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KNEE

Deviations in femoral joint lines using calipered kinematically aligned TKA from virtually planned joint lines are small and do not affect clinical outcomes

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Abstract

Purpose Kinematically aligned total knee arthroplasty (KA TKA) strives to restore the native distal and posterior joint lines of the femur. Because the joint lines of a virtually planned femoral component on the native femur can serve as surrogates of those of the native femur, the present study determined position and orientation deviations of the femoral joint lines following calipered KA TKA from virtually planned joint lines and whether these alignment deviations affect clinical outcomes. Our hypotheses were that the alignment deviations for most knees would be less than 2 mm and/or 2° and that larger alignment deviations would not be associated with lower clinical outcome scores.

Methods A review of lower extremity CT scanograms and CT scans of the knee identified 36 patients treated with calipered KA TKA in one limb and no other skeletal deformities in either limb. 3D models of the operated femur with the implanted femoral component and the native femur were created. The articular surfaces of a 3D model of the implanted femoral component in the TKA knee were shape-matched to the condyles of the native femur to create a virtual plan. The shape-matched femoral component served as a reference from which to determine alignment deviations of the femoral component implanted in the ipsilateral femur. The Forgotten Joint Score (FJS) and Oxford Knee Score (OKS) were obtained at an average of 20 months.

Results For proximal–distal and anterior–posterior positions and varus–valgus and internal–external orientations of the femoral component, the root mean square deviations from the planned joint lines ranged from 1.4 to 1.5 (mm or degrees). The mean differences ranged from −0.1 to 0.2 (mm or degrees) indicating an absence of systematic alignment deviations. The proportion of knees with joint lines within ±2 mm and ±2° of the joint lines of virtually planned knees ranged from 83 to 92%. For the FJS and OKS, the median values were 79 (out of 100) and 45 (out of 48), respectively, and there were no significant correlations between deviations in the positions and orientations and either the FJS or the OKS.

Conclusion Alignment deviations were bounded by 2 mm and 2° for most knees, which previous biomechanical studies have shown reduce the risks of stiffness, loss of extension, loss of flexion, and tibial compartment forces higher than those of the native knee. Moreover, because median FJS and OKS were relatively high, and because larger alignment deviations did not correlate with lower outcome scores, deviations did not affect clinical outcomes. These results validate calipered KA TKA as a surgical technique which closely restores the distal and posterior femoral joint lines to those planned and achieves concomitant high patient-reported outcome scores. Thus, surgeons can use the calipered KA TKA technique with confidence that the surgical alignment goal will be satisfied with sufficient accuracy that high patient-reported outcomes are achieved.

Level of evidence III.

Keywords Total knee replacement · Total knee arthroplasty · Prosthetic knee · Oxford Knee Score · Forgotten Joint Score · Femoral component alignment

Introduction

Kinematically aligned total knee arthroplasty (KA TKA) is an innovative surgical technique with high 10-year implant survival and patient function that is an alternative

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RESET

RECORD OF VERIFICATION CHECKS FOR CALIPERED KINEMATICALLY ALIGNED TKA

SURGEON ____ PATIENT CODE ____ DATE (DD/MM/YYYY) ____

KNEE ☐ RIGHT ☐ LEFT

OA DEFORMITY ☐ VARUS ☐ VALGUS ☐ PF

A/P OFFSET

EXPOSURE ____ mm TRIALING ____ mm DIFFERENCE 0.0 mm

ACL CONDITION

☐ INTACT ☐ TORN ☐ GRAFT

DISTAL FEMORAL RESECTION

Target Thickness: 8mm Unworn, 6mm Worn (No Cartilage)

When initial thickness misses target - recut or use a washer

MEDIAL CONDYLE

☐ UNWORN ☐ WORN

INITIAL THICKNESS ____ mm

RECUT [N] [Y] ____ mm

WASHER [N] [Y] ____ mm

FINAL THICKNESS 0.0 mm

LATERAL CONDYLE

☐ UNWORN ☐ WORN

INITIAL THICKNESS ____ mm

RECUT [N] [Y] ____ mm

WASHER [N] [Y] ____ mm

FINAL THICKNESS 0.0 mm

POSTERIOR FEMORAL RESECTION

Target Thickness: 7mm Unworn, 5mm Worn (No Cartilage)

When initial thickness misses target - recut

MEDIAL CONDYLE

☐ UNWORN ☐ WORN

INITIAL THICKNESS ____ mm

RECUT [N] [Y] ____ mm

FINAL THICKNESS 0.0 mm

LATERAL CONDYLE

☐ UNWORN ☐ WORN

INITIAL THICKNESS ____ mm

RECUT [N] [Y] ____ mm

FINAL THICKNESS 0.0 mm

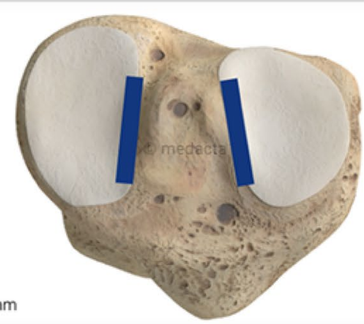
TIBIAL RESECTION

Target: Equal Thickness Measured at Base of Tibial Spines

☐ MEDIAL

☐ LATERAL

____ mm



☐ MEDIAL

☐ LATERAL

____ mm

PCL CONDITION

☐ INTACT ☐ TORN ☐ EXCISED

TIBIAL V-V RECUT [N] [Y] ____ deg

TIBIAL SLOPE RECUT [N] [Y] ____ deg

FINAL CHECK WITH SPACER BLOCK AND TRIAL COMPONENTS

☐ NEGLIGIBLE V-V LAXITY IN EXTENSION

☐ 2-3 MM OF LATERAL OPENING WITH VARUS LOAD IN 15-30° OF FLEXION

FEMUR SIZE ____ TIBIA SIZE ____ INSERT THICKNESS ____ ☐ CR ☐ CS PATELLA SIZE ____

◂**Fig. 1** Worksheet for intraoperatively recording serial verification checks based on caliper measurements of bone resections and positions for a femoral component with 9 mm thick distal femoral condyles and 8 mm thick posterior femoral condyles. The order of the bone cuts progresses from distal femoral, posterior femoral, anterior femoral, chamfer femoral, and tibial resection. The thicknesses of the distal and posterior femoral resections are adjusted so that they equal the thickness of the component within 0 ± 0.5 mm after compensating for 2 mm of cartilage wear when present and a ~ 1 mm kerf from the saw cut

to conventional mechanically aligned total knee arthroplasty (MA TKA) [13]. The 'calipered' kinematic alignment surgical technique uses serial verification checks incorporating ten caliper measurements of bone resections and positions [25, 32] (Fig. 1). The assumption is that these verification checks insure that the surgical alignment goal of restoring joint lines to native is satisfied.

Focusing on femoral joint lines, the surgical alignment goal in calipered KA TKA should be closely satisfied in theory. The thickness of each femoral resection should equal that of the corresponding region of the femoral component after correcting for sawblade kerf and any wear on the articular surfaces (Fig. 1). By measuring the resection thickness with calipers, the thickness can be controlled within ± 0.5 mm [12]. Holding this tolerance could translate into alignment deviations as small as 0.5 mm and approximately 1° for the proximal–distal (P–D) and anterior–posterior (A–P) positions and the varus–valgus (V–V) and internal–external (I–E) axial orientations, respectively. These positions and orientations are termed alignment variables. The P–D position and V–V orientation determine the alignment of the distal femoral joint line and the A–P position and I–E orientation determine the alignment of the posterior femoral joint line.

However, sources of alignment deviation other than the resection thickness affect the final position and orientation of the femoral joint lines in practice. Sources include cementation and compaction of the femoral component [4] and assuming a worn articular cartilage thickness of 2 mm for all patients whereas the actual thickness can be as great as 4 mm [17, 19]. Because these alignment deviations can stack up leading to deviations as large as 4° in V–V orientation, it is of interest to determine alignment deviations from the surgical alignment goal.

A method for determining these deviations is to shape match the articular surfaces of a mirrored 3D model of the femoral component in the KA TKA knee to the articular cartilage surfaces of a 3D model of the native femur in the contralateral knee. Because the shape-matching process optimizes the alignment of a femoral component for KA TKA by closely matching the distal and posterior articular cartilage surfaces [10, 11], the joint lines of the shape-matched femoral component model can serve as surrogates for those of the native femur and thus provide a viable reference from which deviations in KA TKA femoral joint lines can be determined.

Also it is of interest to determine whether the alignment deviations affect clinical outcomes. Alignment deviations less than 2 mm in position and 2° in orientation from the native femoral joint lines reduce the risks of stiffness, loss of extension, loss of flexion, and higher tibial compartment forces than those of the native knee [27, 28, 31]. Thus, the proportion of patients within these limits is a meaningful metric. In addition, patient-reported outcome scores should be documented and assessed for any significant association between the alignment deviations in each alignment variable.

A prior study determined alignment deviations between the planned alignment of the femoral component and the achieved alignment [29]. However, the results do not translate into alignment deviations in the four alignment variables mentioned above and the effect of alignment deviations on clinical outcomes was not studied.

Accordingly, the purposes of the work described by this paper were twofold. One was to determine alignment deviations in the two femoral component positions and two orientations from those of a femoral component virtually planned to the contralateral native knee in 36 patients with a primary calipered KA TKA. A second was to determine whether the resulting alignment deviations affect clinical outcome scores. Our hypotheses were that the alignment deviations for most knees would be less than 2 mm and/or 2° and that larger alignment deviations would not be associated with lower clinical outcome scores. If these hypotheses were supported, then this result would validate calipered KA TKA as a surgical technique which largely achieves the surgical alignment goal.

Methods and materials

Patients

An institutional review board approved this retrospective study (IRB 1362165-1) and the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. From January 2017 to July 2017, 251 primary KA TKAs were performed using ten caliper measurements and serial verification checks (Fig. 1) [25, 32]. All patients fulfilled the Centers for Medicare & Medicaid Services guidelines for medical necessity for TKA treatment and pre-operatively completed the Oxford Knee Score. The indications for TKA included disabling symptoms not resolved after conservative knee treatment, radiographic evidence of Kellgren–Lawrence Grade 2–4 arthritic changes or osteonecrosis, and any severity of flexion, varus, and valgus deformity.

Inclusion criteria were patients having KA TKA performed with asymmetric, fixed bearing, posterior cruciate-retaining (PCR) components (Persona CR, Zimmer-Biomet, Warsaw, IN), a native contralateral limb with no evidence of degenerative joint disease, no skeletal abnormalities or prior surgery in either limb except for the KA TKA, no history of rheumatic or traumatic arthritis, age between 40 and 85 years, a body mass index less than or equal to 40. Note that patients were selected with no restriction on preoperative varus–valgus or flexion-contracture deformity.

Patients considered for inclusion were those operated on between January 2017 and July 2017 by one surgeon who performed primary calipered KA TKA on 251 consecutive patients. Patients were winnowed down to those meeting the inclusion criteria in a three-step process. The first step entailed a review of medical records to identify those patients within the age range and BMI range and those with acceptable medical history. The second and third steps involved a review of CT images. Postoperative AP and lateral CT scanograms of both limbs and CT axial images of both knees were obtained with the Perth protocol. The second step involved a review of the scanograms to identify those patients with a unilateral calipered KA TKA without a skeletal abnormality in either limb. The third step involved a review of multiplane reconstructions of the axial images to identify those patients without subchondral sclerosis, joint space narrowing, marginal osteophytes, and subchondral cysts of the tibiofemoral and patellofemoral joints in the unoperated knee. From these three steps, 36 patients were identified who met the inclusion criteria (Table 1). Patients completed questionnaires to determine the Oxford Knee and Forgotten Joint scores at an average follow up of 20 months (range 18–23 months).

The average age of the 36 patients was 69 ± 8 years, 22 were women, and the body mass index averaged 29 ± 4 kg/m^2 (Table 1). The preoperative Kellgren–Lawrence classification of osteoarthritis was II in 3%, III in 55%, and IV in 42% as determined by standing full extension and 45° flexion knee radiographs. The mean postoperative OKS was not different between patients with a Kellgren–Lawrence classification of II (40 ± 12.4 points), III (40 ± 10.9 points), and IV (41 ± 9.8 points) ($p = 0.9107$). The clinical varus or valgus deformity as measured non-weight bearing ranged from 25° valgus to 15° varus.

Surgical technique

Using ten sequential caliper measurements and a series of verification checks with manual instruments, KA TKA was performed by a single surgeon using a mid-vastus approach following a previously described technique [25]. Asymmetric, fixed bearing, PCR retaining components and a patella button were implanted with cement (Persona CR, Zimmer-Biomet, Warsaw, IN). For the femoral component, the varus–valgus orientation and proximal–distal location were set to restore the native distal femoral joint line by adjusting the thickness of the distal femoral resections as measured with a caliper to within 0 ± 0.5 mm of the thickness of the femoral component condyles after compensating for cartilage wear and saw blade kerf. The internal–external orientation and anterior–posterior position were set to restore the native posterior joint line by adjusting the thickness of the posterior femoral resections as for the distal femoral joint line. These steps set

Table 1 Preoperative patient demographics, clinical characteristics, pre- and postoperative Oxford Knee scores, and Forgotten Joint score

Preoperative demographics, clinical characteristics, and patient-reported outcome scores	Number of patients or knees	Mean (SD), number (%), or median	Range
Demographics			
Age (years)	$N = 36$	69 (7.5)	55 to 86
Sex (male)	$N = 36$	14 (39%)	
Body Mass Index (kg/m^2)	$N = 36$	28.7 (4.0)	22 to 39
Anesthesia Society of Anesthesiologists Score (ASA) (1 is best, 4 is worst)	$N = 36$	1 (0%), 2 (64%), 3 (25%), 4 (11%)	
Preoperative motion and deformity			
Extension (°)	$N = 36$	10 (8.0)	0 to 25
Flexion (°)	$N = 36$	113 (7.8)	105 to 120
Varus (+)/valgus (−) deformity (°)	$N = 36$	1 (13.0)	−25 to 15
Function			
Preoperative Oxford Score (48 is best, 0 is worst)	$N = 36$	23.5 (median)	6 to 41
Postoperative Oxford Score	$N = 36$	45 (median)	7 to 48
Postoperative Forgotten Joint Score	$N = 36$	79 (median)	8 to 100

the femoral component with a bias of 0.3° and precision of ± 1.1° with respect to the flexion–extension plane of the knee [24].

For the tibial component, the varus–valgus orientation was set to restore the native joint line by ensuring that the thicknesses measured with a caliper at the base of the tibial spines medially and laterally were within 0 ± 0.5 mm. With the knee in full extension, the varus–valgus angle of the tibial resection was fine-tuned working in 1° to 2° increments until the varus–valgus laxity was negligible as in the native knee [30]. The internal–external rotation of the tibial component was set using a kinematic tibial template with a negligible bias of 0.1° external and a precision of ± 3.9° [26]. With the knee in 90° of flexion, the slope was set to restore the native joint line in the medial compartment by working in 1° to 2° increments until the offset of the anterior tibia from the distal medial femoral condyle with trial components matched that of the knee at exposure after adjusting for cartilage wear on the femur and ensuring that the internal–external laxity approximated 14° as in the native knee [30]. Ligament releases were not performed. This surgical technique restores the hip–knee–ankle angle, distal lateral femoral angle, and proximal medial tibial angle to native within ± 3° with frequencies of 95%, 97%, and 97%, respectively [25].

Method for determining deviations in alignment variables

CT images of the operated femur and contralateral native femur were segmented using the automatic tools and refined manually using a combination of thresholding and manual segmentation (Mimics® v20.0, Materialise, Belgium). The classic 'marching cubes algorithm' was used to reconstruct 3D models of the operated femur with the implanted femoral component and the contralateral native femur (Fig. 2). Using the iterative closest point (ICP) algorithm, a CAD model of the femoral component was best-fit to the 3D model of the implanted femoral component (Geomagic®, 3D Systems, Cary, NC). A 2 mm thick surface was applied to the 3D model of the contralateral native distal femur to create virtual cartilage surfaces comparable to the average thickness of the distal femoral cartilage (Fig. 2) [23]. Twenty-five cm in length mid-sections of the femoral shafts of the operated femur and the contralateral native femur were formed by cutting the femur 12 cm from the most proximal point of the femoral head and 25 cm distal to the first cut (Fig. 2). A mirror of the mid-section of the operated femur was best-fit to the mid-section of the contralateral native femur to yield a transformation matrix. The root mean squared deviation (RMSD) of the best-fit of the midsections was 0.7 mm (interquartile range 0.6 to 0.8 mm). The transformation matrix was applied to a mirror of the CAD (mCAD) model of the femoral component best-fit to the 3D model of the implanted

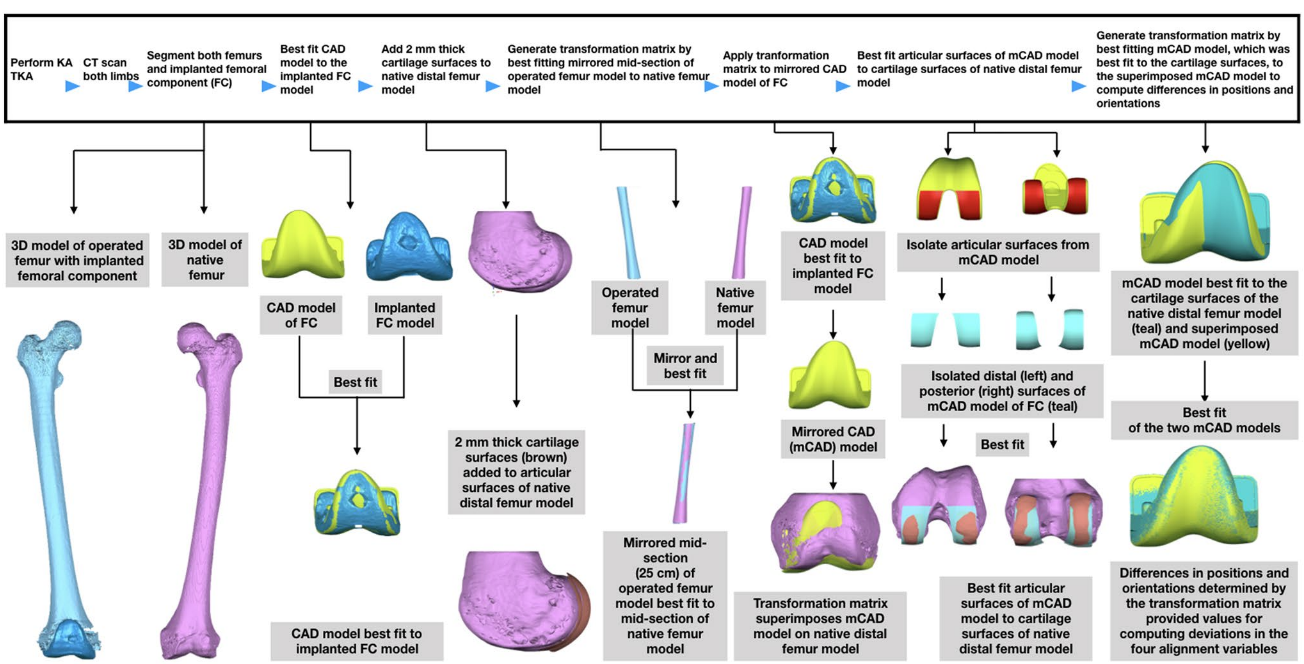


Fig. 2 Diagram illustrating the process for determining deviations in alignment variables of the distal and posterior femoral joint lines following kinematically aligned TKA from virtually planned joint lines on the contralateral native knee

femoral component thus superimposing this mCAD model on the native distal femur model. The articular surfaces of the mCAD model of the femoral component also was best-fit to the virtual cartilage surfaces of the contralateral native distal femur model (Fig. 2). Differences in positions and orientations of the superimposed mCAD model of the femoral component from the mCAD model of the femoral component best fit to the virtual cartilage surfaces (Fig. 3) provided values for computing deviations in alignment variables of the distal (P-D and V-V) and posterior (A-P and I-E) femoral joint lines.

Statistical analysis

To quantify repeatability and reproducibility, three observers independently processed the 3-D bone and femoral component models three times with at least 24 h between trials from the same seven randomly selected patients and determined the differences in position and orientation for each femoral joint line for each trial and each observer. A two-factor mixed-model analysis of variance (ANOVA) was performed for each of the four alignment variables where

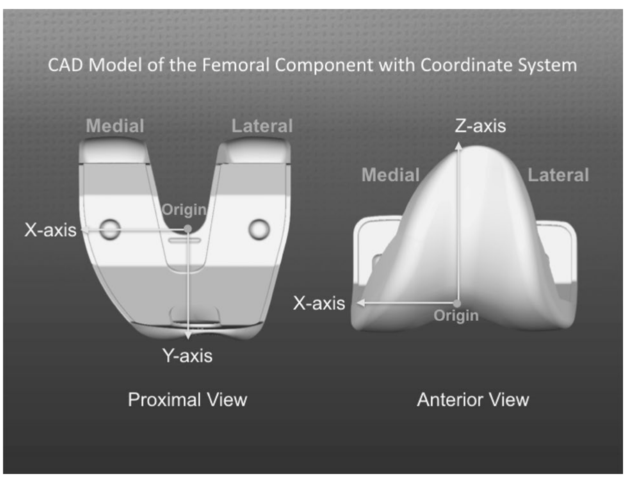


Fig. 3 Diagram illustrating coordinate system in a left knee for determining differences in position and orientation of the mirrored CAD (mCAD) model of the femoral component superimposed on the native distal femur model from the mCAD model best fit to the virtual cartilage surfaces of the native distal femur model. The origin was the midpoint of the line connecting the base of the lugs of the mCAD model of the femoral component. The *X*-axis was parallel to the posterior condyles and pointed in the medial–lateral direction with medial being positive for a left knee. The *Y*-axis was mutually perpendicular to the *X*-axis and the lugs and pointed in the anterior–posterior direction with anterior being positive. The *Z*-axis was mutually perpendicular to the *X*- and *Y*-axes and pointed in the proximal–distal direction with proximal being positive. Differences in position were expressed in this coordinate system whereas differences in orientation were given in a 3-2-1 Euler angle sequence. Note that for a right knee, the lateral direction was positive which required that negative values in this direction be taken and used in further analyses

the two factors were observer at 3 levels and patient at 7 levels. Observer and patient were modelled as random effects. The resulting variance components for observer, patient, and error were used to compute the intraobserver and interobserver ICCs [3]. An ICC value of > 0.9 indicated excellent agreement, 0.75–0.90 indicated good agreement, and 0.5–0.75 indicated moderate agreement [14]. The ICC values for repeatability (i.e. intraobserver) and reproducibility (i.e. interobserver) for the A–P position were 0.98 and 0.98, 0.80 and 0.81 for the P–D position, 0.96 and 0.96 for the M–L position, 0.98 and 0.97 for the V–V orientation, and 0.98 and 0.98 for I–E orientation, respectively, confirming previously established good to excellent repeatability and reproducibility [33].

The systematic deviation (mean difference), random deviation (± 1 standard deviation of difference), and root mean squared deviation (RMSD which combines the systematic and random deviations) of the mCAD model superimposed on the native distal femur model from the best fit of the mCAD model to the cartilage surfaces of the native distal femur model were computed for alignment variables of the distal (P-D and V-V) and posterior (A-P and I-E) femoral joint lines. To determine whether deviations affected clinical outcomes, the proportion of femoral components within 1, 2, and 3 mm or degrees was determined for each alignment variable. Also a simple linear regression was performed with the absolute deviation in each alignment variable for each patient as the independent variable and the corresponding outcome score for that patient for both the FJS and OKS (4 alignment variables $\times$ 2 outcome scores $=$ 8 total simple linear regressions). The latter analysis was to determine whether larger deviations correlate with lower FJS and OKS. Significance was set at $p < 0.05$.

Results

The RMSDs were 1.4 mm for the P–D and A–P positions and were bounded by 1.5° for the V–V and I–E orientations (Table 2). The absolute systematic alignment deviations (i.e. mean differences) were bounded by 0.2 mm and 0.2° whereas the random alignment deviations (i.e. standard deviations of the differences) were much greater at 1.4 mm and 1.4°; thus the random alignment deviations dominated the RMSDs for all alignment variables.

For the P–D and A–P positions, the proportion of implanted femoral components within 2 mm of the contralateral distal femur was at least 91%. For the V–V and I–E orientations, the proportion of femoral components within 2° from the contralateral distal femur was at least 83% (Table 2).

For the patient-reported outcome scores, the FJS median (interquartile range) was 79 (48–95) and the OKS median

Table 2 Descriptive statistics of deviations in femoral joint line alignment variables and percentages of knees with deviations within specified limits for kinematically aligned implanted femoral components from virtually planned femoral components in the native contralateral knee

Alignment variables of the distal (P-D and V-V) and posterior (A-P and I-E) femoral joint lines	Root mean square deviation (RMSD)	Systematic deviation (mean difference)	Random deviation (SD of difference)	Percent within 1 mm or 1° from planned (%)	Percent within 2 mm or 2° from planned (%)	Percent within 3 mm or 3° from planned (%)
Proximal–distal (P-D) position (mm)*	1.4	0.2	1.4	32	92	100
Anterior–posterior (A-P) position (mm)#	1.4	0.1	1.4	50	91	94
Varus–valgus (V-V) orientation (°)€	1.4	0.2	1.4	48	88	100
Internal–external (I-E) orientation (°)§	1.5	−0.1	1.5	39	83	97

The root mean square deviation is the square root of the sum of the squares of the mean difference and the standard deviation of the difference

*Positive: femoral component more proximal than planned; #Positive: femoral component more anterior; €Positive: femoral component more varus; §Positive: femoral component more internal

Table 3 Summary of results from simple linear regressions

Regression variables	R^2	Slope	p value
V–V versus OKS	0.02	−1.8	0.419
I–E versus OKS	0.0008	0.3	0.878
P–D versus OKS	0.006	−1.2	0.659
A–P versus OKS	0.01	−1.4	0.523
V–V versus FJS	0.08	−12.6	0.094
I–E versus FJS	0.002	−2.0	0.788
P–D versus FJS	0.06	−12.6	0.163
A–P versus FJS	0.02	−6.8	0.383

(interquartile range) was 45 (39–47) (Table 1). There was no significant correlation between the deviations in any of the four alignment variables and either the FJS or the OKS (Table 3).

Discussion

The most important findings of the present study were that calipered KA TKA with use of serial verification checks (1) restored the femoral component positions to within 2 mm and orientations to within 2° of the planned femoral joint lines in the contralateral native knee with a frequency of at least 91% and 83%, respectively, and (2) achieved relatively high median FJS and OKS and without larger alignment deviations correlating with lower scores.

For calipered KA TKA, the RMSDs of the four alignment variables reported as a worst case and the percentage of patients within 2 mm or 2° of planned femoral joint lines were comparable to, if not better than, those reported for mechanical alignment with the use of robotic-arm, navigation, patient-specific, and manual instrumentation. The RMSDs for the femoral component positions and orientations ranged from 1.4 to 1.5 (mm or degrees) and were comparable to or lower than those reported for robotic-arm mechanical alignment TKA (2.0° for V–V using optical motion capture) [16]. For the V–V orientation of the femoral component, calipered KA TKA oriented 88% of patients within 2° of the contralateral planned distal femoral joint line. This result was comparable to the navigation alignment of 92% of patients and greater than manual instrumentation alignment of 67% of patients within 2° of the mechanical axis of the femur as measured directly on CT images [21]. For the I–E orientation, calipered KA TKA oriented 83% of patients within 2° of the planned posterior femoral joint line. This result was comparable to the navigation alignment of 91% of patients and greater than manual instrumentation alignment of 68% of patients within 2° of the transepicondylar axis as measured directly from CT images [21]. Calipered kinematic alignment of the femoral component within 2° of the planned femoral joint lines of 88% and 83% of patients in the V–V and I–E orientations, respectively, was comparable to or higher than patient-specific alignment of 79% and 68% of patients in these orientations within 2° of the preoperative plan based on measurements using a navigation system [20]. Calipered KA TKA achieved this consistency with use of two simple, inexpensive sequential intraoperative verification checks (Fig. 1). The two checks were the caliper measurement and adjustments of the distal femoral resections and posterior femoral resections until the thickness of each resection matched the thickness of the corresponding condyle of the femoral component within 0 ± 0.5 mm after compensating for cartilage wear and kerf of the saw cut.

Considering the expense involved in investigating and treating the painful and poorly functioning TKA [15], a surgical technique that is associated with high patient satisfaction and improvement in function is important from both an individual patient and a global health system perspective. The latest and most compelling support for use of kinematic or an 'individualized' alignment philosophy in place of mechanical alignment is based on the new systematic classification of the phenotypes of the native limb and knee joint line [9]. 3D-reconstructed CT images confirmed the great variability of the coronal alignment of the lower limb and joint lines in both non-osteoarthritic [22] and osteoarthritic knees [8]. The currently used classification system (neutral, varus, valgus) oversimplifies the coronal alignment and should be replaced by the use of femoral and tibial phenotypes. The detailed phenotype assessment of a patient's individual anatomy justifies the individualized approach to TKA of restoring the native joint lines and limb alignment, which is the goal of KA TKA.

The patient-reported postoperative FJS and OKS indicated that calipered KA TKA restored relatively high patient satisfaction and function. To appreciate that these scores are relatively high, a comparison to those reported for mechanically aligned TKA is useful. Since the FJS has not been reported as commonly as the OKS, this comparison will be restricted to postoperative OKS from three previous studies. One study with a 1-year follow-up on 578 patients reported a mean OKS of 35.0 [5], a second study with a 1-year follow-up on 602 patients reported a mean OKS of 34.3 [34], and a third study with a 2-year follow-up on 222 patients reported a mean OKS of 35.9 [2]. In comparison, the mean OKS in the present study was 41 or at least 14% higher.

The calipered kinematic alignment technique resulted in a high proportion of patients with deviations less than 2 mm in position and 2° in orientation from the virtually planned femoral joint lines. As demonstrated by several biomechanical studies, meeting these alignment deviation limits is needed to reduce the risks of stiffness, loss of extension, loss of flexion, and tibial compartment forces higher than those of the native knee [27, 28, 31]. The fact that these alignment deviation limits were largely met may explain in part the relatively high FJS and OKS achieved with calipered KA TKA.

Finally larger alignment deviations did not correlate with lower patient-reported outcome scores. Given that (1) the FJS and OKS scores were relatively high; (2) alignment deviations were less than 2 mm and 2° for most patients; (3) larger alignment deviations did not correlate with lower FJS or OKS, and (4) the alignment deviation analysis was a worst case as explained above, it can be reasonably concluded that the alignment deviations in the femoral joint lines resulting from calipered KA TKA do not adversely affect clinical outcomes.

Five limitations should be discussed. First, the study was performed on a subset of 36 of 251 (14%) patients as skeletal deformities or arthroplasties prevented the use of the 3-D computational processes in the others. However, the reported deviations should be generalizable as calipered kinematic alignment of the femoral component is not affected by skeletal deformities or arthroplasties outside the treated knee. Second, the actual alignment deviations are likely less than those reported because using the operated femur as the reference was not possible and using the contralateral native femur and virtual cartilage thickness of 2 mm might have affected the deviations. Side-to-side differences (i.e. asymmetry) in femur morphology exist [6, 7] which could contribute to alignment deviations. Likewise, the use of a 2 mm thick virtual cartilage surface could contribute to alignment deviations because the cartilage thickness varies 1.4 to 4.3 mm between native knees [18]. Third, the difference in flexion-extension (F–E) of the mCAD model of the femoral component from the mCAD model best-fit to the virtual cartilage surfaces of the native distal femur model was not measured because the virtual cartilage surface is cylindrical and does not control random F–E of the best-fit mCAD model. Uncertainty in F–E rotation would not affect our results markedly because the cylindrical nature of the articular surfaces insured that the distal and posterior femoral surfaces were invariant regardless of small variations in F–E rotation. Fourth, although the sample size was not sufficiently large to confidently conclude that the slopes in the regression analyses were not significantly different from zero, the issue is moot because even the highest R-squared value (Table 3) accounted for only 8% of the variability thus rendering none of relationships clinically meaningful [1].

Finally, clinical outcome scores might be affected not only by deviations in the alignment of the femoral component but also by deviations in the alignment of the tibial component so that analyzing the effect of deviations in the alignment of the femoral component on clinical outcomes may seem confounded. However, three of the six alignment variables of the tibial component (I–E orientation, A–P position, and M–L position) are independent of the alignment of the femoral component so that any alignment deviations would randomly affect clinical outcomes. Since the remaining two alignment variables (V–V and F–E orientations), which are not adjusted by the thickness of the tibial insert, are both coupled to alignment of the femoral component, any systematic effect on patient-reported outcomes scores will be due primarily to deviations in alignment variables of the femoral component.

Conclusion

In summary, calipered kinematic alignment of the femoral component with serial verification checks restored the distal and posterior femoral joint lines with sufficiently small deviations from those planned on the native femur of the contralateral knee that clinical outcomes were unaffected. This was accomplished without the use and expense of preoperative radiographs or high-cost imaging modalities such as MRI and CT. Thus, surgeons can use the calipered KA TKA technique with confidence that the surgical alignment goal will be satisfied with sufficient accuracy that high patient-reported outcomes are achieved.

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Compliance with ethical standards

Conflict of interest SMH is a paid consultant for THINK Surgical and Medacta, Inc. MLH receives research support from Zimmer-Biomet and Medacta, Inc.

Ethical approval An institutional review board approved this retrospective study (IRB 1362165-1) and the study was performed in accordance with the ethical standards as laid down inthe 1964 Declaration of Helsinki and its later amendments or comparable ethical standards

References

1. Altman DG (1991) Practical statistics for medical research. Chapman & Hall/CRC, London
2. Anderl W, Pauzenberger L, Kolblinger R, Kiesselbach G, Brandl G, Laky B, Kriegleder B, Heuberer P, Schwameis E (2016) Patient-specific instrumentation improved mechanical alignment, while early clinical outcome was comparable to conventional instrumentation in TKA. Knee Surg Sports Traumatol Arthrosc 24(1):102–111
3. Bartlett JW, Frost C (2008) Reliability, repeatability and reproducibility: analysis of measurement errors in continuous variables. Ultrasound Obstet Gynecol 31(4):466–475
4. Catani F, Biasca N, Ensini A, Leardini A, Bianchi L, Digennaro V, Giannini S (2008) Alignment deviation between bone resection and final implant positioning in computer-navigated total knee arthroplasty. J Bone Joint Surg Am 90(4):765–771
5. Clement ND, MacDonald D, Simpson AH (2014) The minimal clinically important difference in the Oxford knee score and Short Form 12 score after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 22(8):1933–1939
6. Dimitriou D, Tsai TY, Yue B, Rubash HE, Kwon YM, Li G (2016) Side-to-side variation in normal femoral morphology: 3D CT analysis of 122 femurs. Orthop Traumatol Surg Res 102(1):91–97
7. Eckhoff DG, Jacofsky DJ, Springer BD, Dunbar M, Cherian JJ, Elmallah RK, Mont MA, Greene KA (2016) Bilateral symmetrical comparison of femoral and tibial anatomic features. J Arthroplasty 31(5):1083–1090
8. Hess S, Moser LB, Amsler F, Behrend H, Hirschmann MT (2019) Highly variable coronal tibial and femoral alignment in osteoarthritic knees: a systematic review. Knee Surg Sports Traumatol Arthrosc 27(5):1368–1377
9. Hirschmann MT, Moser LB, Amsler F, Behrend H, Leclerq V, Hess S (2019) Functional knee phenotypes: a novel classification for phenotyping the coronal lower limb alignment based on the native alignment in young non-osteoarthritic patients. Knee Surg Sports Traumatol Arthrosc 27(5):1394–1402
10. Howell SM, Hull ML (2012) Kinematic alignment in total knee arthroplasty. In: Norman Scott W (ed) Insall and Scott surgery of the knee. Elsevier, Philadelphia, pp 1255–1268
11. Howell SM, Kuznik K, Hull ML, Siston RA (2008) Results of an initial experience with custom-fit positioning total knee arthroplasty in a series of 48 patients. Orthopedics 31(9):857–863
12. Howell SM, Papadopoulos S, Kuznik KT, Hull ML (2013) Accurate alignment and high function after kinematically aligned TKA performed with generic instruments. Knee Surg Sports Traumatol Arthrosc 21(10):2271–2280
13. Howell SM, Shelton TJ, Hull ML (2018) Implant survival and function ten years after kinematically aligned total knee arthroplasty. J Arthroplasty 33(12):3678–3684
14. Indrayan A (2013) Methods of clinical epidemiology. In: SARD-aGMW (ed) Springer series on epidemiology and public health. Springer, Berlin. https://doi.org/10.1007/978-3-642-37131-8_2
15. Kassam AM, Dieppe P, Toms AD (2012) An analysis of time and money spent on investigating painful total knee replacements. Br J Med Prac 5(3):a526
16. Kayani B, Konan S, Huq SS, Tahmassebi J, Haddad FS (2019) Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning. Knee Surg Sports Traumatol Arthrosc 27(4):1132–1141
17. Koo S, Gold G, Andriacchi T (2005) Considerations in measuring cartilage thickness using MRI: factors influencing reproducibility and accuracy. Osteoarthr Cartil 13(9):782–789
18. Kornaat PR, Koo S, Andriacchi TP, Bloem JL, Gold GE (2006) Comparison of quantitative cartilage measurements acquired on two 3.0T MRI systems from different manufacturers. J Magn Reson Imaging 23(5):770–773
19. Li G, Park SE, DeFrate LE, Schutzer ME, Ji L, Gill TJ, Rubash HE (2005) The cartilage thickness distribution in the tibiofemoral joint and its correlation with cartilage-to-cartilage contact. Clin Biomech 20(7):736–744
20. Lustig S, Scholes CJ, Oussedik SI, Kinzel V, Coolican MR, Parker DA (2013) Unsatisfactory accuracy as determined by computer navigation of VISIONAIRE patient-specific instrumentation for total knee arthroplasty. J Arthroplasty 28(3):469–473
21. Matziolis G, Krocker D, Weiss U, Tohtz S, Perka C (2007) A prospective, randomized study of computer-assisted and conventional total knee arthroplasty. Three-dimensional evaluation of implant alignment and rotation. J Bone Joint Surg Am 89(2):236–243
22. Moser LB, Hess S, Amsler F, Behrend H, Hirschmann MT (2019) Native non-osteoarthritic knees have a highly variable coronal alignment: a systematic review. Knee Surg Sports Traumatol Arthrosc 27(5):1359–1367
23. Nam D, Lin KM, Howell SM, Hull ML (2014) Femoral bone and cartilage wear is predictable at 0 degrees and 90 degrees in the osteoarthritic knee treated with total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 22(12):2975–2981
24. Nedopil AJ, Howell SM, Hull ML (2016) Does malrotation of the tibial and femoral components compromise function in kinematically aligned total knee arthroplasty? Orthop Clin North Am 47(1):41–50

25. Nedopil AJ, Singh AK, Howell SM, Hull ML (2018) Does calipered kinematically aligned TKA restore native left to right symmetry of the lower limb and improve function? J Arthroplasty 33(2):398–406
26. Paschos NK, Howell SM, Johnson JM, Mahfouz MR (2017) Can kinematic tibial templates assist the surgeon locating the flexion and extension plane of the knee? Knee 24(5):1006–1015
27. Riley J, Roth JD, Howell SM, Hull ML (2018) Increases in tibial force imbalance but not changes in tibiofemoral laxities are caused by varus–valgus malalignment of the femoral component in kinematically aligned TKA. Knee Surg Sports Traumatol Arthrosc 26(11):3238–3248
28. Riley J, Roth JD, Howell SM, Hull ML (2018) Internal–external malalignment of the femoral component in kinematically aligned total knee arthroplasty increases tibial force imbalance but does not change laxities of the tibiofemoral joint. Knee Surg Sports Traumatol Arthrosc 26(6):1618–1628
29. Riviere C, Iranpour F, Harris S, Auvinet E, Aframian A, Chabrand P, Cobb J (2017) The kinematic alignment technique for TKA reliably aligns the femoral component with the cylindrical axis. Orthop Traumatol Surg Res 103(7):1069–1073
30. Roth JD, Howell SM, Hull ML (2015) Native knee laxities at 0, 45, and 90 degrees of flexion and their relationship to the goal of the gap-balancing alignment method of total knee arthroplasty. J Bone Joint Surg 97-A(20):1678–1684
31. Shelton TJ, Howell SM, Hull ML (2018) A total knee arthroplasty is stiffer when the intraoperative tibial force is greater than the native knee. J Knee Surg 32(10):1008–1014
32. Shelton TJ, Howell SM, Hull ML (2019) Is there a force target that predicts early patient-reported outcomes after kinematically aligned TKA? Clin Orthop Relat Res 477(5):1200–1207
33. Wakelin EA, Tran L, Twiggs JG, Theodore W, Roe JP, Solomon MI, Fritsch BA, Miles BP (2018) Accurate determination of post-operative 3D component positioning in total knee arthroplasty: the AURORA protocol. J Orthop Surg Res 13(1):275
34. Williams DP, Blakey CM, Hadfield SG, Murray DW, Price AJ, Field RE (2013) Long-term trends in the Oxford knee score following total knee replacement. Bone Joint J 95-B(1):45–51

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