Clinical Research

What Is the Possible Impact of High Variability of Distal Femoral Geometry on TKA? A CT Data Analysis of 24,042 Knees

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Abstract

Background Previous studies analyzing femoral components of TKAs have demonstrated the limited ability of these components to accommodate size variations seen in the patient population, particularly width and femoral offset.

Questions/purposes The purpose of this study was to use a large data set of knee CT scans (1) to determine the variations in the distal and posterior femoral geometries and to

determine whether there is a correlation between distal condylar offset and posterior femoral offset as a potential parameter for symmetry/asymmetry; and (2) to evaluate what proportion of knees would have a substantial mismatch between the implant's size or shape and the patient's anatomy if a femoral component of a modern standard TKA of symmetric (sTKA) or asymmetric (asTKA) designs were to be used.

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Methods A retrospective study was performed on 24,042 data sets that were generated during the design phase for a customized TKA implant. This data set was drawn from European and US-American patients. Measurements recorded for the femur included the overall AP and mediolateral (ML) widths, widths of the lateral condyle and the medial condyle, the distal condylar offset (DCO) between the lateral and medial condyles in the superoinferior direction, and the posterior femoral offset (PFO) as the difference between the medial and lateral posterior condylar offset (PCO) measured in the AP direction. A consecutively collected subset of 2367 data sets was further evaluated to determine the difference between the individual AP and ML dimensions of the femur with that of modern TKA designs using two commercially available implants from different vendors.

Results We observed a high degree of variability in AP and ML widths as well as in DCO and PFO. Also, we found no correlation between DCO and PCO of the knees studied. Instances of a patient having a small DCO and higher PCO were commonly seen. Analysis of the DFOs revealed that overall, 62% (14,906 of 24,042) of knees exhibited DCO > 1 mm and 83% (19,955 of 24,042) of femure exhibited a > 2-mm difference between the lateral and medial PCO. Concerning AP and ML measurements, 23% (544 of 2367) and 25% (592 of 2367) would have a mismatch between the patient's bony anatomy and the dimensions of the femoral component of \pm 3 mm if they would have undergone a modern standard sTKA or asTKA design, respectively.

Conclusions Analysis of a large number of CT scans of the knee showed that a high degree of variability exists in AP and ML widths as well as in DCO and PFO.

Clinical Relevance These findings suggest that it is possible that a greater degree of customization could result in surgeons performing fewer soft tissue releases and medial resections than now are being done to fit a fixed-geometry implant into a highly variable patient population. However, as an imaging study, it cannot support one approach to TKA over another; comparative studies that assess patient-reported outcomes and survivorship will be needed to help surgeons decide among sTKA, asTKA, and customized TKA.

Introduction

TKA is a well-established and successful procedure worldwide for the treatment of end-stage osteoarthritis, restoring function and quality of life [6, 10, 17]. However, up to 30% of patients are not satisfied with their implants [5, 22, 23, 27]. This dissatisfaction is multifactorial; it may be related to incorrect component sizing or rotation, instability, and many other causes. Achieving proper fit and



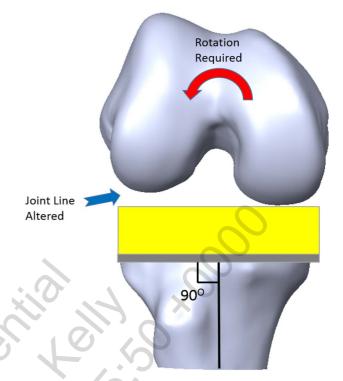


Fig. 1 The use of sTKA in knees with high PFO contributes to instability, more releases, excessive bony resections to reduce the ML gap difference, or to external rotation (red arrow) of the femoral component to close the lateral flexion gap (blue arrow).

anatomic congruence using available fixed-geometry implants establishes intraoperative challenges because femoral geometry varies widely in the population. The geometry varies with gender, ethnicity, and morphotype [2, 7, 11]. Furthermore, multiple anatomic variations of femoral geometry occur within these groups. Hitt et al. [13] found wide variation in femoral fit with available standard symmetric implants, resulting in 4.9 mm (\pm 4.5 mm) average overhang in women. Similarly, Mahoney et al. [18] found that overhang of \geq 3 mm occurred in 57% of TKAs. They reported a 1.9-fold increase in the risk of pain with overhang ≥ 3 mm. Bonnin et al. [4] reported that a mediolateral overhang of the femoral component occurred in 84% of female and in 54% of male patients. They also reported that this overhang may negatively correlate with the incidence of residual pain and reduced functional outcome. To avoid component overhang, surgeons tend to downsize the femoral component as an intraoperative compromise; however, downsizing the femoral component may lead to an increase in laxity [21] and to an increased exposure of cancellous bone, which might be the cause of increased postoperative bleeding [13]. Downsizing the femoral component can also lead to decreased posterior condylar offset (PCO), which results in earlier impingement of the posterior tibial component on the femur and,

therefore, decreased flexion ability [1] and potentially instability [18]. Most implants are symmetric, and particularly in knees with high distal condylar offset (DCO); in our opinion, this may contribute to instability, more releases, or excessive bony resections to reduce the mediolateral gap difference. In addition, using a symmetric TKA in knees with high posterior femoral offset (PFO) may result in the aforementioned compromises and/or in external rotation of the femoral component to close the lateral flexion gap (Fig. 1).

To account for these challenges, implant manufacturers have developed newer implants that are available in more sizes as well as in a narrower mediolateral (ML) to AP ratio. However, variations in the distal and posterior geometries of the medial and lateral femoral condyles is an area that is still not perfectly accommodated by existing standard knee replacements [12]. Furthermore, the restoration of individual anatomy and knee kinematics was depicted as the holy grail in TKA [16].

The purposes of this study were to use a large data set of knee CT scans (1) to determine the variations in the distal and posterior femoral geometries and to determine whether there is a correlation between DCO and PFO as a potential parameter for symmetry/asymmetry; and (2) to evaluate what proportion of knees would have a substantial mismatch between the implant's size or shape and the patient's anatomy if a femoral component of a modern standard TKA of symmetric (sTKA) or asymmetric (asTKA) designs were to be used.

Materials and Methods

Study Design and Setting

We performed a retrospective study on 24,042 CT data sets of the knee that were generated during the design phase for a customized TKA implant (cTKA) from December 2013 to April 2016. The data set was drawn from a crosssection of European and US-American patients.

Variables, Outcome Measures, Data Sources

To quantify the variations in the distal femur geometry, we recorded the following measurements (Fig. 2): overall AP and ML width, width of the lateral condyle, medial condyle, the difference between the distal-lateral and medial condyles (DCO) and the PFO, and the difference between the medial and lateral PCO measured in the AP direction. All measurements were done on a three-dimensional model that was generated after obtaining CT scans, including the hip center, knee, and ankle center.

Two different analyses were performed. The first analysis was a determination of the DCO and PFO for the CT models of 24,042 knees. DCO and PFO were determined by an automated algorithm that defines the J-curves of the distal femur using a US Food and Drug Administration (FDA)cleared software algorithm. This was followed by their comparison to modern sTKA and asTKA designs. The second analysis was an evaluation of the femoral AP and ML dimensions for a subset of 2367 consecutively collected CT models of the knee and their comparison to modern sTKA and asTKA sizes. Specifically, we determined what proportion of knees could not be accommodated using available standard sizes of modern sTKA and asTKA femoral components if the mismatch between the implant and the patient's anatomy is restricted to a maximum of 3 mm.

The comparison of the DCO and PFO for the data set to the sTKAs was performed using information on implant design for both sTKA and asTKA. These included sTKAs that have no DCO or PFO built into the implant (Attune[®] Knee System; DePuy Synthes, Warsaw, IN, USA) and asTKA, which have a fixed DCO and symmetric posterior condyles (Journey Knee System; Smith & Nephew Inc, Memphis, TN, USA).

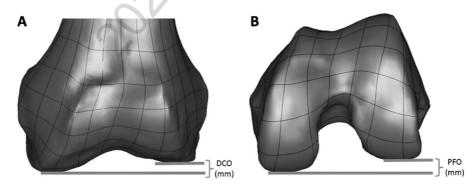


Fig. 2 A-B The DCO was determined by measuring the superoinferior distance between the lowest point on the lateral and medial femoral condyle in extension (**A**). PFO was determined by measuring the superoinferior distance between the lowest point on the lateral and medial femoral condyle in flexion (**B**).



During the visualization and planning of the cTKA, the distal offset was determined by placing the femoral implant in full extension and determining the lowest points on the lateral and medial femoral condyles in the coronal plane. The difference between the lowest points in the superoinferior direction was measured and defined as the

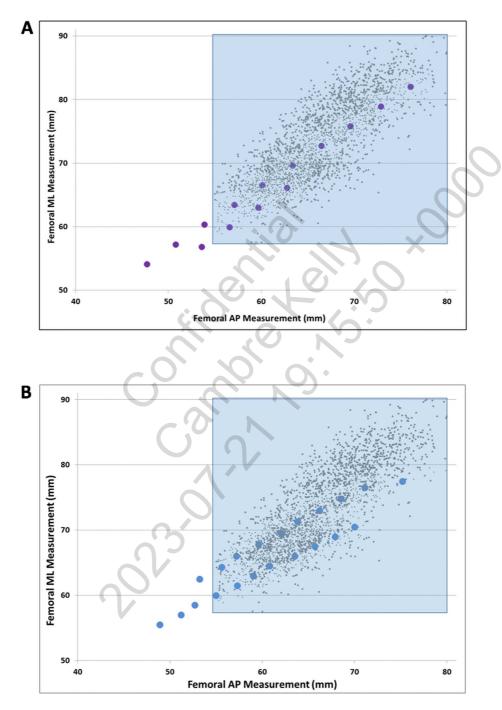


Fig. 3 A-B ML and AP measurements of all available sizes of the standard TKA designs are shown. (**A**) Data concerning the Attune Knee system (DePuy Synthes) are presented as bold purple dots and (**B**) data concerning the Persona Knee System (Zimmer Biomet Inc) are presented as blue bold dots versus respective CT data, presented as gray dots. The bluemarked area represents the area to which the investigations refer. Especially patients with high ML and AP would have suffered from sizing issues \pm 3 mm if they had received a sTKA or asTKA.

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DCO (Fig. 2). To measure the PFO, the femoral component was placed in flexion and the lowest points on the lateral and medial condyles were determined. The difference between these points was defined as the PFO (Fig. 2).

The implant fit analysis was conducted using AP and ML dimensions of the data set when compared with modern sTKA and asTKA sizes for two different implants (Attune[®] Knee System; DePuy Synthes; and Persona[®] Knee System, Zimmer Biomet Inc, Warsaw, IN, USA). The sizes were determined from company data. For each TKA size, the implant AP and ML measurements were recorded. The sizes for sTKA and asTKA that fell within the range of the cTKA (FDA clearance from smallest to largest of iTotal CR[®], Conformis Inc, Boston, MA, USA; marked blue in Fig. 3A-B) were used in the analysis. The sizes of modern sTKA and asTKA that fell outside the cTKA clearance were excluded from the analysis. Each cTKA implant size was mapped to sTKA and asTKA dimension to determine the closest match. The difference in the size of each cTKA to the closest sTKA or asTKA size was used to determine if the match was within 1 mm, between 1 and 2 mm, 2 and 3 mm, etc.

Statistical Analysis

Data analysis was performed using inbuilt and custom functions in Microsoft Excel (Redmond, WA, USA) and Minitab 17.1 (State College, PA, USA).

Descriptive statistics such as mean, SD, and distribution of the distal and posterior offset were calculated for the offset data. These were then compared with the fixed offsets available in other implants in the industry. The proportion of the data that was > 1 mm different than standard offsets was calculated to determine the percentage of patient-specific implant offsets that are different from the standard implants.

For the subset of implant data that was used for the sizing analysis, each implant AP and ML measurement was recorded for the patient-specific data set. For the sTKA and asTKA implants, sizes were determined based on available product information. Then, each patient-specific implant dimension was used to find the closest match of sTKA and asTKA implant sizes (nearest neighbor). The amount of difference between the patient-specific implant dimension and the sTKA and asTKA implant dimension was recorded. Differences of ≥ 3 mm were considered clinically important differences [17].

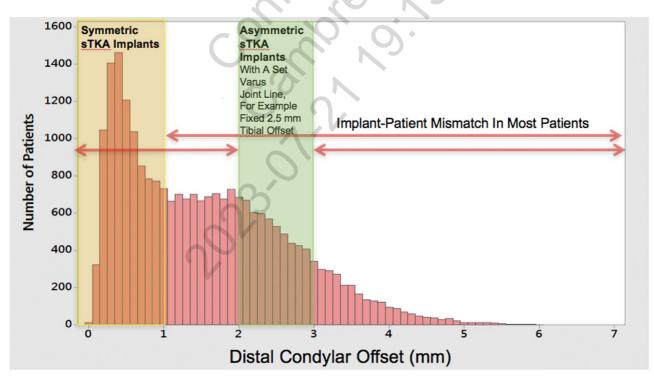


Fig. 4 The number of patients versus DCO is presented: the orange area represents the DCO that can be addressed with a sTKA without requiring further adjustments. The green area represents the DCO that can be addressed with a asTKA with a set varus joint line (fixed 2.5-mm tibial offset like in the Journey Knee System [Smith & Nephew Inc]) without requiring further adjustments. More than 60% of patients with a DCO > 1 mm are not addressed by a sTKA requiring further adjustments. Fifty-six percent of patients having a DCO of < 2 mm or > 3 mm are not addressed by an asTKA with a set varus joint line (fixed 2.5-mm tibial offset like in the Journey Knee System [Smith & Nephew Inc]) requiring further adjustments.



Femoral offsets	Mean (mm)	Minimum (mm)	First quartile (mm)	Median (mm)	Third quartile (mm)	Maximum (mm)	SD (mm)
Distal condylar offset	1.55	0.02	0.6	1.39	2.28	5.96	1.08
Posterior femoral offset	2.90	0.23	2.2	2.75	3.44	8.11	0.96

Table 1. Distribution of	of the distal condylar offs	et and posterior femoral	offset for the patient popula	tion analyzed in this study

Results

We found patient geometry to be quite variable (Fig. 4). The mean DCO was 1.55 mm (SD \pm 1.08). The highest DCO was 5.96 mm (Table 1). The mean PFO was 2.90 mm (SD \pm 0.96). The highest PFO was 8.11 mm (Table 1). Furthermore, we found no clear correlation between DCO and PCO of the knees studied. Instances of patient having a small DCO and higher PCO were commonly seen. Overall, the distribution of the data for the PFO was skewed to the right when compared with the DCO, suggesting that there is no direct correlation between a patient's distal and posterior offsets (Fig. 5). Further analysis showed high variability of AP and ML widths (Fig. 3A-B).

Concerning possible mismatch of sTKA or asTKA with distal geometry, 62% (14,906 of 24,042) of knees exhibited DCO > 1 mm. Therefore, if addressed by a sTKA, 38% (9136 of 24,042) of the knees would match without artificially changing the varus joint line. If addressed by an asTKA implant with a set varus joint line such as the fixed 2.5-mm tibial offset seen in the Journey Knee System (Smith & Nephew Inc), 56% (13,464 of 24,042) of knees having an

offset of < 2 mm or > 3 mm are not addressed by this fixed implant geometry requiring further adjustments (Fig. 4). Only 20% (4808 of 24,042) had < 2 mm PFO corresponding to approximately 3° of external rotation typically used during standard TKA to close the lateral flexion gap. In all, 83% (19,955 of 24,042) of femurs exhibited a > 2-mm difference of PFO (Fig. 6). Concerning AP and ML measurements, 23% (544 of 2367) of patients would have a mismatch between the patient's bony anatomy and the dimensions of the femoral component of $\geq \pm 3$ mm if the TKA design Attune (Attune[®] Knee system; DePuy Synthes) were used and 25% (592 of 2367) of patients would have a mismatch between the patient's bony anatomy and the dimensions of the femoral component of $\geq \pm 3$ mm if the TKA design Persona (Persona Knee System, Zimmer Biomet Inc; and the Attune Knee System) were used, although this was partly addressed by additional femoral sizes (Fig. 3A-B).

Discussion

Achieving proper fit and anatomic congruence is one of the main goals in TKA; however, using available fixed-

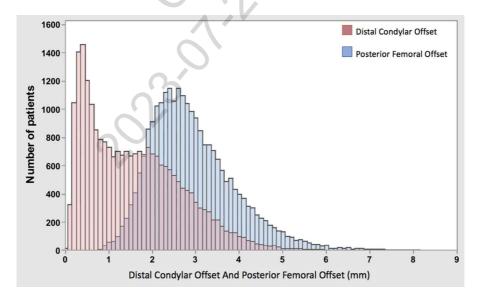


Fig. 5 The number of patients versus DCO and PFO is presented: the difference in the distribution of the DCO and PFO demonstrates that there is no direct correlation in the offsets for the patient population analyzed.

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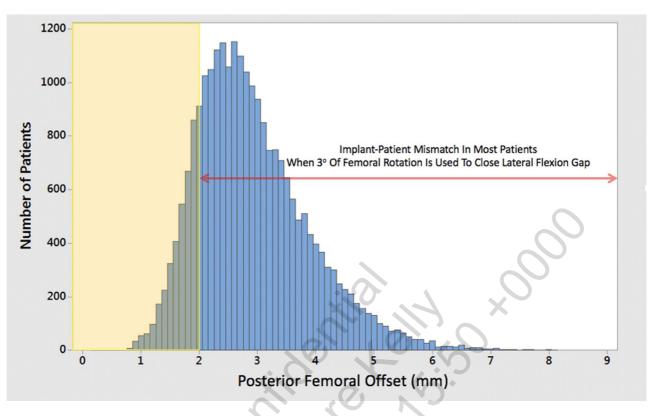


Fig. 6 The number of patients versus PFO is presented: just 20% had a PFO of < 2 mm corresponding to approximately 3° of external rotation typically used during standard TKA to close the lateral flexion gap (orange area). Eighty-three percent of femurs exhibited PFO > 2 mm.

geometry implants establishes intraoperative challenges because of the widely varying anatomy in the population. The first objective of this study was to determine the variations in the distal and posterior femoral geometries in size and offset by evaluating a large CT data set. Our second goal was to evaluate if that would result in substantial mismatch between the implant's size or shape and the patient's anatomy if a femoral component of a modern standard TKA of sTKA or asTKA design were used. Our key finding was that the geometry of the distal femur was highly variable in terms of AP and ML widths as well as in terms of femoral condylar offsets. We also found that a high proportion of knees would have a substantial mismatch between the implant's size or shape and the patient's anatomy if a femoral component of modern standard TKA of sTKA or asTKA designs were to be used.

Our study had several limitations. First and most important is the virtual nature of measurements, which cannot be directly transferred to the intraoperative situation and may not be associated with differences in pain or function after TKAs performed in clinical practice. Another limitation of the present study is that CT does not display cartilage thickness, which varies between 0 and 5 mm; Clarke [8] reported a mean of 2 mm for the posterior condyle, therefore making preoperative measurement of

the PCO inaccurate. Furthermore, when the posterior condyles in knees with varus alignment are considered, the cartilage thickness of the medial condyle is usually found to be less than the cartilage thickness of the lateral condyle. As a consequence, overresection of the medial posterior condyle and underresection of the lateral posterior condyle may occur. A further consequence may be additional rotational requirements and balancing. However, no standard TKA instrumentation allows for cartilage estimation but focuses on bony landmarks, cuts, and ligament balance. That being so, we believe that although our measurement approach may have shortcomings, those shortcomings directly parallel those that are in common use in clinical practice in that our measurement approaches based on cartilage are similar to the alignment guides used during TKA. Even so, this issue should be considered-and we hope remedied-by future studies and perhaps future instrument systems. Furthermore, cartilage and bone loss can influence ligament balance and laxity, and these factors differ between patients [24]; likewise, surgeons may differ in terms of how they achieve ligament balance, making this even more complicated. To try to mitigate this, given that these differences are likely to be more severe in knees with large deformities, we excluded knees with varus or valgus deformities $> 15^{\circ}$. We note also that our data set includes



implant dimensions that were generated from the design process of a cTKA but does not include patient demographic information; that being so, we cannot assume that our findings apply equally to men and women or different ethnicities. Furthermore, because mapping the entire database of implant dimensions was prohibitive when comparing sTKA and asTKA, a large consecutive series was selected to limit the effect of selection bias. Because the conclusions drawn are limited to cases that fall into the range of sizes supported by the collected data, our conclusions should apply to patients having knees with dimensions falling into the FDA clearance range of cTKA. Hence, our conclusions do not apply to small knees with dimensions that do not fall in the clearance range, thereby probably excluding parts of the Asian population. However, to our best knowledge, this is the largest data set evaluated so far depicting a large cross-section of European and US-American patients and highlighting that surgeons intraoperatively have to deal with individual anatomic geometries. Finally, our comparisons were done using three modern TKA designs, including symmetric and asymmetric designs; therefore, our findings may not apply to every available commercial implant. However, said modern standard TKA designs are of particular interest because they are commonly used worldwide.

Concerning our first research purpose, we found considerable variation in distal and posterior femoral geometry in this large data set of CT scans of the knee, and we found no correlation between DCO and PFO. Addressing a highly varying geometry of the proximal femur using available fixed-geometry implants can be challenging. Our results add further important information and are mainly consistent with other anatomic reports. Meric et al. [20] investigated 13,546 CT scans and measured an average femoral rotation angle of 3.3° (variability of 14°, ranging from 3° internal rotation to 11° external rotation) supporting our statement of high variability in the PFO. They also measured the distal femoral valgus angle, which was 5.7° on average (range, 1°-16°), also supporting our statement of high variability in the DCO. However, their results are presented in angles. This study presents results in millimeters, which is more useful because it may help the surgeon intraoperatively to determine the appropriate resection amount and to choose the correct amount of rotation. Furthermore, it is considered to be a strength of the present study that not only the variability in PFO and DCO was shown, but also in AP and ML measurements. Weinberg et al. [26], who measured the PCO of 1058 femurs, support our findings with a further statement that the PCO varies not only among individuals, but also within individuals. Surgeons should be aware of this fact when doing bilateral TKA. Our data showed that there was a difference between the DCO and PCO for the same knee model. This might result in asymmetric flexion-extension gaps, leading

surgeons to make additional bone cuts or soft tissue releases to achieve equal flexion-extension gaps if using a gap-balancing technique. This issue is further stressed by the usual lack of estimation of cartilage in standard instrumentation and standard referencing in TKA, which, however, has great influence for all bony cuts as well as rotational issues.

Concerning our second research purpose, we found that a high proportion of knees would have a substantial mismatch between the implant's size or shape and the patient's anatomy if a femoral component of a modern standard TKA of sTKA or asTKA designs were to be used. A total of 62% (14,906 of 24,042) of patients had a DCO > 1 mm and 56% (13,464 of 24,042) of patients had a DCO <2 mm or > 3 mm, thus requiring further adjustments with sTKA or asTKA with a fixed 2.5-mm tibial offset, respectively. The highest DCO was even 5.96 mm. Eightythree percent (19,955 of 24,042) of femurs exhibited PFO> 2 mm. Such large offsets cannot be compensated with 3° of external rotation, which is often recommended in standard TKA (usually sTKA) to establish a balanced rectangular flexion gap. The highest PFO was even > 8 mm. Therefore, external rotation of $> 3^\circ$, or more bony resection medially, or medial release must be accepted to address the wider lateral flexion gap. On the other hand, the lowest PFO was just 0.02 mm, which also cannot be addressed with 3° of standard external rotation. Those findings highlight that restoration of the femoral condyles is still a challenge, although it has been known to be an important factor in TKA [1, 3, 14]. Surgeons intraoperatively face the dilemma that they have to accept disadvantages such as more releases or excessive bony resections to close the ML gap difference. Excessive femoral bone resection may elevate the joint line and narrow the attachment sites of the collateral ligaments, leading to midflexion instability [15]. Furthermore, a high proportion of patients would have suffered sizing issues of \pm 3 mm in AP and ML widths if they had received a modern sTKA or asTKA. An overhang of > 3 mm increases the risk of residual pain and may compromise the functional outcome [4, 18]. On the other hand, undersizing may cause laxity [21] and may increase the risk of postoperative bleeding [13].

Custom TKA could be one way to address the issues related to anatomic mismatch that we identified, but custom TKA has not been proven superior to off-the-shelf designs, and it adds substantial costs to the procedure. Also, kinematically aligned TKA might address some of the aforementioned topics. However, clinical benefit still is controversially discussed [25, 28, 29] and because it is recommended to use computer navigation or patientspecific instruments to ensure accuracy, it likely adds cost to the procedure. Although our findings may suggest that additional releases likely are needed with off-the-shelf designs to address the anatomic differences between

implant sizes and patients' anatomies, and these soft tissue releases may weaken supportive knee ligaments, there is no robust evidence of which we are aware that this results in compromises to pain relief or function. Another remaining gap in our knowledge pertains to the variability of the geometry of the proximal tibia. The tibia shows distinct intraas well as interindividuality concerning asymmetry and obliquity of the proximal tibia in the sagittal as well as frontal plane. These may result in mismatch between the implant and the patient's anatomy and may lead to overhang with possible soft tissue irritation, undercoverage with possible implant subsidence, and malrotation resulting from compromise between coverage and size [9, 19]. Those gaps were beyond the scope of this article, however. Furthermore, future studies may focus on effects resulting from any geometric interaction between the femur and tibia, which are both of highly variable geometry. In addition, future studies should examine variability of the geometries in different patient subgroups, including different ethnicities (such as examining patients from Asia).

In conclusion, this CT data set analysis showed that a high degree of variability exists in DCO, AP and ML sizes as well as in PFO. These findings suggest that it is possible that a greater degree of customization could result in surgeons performing fewer soft tissue releases and medial resections than now are being done to fit a fixed-geometry implant into a highly variable patient population. However, as an imaging study, it cannot support one approach to TKA over another; comparative studies that assess patient-reported outcomes and survivorship will be needed to help surgeons decide among sTKA, asTKA, and cTKA.

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