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Internal–external malalignment of the femoral component in kinematically aligned total knee arthroplasty increases tibial force imbalance but does not change laxities of the tibiofemoral joint

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Abstract

Purpose The purposes of this study were to quantify the increase in tibial force imbalance (i.e. magnitude of difference between medial and lateral tibial forces) and changes in laxities caused by 2° and 4° of internal–external (I–E) malalignment of the femoral component in kinematically aligned total knee arthroplasty. Because I–E malalignment would introduce the greatest changes to the articular surfaces near 90° of flexion, the hypotheses were that the tibial force imbalance would be significantly increased near 90° flexion and that primarily varus–valgus laxity would be affected near 90° flexion.

Methods Kinematically aligned TKA was performed on ten human cadaveric knee specimens using disposable manual instruments without soft tissue release. One 3D-printed reference femoral component, with unmodified geometry, was aligned to restore the native distal and posterior femoral joint lines. Four 3D-printed femoral components, with modified geometry, introduced I–E malalignments of 2° and 4° from the reference component. Medial and lateral tibial forces were measured from 0° to 120° flexion using a custom tibial force sensor. Bidirectional laxities in four degrees of freedom were measured from 0° to 120° flexion using a custom load application system.

Results Tibial force imbalance increased the greatest at 60° flexion where a regression analysis against the degree of I–E malalignment yielded sensitivities (i.e. slopes) of 30 N/° (medial tibial force > lateral tibial force) and 10 N/° (lateral tibial force > medial tibial force) for internal and external malalignments, respectively. Valgus laxity increased significantly with the 4° external component with the greatest increase of 1.5° occurring at 90° flexion ($p < 0.0001$).

Conclusion With the tibial component correctly aligned, I–E malalignment of the femoral component caused significant increases in tibial force imbalance. Minimizing I–E malalignment lowers the increase in the tibial force imbalance. By keeping the resection thickness of each posterior femoral condyle to within ± 0.5 mm of the thickness of the respective posterior region of the femoral component, the increase in imbalance can be effectively limited to 38 N. Generally laxities were unaffected within the ± 4º range tested indicating that instability is not a clinical concern and that manual testing of laxities is not useful to detect I–E malalignment.

Keywords Knee replacement · Varus–valgus · Contact force · Internal–external · Alignment · Anterior–posterior · Compression–distraction · Malrotation

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Introduction

The goal of kinematically aligned total knee arthroplasty (TKA) is to restore native alignments of the limb, knee, and joint lines with the intent of restoring knee function to native without ligament release. Hence, the femoral component is kinematically aligned when the thicknesses of the distal and posterior resections of the femoral condyles are equal to the thicknesses of the corresponding portions of the femoral component after compensating for cartilage wear and kerf of the saw blade [25, 44]. However, the use of manual cutting guides and oscillating saws can lead to errors in making these resections [7, 22, 29, 46]. Internal–external (I–E) alignment of the femoral component is set by the resection thicknesses of the two posterior femoral condyles [45]. If the two resections are not equal in thickness after accounting for cartilage wear, then the femoral component will be malaligned in either internal or external rotation which can lead to condylar lift-off, pain, early implant failure, and need for revision surgery [6, 8, 14, 20, 53].

To assess the effects of I–E malalignment of the femoral component on knee function, multiple biomechanical metrics are useful. One is the tibial force imbalance between the medial and lateral compartments of the tibiofemoral joint [13, 20, 28, 42]. A second is the laxities of the tibiofemoral joint [1, 9, 17, 37, 52, 59]. These two metrics are determined by the interaction between the articular surfaces and the soft tissue restraints of the knee. Hence, changes in alignment of the articular surfaces could cause changes in the tibial force imbalance and laxities, which could adversely affect patient-reported function and satisfaction after TKA [2, 16, 17, 34, 54].

Few studies have evaluated the effects of I–E malalignment of the femoral component on tibial force imbalance and/or laxities. Two studies introduced I–E malalignments using different means and studied the effect on various laxities in cadaveric knees [1, 48]. Two other studies tested cadaveric knees with I–E malalignments but one measured the effect on orientations of the tibia on the femur during active quadriceps loading [41] and the other measured the effect on length change patterns in the medial and lateral extensor retinacula [18]. The most recent study measured both laxities and tibial force in cadaveric knees following I–E malalignments [35]. Taking a different approach than testing cadaveric knees, a final study performed a finite element analysis to assess the effect of internal rotation on stresses in the tibial polyethylene [33]. Although previous studies used various methods of aligning the tibial and femoral components, no study known to the authors has investigated tibial force imbalance and/or laxities in kinematically aligned TKA. Because kinematically aligned TKA is founded on a patient-specific alignment paradigm where the goal is to restore the native joint lines and native limb and knee alignments without soft tissue release whereas other methods of aligning components are founded on different alignment paradigms which often require soft tissue release, results from studies using other alignment methods might not apply to kinematically aligned TKA.

Accordingly, this study was conducted to quantify the increase in tibial force imbalance (i.e. magnitude of difference between medial and lateral tibial forces) and changes in laxities caused by 2° and 4° of I–E malalignment of the femoral component in kinematically aligned TKA. Changes in bidirectional laxities in four degrees of freedom, which include I–E rotation, varus–valgus (V–V) rotation, anterior–posterior (A–P) translation, and compression–distraction (C–D) translation, were of interest. Values of 2° and 4° of I-E malalignment were selected based on previous literature which has examined femoral component malalignment in vitro and in vivo [1, 18, 41, 48], a pilot test conducted in our laboratory, and the clinical experience of an experienced surgeon. Because I–E malalignment would introduce the greatest changes to the articular surfaces near 90° of flexion, the hypotheses were that the tibial force imbalance would be significantly increased near 90° flexion and that, of the eight laxities, primarily varus–valgus rotation would be affected near 90° flexion. Tibial force imbalance is a clinically relevant dependent variable of possible interest because several recent studies using alignment methods different from kinematically aligned TKA have found that patient reported outcomes are related to the tibial force imbalance [20, 27, 39]. Laxities also are a dependent variable of interest because tibial force imbalance might be detected based on laxities. Further large increases in laxities might be indicative of instability.

Materials and methods

Based on a power analysis to be described later in the Statistical Analysis subsection, ten fresh-frozen human cadaveric knees (average age = 82 years, range = 65–98 years) were included (9 males, 1 female). Each knee was screened using an anteroposterior radiograph. Specimens were excluded when there were signs of degenerative joint disease (i.e., marginal osteophytes, joint space narrowing, chondrocalcinosis, or subchondral sclerosis) or evidence of previous surgery to the knee.

The native knee was dissected and aligned in a six degree-of-freedom load application system (Fig. 1) in preparation for measuring tibial forces in the medial and lateral compartments and laxities using previously described protocols [52]. The thigh was transected 20 cm proximal and

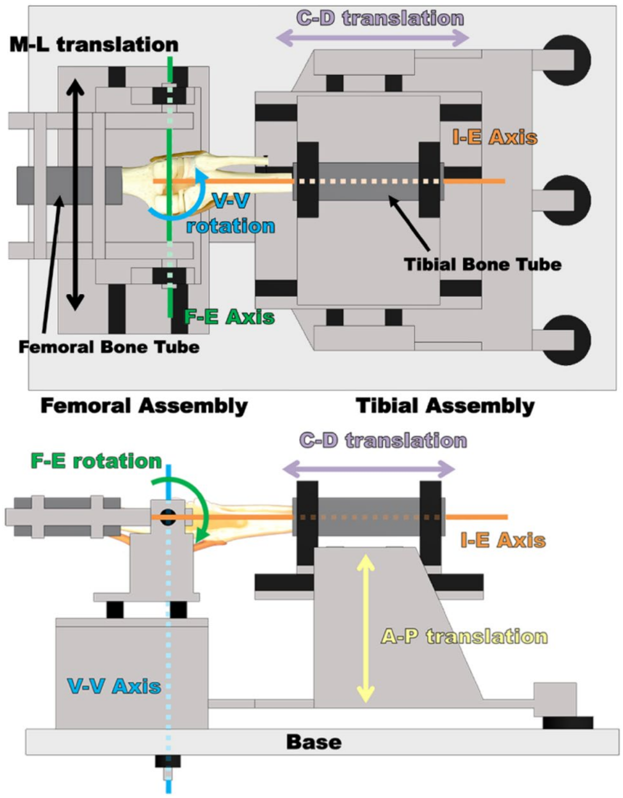

Fig. 1 Functional diagram of the custom six degree-of-freedom load application system [4]. The system consists of two independent assemblies, the femoral assembly and the tibial assembly. The system embodies the coordinate system of Grood and Suntay [19]. As such, the flexion–extension axis is fixed in the femur and the internal–external rotation axis is fixed in the tibia. The femoral assembly allows two degrees of freedom, flexion–extension (F–E) rotation and medial–lateral (M–L) translation. The tibial assembly allows internal–external (I–E) rotation, compressive–distractive (C–D) translation, varus–valgus (V–V) rotation and anterior–posterior (A–P) translation. The patella points down. The system operates under closed-loop load control with actuators for each degree of freedom except medial–lateral translation. Forces of major muscle groups crossing the knee also can be applied. Transducers include load cells for each actuator and highly accurate motion sensors (LVDTs and RVDTs) for each degree of freedom. Using a functional axis alignment procedure, the position and orientation of the femur and tibia relative to the load application system are adjusted using alignment fixtures until the F–E axis of the tibiofemoral joint, which is fixed to the femur [23], and I–E rotation axis of the tibiofemoral joint, which is fixed in the tibia [23], are closely aligned with the F–E and I–E rotation axes, respectively, of the load application system

the shank was transected 25 cm distal to the joint line of the knee. Soft tissues other than skin and fat were retained between 15 cm proximal and 12 cm distal of the joint line of the knee. To apply muscle forces, straps were sutured on to the semimembranosus/semitendinosus, quadriceps, and biceps femoris tendons. Intramedullary rods cemented into the medullary canals of the femur and tibia were attached to alignment fixtures connected to the load application system.

Subsequent to a functional axis alignment procedure [4], the shafts of the femur and tibia were cemented within square aluminum tubes, which rigidly fixed the position and orientation of the knee and enabled removal and reinsertion of the native knee and the TKA during subsequent testing in the load application system [4]. The knee was subjected to a preconditioning protocol consisting of first cycling the knee five times between ± 2.5 N m in flexion–extension (F–E) and then extending the knee under 2.5 N m to define 0° flexion [36].

Internal–external malalignment of the femoral component was simulated by modifying the design of the femoral component (Persona CR, Zimmer Biomet, Inc.) using computer-aided design software (SolidWorks 2014, Dassault Systèmes) and 3D printing the malaligned femoral components using an acrylic-like plastic (VeroWhite, Objet Eden260VS, Stratasys, Ltd.). The Persona femoral component design was modified by rotating the exterior surfaces of the femoral components relative to the interior surfaces, such that the malaligned femoral components with modified geometry and the reference femoral component with unmodified geometry could all be implanted using the same cement mantle on the same cadaveric knee specimen (Fig. 2). Five femoral components were 3D printed, with malalignments of 2° internal, 4° internal, 2° external, and 4° external, and a 0° reference femoral component with unmodified geometry. All malalignments were malrotations about the center of the femoral component. The thickness of each condyle of each 3D printed femoral component as measured with a micrometer was confirmed to be within ± 0.1 mm of the designed thickness.

A kinematically aligned TKA was performed using cruciate-retaining components (Persona CR, Zimmer Biomet, Inc, Warsaw, IN, USA) and disposable manual instruments without soft tissue release following a previously described technique [25, 45]. In brief, a mid-sagittal osteotomy of the patella exposed the knee [40]. Using distal femoral and posterior femoral reference guides, the femur was resected with the goal of maintaining the native distal and posterior femoral joint lines, respectively. The goal was accomplished by matching the thicknesses of the distal medial, distal lateral, posterior medial, and posterior lateral femoral resections as measured with a caliper to the corresponding condylar regions of the femoral component after correcting for the kerf of the saw blade [25]. The I–E rotation of the tibial component was set parallel to the F–E plane of the knee. Because the reliability of using the tibial tubercle to identify the F–E plane of the native knee has been questioned [10], the A–P axis of the tibial component was aligned parallel to F–E plane of the knee using templates which have been shown to align the A–P axis of the tibial component with a root mean squared error of 4° to the F–E plane of the knee [24]. The V–V cut for the tibial component

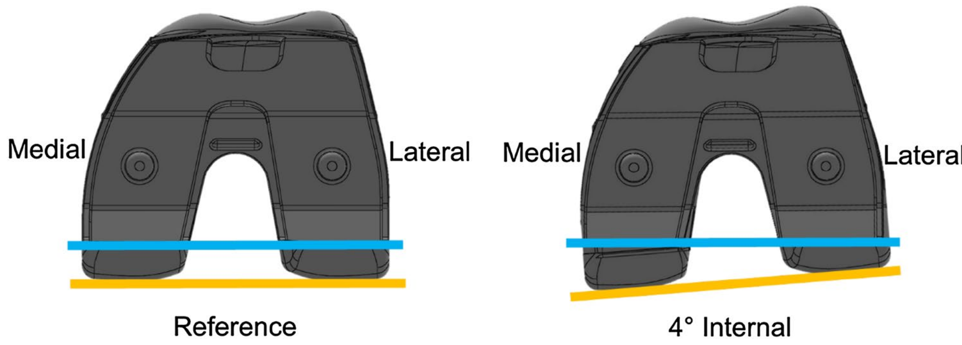

Fig. 2 Rendering of 3D models showing the axial view of the 3D-printed reference femoral component and the 3D-printed femoral component with a 4° internal malalignment. The orange line shows the orientation of the posterior joint line of the femoral component, and the blue line shows the orientation of the inside surface of the femoral component. A 4° internal rotation of the exterior surfaces relative to the interior surfaces reduced the thickness of the lateral posterior femoral condyle, increased the thickness of the medial posterior femoral condyle, and malaligned the posterior femoral joint line. Reducing the thickness of the lateral posterior condyle of the femoral component and increasing the thickness of the medial posterior condyle of the femoral component simulated an angular error in resecting the articular surfaces of the posterior femoral condyles of the bone

was adjusted after inserting trial components until there was minimal V–V laxity at 0° flexion [25, 45, 49]. The F–E cut or posterior slope for the tibial component was adjusted after inserting trial components until the A–P distance or offset between the distal medial condyle of the femoral component and the anterior cortex of the tibia measured with a caliper at 90° flexion matched that at the time of exposure [25]. After the correctly sized trial components were determined, the reference 3D-printed femoral component was coated with petroleum jelly and cemented to the distal femur. A size D Persona tibial baseplate was coated with petroleum jelly and cemented into the proximal tibia after which the correctly sized tibial insert was attached. The petroleum jelly allowed the components to be released from the cemented surfaces which enabled accurate exchanges of femoral components and the tibial force sensor described below. After the cement hardened, the components were removed. The patella was not resurfaced.

Tibial forces in the medial and lateral compartments were measured with each of the five 3D-printed femoral components using a custom tibial force sensor [51]. The tibial force sensor had the same exterior size and shape as the correctly sized Persona tibial component and insert. The tibial force sensor measured force independently in the medial and lateral compartments and over the full area of the liner with a maximum root mean squared error of 6 N [51].

The testing order of the five 3D-printed femoral components was randomized. After inserting a 3D-printed femoral component, the patellar osteotomy was closed with two transverse bone screws. To stabilize the TKA knee during flexion, constant forces of 26, 80, and 15 N were applied to the semimembranosus/semitendinosus, quadriceps, and biceps femoris tendons, respectively, which were proportional to the muscle cross-sectional area [58] and smaller than forces used to stabilize the TKA in other studies [11, 17, 26, 31, 32, 55–57]. The tibial forces in the medial and lateral compartments were measured at 30° increments as the TKA knee was moved passively from 0° to 120° flexion and back to 0°. The tibial force difference was computed as the medial tibial force minus the lateral tibial force and the tibial force imbalance was the magnitude of the difference. To negate friction effects, the force in each compartment at a particular flexion angle was the average of that during flexion and during extension [50]. After a test was completed for a 3D-printed femoral component, the patellar osteotomy was opened, a different 3D-printed femoral component was inserted, and the test was repeated.

Eight laxities were measured in four degrees of freedom with each of four malaligned femoral components and the reference femoral component using the load application system and methods described previously [52]. Because a size D keel was used in the tibia during the TKA but the correctly sized tibial baseplate might be greater than size D depending on the knee specimen, a set of tibial baseplates was 3D printed that had a size D keel with proximal mating features in sizes E–H. These 3D-printed tibial baseplates were used during laxity testing. With the correctly sized components implanted, the knee was subjected to a preconditioning protocol consisting of first passively flexing and extending the knee five times from 0° to 120° flexion. Next, the knee was moved to a flexion angle randomly selected from 0°, 60°, and 120° and then cycled five times between prescribed load limits for each degree of freedom in a random order [5]. The prescribed load limits were ± 3 N m for I–E rotation [9], ± 5 N m for V–V rotation [37], ± 45 N for A–P translation [15], and ± 100 N for C–D translation [38]. The limits of each load were selected to engage the soft tissues sufficiently to load them beyond the initial toe region of the tibiofemoral joint's load-deformation curve [15, 37]. The protocol was repeated for the remaining two flexion angles. The order of flexion angle–degree of freedom combinations was randomized. For each combination, the knee was loaded to the positive limit, loaded to the negative limit, unloaded (i.e. no applied loads other than muscle forces), loaded to the negative limit, loaded to the positive limit, and unloaded. The positive laxity was the average of the two positive limits minus the average of the two unloaded positions. The negative laxity was the average of the two negative limits minus the average of the two unloaded positions. The positive laxity and negative laxity were measured over a range of flexion angles from 0° to 120° in 30° increments.

Following University of California policies, this study did not require institutional review board (IRB) approval because de-identified cadaveric specimens were used.

Statistical analysis

A preliminary power analysis was performed using the standard deviations from the first five specimens to detect clinically important changes in laxities taken from the literature. The change in V–V laxity of 1.5° was based on a study that showed patients with osteoarthritis who reported having an unstable knee had 1.5° more V–V laxity than those that did not report instability [12]. The changes in A–P laxity and I–E laxity of 1.8 mm and 3.6°, respectively, were based on a study that showed a 40% increase in polyethylene wear when A–P translation increased by 1.8 mm and I–E rotation increased by 3.6° [30]. The change in C–D laxity of 1 mm was based on a study which reported changes in the A–P, I–E, and V–V laxities due to a change in liner thickness of 1 mm [43]. The preliminary power analysis showed that a sample size of ten specimens was necessary ($\alpha = 0.05$, $(1 - \beta) = 0.95$) to detect changes in laxities above. A post-hoc power analysis using the standard deviations from all ten specimens confirmed that a power of at least 0.97 was achieved for all laxities measured.

To determine whether I–E malalignment of the femoral component in kinematically aligned TKA caused changes in the tibial force difference, a simple linear regression was performed. The regression related the mean change in the tibial force difference at the flexion angle where the changes in the tibial force difference were greatest to the degree of I–E malalignment. The regression was performed separately for internal malalignments and external malalignments as each is likely to affect the medial and lateral structures differently due to the differences in stiffness of the soft tissue restraints [9, 21, 57].

To determine whether I–E malalignment of the femoral component in kinematically aligned TKA caused changes in laxities, a two factor repeated measures ANOVA was performed for each laxity. The two factors were femoral component malalignment at five levels (2° internal, 4° internal, 2° external, 4° external, and 0° reference) and flexion angle at five levels (0°–120° in 30° increments). Tukey's test was used to compare the means of each of eight laxities using each of four degrees of malalignment to those of the reference component. The level of significance, α, was set at 0.05.

Results

Internal and external malalignments caused increases in tibial force imbalance which were greatest at 60° flexion where the increase for internal malalignments was due to the medial tibial force increasing relative to the lateral tibial force and the increase for external malalignments was due to the lateral tibial force increasing relative to the medial tibial force (Fig. 3). The simple linear regressions between the average increase in tibial force difference at 60° flexion and degree of I–E malalignment indicated that the average increases lie nearly on a straight line with sensitivities (i.e. slopes) of 30 and 10 N/° for internal and external malalignments, respectively (Fig. 4).

There were no statistically significant changes in any of the eight laxities with the 2° malaligned femoral components (Figs. 5, 6, 7, 8). With the 4° external component, however, valgus laxity increased significantly at 60°, 90°, and 120° with the greatest change occurring at 90° flexion (1.5° ± 0.8°; $p < 0.0001$) (Fig. 5).

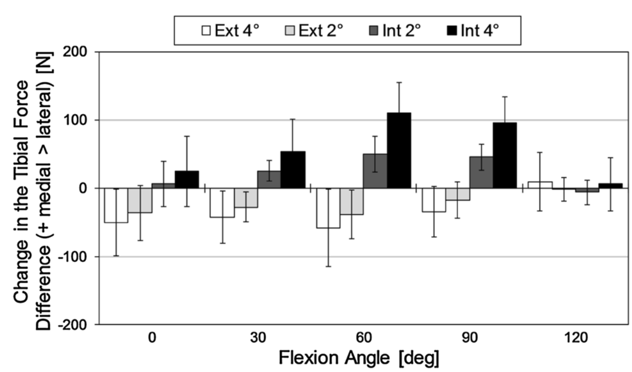

Fig. 3 Bar graph showing the mean (bar) and standard deviation (error bar) of the change in tibial force difference for each of four malaligned femoral components as a function of flexion angle. Tibial force difference was computed as medial tibial force minus lateral tibial force. The tibial force imbalance was the magnitude of the difference

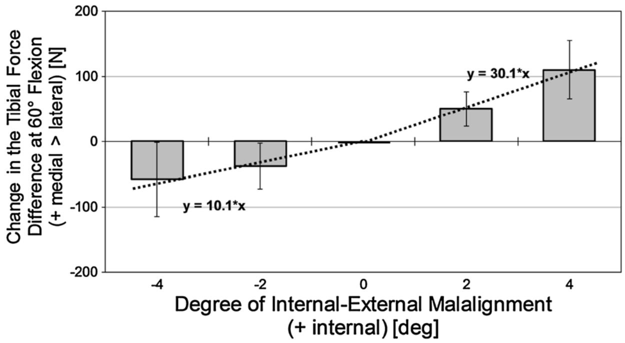

Fig. 4 Bar graph showing the mean (bars), standard deviation (error bars), and simple linear regressions of change in tibial force difference of each malaligned femoral component from the reference component and degree of I–E malalignment at 60° of flexion where the change was the greatest. The tibial force difference was computed as the medial tibial force minus the lateral tibial force and the tibial force imbalance was the magnitude of the difference. Regressions were performed separately for internal malalignments and external malalignments. Regressions were forced through 0° for the reference component

Discussion

One key finding is that I–E malalignment of the femoral component caused statistically significant increases in tibial force imbalance, which has potential clinical implications. The relationship between tibial force imbalance and patient-reported outcomes has been studied recently for mechanically aligned TKA. One study reported that patients with a tibial force imbalance less than 67 N at 10°, 45°,and 90° had better patient-reported outcome scores [20]. A second study found that tibial force imbalance (i.e. medial > lateral) greater than 45 N at extension was associated with significantly better patient-reported outcome scores [27]. A final study found that greater increase in activity level was associated with tibial force imbalance less than 67 N when averaged at 0°, 45°,and 90° [39]. Considering the preponderance of these findings, it can be concluded that a relationship may exist between tibial force imbalance and patient-reported outcomes in mechanically aligned TKA. Assuming that a relationship between tibial force imbalance and patient-reported outcomes exists for kinematically aligned TKA, surgeons performing kinematically aligned TKA should strive to minimize I–E malalignment of the femoral component to limit tibial force imbalance.

During kinematically aligned TKA, the intraoperative check to verify the I–E alignment of the femoral component is to use calipers to measure the thicknesses of the two posterior condylar bone resections [25, 45]. Ideally, the thicknesses of the bone resections should match the thicknesses of the corresponding regions on the femoral component after accounting for cartilage wear and kerf of the saw blade [25, 44]. By measuring the thicknesses of the bone resections with a caliper (Zimmer Biomet, 1 mm increments, 0.5 mm resolution) and comparing that measurement to the thicknesses of the corresponding regions of the femoral component, a difference of 0.5 mm using kinematically aligned TKA with manual instruments is achievable. Using the 30 N/deg slope of the regression line for internal malalignment (which is larger than that for external malalignment hence conservative) and recognizing that 0.8 mm added and subtracted from opposite posterior condyles of the femoral component produced 2° of I–E malalignment, a difference of 0.5 mm on each posterior condyle limits the increase in

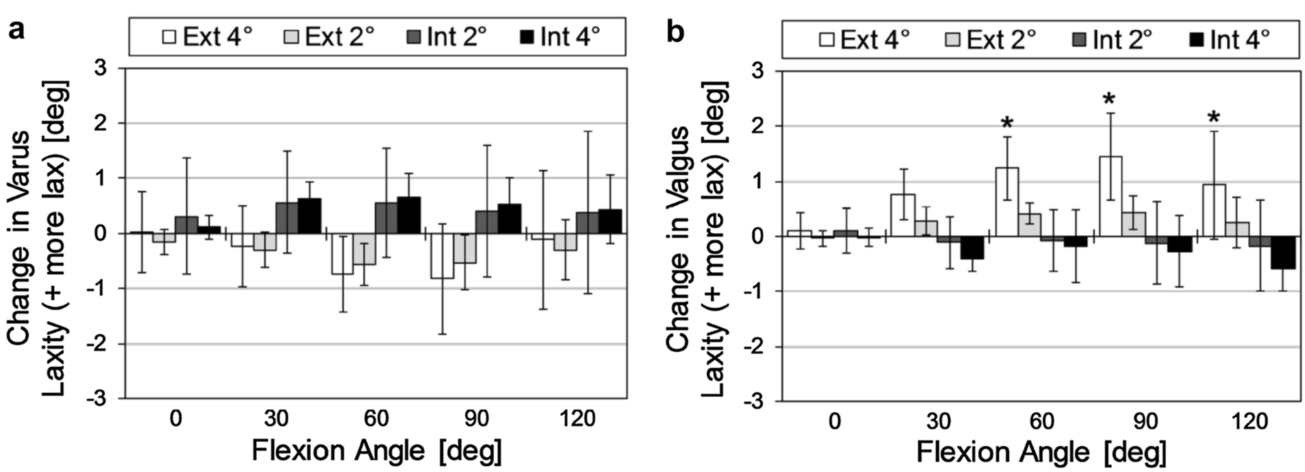

Fig. 5 Bar graphs showing the mean (bar) and standard deviation (error bar) of the change in the varus laxity of each malaligned femoral component from the reference femoral component, and change in the valgus laxity of each malaligned femoral component from the reference femoral component. Statistically significant differences based on Tukey's test ($p < 0.05$) are marked with an asterisk (*). The greatest statistically significant increase in valgus laxity occurred with the 4° external femoral component at 90° flexion

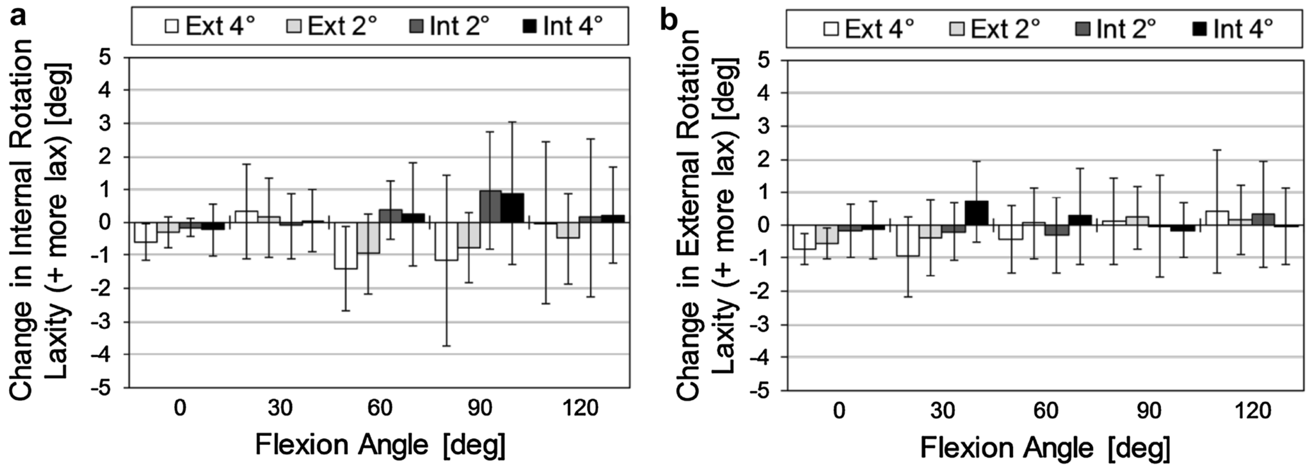

Fig. 6 Bar graphs showing the mean (bar) and standard deviation (error bar) of the change in the internal laxity of each malaligned femoral component from the reference femoral component, and change in the external laxity of each malaligned femoral component from the reference femoral component. There were no statistically significant differences in laxities between any of the malaligned femoral components and the reference femoral component

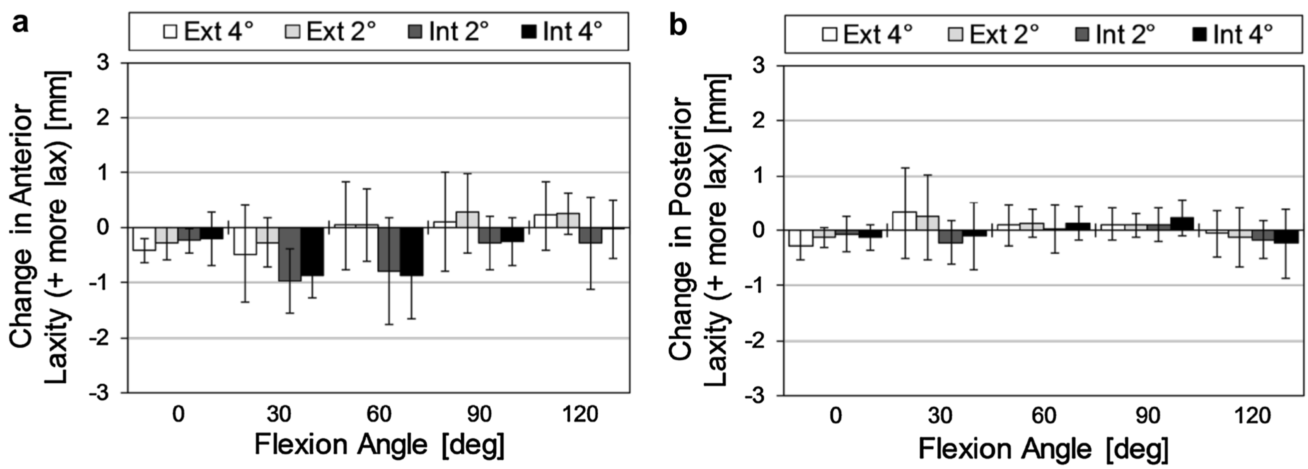

Fig. 7 Bar graphs showing the mean (bar) and standard deviation (error bar) of the change in the anterior laxity of each malaligned femoral component from the reference femoral component, and change in the posterior laxity of each malaligned femoral component from the reference femoral component. There were no statistically significant differences in laxities between any of the malaligned femoral components and the reference femoral component

tibial force imbalance to 38 N on average. Obtaining a tolerance of 0.5 mm for the thicknesses of the posterior femoral resections in kinematically aligned TKA is critical; if left uncorrected, then any correction would need to be made in the V–V angle of the tibial component which would result in malalignment of this component.

A second key finding is that 2° or 4° of I–E malalignment generally did not cause statistically significant changes in laxities. Of the four degrees of freedom tested (V–V, I–E, A–P, and C–D), laxities in the V–V degree of freedom are of high interest since soft tissue balancing addresses primarily this degree of freedom [2, 3, 47, 48, 59]. As expected, internal malalignment caused an increase in varus laxity (Fig. 5a) because material was removed on the lateral posterior condyle (Fig. 2) and a decrease in valgus laxity (Fig. 5b) because material was added in the medial posterior condyle (Fig. 2). In contrast, external malalignment caused an increase in valgus laxity (Fig. 5b) and a decrease in varus laxity with the largest changes occurring at 90° flexion (Fig. 5a). The significant increase in valgus laxity at 90° of flexion is likely due to the non-linear relationship between applied valgus moment and valgus rotation at 90° flexion [37] in conjunction with a shift in the unloaded position of 2.2° varus (i.e. the tibia was on average in 2.2° more varus at 90° of flexion with the 4° external malalignment than with the

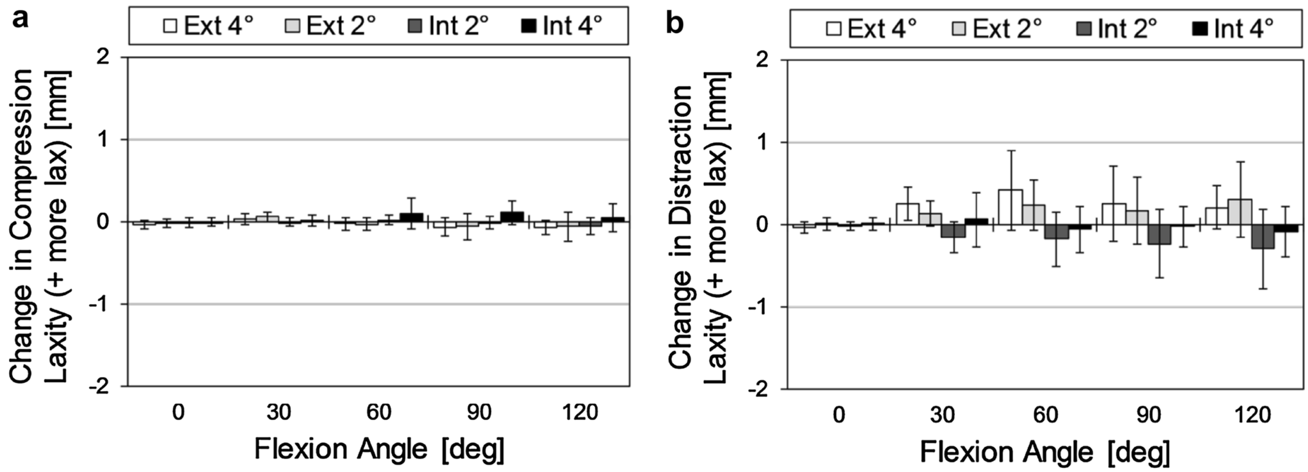

Fig. 8 Bar graphs showing the mean (bar) and standard deviation (error bar) of the change in the compression laxity of each malaligned femoral component from the reference femoral component, and change in the distraction laxity of each malaligned femoral component from the reference femoral component. There were no statistically significant differences in laxities between any of the malaligned femoral components and the reference femoral component

reference component). Significant effects on V–V laxity in the range 0°–30° flexion were not expected and were not observed because the distal surfaces of the femoral condyles, rather than the posterior surfaces, are in contact with the tibial component, and the distal surfaces were not malaligned.

A caveat should be made in attaching clinical importance to the significant finding of an increase in valgus laxity at 90° for the 4° valgus malaligned femoral component. Laxity measured in patients with osteoarthritic knees who reported that V–V instability severely limited their activity increased by 4° total (i.e. 2° increase in each of varus and valgus) at 25° flexion over those patients reporting no instability [12]. Although varus laxity increases by 50% in going from 25° to 90° flexion, valgus laxity remains constant [49]. Accordingly, it could be reasonably expected that the increase in laxity at 90° flexion rendering the knee unstable would be comparable to that at 25° flexion. Making this assumption and recognizing that the 1.5° increase in valgus laxity is less than 2°, it can be argued that, although statistically significant, this increase is not clinically important. Further it should be noted that an I–E malalignment of 4°, although possible, is unlikely to go undetected and hence uncorrected in practice as long as the simple quality assurance check of measuring the thickness of the posterior femoral condyle resections with calipers is performed intraoperatively [25, 45]. This is because an I–E malalignment of 4° equates to a resection error of approximately 1.6 mm on each posterior femoral condyle and this error can be readily detected with calipers. In any case, because none the eight laxities showed a significant and clinically important increase, manually checking laxities to detect I–E malalignment of the femoral component may not be a reliable method and instability resulting from large increases in laxities is not a clinical concern.

In comparing the findings reported herein to those of previous studies, perhaps the most relevant previous study is that by Manning et al. who measured both laxities and tibial forces following I–E malalignments [35]. Similar to the findings herein, this previous study reported no significant increase in laxities and a significant increase in medial compartment tibial force for internal malalignment beyond 60° flexion. However, in contrast to the findings herein, this previous study reported no increase in lateral compartment tibial force for external malalignment. This disparity in results is likely due to the differences in surgical technique; among the differences the previous study used measured resection to rotationally align the femoral component, anterior referencing to size the femoral component, and soft tissue release whereas the current study used kinematic alignment, posterior referencing, and no soft tissue release. This disparity in results emphasizes that conclusions drawn from one surgical technique cannot be generalized to other surgical techniques.

Several potential limitations should be discussed. One concerns the coefficient of friction of the 3D printed femoral components on the ultra-high molecular weight polyethylene (UHMWPE) tibial liner. Because the femoral components were 3D printed out of an acrylic-like plastic which differs from femoral components used in TKA that typically are made of cobalt-chrome, the difference in the coefficients of friction could affect the laxities. However, any effect was systematic and would likely not change the conclusions of the present study because differences from the reference were of interest. Additionally, each femoral component was wet sanded with superfine (i.e., 1000-grit) sandpaper and a thin film of bovine serum was applied as a lubricant before testing. A pilot study showed that the static coefficient of friction of a lubricated 3D femoral component on UHMWPE ($\mu = 0.18$) was close to that of the cobalt-chrome femoral component on UHMWPE ($\mu = 0.14$).

A second potential limitation concerns the forces applied to the muscles. Using muscle forces with different magnitudes might affect the changes in tibial forces and laxities. Accordingly, the muscles forces were kept as small as possible while still maintaining stability of the knee. This allowed soft tissue restraints to have as much relative contribution to knee stability as possible. The muscle forces used in the present study were small relative to muscle forces used in previously published in vitro studies [11, 26, 31, 32, 55–57]. Moreover, because differences in tibial forces and changes in laxities were of interest, the effect of muscle forces was systematic and negated in computing differences/changes. Hence, the use of small muscle forces in conjunction with analysis of differences/changes minimized the effect of muscle forces on the results.

In addition, the use of small load limits might have affected the changes in laxities. The load limits of ± 5 N m for V–V moment [37], ± 3 N m for I–E torque [9], ± 45 N for A–P force [15], and ± 100 N for C–D force confined the laxity measurements to the low stiffness region of the load–displacement curve [15]. Confining the laxity measurements to the low stiffness region was done purposely because any instability as a result of increasing laxity should manifest in the low stiffness regions.

The I–E malalignments were created by rotating about the center of the reference femoral component. Creating I–E malalignments by rotating about the peripheral edge of one condyle of the femoral component instead of the center could affect the results. However, rotating about the center of the reference femoral component isolated the I–E malalignment as an independent variable for study. Rotating about the peripheral edge would have introduced not only I–E malalignment but also anterior–posterior malalignment.

A final limitation, which is intrinsic in any study that malaligns the femoral component and determines the effects on tibiofemoral laxities and tibial forces, is that the effects do not apply when the alignment of the tibial component is different from that in the study. Hence the results and their interpretation in the present study apply only when the tibial component is correctly aligned. The requirements and corresponding procedures for correctly aligning the tibial component were described earlier in the methods.

The clinical relevance of the results is that I–E malalignment of the femoral component in kinematically aligned TKA should be avoided to limit increases in tibial force imbalance. Measuring laxities intraoperatively is not useful for detecting tibial force imbalance. Accordingly some other quantity should be measured such as tibial forces using an appropriate sensor. However, high increases in tibial force imbalance can be effectively prevented by measuring the thicknesses of the posterior femoral resections with a caliper and insuring that these thicknesses are within 0.5 mm of the corresponding thickness of the posterior regions of the femoral component. Instability resulting from large increases in laxity is not a clinical concern and manual testing of laxities is not useful to detect I-E malalignment.

Conclusion

Significant increases in tibial force imbalance, which were most pronounced at 60° flexion, occurred for I–E malalignment of the femoral component. The slope of the regression line was greater for internal than external malalignments. Based on the slope for internal malalignments, the increase in imbalance can be effectively limited to 38 N by keeping differences in resection thickness to within ± 0.5 mm of the thickness of the respective posterior region of the femoral component. Additionally, none of eight increases in laxities was statistically significant and clinically important.

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Compliance with ethical standards

Conflict of interest J. D. Roth has a postdoctoral fellowship from Think Surgical, S. M. Howell is a paid consultant for Think Surgical and Medacta and receives royalties from Zimmer-Biomet. M. L. Hull receives research funding from Zimmer-Biomet.

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Informed consent N/A

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