# Simulation of Total Knee Arthroplasty in 5° or 7° Valgus: A Study of Gap Imbalances and Changes in Limb and Knee Alignments From Native

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**ABSTRACT:** This study calculated the frequency of occurrence of gap imbalances between medial and lateral compartments at 0° flexion and within a compartment between 0° and 90° flexion, and changes in limb and knee alignment from native after computer simulation of total knee arthroplasty (TKA) with the knee set in 5° or 7° valgus at 0° flexion. TKA was simulated on 49 3D bone models of native limbs. At 0° flexion, the femoral component was set in 5° or 7° valgus from the anatomic axis of the femur, and the tibial component was set 0° to the tibial anatomic axis. At 90° flexion, internal-external rotation of the femoral component was set perpendicular to the anteroposterior axis of the trochlear groove (Method 1), parallel to the transepicondylar axis (Method 2), 3° externally rotated to the posterior condylar axis (Method 3), and gap-balanced to the tibial resection at 0° flexion (Method 4). For 5° and 7° valgus knees, the frequency of occurrence of TKAs (1) with ≥2 mm gap imbalance between compartments at 0° flexion was ≥49%, (2) with ≥2 mm gap imbalance within a compartment between 0° and 90° flexion ranged from 43–69% for Methods 1, 2, and 3, and (3) with ≥2° change in limb and knee alignment from native was ≥47%. Achieving balanced gaps between compartments at 0° flexion may often require soft tissue release. Unbalanced gaps within a compartment between 0° and 90° flexion represent a potential instability which is difficult to surgically correct. © 2016 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res 35:2031–2039, 2017.

**Keywords:** neutral limb alignment; transepicondylar axis; gap balancing; tibiofemoral

According to an instructional review of total knee arthroplasty (TKA), neutral mechanical alignment of the limb at 0° of flexion can be achieved on average with approximately 5°–7° of anatomical valgus at the knee.[1] Hence, 5° and 7° valgus are commonly used angles for setting the femoral component using an intramedullary alignment rod.[2–6] Accordingly, a TKA is considered well-aligned when the angle of the femoral component at 0° of flexion is set in 5° or 7° valgus to the femoral anatomic axis and the angle of the tibial component is set at 0° to the tibial anatomic axis when viewed on a short-leg radiograph of the knee.[1–5]

There are four commonly used methods for setting the internal and external rotation of the femoral component with the knee in 90° of flexion. The posterior joint line of the femoral component can be set perpendicular to the anteroposterior axis of the trochlear groove (Whiteside's line),[7] parallel to the transepicondylar axis,[8,9] 3° externally rotated to the posterior condylar axis,[10] or parallel to the tibial resection with the joint distracted after balancing to create a rectangular extension gap at 0° of flexion.[11]

A TKA with the knee set in 5° or 7° valgus at 0° of flexion and with use of four methods for setting the internal and external rotation of the femoral component at 90° of flexion can cause gap imbalances and changes in limb and knee alignments from that of the native limb and knee. Gap imbalances between the medial and lateral compartments at 0° of flexion occur when the resections of the distal femur and proximal tibia form a trapezoidal gap (Fig. 1). A trapezoidal gap is formed when the total thickness of the bone removed from the distal aspect of the femur and proximal aspect of the tibia in one compartment is different from that in the other compartment after compensating for articular cartilage and bone wear and saw blade kerf.[12] Gap imbalances within a compartment between 0° and 90° of flexion occur when the thicknesses of bone resected (after compensating for the wear of cartilage and bone and kerf of the saw blade) from the distal femoral and posterior femoral condyles at 0° flexion and 90° flexion respectively, are not equal to the corresponding thicknesses of the distal and posterior regions of each condyle of the femoral component (Fig. 2).[12] Changes in alignments of the limb and knee from native occur because few native limbs have neutral mechanical alignment (Fig. 3).[13–15]

Gap imbalances and changes in alignments of the limb and knee are considered undesirable. Balancing gaps often requires releasing soft tissue structures[16–20] which involves additional surgery, adds complexity, and extends the time of the operation whereas changes in limb and/or knee alignment from native might be perceived by the patient as unnatural.[13,21]

A previous computer simulation study of a mechanically aligned TKA performed on native lower extremities with the limb set to a 0° mechanical axis showed that clinically important gap imbalances ≥2 mm and changes in limb and/or knee alignment ≥2° occurred

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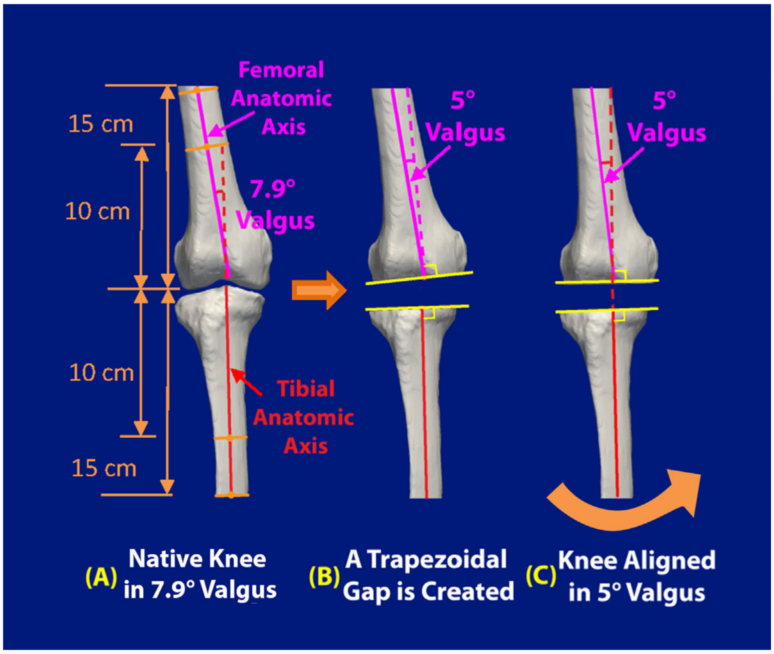


**Figure 1.** Illustrations show the creation of a gap imbalance between the medial and lateral compartments at 0° flexion on an example native right lower limb caused by a simulated TKA set in 5° valgus. (A) The included angle between the anatomic axis of the femur and the extension of the anatomic axis of the tibia measured knee alignment which was 7.9° valgus in the native limb. (B) The resection of the distal femur 5° valgus to the femoral anatomic axis and the resection of the proximal tibia perpendicular to the tibial anatomic axis created a trapezoidal-shaped gap (i.e., gap imbalance between compartments at 0° of flexion). (C) To set the knee at 5° valgus, the tibia was rotated 2.9° varus to create a rectangular gap which generally would require release of lateral soft tissue structures and changed the knee alignment from native (i.e., from 7.9° valgus to 5° valgus).

in the majority of limbs[12]; however, no study to the authors' knowledge has performed these analyses for a TKA with the knee set in 5° or 7° valgus and four methods for setting internal and external rotation of the femoral component with the knee in 90° flexion. Accordingly, the purpose of the present study was to calculate the frequency of occurrence and amount of gap imbalance between the medial and lateral compartments at 0° flexion and within a compartment between 0° and 90° flexion and changes in alignments of the limb and knee from native after simulating a TKA with the knee set in 5° or 7° valgus on a native lower extremity and using four methods for setting the internal and external rotation of the femoral component in 90° of flexion.

## MATERIALS AND METHODS

After being exempted from institutional review board approval, forty-nine 3D bone models of the native lower limbs were created from computed tomograms with a slice thickness of 1.25 mm. Using the shape matching function in Geomagic (3D Systems, Cary, NC), the morphological difference between

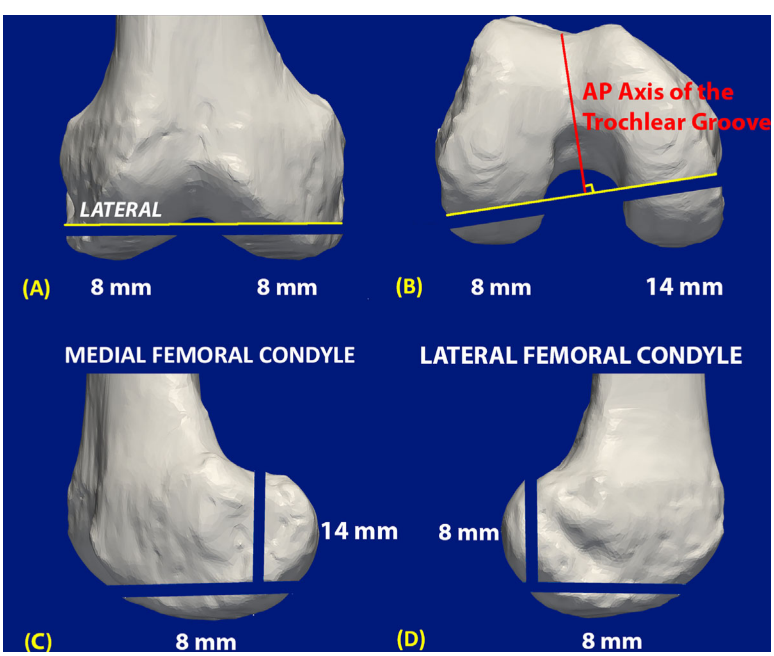


**Figure 2.** Illustrations of the anterior, distal, medial, and lateral aspects of an example native right femur and the distal femoral and posterior femoral resection thicknesses used to compute gap imbalance within a compartment between 0° and 90° of flexion. Eight millimeters was the minimum thickness of a resection from the distal and posterior femoral condyles, which was equal to the thickness of the corresponding region of the medial and lateral condyles of the femoral component used in the simulation. (A) In this example, cutting the distal femur to set the knee in 5° valgus created an 8-mm distal medial resection and an 8-mm distal lateral resection. (B) Cutting the posterior aspect of the femur perpendicular to the anteroposterior axis of the trochlear groove (Whiteside's Line) created an 8-mm posterior lateral resection and a 14-mm posterior medial resection. (C) Assuming that any length gained from releasing a tight collateral ligament to make a rectangular gap at 0° flexion is equal to the length gained at 90° flexion which is supported by previous studies,[26] the medial compartment had 6 mm of gap imbalance in extension (gap at 0° < gap at 90°). (D) The lateral compartment did not have any gap imbalance because the thicknesses of the resections on the distal and posterior femoral condyles matched those of the respective regions on the condyles of the femoral component.

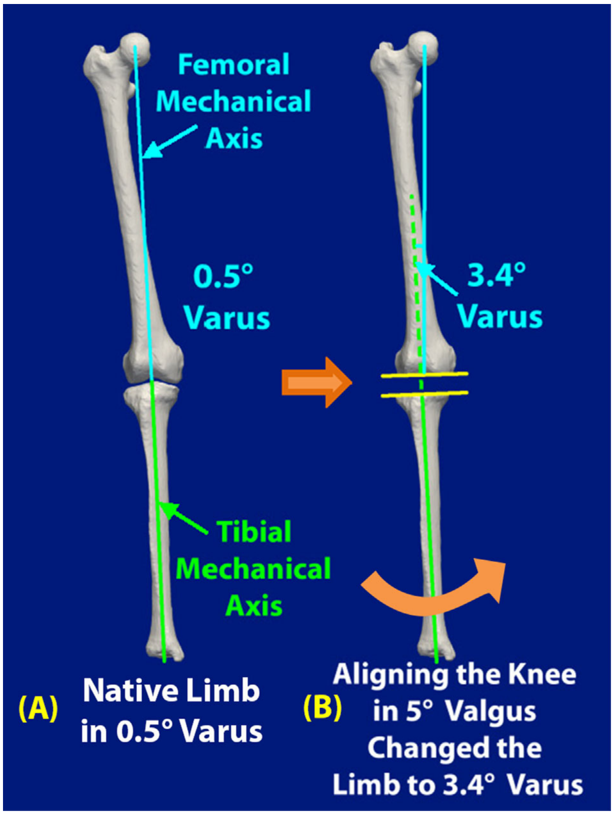


**Figure 3.** Illustrations show the change in limb alignment in 0° flexion on an example native right lower limb caused by a simulated TKA set in 5° valgus. (A) The included angle between the mechanical axis of the femur and the extension of the mechanical axis of the tibia measured limb alignment which was 0.5° varus in the native limb. (B) Setting the knee alignment of the total knee arthroplasty to 5° valgus changed the 0. 5° varus alignment of the native limb by 2.9° to 3.4° varus.

3D bone models created with a 0.625 mm slice thickness and 1.25 mm slice thickness was determined. The root mean squared difference (RMSD) between the models differed by only 0.1 mm which indicates that 1.25 mm was adequate.

These native lower limbs were selected by reviewing computed tomograms stored in a prospective database of patients treated with a primary TKA between August 2013 and September 2014. Each patient had an axial computed tomogram of the hip, knee, ankle, and an anterior-posterior and lateral scanogram of the entire limb of both legs on the day of discharge. For each patient, 3D models of the femoral head, knee, and tibial plafond were created using proprietary software (TechMah Corporation, Knoxville, TN). We included those patients with an unoperated limb that had no evidence of arthritis, fracture, internal fixation, or a joint replacement on the computed tomograms and scanograms, and that after reconstruction into 3D bone models showed a complete femoral head, knee, and distal tibial plafond. The 3D bone models were shape-fit to the 2D projection on the anterior-posterior scanograms to create a full 3D model of the limb with open-source software (ParaView version 3.8.1, 64-bit; Kitware, Clifton Park, NY). In performing the shape-fit of the 3D bone models, note that all of the models were simultaneously shape-fit to the scanogram. This was advantageous in limiting any rotational errors in the coronal plane because such errors manifested as medial-lateral offsets of the femoral head and/or the distal tibial plafond which were easily detected and corrected. For example, a 0.5 mm medial-lateral offset which could be detected in the shape-fit process translated into only a 0.05° angular error which was negligible. The mean age and standard deviation of the subjects was 67 ± 10 years (range, 32–84 years), and sixteen subjects were male and thirty-three were female. We analyzed 21 right limbs and 28 left limbs. The race of the subjects was 85% white, 8% Asian, 2% black, and 2% unknown.

ParaView software was used to perform the simulations of the TKA with the knee set in 5° or 7° valgus, starting with projecting the limb in standard sagittal, coronal, and axial planes.[12] The standard sagittal plane was the plane in which the posterior and distal articular surfaces of the femoral condyles were superimposed. The standard coronal plane was the plane which was simultaneously tangent to the most posterior points on the femoral condyles and the greater trochanter. The standard axial plane was mutually perpendicular to the standard sagittal and coronal planes. The flexion-extension axis of the tibia on the femur was the cylindrical axis.[14,21] The 0° flexion reference was formed when the mechanical axes of the tibia and femur (defined in the next paragraph below) projected onto the standard sagittal plane were parallel. The 90° flexion angle was measured from this reference.

With the knee at 0° flexion and the limb viewed in the standard coronal plane, a line bisecting the width of the femoral shaft at 10 cm and 15 cm above the femoral joint line constructed the femoral anatomic axis (Fig. 1).[3] A line bisecting the width of the tibial shaft at 10 cm and 15 cm below the tibial joint line constructed the tibial anatomic axis.[3] A line from the center of the femoral head to the center of the distal femur at the middle of the intercondylar notch constructed the mechanical axis of the femur. A line from the center of the proximal tibia at the midpoint between the two tibial spines to the center of the distal tibial plafond constructed the mechanical axis of the tibia. The included angle between the anatomic axis of the femur and the extension of the anatomic axis of the tibia quantified knee alignment. The included angle between the mechanical axis of the femur and the extension of the mechanical axis of the tibia quantified limb alignment.[3,5] Negative angles indicate varus and positive angles indicate valgus in both cases.

The distal aspect of the femur was cut at 5° and 7° valgus to the femoral anatomic axis and the proximal aspect of the tibia was cut perpendicular to the tibial anatomic axis (Fig. 1). A femoral component with an 8-mm thickness of the distal and posterior regions of the femoral condyles and a tibial component with 8-mm thick medial and lateral condyles were used for the simulation. The minimum thickness of the bone resection from the distal region of a femoral condyle was 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.[22] The minimum thickness was from the condyle which created the smaller gap once resected. The thickness of the distal resection of the contralateral femoral condyle, which created the larger gap once resected, was measured. The slope of the tibial resection was set parallel to the slope of the lateral tibial plateau. The minimum thickness of the bone resection of a tibial condyle was 8 mm at the center of a compartment, which equaled the 10-mm thickness of the tibial component after accounting for a mean articular cartilage thickness of 2 mm.[22] The thickness of the resection of the other tibial condyle was measured.

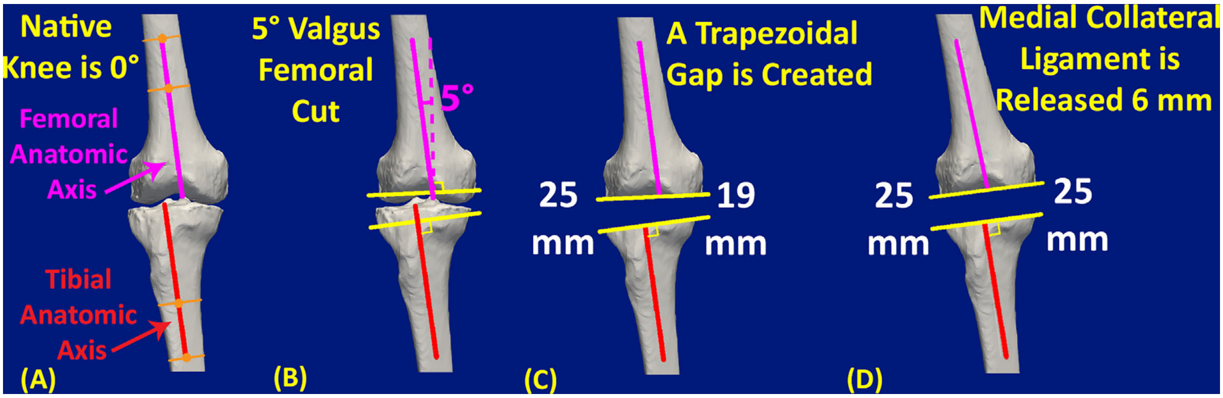


**Figure 4.** Illustrations showing the method for identifying the side of gap imbalance between compartments at 0° flexion and an example calculation of the gap imbalance when the bones are cut to set the knee in 5° valgus. (A) This native right knee has a 0° knee alignment. (B) Cutting the femur in 5° valgus to the anatomic axis of the femur and the tibia perpendicular to the anatomic axis of the tibia creates a trapezoidal gap (i.e., gap imbalance between compartments at 0° flexion). (C) Because the medial gap is smaller than the lateral gap by a difference of 6 mm, a 6 mm medial-lateral gap imbalance is created. (D) To create a rectangular (i.e., balanced) gap between compartments at 0° flexion, a 6 mm release of medial soft tissue structures generally would be required because the combined thickness of the distal aspect of the femur and proximal aspect of the tibia in the medial compartment is 6 mm less than the combined thickness in the lateral compartment.

Internal–external rotation of the femoral component was set either perpendicular to the anteroposterior axis of the trochlear groove (Whiteside line),[7] parallel to the trans-epicondylar axis,[23] externally rotated 3° with respect to the posterior condylar axis,[10] or parallel to the tibial resection after creating a rectangular gap in 0° flexion. In the gap balancing technique (i.e., latter case), the knee was flexed from 0°–90° flexion while maintaining the same lengthening within a compartment as that required to create a rectangular gap at 0° flexion; 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.[22] The thickness of the resection of the posterior region of the other femoral condyle was measured.

Four dependent variables were computed as described below. At 0° of flexion, the imbalance between the compartments was calculated as: Gap imbalance = magnitude of ([thickness of distal resection from medial femoral condyle] + [thickness of proximal resection from medial tibial condyle]) − ([thickness of distal resection from lateral femoral condyle] + [thickness of proximal resection from lateral tibial condyle]) after compensating for articular cartilage and bone wear and saw blade kerf[12] (Fig. 4). Between 0° and 90° of flexion, the imbalance within a compartment was computed as: Gap imbalance = magnitude of ([thickness of distal femoral resection] − [thickness of distal femoral condyle of femoral component]) − ([thickness of posterior femoral resection] − [thickness of posterior femoral condyle of femoral component]) (Fig. 2). The changes in limb and knee alignments from native were calculated. A gap imbalance ≥2 mm and a change in alignment ≥2° were considered clinically important and undesirable 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.[12,13,24,25]

High reproducibility for these dependent variables has been reported with intraclass correlation coefficients ranging from 0.71–0.98 among the calculations made by different observers.[12]

### Statistical Analysis

Descriptive statistics including mean, range, and standard deviation were computed for each of the dependent variables with JMP software (version 10.0.2 for Macintosh; SPSS Inc., Chicago, IL). A 95% confidence interval was placed on the frequency of occurrence of gap imbalance ≥2 mm and change in limb and knee alignments ≥2°. McNemar's test compared the differences in frequency of occurrence between each of the dependent variables for 5° versus 7° valgus.

## RESULTS

Of the TKAs with the knee set in 5° and 7° valgus, the frequency of occurrence of a gap imbalance ≥2 mm between compartments at 0° flexion was 59% and 49% respectively, (Fig. 5) but was not different statistically ($p = 0.49$).

Of the TKAs with the knee set in 5° and 7° valgus, the frequency of occurrence of gap imbalance ≥2 mm within the medial compartment between 0° and 90° of flexion was 53% and 53% ($p = 0.84$), respectively, of the simulated TKAs with the femoral component aligned perpendicular to the anteroposterior axis of the trochlear groove (range, 2–7 mm); 59% and 69% ($p = 0.40$), respectively, of the simulated TKAs with the femoral component aligned parallel to the trans-epicondylar axis (range, 2–7 mm); and 61% and 43% ($p = 0.10$), respectively, of the simulated TKAs with the femoral component externally rotated 3° with respect to the posterior condylar axis (range, 2–3 mm) (Fig. 6). Of the simulated TKAs with the knee set in 5° and 7° valgus, none had a ≥2 mm gap imbalance in the lateral compartment between 0° and 90° of flexion. Gap imbalance in the medial and lateral

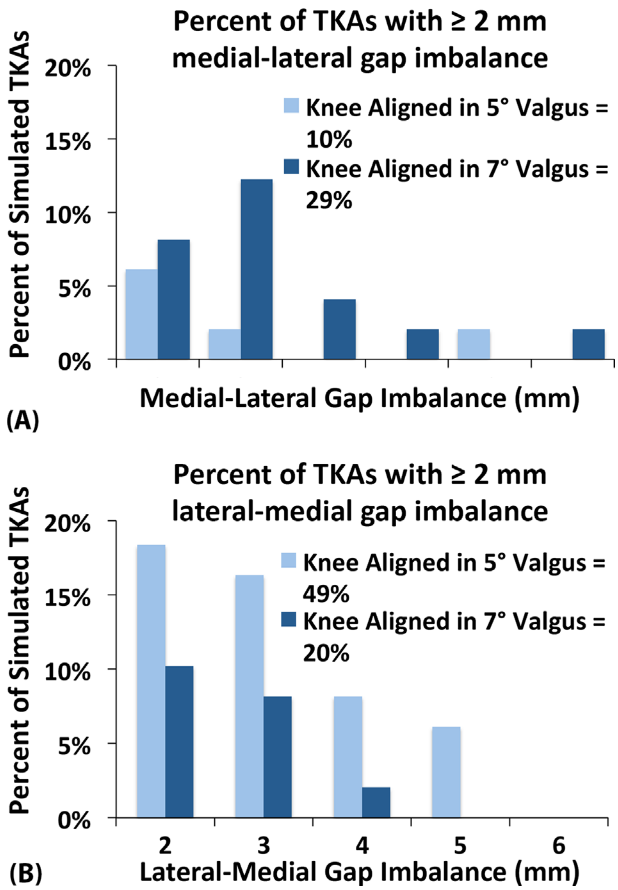


**Figure 5.** Histograms showing the frequency of occurrence in percent of simulated TKAs with a ≥2 mm gap imbalance between the medial and lateral compartments at 0° of flexion. (A) A medial-lateral gap imbalance (i.e., medial gap < lateral gap) occurred in 10% of the TKAs with the knee set in 5° valgus and 29% of the TKAs with the knee set in 7° valgus. (B) A lateral-medial gap imbalance (i.e., lateral gap < medial gap) occurred in 49% of the TKAs with the knee set in 5° valgus and 20% of the TKAs with the knee set in 7° valgus.

compartments between 0° and 90° of flexion did not occur with the gap-balancing technique.

Of the simulated TKAs with the knee set in 5° and 7° valgus, the frequency of occurrence of changes in limb or knee alignment ≥2° from native was 51% and 47% ($p = 0.80$), respectively (Fig 7).

## DISCUSSION

A previous simulation of mechanically aligned TKA set the limb at a 0° mechanical axis with four methods for setting the rotation of the femoral component at 90° of flexion and showed undesirable and frequent gap imbalances and changes in limb and knee alignments from native.[12] Building on this previous simulation, the purpose of the present study was to calculate the frequency of occurrence and amount of gap imbalance between the medial and lateral compartments at 0° flexion and within a compartment between 0° and 90° flexion and changes in alignments of the limb and knee from native after simulating a TKA with the knee set in 5° or 7° valgus on a native lower extremity

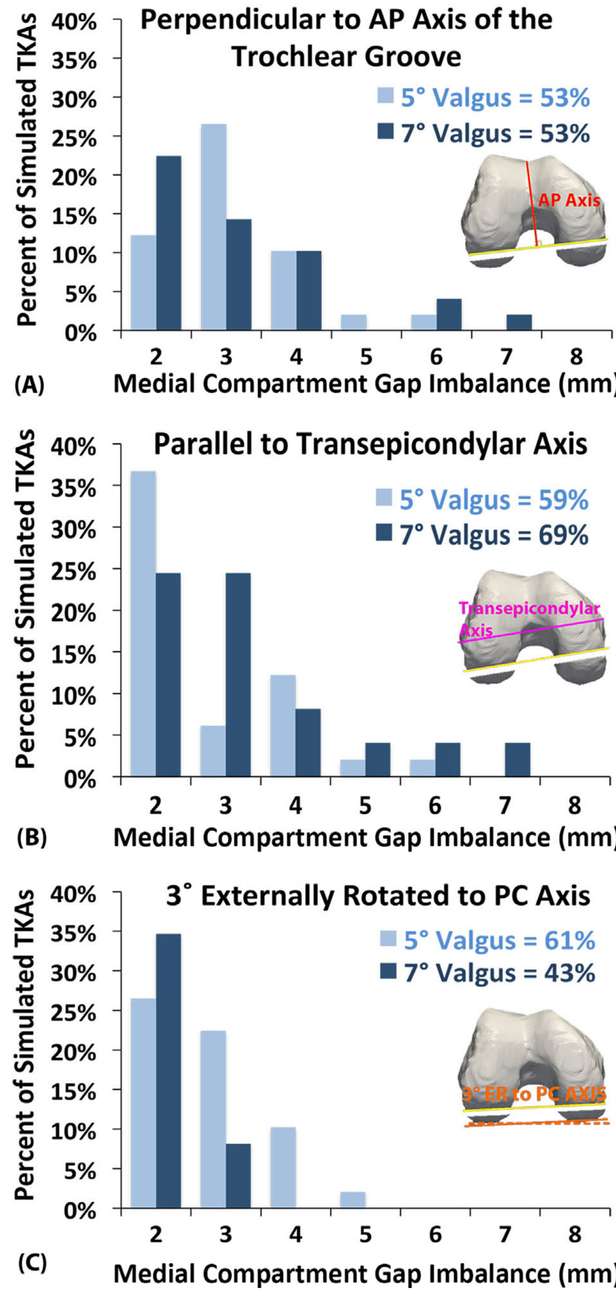


**Figure 6.** Histograms showing the frequency of occurrence in percent of simulated TKAs with ≥2 mm gap imbalance within the medial compartment between 0° and 90° of flexion with the knee set in 5° or 7° valgus and internal-external rotation of the femoral component set perpendicular to the anteroposterior axis of the trochlear groove (Whiteside's line) (A), parallel to the transepicondylar axis (B), and 3° externally rotated to the posterior condylar (PC) axis (C). Gap imbalance within a compartment between 0° and 90° flexion was not observed on the lateral side. Gap imbalance 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.

and using four methods for setting the internal and external rotation of the femoral component in 90° of flexion. The posterior joint line of the femoral component was set: (Method 1) perpendicular to the anteroposterior axis of the trochlear groove[7]; (Method 2)

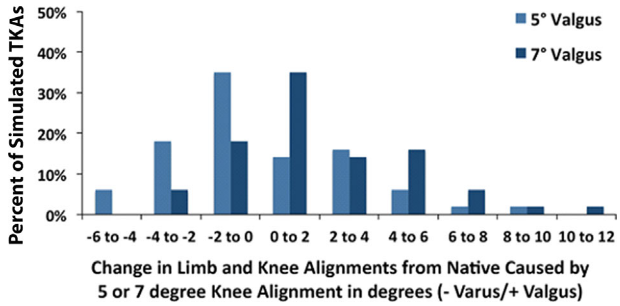


**Figure 7.** Histograms showing the frequency of occurrence in percent of simulated TKAs with changes in limb and knee alignments ≥2° from native with the knee set in 5° or 7° valgus. Of the TKAs with the knee set in 5° valgus, the change in limb and knee alignments ranged from −5° (i.e., in the varus direction) to 8° (in the valgus direction), with a mean change of 0° ± 2.9°. Of the TKAs with the knee set in 7° valgus, the change in limb and knee alignments ranged from −3° (i.e., in the varus direction) to 10° (in the valgus direction), with a mean change of 2° ± 2.9°.

parallel to the transepicondylar axis[8,9]; (Method 3) 3° externally rotated to the posterior condylar axis[10]; and (Method 4) parallel to the tibial resection with the joint distracted after balancing to create a rectangular extension gap at 0° of flexion.[11] The most important findings were that a simulated TKA with the knee set in 5° or 7° valgus with four methods for setting the rotation of the femoral component at 90° of flexion resulted in a high frequency of occurrence and a wide range of undesirable gap imbalances ≥2 mm between compartments at 0° of flexion, a high frequency of occurrence and wide range of undesirable gap imbalances ≥2 mm within the medial compartment between 0° and 90° of flexion for three of the four methods for setting the rotation of the femoral component at 90° flexion, and a high frequency of occurrence and wide range of undesirable changes ≥2° in limb and knee alignment from native.

Two potential limitations should be discussed before interpreting the findings of our study. First, the thicknesses of the condyles of the femoral component must be known to determine the gap imbalance within a compartment between 0° and 90° of flexion (Fig. 2). In our study, we simulated a femoral component with equal thickness in both the distal and posterior regions which is representative of some but not all commercially available femoral components. However the results of the gap imbalance calculations would not be affected if the thicknesses of the condyles of the distal and posterior regions of the femoral component differed as long as the minimum resection thicknesses were equal to those of the distal and posterior regions of the femoral component.

Second, the gap imbalance within a compartment between 0° and 90° of flexion was calculated with the assumption that releasing soft tissue structures to create a rectangular gap at 0° flexion would increase the length of the soft tissue structures and hence the gap in that compartment by the same amount at both 0° and 90° flexion. Controlling the length of release is a complex subject because of the several and varied types of soft tissue structures involved on both the medial and lateral sides of the joint.[16–19] Restricting attention to the collateral ligaments, different techniques have been reported for releasing these structures including sharp dissection of either all or part of a ligament particularly different regions of the MCL[16] and the needle technique.[20] Using sharp dissection to release all of the MCL[26] or the needle technique for more controlled release of the MCL,[20] the length increase is within 1 mm at 0° and 90° flexion, thus supporting our assumption for the MCL that the length increase is equal at both 0° and 90° flexion. Likewise using sharp dissection to release the LCL,[27] the length increase is within 1 mm at 0° and 90° flexion also supporting our assumption for the LCL that the length increase is equal at both 0° and 90° flexion. While our assumption is supported for the collateral ligaments using the techniques in the references cited above, the use of other techniques and/or the release of other structures could result in different length increases at 0° and 90° flexion.

One important finding was that a TKA with the knee set in 5° or 7° valgus frequently creates undesirable gap imbalances ≥2 mm in either the medial or lateral compartment at 0° flexion (Fig. 5). Because there is little varus-valgus laxity at 0° flexion[28] and because the collateral ligaments are stiff,[29,30] if left uncorrected, then a gap imbalance ≥2 mm would lead to a tight collateral ligament in extension. A tight collateral ligament in extension is associated with difficulty in gaining extension and increased tibial contact forces.[31] To avoid these undesirable outcomes, a soft tissue release would be required to create a rectangular gap and the magnitude of the release could vary widely (Fig. 5). Our results indicate that 49–59% of native knees would require release of the medial soft tissue structures (e.g., medial collateral ligament) by 2–7 mm or the lateral soft tissue structures (e.g., lateral collateral ligament) by 2–5 mm. Therefore, these ranges of release would need to be performed when treating arthritic knees even with mild deformity to establish a rectangular gap at 0° flexion. However obtaining a rectangular gap clinically at 0° flexion is difficult and is not always achieved even with meticulous attention to technique.[32]

The second important finding was the frequent undesirable gap imbalances ≥2 mm within the medial compartment between 0° and 90°flexion and the wide range in the magnitude of this imbalance (Fig. 6). If left uncorrected, then the gap imbalance within the medial compartment could manifest as valgus instability (i.e., valgus laxity greater than that of the native knee). However the instability is difficult to correct surgically.

The gap imbalance within a compartment between 0° and 90° flexion was restricted to the medial

**Table 1.** Summary of Results for the Present Study Which Set the Knee in 5° or 7° Valgus at 0° Flexion and Used Four Methods for Setting the Internal-External Rotation of the Femoral Component at 90° Flexion and Comparison to Those of a Previous Study Which Set the Limb With a 0° Mechanical Axis and Used the Same Four Methods for Setting the Internal-External Rotation of the Femoral Component[12]

| | Knee Set in 5° Valgus (%) | Knee Set in 7° Valgus (%) | Limb Set With 0° Mechanical Axis (%) |
|---|---|---|---|
| Percent of limbs with gap imbalance ≥2 mm between compartments at 0° flexion | 59 (45–72) | 49 (36–63) $p = 0.40$ | 64 (49–75) |
| Percent of limbs with gap imbalance ≥2 mm within a compartment between 0° and 90° flexion (Method 1) | 53 (39–66) | 53 (39–66) $p = 0.84$ | 62 (47–74) |
| Percent of limbs with gap imbalance ≥2 mm within a compartment between 0° and 90° flexion (Method 2) | 59 (45–72) | 69 (55–80) $p = 0.40$ | 80 (66–88) |
| Percent of limbs with gap imbalance ≥2 mm within a compartment between 0° and 90° flexion (Method 3) | 61 (47–74) | 43 (30–57) $p = 0.10$ | 42 (30–57) |
| Percent of limbs with gap imbalance ≥2 mm within a compartment between 0° and 90° flexion (Method 4) | 0 | 0 (NA) | 0 |
| Percent of limbs with alignment change ≥2° from native | 52 (37–64) | 47 (34–61) $p = 0.80$ | 58 (43–70) |

At 90° flexion, internal-external rotation of the femoral component was set perpendicular to the anteroposterior axis of the trochlear groove (Method 1), parallel to the transepicondylar axis (Method 2), 3° externally rotated to the posterior condylar axis (Method 3), and gap-balanced to the tibial resection at 0° flexion (Method 4). percentages in parentheses indicate 95% confidence intervals. $p$-Values indicate whether the proportions with the knee set in 5° vs. 7° valgus are significantly different.

compartment because 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 excessively externally rotated the femoral component with respect to the 5° and 7° valgus cut of the distal femur.[12,33] The gap-balancing method prevented this type of imbalance because the two posterior femoral resections equaled the thickness of the two distal femoral resections. However, one disadvantage of the gap-balancing method is that the soft tissue restraints are over tightened at 45° and 90° of flexion relative to the native laxities. This occurs because the goal of gap-balancing is to create uniform tension in the periarticular soft-tissue restraints and equal laxities throughout the arc of flexion but laxities are generally greater in flexion than extension.[28] Over tightened soft tissue restraints may be perceived by patients as pain, stiffness, and/or limited flexion.

The final finding was the frequent change in the alignments of the limb and knee from native with a TKA with the knee set in 5° or 7° valgus and the wide range of these changes (Fig. 7). It is generally believed that a TKA with the knee set in 5° or 7° valgus also sets the limb in an acceptable hip-knee-ankle angle that ranges from −3° varus to 3° valgus.[1] In contrast, the present study showed that 26% and 12% of the native limbs with the knee set in 5° or 7° valgus were changed to a hip-knee-ankle angle of less than −3° varus (up to −5°) or more than 3° valgus (up to 10°), which is contrary to current opinion.

Although the frequency of occurrence of gap imbalances ≥2 mm and changes in limb and knee alignments ≥2° differed when the knee was set in 5° valgus versus 7° valgus, McNemar's test revealed no statistically significant differences in any of the dependent variables measured between the two alignment methods (Table 1). This possibly occurred because the differences were small. Regardless, the most important findings of this study are that setting the knee in 5° and 7° valgus caused undesirable gap imbalances ≥2 mm and undesirable changes in limb and knee alignments ≥2° in a large percentage of subjects for both alignment methods (Table 1).

A comparison of the results herein to those of the previous simulation which set the limb at a 0° mechanical axis and the same four methods of setting the internal-external rotation of the femoral component at 90° flexion were used shows that all three methods for establishing a neutral hip-knee-ankle angle give comparable results (Table 1). Hence regardless of the method used to establish a neutral hip-knee-ankle angle, undesirable gap imbalances ≥2 mm and undesirable changes in limb alignment ≥2° from native occur frequently in these simulations of TKA.

The results of our simulation are consistent with clinical practice of TKA in which soft tissue release is performed routinely to establish rectangular gaps in extension and flexion. For example, soft tissue release was performed in 70% of patients when the knee was set in the range of 5°–8° valgus,[34] in 76% of patients with varus knees when the knee was set in 5° valgus,[16] in at least 50% of patients depending on the deformity (i.e., varus or valgus) using the gap-balancing method,[32] and in the majority of patients using the gap-balancing method.[35] These percentages are in general agreement with those of Table 1. Indeed one of the important contributions of our study is that our simulation provides a biomechanical explanation behind the need for soft tissue release in clinical practice of TKA using methods aimed at establishing neutral alignment at 0° flexion in the coronal plane.

In our experience, prevention is the best method for avoiding gap imbalances between compartments at 0° flexion, gap imbalances within a compartment between 0° and 90° flexion, and changes in limb and knee alignments from native. Prevention can be achieved by kinematic alignment instead of the knee set in 5° or 7° valgus. Kinematically aligned TKA minimizes the risk of these undesirable changes because it creates distal and posterior femoral resections equal in thickness to the respective regions on the femoral component condyle after compensating for wear and kerf.[36,37] Achieving this alignment amounts to restoring the worn articular surfaces of the femur to native. A similar restoration approach is followed for the tibia. By restoring worn articular surfaces of the tibiofemoral joint to native, the alignments of the limb and joint lines are restored to native, and gaps are closely balanced so that soft tissue releases generally are not required. Restoring the native alignments of the limb and joint lines leads to more physiological periarticular soft tissue strains during loaded as well as unloaded motor tasks.[38] This may explain why kinematically aligned TKA results in high patient-reported satisfaction, function, and flexion.[22,24,25,37]

In summary, a TKA with the knee set in 5° or 7° valgus frequently creates (1) undesirable gap imbalances $\geq$2 mm between compartments at 0° flexion that often require soft tissue release which can be difficult to satisfactorily control, (2) undesirable gap imbalances $\geq$2 mm and associated instability particularly within the medial compartment between 0° and 90° flexion which are complex and difficult to correct surgically, and (3) undesirable changes in limb and knee alignments from native that are unnatural in a high percentage of knees. Setting the knee in 5° or 7° valgus results in a hip-knee-ankle angle outside of $0° \pm 3°$ in a noteworthy percentage of knees.

## AUTHORS' CONTRIBUTIONS

Y. Gu performed the simulations, measured the dependent variables, and wrote the draft of the manuscript. S. M. Howell was the Co-PI on the research grant which funded the study, co-supervised Y. Gu in all phases, and wrote portions of the manuscript. M. L. Hull was the PI on the research grant which funded the study, supervised Y. Gu in all phases, performed the statistical analyses, wrote portions of the manuscript, completed the revision, and approved the submitted version. All authors read and approved the submitted version of the manuscript.


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## CONFLICTS OF INTEREST

Y. Gu is employed by Mako Surgical Corporation. S. M. Howell is a paid consultant for Zimmer-Biomet and Think Surgical. He also receives royalties from Zimmer-Biomet. M. L. Hull receives research funding from Zimmer-Biomet and Think Surgical.

## REFERENCES


1. Abdel MP, Oussedik S, Parratte S, et al. 2014. Coronal alignment in total knee replacement: historical review, contemporary analysis, and future direction. Bone Joint J 96-B:857–862.
2. Engh GA, Petersen BE. 1990. Comparative experience with intramedullary and extramedullary alignment in total knee arthroplasty. J Arthroplasty 5:1–8.
3. Peterson TL, Engh GA. 1998. Radiographic assessment of knee alignment after total knee arthroplasty. J Arthroplasty 3:67–72.
4. Ritter MA, Davis KE, Davis P, et al. 2013. Preoperative malalignment increases risk of failure after total knee arthroplasty. J Bone Joint Surg Am 95-A:126–131.
5. Ritter MA, Davis KE, Meding JB, et al. 2011. The effect of alignment and BMI on failure of total knee replacement. J Bone Joint Surg Am 93-A:1588–1596.
6. Shakespeare D. 2006. Conventional instruments in total knee replacement: what should we do with them? Knee 13:1–6.
7. Whiteside LA, Arima J. 1995. The anteroposterior axis for femoral rotational alignment in valgus total knee arthroplasty. Clin Orthop Relat Res 321:168–172.
8. Berger RA, Rubash HE, Seel MJ, et al. 1993. Determining the rotational alignment of the femoral component in total knee arthroplasty using the epicondylar axis. Clin Orthop Relat Res 286:40–47.
9. Katz MA, Beck TD, Silber JS, et al. 2001. Determining femoral rotational alignment in total knee arthroplasty: reliability of techniques. J Arthroplasty 16:301–305.
10. Siston RA, Patel JJ, Goodman SB, et al. 2005. The variability of femoral rotational alignment in total knee arthroplasty. J Bone Joint Surg Am 87-A:2276–2280.
11. Dennis DA, Komistek RD, Kim RH, et al. 2010. Gap balancing versus measured resection technique for total knee arthroplasty. Clin Orthop Relat Res 468:102–107.
12. Gu Y, Roth JD, Howell SM, et al. 2014. How frequently do four methods for mechanically aligning a total knee arthroplasty cause collateral ligament imbalance and change alignment from normal in white patients? J Bone Joint Surg Am 96-A:e101(1)–e101(9).
13. Bellemans J, Colyn W, Vandenneucker H, et al. 2012. The Ranawat Award paper: is neutral mechanical alignment normal for all patients? The concept of constitutional varus. Clin Orthop Relat Res 470:45–53.
14. Eckhoff DG, Bach JM, Spitzer VM, et al. 2005. Three-dimensional mechanics, kinematics, and morphology of the knee viewed in virtual reality. J Bone Joint Surg Am 87-A:71–80.
15. Vanlommel L, Vanlommel J, Claes S, et al. 2013. Slight undercorrection following total knee arthroplasty results in superior clinical outcomes in varus knees. Knee Surg Sports Traumatol Arthrosc 21:2325–2330.
16. Whiteside LA, Saeki K, Mihalko WM. 2000. Functional medial ligament balancing in total knee arthroplasty. Clin Orthop Relat Res 380:45–57.
17. Kanamiya T, Whiteside LA, Nakamura T, et al. 2002. Ranawat Award paper: effect of selective lateral ligament release on stability in knee arthroplasty. Clin Orthop Relat Res 404:24–31.
18. Krackow KA, Mihalko WM. 1999. The effect of medial release on flexion and extension gaps in cadaveric knees:

implications for soft-tissue balancing in total knee arthroplasty. Am J Knee Surg 12:222–228.
19. Krackow KA, Mihalko WM. 1999. Flexion-extension joint gap changes after lateral structure release for valgus deformity correction in total knee arthroplasty: a cadaveric study. J Arthroplasty 14:994–1004.
20. Bellemans J, Vandenneucker H, Van Lauwe J, et al. 2010. A new surgical technique for medial collateral ligament balancing: multiple needle puncturing. J Arthroplasty 25: 1151–1156.
21. Eckhoff D, Hogan C, DiMatteo L, et al. 2007. Difference between the epicondylar and cylindrical axis of the knee. Clin Orthop Relat Res 461:238–244.
22. Nam D, Nunley RM, Barrack RL. 2014. Patient dissatisfaction following total knee replacement: a growing concern? Bone Joint J 96-B:96–100.
23. Victor J, Van Doninck D, Labey L, et al. 2009. A common reference frame for describing rotation of the distal femur: a ct-based kinematic study using cadavers. Bone Joint J 91-B:683–690.
24. Dossett H, Estrada N, Swartz G, et al. 2014. A randomised controlled trial of kinematically and mechanically aligned total knee replacements two-year clinical results. Bone Joint J 96-B:907–913.
25. Howell SM, Papadopoulos S, Kuznik K, et al. 2015. Does varus alignment adversely affect implant survival and function six years after kinematically aligned total knee arthroplasty? Int Orthop 39:2117–2124.
26. Haimes JL, Wroble RR, Grood ES, et al. 1994. Role of the medial structures in the intact and anterior cruciate ligament-deficient knee. Am J Sports Med 22:402–409.
27. Matsueda M, Gengerke TR, Murphy M, et al. 1999. Soft tissue release in total knee arthroplasty. Cadaver study using knees without deformities. Clin Orthop Relat Res 366:264–273.
28. Roth JD, Hull ML, Howell SM. 2015. The limits of passive motion are variable between and unrelated within normal tibiofemoral joints. J Orthop Res 33:1594–1602.
29. Markolf KL, Mensch JS, Amstutz HC. 1976. Stiffness and laxity of the knee-the contributions of the supporting structures. A quantitative in vitro study. J Bone Joint Surg Am 58-A:583–594.
30. Robinson JR, Bull AM, Amis AA. 2005. Structural properties of the medial collateral ligament complex of the human knee. J Biomech 38:1067–1074.
31. Manrique J, Gomez MM, Parvizi J. 2015. Stiffness after total knee arthroplasty. J Knee Surg 28:119–126.
32. Griffin FM, Insall JN, Scuderi GR. 2000. Accuracy of soft tissue balancing in total knee arthroplasty. J Arthroplasty 15:970–973.
33. Howell SM, Howell SJ, Hull ML. 2010. Assessment of the radii of the medial and lateral femoral condyles in varus and valgus knees with osteoarthritis. J Bone Joint Surg Am 92-A:98–104.
34. Aunan E, Kibsgard T, Clarke-Jenssen J, et al. 2012. A new method to measure ligament balancing in total knee arthroplasty: laxity measurements in 100 knees. Arch Orthop Trauma Surg 132:1173–1181.
35. Heesterbeek PJ, Wymenga AB. 2010. Correction of axial and rotational alignment after medial and lateral releases during balanced gap TKA. A clinical study of 54 patients. Acta Orthop 81:347–353.
36. Howell SM, Hull ML. 2012. Principles of kinematic alignment in total knee arthroplasty with and without patient specific cutting blocks (OtisKnee). In: Scott S editor. Insall and scott surgery of the knee, 5th ed. Philadelphia, PA: Elsevier. p 1255–1268.
37. Howell SM, Papadopoulos S, Kuznik KT, et al. 2013. Accurate alignment and high function after kinematically aligned performed with generic instruments. Knee Surg Sports Traumatol Arthrosc 21:2271–2280.
38. Delport H, Labey L, Innocenti B, et al. 2014. Restoration of constitutional alignment in TKA leads to more physiological strains in the collateral ligaments. Knee Surg Sports Traumatol Arthrosc 23:2159–2169.