

2.1.1. Selection of subjects and design of the kinematic tibial template

One hundred and sixty-six, 3-dimensional bone models of the extended knee were reconstructed from 99 magnetic resonance imaging (MRI) scans and 67 computer tomographic (CT) scans from subjects with normal knees on imaging. Bone models derived from MRI data were previously segmented for a soft tissue and cartilage study. CT scans were randomly selected from TKA patients whose contralateral knee showed no signs of degenerative arthritis. The mean age of the subjects was 63 years old

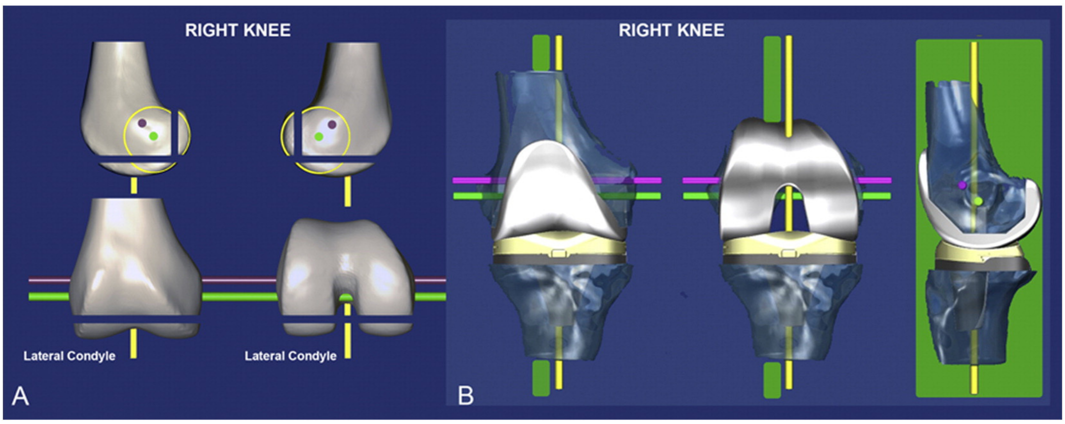

Figure 1. A. The flexion axis of the tibia is the transverse green line, the flexion axis of the patella is the transverse magenta line, and the rotational axis of the tibia is the vertical yellow line. B. The flexion-extension plane of the extended knee (50% opaque green rectangles) lies perpendicular to the native distal and posterior femoral joint lines and the flexion axes of the tibia and patella.

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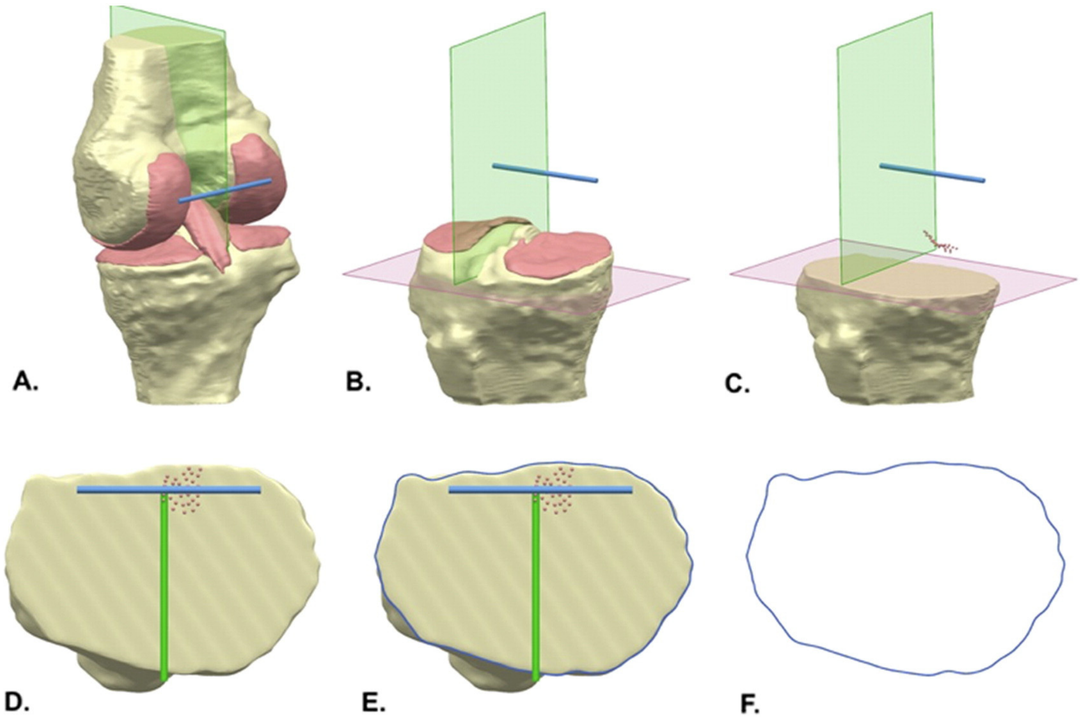

Figure 2. A. The F-E plane (green rectangle) is constructed perpendicular to the F-E axis of the knee (not shown) and the posterior joint line of the femur (cyano line) B. The F-E plane is projected to the tibia and perpendicular to the plane for the tibial resection (red rectangle). C. The V-V and F-E planes of the tibial resection are set parallel to the native joint line as depths of 9, 10, and 11 mm distal to the center of the medial tibial condyle. D. A transverse view of the tibial resection shows the projections of the F-E plane, posterior joint line of the femur, and insertion of the PCL (red dots). E. The irregularly- shaped blue line traces the cortical edge of the tibia F. The average tibial resection was computed from the three tracings of the cortical edge of the resections made at 9, 10, and 11 mm.

(range 46 to 77). Seventy-seven patients were male. Proprietary segmentation software constructed three-dimensional bone models of the femur and tibia (TechMah, LLC, Knoxville, TN). An expert quality assured the overlay of the segmented voxels on each image with commercial software (Avizo, FEI Inc., Hillsboro, Oregon, http://www.fei.com).

We designed a series of seven KTTs with the goal that when a surgeon orients the best-fitting KTT within the cortical contour of the tibial resection the A-P axis of the KTT is set parallel to the F-E plane of the knee. The best-fit KTT was defined as the template which provides maximum coverage when placed within the cortical edge of the tibial resections without overhang and when oriented parallel to the anterior-medial aspect of the cortical edge. Figures 2, 3 and Supplemental material details the processes for analyzing the three-dimensional bone models of the normal knees to create the cortical contour of the tibial resection and the rationale for designing the seven KTTs.

2.1.2. Virtual determination of the bias and precision of the use of the KTT to locate the F-E plane of the knee

Eleven evaluators with three different levels of training (five orthopedic surgeons experienced with TKA, three fellows/ residents in orthopedic training, and three students) agreed to participate in the study and installed proprietary software on their personal computer (PlateValidation software, TechMah, LLC, Knoxville, TN). The software presented a proximal view of the tibial resection and cortical edge to the evaluator and showed a KTT placed outside the cortical edge of the tibial resection and randomly rotated (Figure 4). With the evaluator blinded to the orientation of the F-E plane of the knee the size and orientation of the KTT was manipulated within the cortical edge of the resection. Software saved the evaluator's selected size and orientation of the KTT for each of the 166 subjects in an output file. The output file was returned via email and the angle between the A-P axis of the KTT and the F-E plane of the knee was computed for each subject. The mean and standard deviation determined the bias and precision (i.e. accuracy), which could be expected when virtually setting the KTT to find the F-E plane of the knee and then set the I-E rotation of a tibial component.

2.2. Intraoperative validation study

For the intraoperative validation, a single surgeon performed KA TKA on 118 consecutive patients with end-stage osteoarthritis using a cruciate-retaining implant with a fixed tibial bearing (Persona CR, Zimmer Biomet, Warsaw, IN). All patients fulfilled the Centers for Medicare & Medicaid Services guidelines for medical necessity indications for performing TKA including (1)) radiographic evidence of Kellgren-Lawrence Grade II to IV arthritic change or osteonecrosis; (2) any severity of clinical varus or valgus

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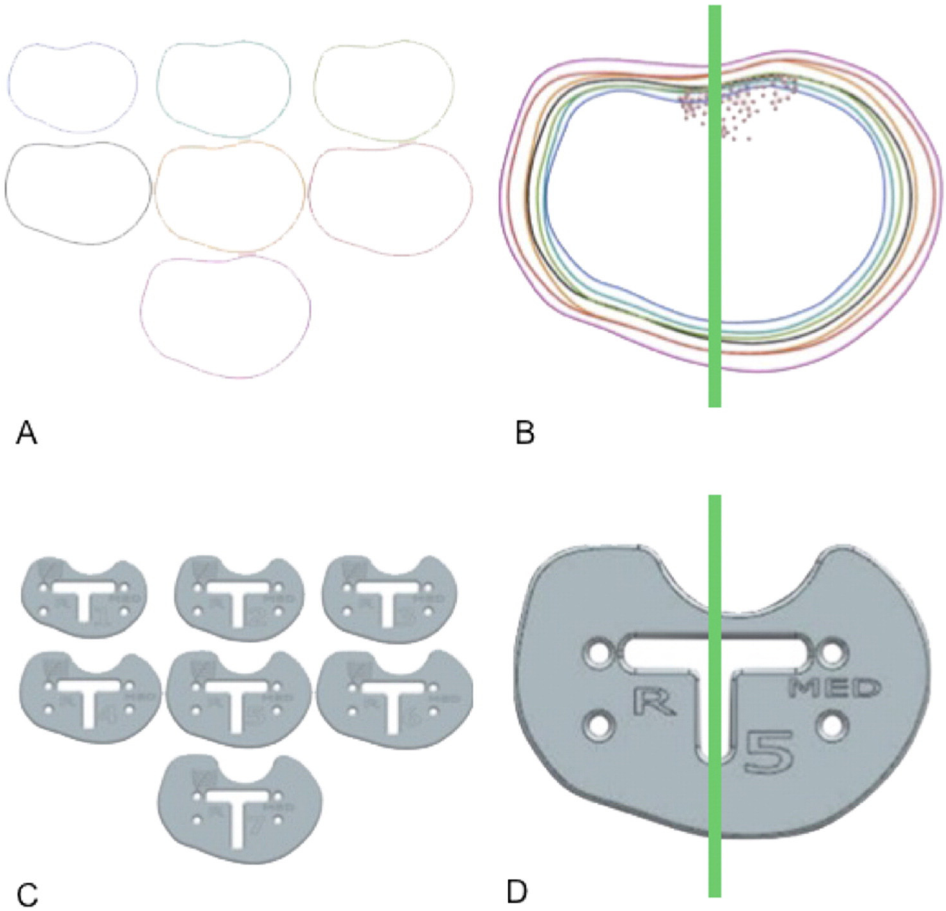

Figure 3. The F-E plane of the knee is defined as a line perpendicular to a line connecting the centers of circles best fit to the cortical edge of the medial and lateral tibial condyles (not shown) [11]. The average cortical edges of the tibial resections for the 166 normal knees were clustered into seven discrete groups (top row). Seven KTT were designed with a posterior cut-out for the PCL so that the A-P portion of the T-shaped slot located the F-E plane of the knee when the KTT was best-fit within the cortical edge of the tibial resection (bottom row).

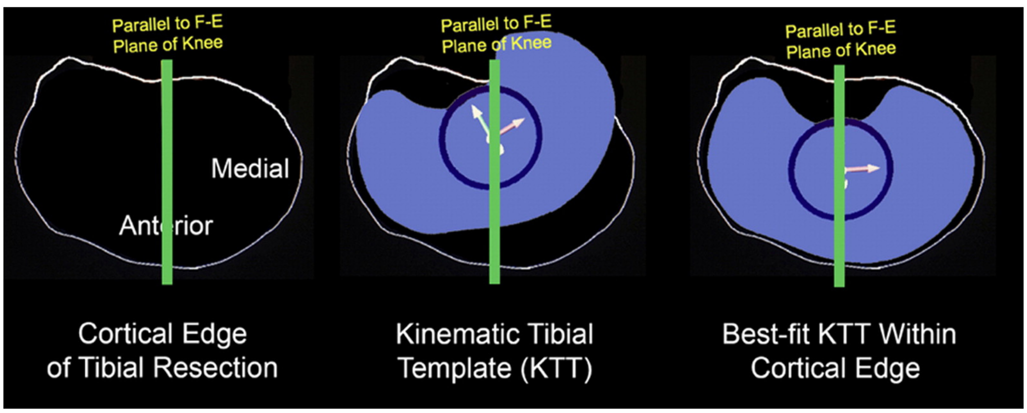

Figure 4. A. In the software used by each evaluator to best-fit the KTT, irregular white line traces the cortical edge of the tibial resection, and the vertical green line is the F-E plane of the knee propagated from the femur. The vertical green line was not visible to the evaluators. B. Evaluators were shown a KTT randomly translated, rotated, and offset from the cortical edge of the tibial resection. C. The evaluator could retain or choose a larger or smaller KTT. They translated and rotated the KTT until best-fit within the cortical edge of the tibial resection. The size and position of the KTT was saved for each of the 166 subjects. The mean and standard deviation of the angle between the vertical green line and the green arrow on the KTT determined the bias and precision from the F-E plane of the knee for each evaluator.

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deformity clinical varus or valgus deformity as measured non-weight bearing with a goniometer (ranged from −30° valgus to 20° varus); (3) and any severity of flexion contracture. The mean age of patients was 69 ± 8.8 years old. Forty-eight patients were male. Mean BMI was 30 ± 5.1. Preoperatively, the mean Oxford Knee Score was 19 ± 8 (range from six to 36) (0 worse, 48 best). Ninety-four patients had a varus deformity and 24 a valgus deformity. The angle of the knee on a standing radiograph ranged from 20° varus to −25° valgus with a mean of 6° ± 11° varus. Postoperatively, the hip-knee-ankle angle of the limb on a rotationally controlled computer tomogram ranged from six degrees varus to −6° valgus with a mean of 0° ± 3°. The proportion of subjects with a hip-knee-ankle angle within 0 ± 3 degrees was 72%, greater than three degrees varus was 16%, and greater than −3° valgus was 12%.

Each kinematically aligned TKA was performed with a caliper and manual instruments using a previously described technique [14,18]. The following steps are detailed because they set the varus-valgus (V-V), proximal-distal (P-D), I-E, anterior–posterior (A-P), and flexion-extension (F-E) locations of the femoral and tibial components.

For the placement of the femoral component, the V-V and P-D locations of the distal femoral resection was set with use of an offset distal femoral referencing guide that contacted the distal medial and lateral femoral condyles. The offset was selected to compensate for 2 mm of cartilage wear on the worn condyle(s), which corrected the varus-valgus deformity caused by wear. The P-D level of the distal femoral resection was set so the thickness of the resections of the distal medial and lateral femoral condyles measured to within 0 ± 0.5 mm with a caliper equaled the condylar thickness of the femoral component after compensating for cartilage wear and kerf. The A-P and I-E locations of the posterior femoral resection was set parallel to the F-E plane of the extended knee by placing a 0° rotation posterior referencing guide in contact with the posterior femoral condyles at 90° and removing posterior femoral resections within 0 ± 0.5 mm of the thickness of the condyles of the femoral component after compensating for cartilage wear and kerf. When necessary, the A-P position of the four-in one block was adjusted to correct for a one or two millimeters over or under posterior resection. The anterior and chamfer cuts held the femoral component in the corrected position. Compensation for cartilage and bone wear at 90° on the posterior femoral condyles was rarely needed when treating grade 3 and 4 Kellgren-Lawrence osteoarthritic knees [14,15,17] Adjusting the thickness of the medial and lateral posterior resections to match the thickness of the condyles of the femoral component within ±0.5 mm after compensating for cartilage wear and kerf sets the A-P axis of the femoral component parallel to the F-E plane of the knee with a bias of 0.3° and precision of ±1.1° [17].

For the placement of the tibial component, the V-V, P-D, and F-E locations of the tibial resection were set with use of an extramedullary tibial guide and an angel wing inserted in the saw slot alongside the medial border of the tibia. The V-V position of the tibial component was set by medial translation of the slider at the ankle section of the guide until the saw slot was parallel to the tibial articular surface after a visual compensation for cartilage and bone wear. When the extension gap was asymmetric or trapezoidal, the V-V angle of the tibial resection was fine-tuned in increments of one to two degrees until the V-V laxity with trial components was eliminated. The F-E position of the tibial component was set by adjustment of the slope of the tibial guide until parallel to the slope of the medial joint line. The P-D position of the tibial component was set by adjustment of the level of the saw slot to remove enough tibial bone to accommodate at least a 10 mm thick tibial component [13,14]. The KTT were machined from medical grade plastic (RADEL) enabling ethylene oxide gas, radiation, steam autoclaving, dry heat, and cold sterilization. The largest KTT that fit within the cortical edge of the tibial resection was selected and oriented (Figure 5). A line was drawn in the

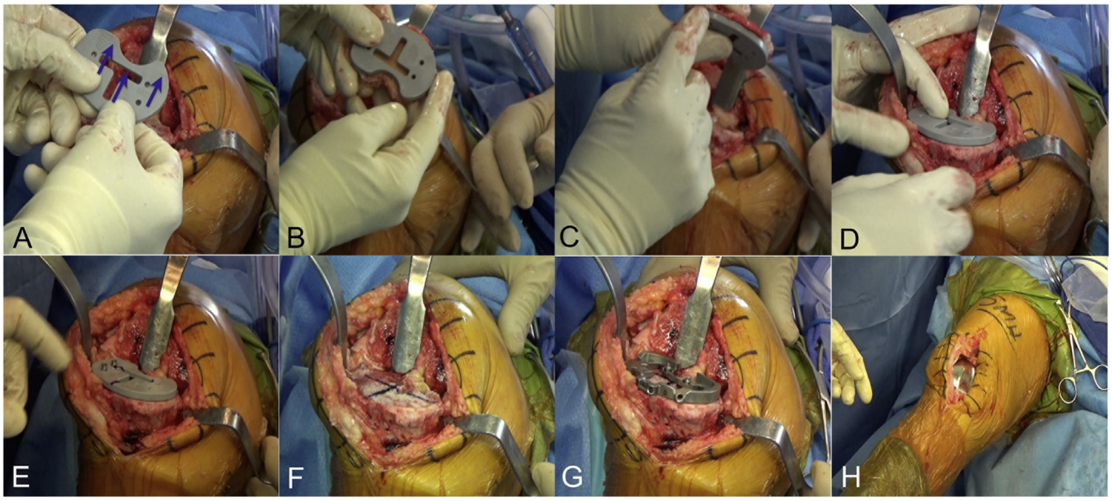

Figure 5. A. The KTT has a T-shaped slot with the A-P portion of the slot oriented parallel to the F-E plane of the knee (blue arrows). B & C. The largest KTT that fits within the cortical edge of back side of the tibial resection is selected. D. The KTT is placed on the tibia and oriented until the medial and anterior edge of the KTT closely parallels the cortical edge of the tibial resection. E & F. The KTT is pinned and A-P and transverse lines are drawn on the tibial resection through the T-shaped slot. G. The A-P axis of the tibial component is set parallel to the A-P line. H. Final check for stability and motion.

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vertical arm of the T-shaped slot of the KTT and the I-E rotation of the A-P axis of the tibial component was set parallel to the line. In all cases, the patella was resurfaced and all components were cemented.

For the evaluation of accuracy, a 1.25-mm thick axial CT scan of the hip, knee, and ankle was performed on each patient prior to discharge, using a previously described technique [18,21]. On the CT scan, the angle between a line drawn perpendicular to the line connecting the lugs of the femoral component defined the F-E plane of the knee. The I-E malrotation of the tibial component was the angle formed by the line parallel to the F-E plane of the knee and the A-P axis of the tibial component (+ indicated external and − indicated internal malrotation) (Figure 6) [17].

2.3. Statistical analysis

The bias (mean) and precision (standard deviation) were computed for each measured quantity when appropriate (JMP, 10.02, http://www.jmp.com). For the virtual feasibility study, the use of 166 knees adequately powered the present study as 24 and 90 knees detect a clinically important mean difference of six degrees [22] and a smaller difference of three degrees with an $\alpha = 0.05$ and a power $= 0.80$ and the maximum standard deviation of five degrees in the planned I-E rotation of the tibial component between observers, respectively. A one-factor (eleven observers) analysis of variance (ANOVA) and post-hoc Tukey's Test determined whether the bias and precision of the angle between the A-P axis of the KTT and the F-E plane were different between observers. For the intraoperative validation study, the bias and precision of the angle between the A-P axis of the tibial and the A-P axis of the femoral component was computed. Significance was $p < 0.05$.

3. Results

For the virtual feasibility study, the bias and precision of the I-E rotation of the 1826 best-fit KTT from the F-E plane for the eleven observers was 0.7° external ±4.6° (Figure 7). The difference in the bias (0.7°) and precision (0.3°) between the five arthroplasty surgeons (0.7° external ±4.5°), three resident-fellows (0.4° external ±4.6°), and three students (1.1° external ±4.9°) were small enough to be clinically unimportant though significant ($p < 0.032$). The maximum differences in bias and precision were less than 1° between the three levels of evaluators.

For the in-vivo validation study, the bias and precision of the I-E rotation of the 118 best-fit KTT from the F-E plane was 0.1° external ±3.9° for the single surgeon.

4. Discussion

Current methods used in mechanically aligned TKA for setting the internal-external (I-E) rotation of the tibial component select bony landmarks with some degree of subjectivity that has some inaccuracy [5]. Accordingly, we developed KTTs and determined the accxuracy of their use in a virtual feasibility study and validated their use in an in-vivo study by quantifying the bias and precision for locating the orientation of the F-E plane of the extended knee. The most important findings of the study were that the KTT found the F-E plane of the knee with a bias of less than 1.2° external and a precision of less than ±5°.

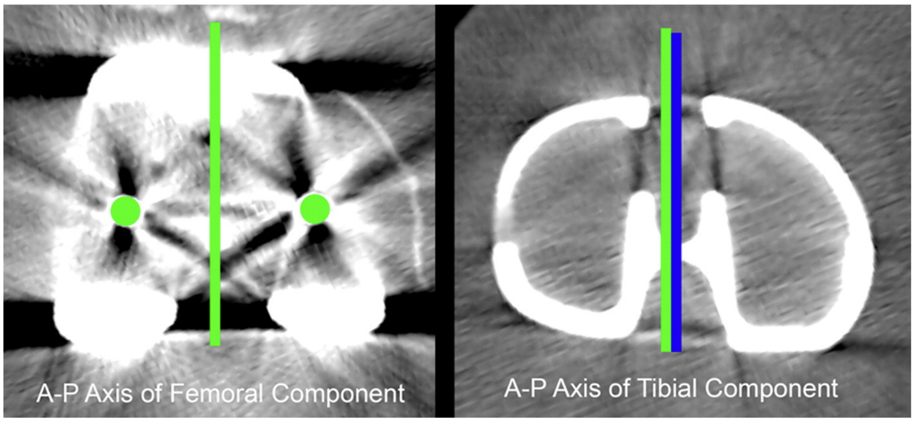

Figure 6. The axial CT view of the femur (left) that best shows the femoral fixation lugs (green circles) is selected. The A-P axis of the femoral component (green line) is drawn perpendicular to a line connecting the center of the lugs (not shown). The axial CT view of the tibia (right) that best shows the proximal surface of the anatomically shaped tibial baseplate is selected. The A-P axis of the tibial component is drawn bisecting the anatomically shaped tibial component (blue line). In this example the angle between the A-P axis of the femoral and tibial component is 0°.

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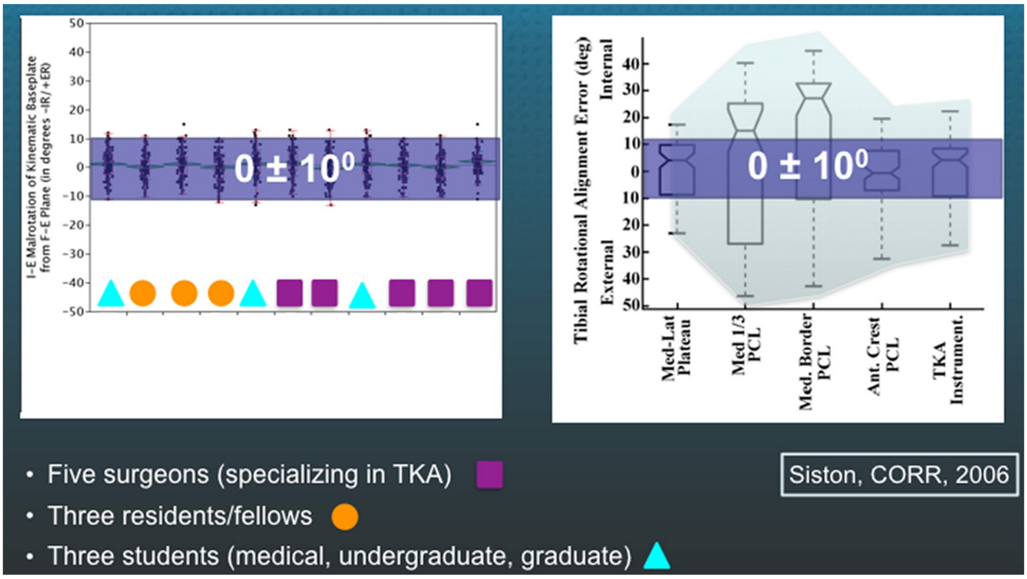

Figure 7. Left boxplot of the virtual feasibility study shows the variability of the I-E malrotation of the selected tibial reference line from the F-E plane of the knee for the eleven observers with different levels of training. The I-E malrotation of the from the F-E plane (blue shaded rectangle) generally lies between 0 ± 10° of the target which is the range associated with high patient reported outcome scores and high function. Right boxplot from the study by Siston et al. [5] shows the higher variability (green shaded polygon) for the angle between the selected tibial reference lines by eleven arthroplasty surgeons and reference lines that target the medial border, medial 3rd and anterior crest of the tibial tubercle.

Three limitations should be discussed. First, the generalization of the findings is dependent on the position of the knee used for locating the orientation of the F-E plane of the knee. The F-E plane of the knee was located in the fully extended knee because there is minimal variability in I–E rotation of the tibia on the femur between subjects, and because the knee is a near rigid body with negligible I–E rotation of the tibia on the femur [23–26]. In knee flexion, the range of I-E rotation of the tibia on the femur has larger variability between subjects and is much greater than full extension, which means the rotational relationship of the tibia on the femur is unpredictable in flexion [25–27]. Second, the KTTs were designed using a tibial resection plane performed according to the principles of kinematic alignment and not mechanical alignment. Kinematic alignment cuts the tibia to restore the native V-V and F-E planes of the proximal tibial joint line, which are different from the target tibial resection plane in mechanical alignment, which is perpendicular to the mechanical axis of the tibia [14,23]. Hence, the shape and size of the KTTs were specifically designed to best-fit a kinematically aligned and not a mechanically aligned tibial resection. Finally, the analysis of the intraoperative use of the KTT was by a single surgeon and the bias and precision might be different from others.

The virtual feasibility study that used eleven observers with three levels of training reported a bias of less than 1.2° and a precision of less than ±5.0° for setting the I-E rotation of the tibial component to the target reference line of the F-E plane of the knee, which are both lower than those reported in other studies (Figure 7). The bias and precision for setting the I-E rotation of the tibial component to the target reference line of an A-P reference axis on the tibia by eleven arthroplasty surgeons each working with 10 cadaveric specimens is estimated to be −28° internal ±27° for the tibial reference line connecting the center of the posterior cruciate ligament fossa to the medial border of the tibial tubercle, −15° internal ±28° for the tibial reference line connecting the center of the posterior cruciate ligament fossa to the medial 3rd of the tibial tubercle, and 0° internal ±11° for the tibial reference line connecting the center of the posterior cruciate ligament fossa to the most anterior point of the tibial tubercle [5]. Accordingly, the precision of finding the F-E plane of the knee with the KTT used with kinematically aligned TKA by observers with three levels of training is two to seven times better than the precision of finding the A-P reference axis on the tibia with use of targets by highly trained arthroplasty surgeons that identify regions of the tibial tubercle to construct three tibial reference lines used with mechanically aligned TKA.

Our intraoperative validation study of kinematic alignment with a KTT reported a bias of 0.1° and precision of ±3.9° for setting the I-E rotation of the tibial component to the A-P axis of the femoral component and the F-E plane of the knee, which is comparable if not lower than the bias of −1.0° internal and precision of ±5.4° reported by another study of kinematically aligned TKA [14]. The other study treated 101 subjects and set the I-E rotation of the A-P axis of the tibial component parallel to the major axis of the elliptical-shaped boundary of the lateral tibial condyle, which was used to locate the F-E plane of the knee [14,17,18]. These patients reported high satisfaction and function as measured by a mean Oxford Knee of 42 (48 best, 0 worst) and mean WOMAC score of 89 (100 best, 0 worst) [17]. Accordingly, the accuracy for both the novel KTT and the major axis methods for setting the I-E rotation of the tibial component is compatible with a well-functioning kinematically aligned TKA.

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The KTT is a generic tool that can be used to accurately locate the F-E plane of the knee for those surgeons that prefer symmetric, asymmetric, and anatomic shaped tibial components. Some investigators have suggested that the anatomic design of the tibial component as a factor in reducing I-E malrotation [28]. Others are concerned that maximizing coverage might increase the risk for tibial malrotation [29,30]. The KTT addresses both concerns by accurately locating the orientation of the F-E plane regardless of the design differences between tibial component.

There are theoretical concerns that performing kinematically aligned TKA on patients with severe varus-valgus deformities may lead to early implant failure. Five randomized clinical trials comparing kinematically aligned TKA to mechanically aligned TKA used different limits of varus and valgus deformity to exclude patients for treatment with kinematic alignment. Two studies used no limits [6,31], two studies excluded patients with a varus or valgus limit of >10° [8,32], and one study excluded patients with a varus or valgus limit of >15° [33]. The two randomized trials that used no limits showed greater improvement in pain relief, patient reported outcomes, and knee flexion in the kinematic alignment group relative to the mechanical alignment group [6,31], when compared to three trials that used limits [8,32,33]. Case series of 214, 219, and 3212 knees treated with kinematically aligned TKA that used no limits reported high implant survival and negligible varus loosening of the tibial component at three-, six- and up to nine-years post-operatively, respectively [16,34,35]. Explanations for the high mid-term implant survival were that kinematic alignment sets the joint line of the knee parallel in orientation relation to the floor during single- and double-leg standing [31,36,37], and that intraoperative forces in the medial and lateral tibial compartments after kinematically aligned TKA were close to the native knee and three to six times lower than after mechanically aligned TKA [38–40]. Since studies of kinematically aligned TKA that used no limits have shown high clinical outcomes [6,31], a joint line parallel to the floor consistent with the native knee [31,37], a low risk of implant failure for any cause at up to six-years [6,16,34,41], and a negligible risk of varus subsidence of the tibial component at two- to nine-years [35], excluding patients for treatment with kinematic alignment based on the degree of varus or valgus deformity may be more theoretical than real (Figure 8). Accordingly, we perform kinematic alignment on all degrees of preoperative varus and valgus deformity.

It has been suggested that kinematically aligned TKA restores near normal knee kinematics [42,43], and a lower prevalence of undesirable adduction and external rotation of the tibial component with knee flexion than mechanically aligned TKA [44]. However, others have shown that kinematically aligned TKA has greater variability in tibiofemoral and patellofemoral [45], and higher contact stress and bone strain in the medial tibia in varus knees when compared to mechanically aligned TKA [43]. Hence, further study is required to determine how closely kinematic alignment restores native knee kinematics and how the restored kinematics affect long-term implant survival.

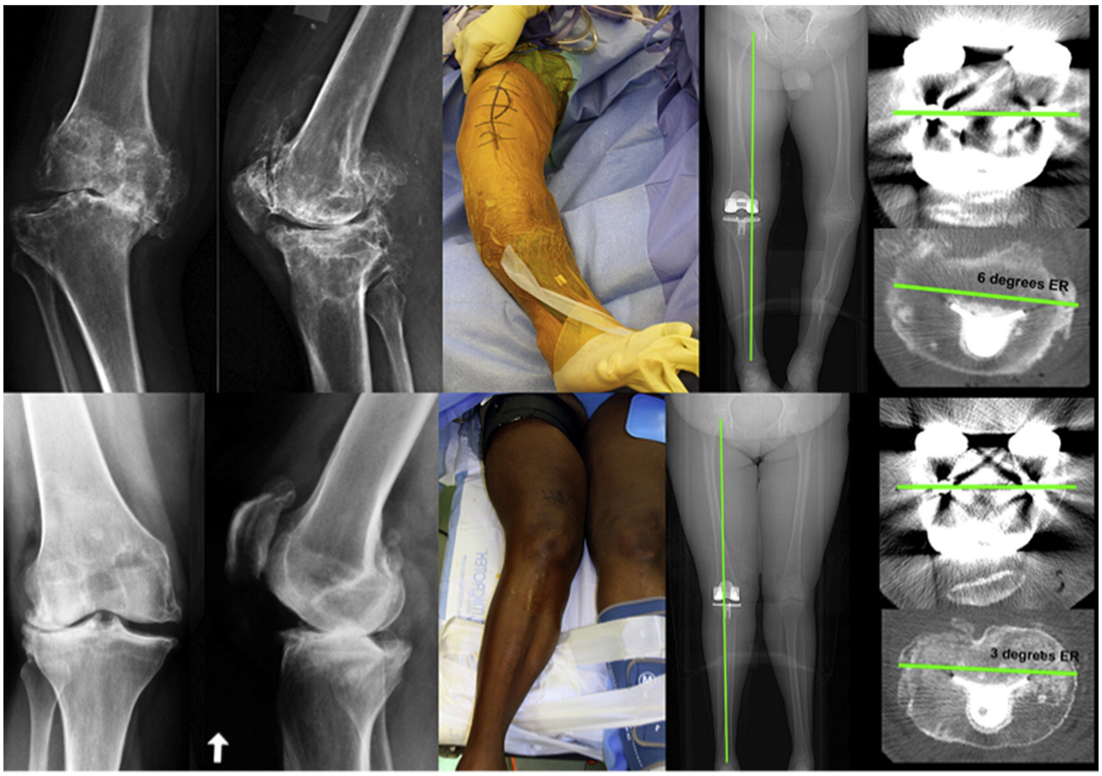

Figure 8. Composite of preoperative radiographs, intraoperative photographs, postoperative computer tomographic scanogram of the limb, and post-operative axial views of the femoral and tibial components showing effective treatment of knees with a severe preoperative varus (top row) and a severe valgus (bottom row) deformity with kinematic alignment.

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In summary, this study supports the notion that a KTT can assist the surgeon in accurately setting the I-E rotation of the tibial component parallel to the F-E plane of the knee when performing kinematically-aligned TKA with any design of tibial component.

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Conflict of interest

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