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Exhibit Selection

How Frequently Do Four Methods for Mechanically Aligning a Total Knee Arthroplasty Cause Collateral Ligament Imbalance and Change Alignment from Normal in White Patients?

AAOS Exhibit Selection

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Background: Mechanically aligned total knee arthroplasty can create a tight collateral ligament in 0° of extension, instability in a compartment between 0° of extension and 90° of flexion that is uncorrectable by collateral ligament release, and changes in limb and knee alignment from normal. The goal of the present study was to calculate the frequency and range of these undesirable consequences.

Methods: Four methods of mechanically aligned total knee arthroplasty were simulated on fifty normal three-dimensional bone models of the lower extremity from white subjects. Each method resected the distal aspect of the femur and proximal aspect of the tibia perpendicular to their respective mechanical axes. Setting the posterior joint line perpendicular to the anteroposterior axis of the trochlear groove (Method 1), parallel to the transepicondylar axis (Method 2), externally rotated 3° with respect to the posterior condylar axis (Method 3), and parallel to the tibial resection in 90° of flexion with the use of gap-balancing (Method 4) aligned internal-external rotation of the femoral component.

Results: The proportion of total knee arthroplasties requiring a ≥2-mm release of a tight collateral ligament was 34% for the medial collateral ligament and 30% for the lateral collateral ligament. The proportion of total knee arthroplasties with ≥2 mm of instability between 0° of extension and 90° of flexion was 56% in the medial compartment and 6% in the lateral compartment for Method 1, 74% and 6% for Method 2, and 42% and 0% for Method 3. Method 4 did not cause ligamentous instability. The proportion of arthroplasties with a ≥2° change from normal was 58% for limb alignment and 58% for knee alignment.

Conclusions: Surgeons should be aware that, when using the four methods of mechanically aligning a total knee arthroplasty, they will frequently have to manage a wide range of collateral ligament imbalances that are complex, cumulative, and uncorrectable by collateral ligament release, and a wide range of changes in limb and knee alignment from normal. Patients who perceive these changes in stability, limb alignment, and knee alignment may be dissatisfied and require counseling.

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There are four usual methods for mechanically aligning a total knee arthroplasty. Each method resects the distal aspect of the femur and proximal aspect of the tibia perpendicular to their mechanical axes with the goal of restoring neutral alignment to the limb in the coronal plane. Each method uses a different strategy for aligning internal and external rotation of the femoral component. The posterior joint line of the femoral component can be set perpendicular to the anteroposterior axis of the trochlear groove (Whiteside line)[1], parallel to the transepicondylar axis[2,3], externally rotated 3° with respect to the posterior condylar axis[4], or parallel to the tibial resection to create a balanced rectangular gap in 90° of flexion[5].

Mechanically aligning a total knee arthroplasty can cause two types of collateral ligament imbalance. One is a tight collateral ligament in 0° of extension, which occurs when the resection of the distal aspect of the femur and proximal aspect of the tibia forms a trapezoidal gap (Fig. 1). The compartment with the tight collateral ligament in 0° of extension has the least thickness of bone removed from the distal aspect of the femur and proximal aspect of the tibia. The magnitude of the release of the tight collateral ligament needed to create a balanced rectangular gap in 0° of extension is the difference between the sum of the thicknesses of the bone removed from the distal aspect of the femur and proximal aspect of the tibia in the medial compartment and the sum of the thicknesses in the lateral compartment.

The second type of collateral ligament imbalance is instability in a compartment between 0° of extension and 90° of flexion that is uncorrectable by collateral ligament release

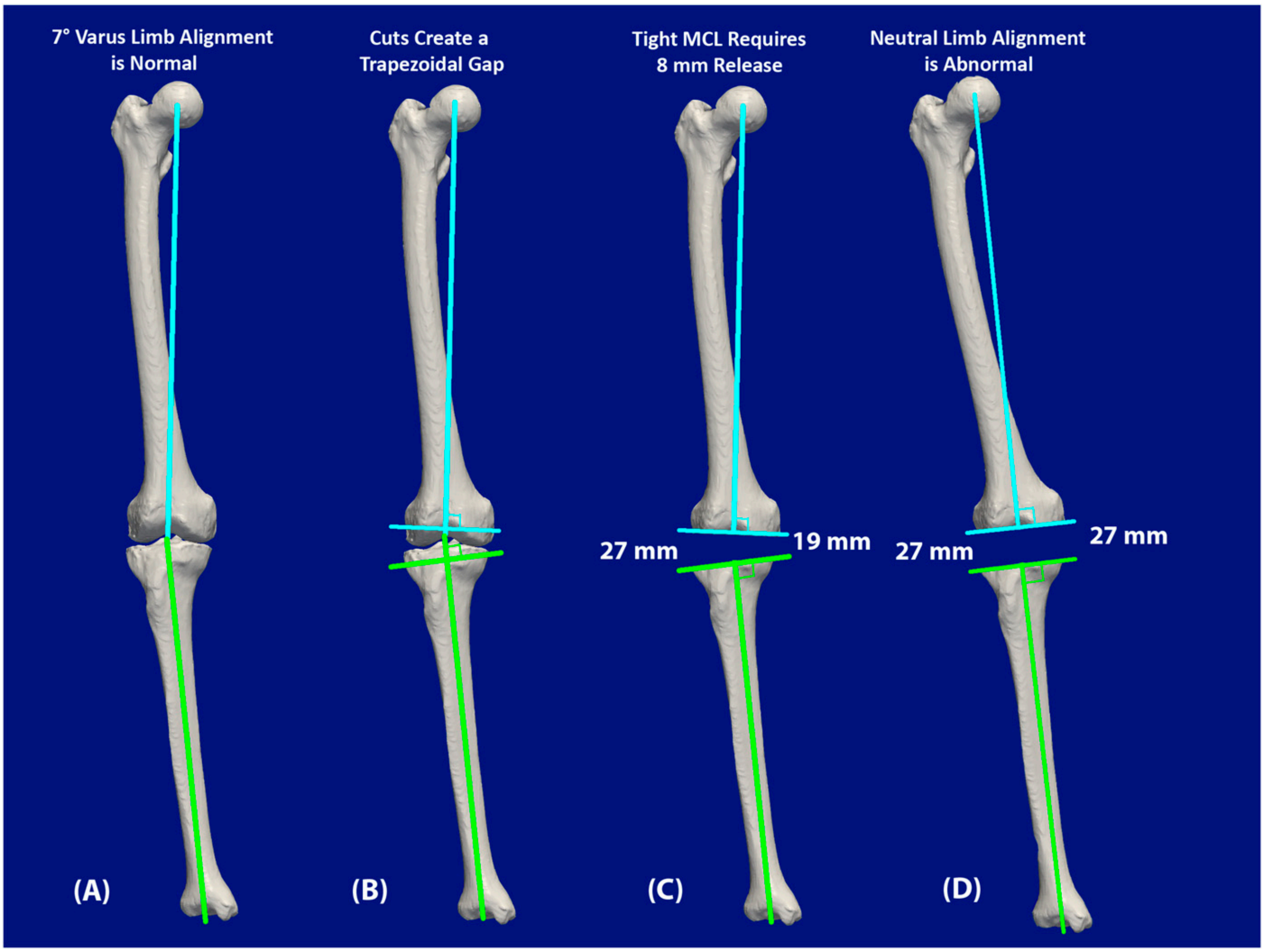

Fig. 1

Figs. 1-A through 1-D Illustrations showing the method for identifying the side of the tight collateral ligament and calculating the magnitude of the collateral ligament release in 0° of extension required to create a balanced rectangular extension gap. MCL = medial collateral ligament. **Fig. 1-A** The 7° varus alignment of a normal right lower limb projected in the coronal kinematic plane. **Fig. 1-B** Cutting the distal aspect of the femur and proximal aspect of the tibia perpendicular to their mechanical axes creates a trapezoidal gap. **Fig. 1-C** The combined thickness of the distal aspect of the femur and proximal aspect of the tibia is 27 mm in the lateral compartment and 19 mm in the medial compartment. **Fig. 1-D** An 8-mm release of the MCL is needed to create a balanced rectangular gap; this changes the alignment of the limb 7° from normal to neutral, which might be perceived as abnormal by the patient.

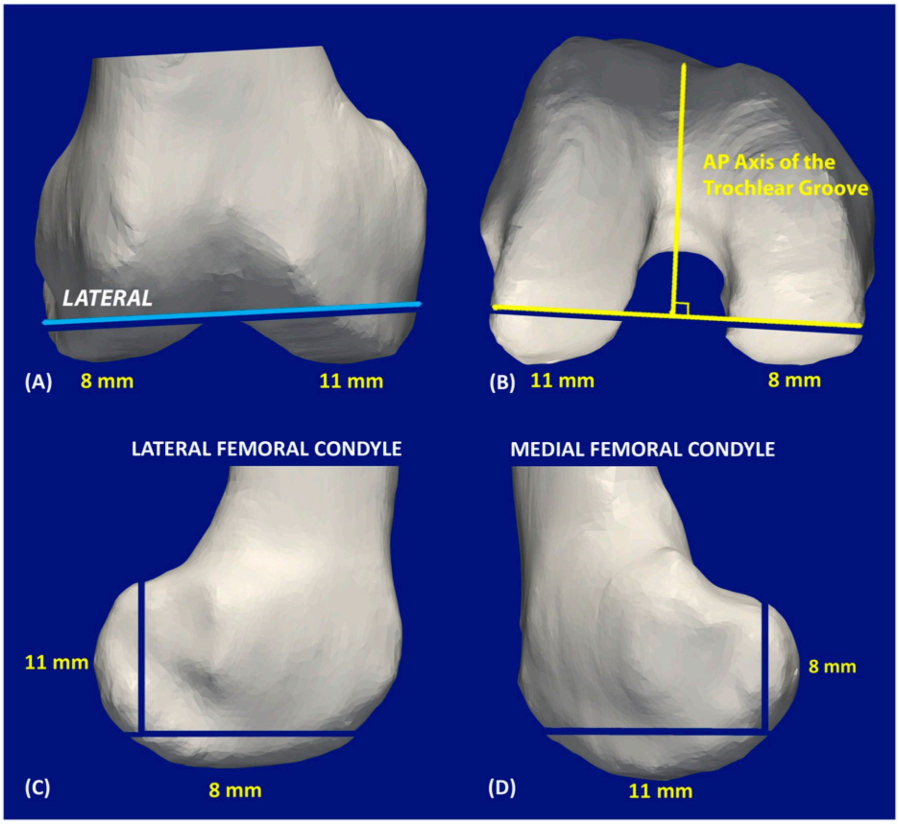

Fig. 2

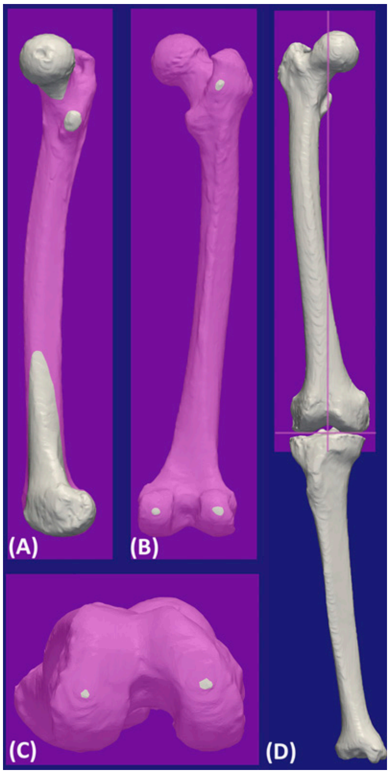

Fig. 3

Figs. 2-A through 2-D Illustrations of the distal aspect of a right femur showing the method for calculating the instability in a compartment between 0° of extension and 90° of flexion that is uncorrectable by a collateral ligament release. This instability occurs in a compartment when the thicknesses of the distal and posterior femoral resections (after adjusting for cartilage wear) are not equal to the thicknesses of the distal and posterior regions of the femoral component condyles. AP = anteroposterior. **Fig. 2-A** The distal aspect of the femur showing an 8-mm distal lateral resection and an 11-mm distal medial resection. **Fig. 2-B** The posterior aspect of the femur showing an 11-mm posterior lateral resection and an 8-mm posterior medial resection. **Fig. 2-C** Assuming the use of a femoral component with an 8-mm thickness of the distal and posterior regions of the condyles, the lateral compartment has a stable gap in 0° of extension and a 3-mm loose gap in 90° of flexion. **Fig. 2-D** The medial compartment has a 3-mm loose gap in 0° of extension and a stable gap in 90° of flexion. Therefore, the instability in each compartment is uncorrectable by a collateral ligament release. **Figs. 3-A through 3-D** Illustrations of a right lower limb showing the method for projecting the limb in the sagittal, coronal, and axial kinematic planes. **Fig. 3-A** With the tibia hidden, the femur is projected in the sagittal kinematic plane by superimposing the articular surface of the femoral condyles. **Fig. 3-B** The femur is projected in the coronal kinematic plane by aligning the most posterior points on the femoral condyles and greater trochanter that are tangent to the viewing plane. **Fig. 3-C** The distal aspect of the femur is projected in the axial kinematic plane by rotating the femur perpendicular to the other two viewing planes and aligning the most distal points of the femoral condyle that are tangent to the viewing plane. **Fig. 3-D** The tibia is unhidden, the rotational transformations that had been used to align the femur are applied to the tibia, and the limb is projected in the coronal kinematic plane for the simulations.

(Fig. 2). This instability occurs in a compartment when the thicknesses of the distal and posterior femoral resections (after adjusting for wear) are not equal to the thicknesses of the distal and posterior regions of the femoral component condyles. If the thicknesses of the distal and posterior regions of the femoral component condyles are equal, and if a compartment has a distal femoral resection that is thinner than the posterior femoral resection, then the gap in 0° of extension will be tighter than the gap in 90° of flexion. A release of the collateral ligament of that compartment to relieve the tightness in 0° of extension and create a balanced rectangular gap would further increase the instability in 90° of flexion, assuming that releasing a collateral ligament would increase the gap by a constant amount between 0° of extension and 90° of flexion[6,7].

Mechanically aligning a total knee arthroplasty can change the alignment of the limb and knee from normal, as few normal limbs have a neutral axis[8-10]. A change in either limb or knee alignment from normal might be perceived by the patient as unnatural[8,11].

We are unaware of any studies that have characterized the frequency and magnitude of collateral ligament tightness in 0° of extension, instability in a compartment between 0° of extension and 90° of flexion that is uncorrectable by collateral ligament release, and changes in limb alignment and knee alignment from normal. Characterizing the frequency of a ≥2-mm change in collateral ligament balance or ≥2° change in alignment is of interest because a change of this magnitude may be undesirable to the surgeon and patient. The present analysis simulated four methods for mechanically aligning a total knee arthroplasty, using three-dimensional bone models of normal limbs from white individuals, and calculated the frequency and range of these undesirable collateral ligament imbalances and alignment consequences.

Methods and Materials

After being exempted from institutional review board approval, fifty normal three-dimensional bone models of the lower extremity of white subjects were created from computed tomograms with a slice thickness of 1 mm. Each model had a complete femoral head and distal tibial plafond and showed no evidence of arthritis, fracture, internal fixation, or a joint replacement. The mean age (and standard deviation) of the subjects was 50 ± 15 years (range, twenty-three to eighty-one years). Twenty-seven subjects were male and twenty-three were female.

ParaView open-source software (version 3.8.1, 64-bit; Kitware, Clifton Park, New York) was used to perform the simulations of the four methods for mechanically aligning a total knee arthroplasty and the subsequent calculations of collateral ligament imbalance and the change in limb and knee alignment from normal. To establish a clinically applicable and repeatable projection from which to make the measurements, the simulations were performed on the limb projected in the sagittal, coronal, and axial kinematic planes (Fig. 3)[9,11-14].

The simulation of mechanically aligning the limb in the coronal plane was performed by means of the following steps. A line from the center of the femoral head to the center of the distal aspect of the femur at the middle of the intercondylar notch defined the mechanical axis of the femur[15]. A line from the center of the proximal aspect of the tibia, at the midpoint between the two tibial spines, to the center of the distal tibial plafond defined the mechanical axis of the tibia (Fig. 1)[15]. The angle between the mechanical axes of the femur and tibia quantified the limb alignment, and the angle between a line bisecting the distal one-fourth of the femur and a line bisecting the proximal one-fourth of the tibia quantified the knee alignment (with negative indicating varus and positive indicating valgus in both cases)[16].

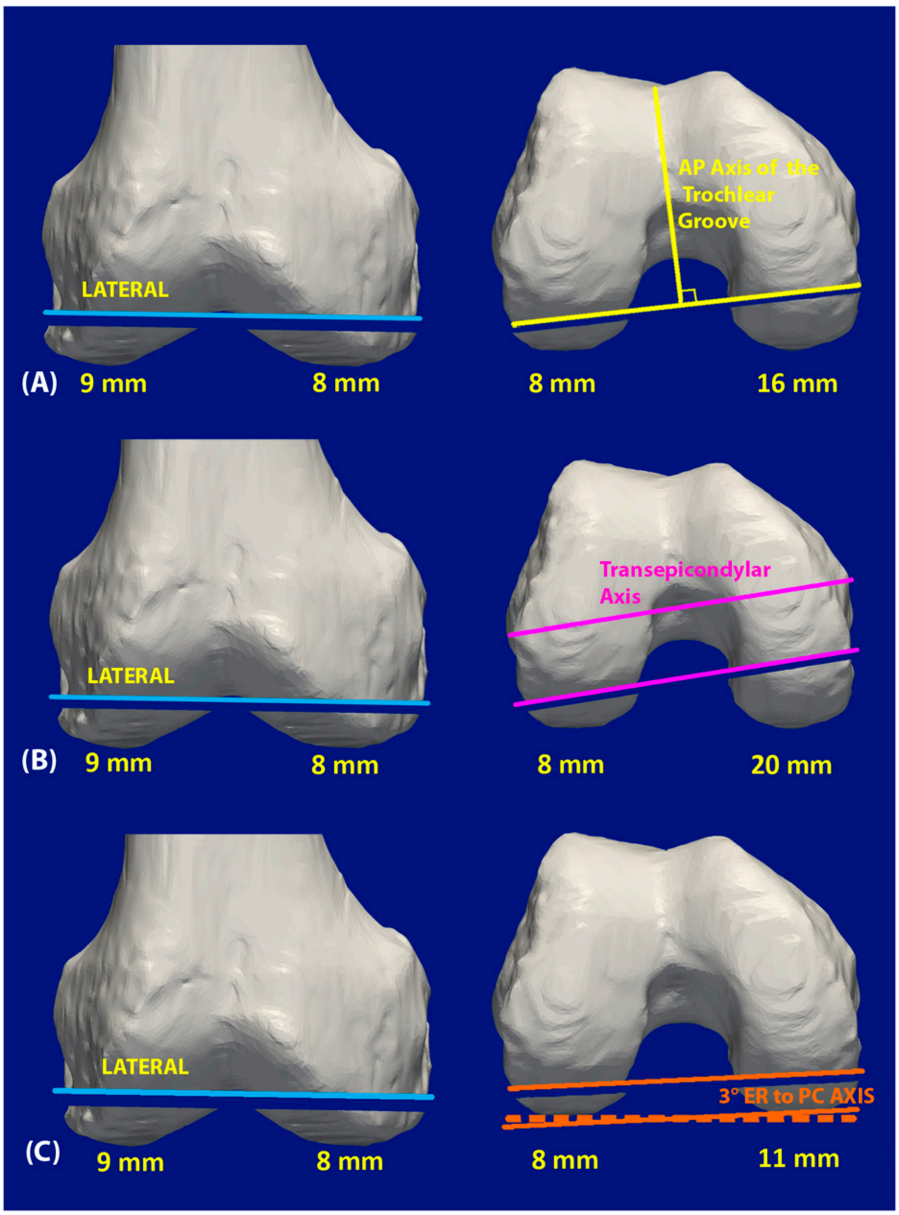

Fig. 4
Illustrations showing the distal aspect of a right femur projected in the coronal (left) and axial (right) kinematic planes and the differences between the thicknesses of the distal and posterior femoral resections for three methods of mechanical alignment. The internal-external rotation of the femoral component is aligned by setting the posterior joint line perpendicular to the anteroposterior (AP) axis of the trochlear groove (Whiteside line) (**Fig. 4-A**), parallel to the transepicondylar axis (**Fig. 4-B**), and externally rotated (ER) 3° with respect to the posterior condylar (PC) axis (**Fig. 4-C**).

With the extremity viewed in the coronal kinematic plane, the distal aspect of the femur and proximal aspect of the tibia were cut perpendicular to their respective mechanical axes. A femoral component with an 8-mm thickness of the distal and posterior regions of the femoral condyles and a tibial component with 9-mm-thick medial and lateral condyles were used for the simulation. For this component design, the minimum thickness of the bone resection from the distal region of a femoral condyle was therefore 6 mm, which equaled the 8-mm thickness of the corresponding region of the femoral component condyle after accounting for a mean articular cartilage thickness of 2 mm[17]. The thickness of the distal resection of the other femoral condyle was measured. The slope of the tibial resection was set parallel to the slope of the lateral tibial plateau in the sagittal kinematic plane. The minimum thickness of the bone resection of a tibial condyle was 7 mm at the center, which equaled the 9-mm thickness of the tibial component after accounting for a mean articular cartilage thickness of 2 mm[17]. The thickness of the resection of the other tibial condyle was measured.

In the four simulations, alignment of the internal and external rotation of the femoral component was performed by setting the posterior joint line perpendicular to the anteroposterior axis of the trochlear groove (Whiteside line), parallel to the transepicondylar axis, externally rotated 3° with respect to the posterior condylar axis, or parallel to the tibial resection after balancing the gap in 0° of extension (Fig. 4). The anteroposterior axis of the trochlear groove was defined by a line drawn through the deepest point on the trochlear groove and the center of the intercondylar notch[1]. The transepicondylar axis was defined by fitting a cylinder to the distal and posterior articular surfaces of the femoral condyles with the knee in extension and then elongating the cylinder along its axis and perpendicular to the sagittal kinematic plane until only a point of bone remained on the medial and lateral condyles[15]. The 3° externally rotated line was drawn in the axial kinematic plane at an angle of 3° relative to a line tangent to the posterior regions of the condyles[4]. In the gap balancing technique, the knee was flexed from 0° of extension to 90° of flexion while maintaining the same distraction required to establish a balanced rectangular gap after lengthening a tight collateral ligament with the knee in 0° of extension; the posterior regions of the femoral condyles were then resected parallel to the tibia. The minimum thickness of the bone resection from the posterior region of the femoral condyle was 6 mm, which equaled the 8-mm thickness of the condyle of the femoral component after accounting for a mean articular cartilage thickness of 2 mm[17]. The thickness of the resection of the posterior region of the other femoral condyle was measured.

The need for a collateral ligament release was assessed; if needed, the ligament requiring release was identified and the magnitude of the release required to correct a tight collateral ligament in 0° of extension and create a balanced rectangular gap was calculated (Fig. 1). For each condyle, the presence of instability in the medial and lateral compartments between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release was assessed; if present, the magnitude of the instability was calculated (Fig. 2). The changes in limb and knee alignment from normal were calculated.

Statistical Analysis

To determine the reproducibility of the measurements, three observers independently performed the total knee arthroplasty simulations using each of the four alignment methods on ten specimens randomly selected from the fifty bone models. For each alignment method, analysis of variance was used to determine the intraclass correlation coefficient (ICC) for the calculation of the collateral ligament release in 0° of extension, the instability in a compartment between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release, and the changes in limb and knee alignment. JMP software (version 10.0.2 for Macintosh; SPSS Inc., Chicago, Illinois) was used to calculate the descriptive statistics and the ICCs.

Source of Funding

There was no external funding source for this study.

Results

A tight collateral ligament requiring a release of ≥2 mm to create a balanced rectangular gap in 0° of extension occurred in 64% of the mechanically aligned total knee arthroplasties, with 34% requiring a ≥2-mm release of the medial collateral ligament and 30% requiring a ≥2-mm release of the lateral collateral ligament (Fig. 5).

A ≥2-mm instability in the medial compartment between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release occurred in 56% of the arthroplasties with the femoral component aligned perpendicular to the anteroposterior axis of the trochlear groove (instability range, 2 to 8 mm), 74% of the arthroplasties with the femoral component aligned parallel to the transepicondylar axis (range, 2 to 12 mm), and 42% of the arthroplasties with the femoral component externally rotated 3° with respect to the posterior condylar axis (range, 2 to 5 mm) (Fig. 6). A ≥2-mm instability in the lateral compartment between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release

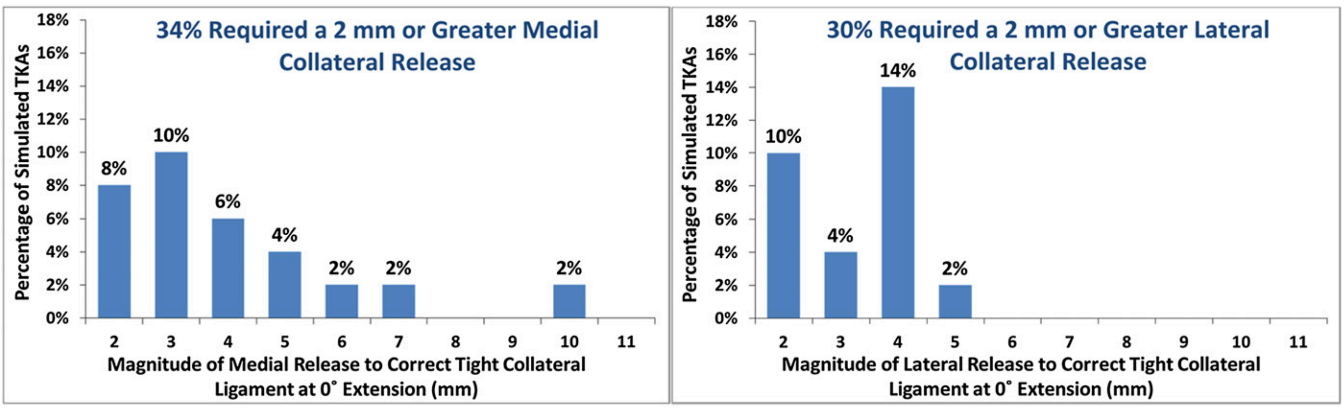

Fig. 5

Histograms showing the percentage of simulated mechanically aligned total knee arthroplasties (TKAs) with a ≥2-mm release of the medial or lateral collateral ligament to correct a tight collateral ligament in 0° of extension and create a balanced rectangular gap. A medial collateral ligament release ranging from 2 to 10 mm was required in 34% of limbs (left). A lateral collateral ligament release ranging from 2 to 5 mm was required in 30% of limbs (right).

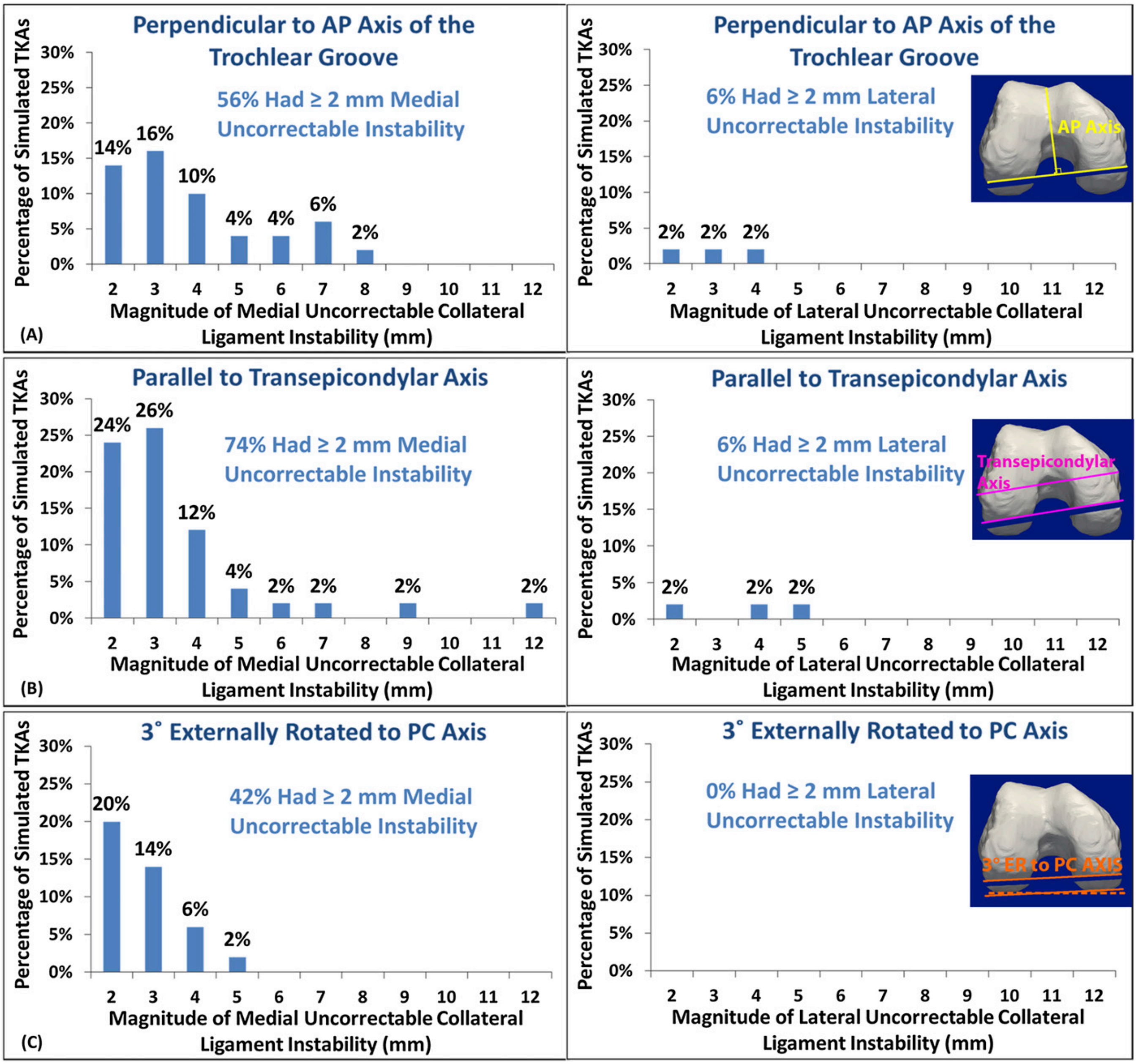

Fig. 6

Histograms showing the percentage of simulated total knee arthroplasties (TKAs) with a ≥2-mm instability in a compartment between 0° of extension and 90° flexion that is uncorrectable by collateral ligament release when mechanical alignment was performed by setting the posterior joint line of the femoral component perpendicular to the anteroposterior (AP) axis of the trochlear groove (Whiteside line) (**Fig. 6-A**), parallel to the transepicondylar axis (**Fig. 6-B**), and externally rotated (ER) 3° with respect to the posterior condylar (PC) axis (**Fig. 6-C**). Instability did not occur with use of the gap-balancing method because the distal and posterior femoral resections equaled the thickness of the distal and posterior regions of the femoral component condyles.

occurred in 6% of the arthroplasties with the femoral component aligned perpendicular to the anteroposterior axis of the trochlear groove (instability range, 2 to 4 mm), 6% of the arthroplasties with the femoral component aligned parallel to the transepicondylar axis (range, 2 to 5 mm), and 0% of the arthroplasties with the femoral component externally rotated 3° with respect to the posterior condylar axis. Instability in the medial and lateral compartments between 0° of extension and 90° of flexion did not occur with the gap-balancing technique.

The changes in limb alignment and knee alignment were the same in each patient. A ≥2° change in alignment from normal was observed in 58% of the limbs and 58% of the knees. The change in alignment ranged from −4° (i.e., in the varus direction) to 7° (in the valgus direction), with a mean change of 3° in the valgus direction (Fig. 7).

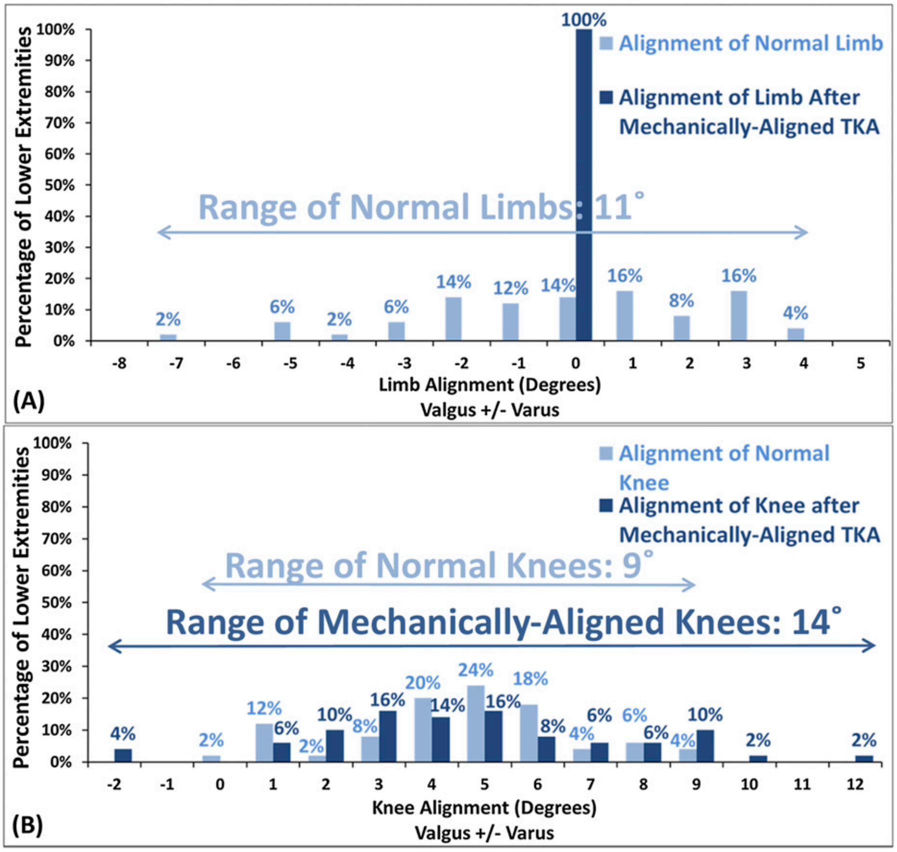

Fig. 7

Histograms showing the range of limb alignment (**Fig. 7-A**) and knee alignment (**Fig. 7-B**) of the normal extremity before and after simulating a mechanically aligned total knee arthroplasty (TKA). The change in alignment from the normal to the neutral limb ranged from −4° (in the varus direction) to 7° (in the valgus direction), which some patients might perceive as unnatural. Mechanically aligning the TKA reduced the normal range of limb alignment from 11° to neutral and paradoxically increased the range in knee alignment from 9° (0° to 9° [valgus]) to 14° (−2° [varus] to 12° [valgus]).

The ICC determined from independent calculations made by the three observers ranged from 0.71 to 0.98 for the collateral ligament tightness in 0° of extension, the instability in a compartment between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release, and the changes in limb and knee alignment. These high ICC values indicate high reproducibility among the calculations made by the three observers.

Discussion

One-fifth of patients with a mechanically aligned total knee arthroplasty report dissatisfaction as a result of instability, stiffness, or unexplained pain[18-20]. The present analysis simulated four methods for mechanically aligning a total knee arthroplasty and determined the frequency and magnitude of two types of collateral ligament imbalance and of changes in limb and knee alignment from normal. A collateral ligament imbalance of ≥2 mm and a change in alignment of ≥2° were both considered "large" because surgeons exchange tibial liners that differ by increments of 1 and 2 mm in thickness to fine-tune stability and alignment and because patients might perceive changes of this magnitude as unnatural and express dissatisfaction[21-23]. The most important findings were that mechanically aligning a total knee arthroplasty typically resulted in a wide range of tightness in the medial or lateral collateral ligament in 0° of extension, a wide range of instability in the medial and lateral compartments between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release, and a wide range of changes in limb and knee alignment from normal.

Five limitations should be discussed before interpreting the findings of our study. First, the axial rotational position of the knee varies with respect to the hip and the ankle and affects the projection of the lower extremity and measurement of component, limb, and knee alignment[6,16,22]. In the present study, the use of a standard and functional projection of the extremity in the three kinematic planes to perform the simulation of the total knee arthroplasty and subsequent calculations minimized this limitation. Second, the high intraclass correlations for each of the four methods indicated that the simulation was more reproducible for aligning the internal-external rotation of the femoral component compared with the use of traditional or navigated instruments[4]. The rotational error with traditional and navigated instruments has been reported to range from 13° of internal rotation to 16° of external rotation[4], which indicates that the range of instability in a compartment between 0° of extension and 90° of flexion that is uncorrectable by collateral ligament release is likely to be much greater in clinical practice than in the present study. Third, a surgeon using this method to assess instability in a compartment between 0° of extension and 90° of flexion that is uncorrectable by collateral ligament release must both know and account for the thicknesses of the condyles of the femoral component to determine whether a resection of the distal and posterior regions of the femoral condyles creates a tight or loose gap in 0° of extension and 90° of flexion (Fig. 2). Fourth, the instability between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release was calculated with the assumption that releasing a collateral ligament would increase the gap in that compartment by a constant amount between 0° of extension and 90° of flexion[6,7]. This is a reasonable assumption because little evidence has indicated that selective release of the collateral ligaments to create more varus-valgus laxity at one flexion angle than at another can be achieved with millimeter accuracy[24]. Finally, the results of this analysis of limbs from white subjects might be different from the results for other ethnic groups such as the Asian population, which has a higher prevalence of varus knees[25].

One important finding is that mechanically aligning a total knee arthroplasty frequently creates tightness in the medial or lateral collateral ligament in 0° of extension that requires a release to create a balanced rectangular gap, and the magnitude of the release varies widely. Although some surgeons believe that only severely deformed arthritic knees are likely to have lax or tight collateral ligaments after total knee arthroplasty, our results indicate that even in two-thirds of arthritic knees with mild deformities, the surgeon should be prepared to release the medial collateral ligament by 2 to 10 mm or the lateral collateral ligament by 2 to 5 mm to establish a balanced rectangular gap in 0° of extension. In varus knees, the use of multiple punctures was reported to achieve a "successful" lengthening of the medial collateral ligament that ranged from 2 to 4 mm in 0° of extension and 2 to 6 mm in 90° of flexion[26]. Therefore, the release of a collateral ligament is imprecise, and this may explain Insall's observation that obtaining a balanced rectangular gap in 0° of extension is difficult and is not always achieved in total knee arthroplasty even with meticulous attention to technique[27].

The second important finding was the frequent instability in a compartment between 0° of extension and 90° of flexion that was uncorrectable by collateral ligament release and the wide range in the magnitude of this instability. The instability was more frequent and greater in the medial compartment because the resection of the posterior region of the medial femoral condyle is greater than that of the distal region of this condyle. This was caused by excessive external rotation of the femoral component resulting from the use of the anteroposterior axis of the trochlear groove (Whiteside line), the transepicondylar axis, or a line externally rotated 3° with respect to the posterior condylar line[22]. The gap-balancing method prevented this type of instability because the two posterior femoral resections equaled the thickness of the two distal femoral resections. The simulation in the present study created one distal and one posterior femoral resection that matched the thickness of the region of the femoral condyle, which is a pattern that might not occur in clinical practice. In clinical practice, the proximal-distal and anterior-posterior translations and the varus-valgus and internal-external rotations of the femoral component may be selected so that three or four of the femoral resections do not match the thickness of the region of the femoral component condyle after correcting for wear and kerf. Therefore, balancing a knee in clinical practice with three or four unmatched femoral resections is more complex than balancing the simulated total knee arthroplasty in the present study with two unmatched femoral resections.

Understanding the design of the total knee arthroplasty implant is essential for deciding how to prevent instability in a compartment between 0° of extension and 90° of flexion that is uncorrectable by collateral ligament release. The surgeon must know the thicknesses of the distal and posterior regions of the femoral component condyles before planning the resections of the distal and posterior regions of the condyles. The only method for preventing this type of instability is to perform bone resections from the distal and posterior regions of the femoral condyles that match the thicknesses of the corresponding condyles on the femoral component after correcting for wear.

The final finding was the frequent change in the alignment of the limb and knee from normal with all four mechanical alignment methods and the wide range of these changes. One reason that a mechanically aligned total knee arthroplasty frequently changes limb alignment from normal is that 20% of normal individuals have a natural alignment at the end of growth that is $\leq -3°$ (at least 3° varus), whereas <2% have neutral limb alignment[8,9]. A slight undercorrection following total knee arthroplasty results in superior clinical outcomes in varus knees, which means that the restoration of limb alignment to neutral in these cases is not desirable and would be unnatural[8,10]. Another undesirable consequence is that mechanical alignment of a total knee arthroplasty causes a paradoxical increase in variability in knee alignment (from 0° to 9° [valgus] for the normal knee to −2° [varus] to 12° [valgus] for the mechanically aligned total knee arthroplasty). Because knees with an orientation of <2.5° valgus (i.e., varus or only slightly valgus) have a high failure rate[28,29], and because mechanical alignment of the limb during knee arthroplasty increases the varus alignment of the knee[30], mechanical alignment increases the rate of failure.

In our experience, prevention is the best method for avoiding the wide range of collateral ligament imbalances and changes in limb and knee alignment from normal. Aligning the femoral and tibial components so that the natural angle and level of the distal and posterior joint lines are restored prevents changes in the limb and knee alignment and avoids collateral ligament imbalance. Collateral ligament imbalance is avoided because the dista1 and posterior femoral resections are equal in thickness to the respective regions on the femoral component condyles after correcting for wear and kerf[23,31,32]. A total knee arthroplasty aligned as above and performed with generic or patient-specific instruments results in better satisfaction, function, and flexion as well as more normal contact kinematics compared with mechanically aligned total knee arthroplasty[21,23,31-33].

In summary, surgeons choosing any of four methods for mechanically aligning a total knee arthroplasty should be aware that they will frequently have to manage a wide range of instability patterns that are complex, cumulative, and uncorrectable as well as changes in limb and knee alignment that might be perceived as unnatural by some patients. The authors prefer to use a total knee arthroplasty that restores the natural angle and level of the distal and posterior femoral joint lines to avoid all of these undesirable consequences and improve patient satisfaction and function[23,31,32,34]. ■

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