

Differences in Trochlear Morphology from Native Using a Femoral Component Interfaced with an Anatomical Patellar Prosthesis in Kinematic Alignment and Mechanical Alignment

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Abstract

Patellofemoral complications following total knee arthroplasty can be traced in part to alignment of the femoral component. Kinematic alignment (KA) and mechanical alignment (MA) use the same femoral component but align the component differently. Our objective was to determine differences in trochlear morphology from native for a femoral component interfaced with an anatomical patellar prosthesis in KA and MA. Ten three-dimensional femur-cartilage models were created by combining computed tomography and laser scans of native human cadaveric femurs free of skeletal abnormalities. The femoral component was positioned using KA and MA. Measurements of the prosthetic and native trochlea were made along the arc length of the native trochlear groove and differences from native were computed for the medial-lateral and radial locations of the groove and sulcus angle. Mean medial-lateral locations of the prosthetic groove were within 1.5 and 3.5 mm of native for KA and MA, respectively. Mean radial locations of the prosthetic groove were as large as 5 mm less than native for KA and differences were greater for MA. Sulcus angles of the prosthetic trochlea were 10 degrees steeper proximally, and 10 degrees flatter distally than native for both KA and MA. Largest differences from native occurred for radial locations and sulcus angles for both KA and MA. The consistency of these results with those of other fundamentally different designs which use a modified dome (i.e., sombrero hat) patellar prosthesis highlights the need to reassess the design of the prosthetic trochlea on the part of multiple manufacturers worldwide.

Keywords

- ▶ total knee arthroplasty
- ▶ femoral component
- ▶ patellofemoral complications
- ▶ kinematic alignment
- ▶ mechanical alignment

Possible patellofemoral complications after total knee arthroplasty (TKA) are many and include patellar instability, anterior knee pain, patellar crepitus, and less frequently patellar subluxation, patellar dislocation, patellar component loosening, patellar component wear, patellar component fracture, and soft-tissue impingement.¹⁻⁵ These

complications have reported incidences of 1 to 20% for both resurfaced and unresurfaced patellae,⁶⁻⁸ and they represent one of the major causes for revision surgeries.^{3,9,10} One key factor in the development of patellofemoral complications is alignment of the femoral component^{1,4,9,11} which affects the position and orientation of the trochlear

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groove where the patella tracks during knee flexion-extension.

Two methods which differ fundamentally in aligning the femoral component are mechanical alignment (MA) and kinematic alignment (KA). MA aligns the femoral component so that the distal femoral joint line is perpendicular to the mechanical axis of the femur and the internal-external rotation is set according to one of several methods.¹² In contrast, KA aligns the femoral component to restore the native (i.e., prearthritic) distal and posterior femoral joint lines. Because KA-specific components have yet to be offered in the marketplace, KA necessarily uses femoral components designed for MA and sets the components an average of 4.6 degrees less varus, and 2.8 degrees less external rotation than MA.¹³ Hence it is of interest to determine how well femoral components designed for MA but used commonly in KA restore native trochlear morphology.

A previous study involving three femoral component designs used in conjunction with modified dome (i.e., sombrero hat) patellar prostheses determined differences in morphological variables from native.¹³ Based on these differences, the trochlear morphology was better restored to native with KA than MA but the native trochlear morphology with KA was not restored for any of the three designs. Because this previous study was limited to designs used in conjunction with a modified dome patellar prosthesis, it was of interest to determine whether the conclusions apply to a fundamentally different femoral component design which interfaces with an anatomical patellar prosthesis.

The objectives were twofold. By aligning computer-aided design models of a femoral component interfaced with an anatomical patellar prosthesis in KA and MA on highly accurate three-dimensional (3D) femur-cartilage models of native limbs, the primary objective was to determine differences in morphology between prosthetic and native trochleae. Based on any differences, possible strategies for improving the prosthetic trochlea to better restore patellar tracking to native might be devised. A secondary objective was to determine which alignment technique more closely restores the trochlear morphology to native. If KA better restores the trochlear geometry to native than MA despite using an off-the-shelf femoral component design presumably customized for MA, then this finding would allay any concerns that patellofemoral function might be compromised using the femoral component in KA despite fundamental differences in alignment between KA and MA.

Materials and Methods

Since the materials and methods have been described in detail elsewhere,¹³ salient aspects of the methods necessary to understand the present manuscript are described below. Ten unpaired fresh-frozen human cadaveric lower limbs without evidence of prior fracture after review of computed tomography (CT) scan and without femoral articular wear at inspection during dissection were studied (median age: 75.5 years ranging from 51–94 years, seven females and three males). Soft tissue was removed from the diaphysis of the femur. Nine fiducial

markers were widely arrayed and rigidly fixed to the femoral diaphysis. A CT scan of the entire limb was performed using a 0.625-mm slice thickness, small scan field of view, tube potential of 140 kV, and tube current of 250 mA (General Electric Lightspeed 16, www3.gehealthcare.com). The femur and each fiducial marker were segmented with an automatic thresholding tool followed by manual refinement (Mimics, Materialize, Mimics, www.materialise.com) after which the segmented images were converted into a 3D femur model with fiducial markers.¹⁴ The knee joint was disarticulated and all soft tissues were removed from the femur. The bone and cartilage surfaces of the distal femur and fiducial markers were scanned with a 0.2-mm resolution laser scanner with a repeatability of < 70 microns (Metrascan 3D Scanner, www.creaform3d.com).¹⁵ A 3D distal femur-cartilage model with best-fit spherical fiducial markers was created from a point cloud. The centers of the fiducial markers were superimposed to register the 3D femur model from CT and the 3D distal femur-cartilage model from laser scanning. Once registered, the result was a 3D femur-cartilage model (►Fig. 1).

To position the femoral component (GMK Sphere, Medacta, Inc.) in KA and MA, the 3D femur-cartilage model was projected in standard sagittal, coronal, and axial planes.¹³ For each 3D femur-cartilage model, both alignments used the same size femoral component. For KA, the varus-valgus rotation, proximal-distal position, internal-external rotation, and AP position of the femoral components were set coincident to the distal and posterior cartilage surface of the femur at 0 and 90 degrees, respectively. For MA the varus-valgus rotation was set perpendicular to the coronal mechanical axis, the proximal-distal location was set so that the thinner resection of a distal femoral condyle matched the thickness of the condyle of the femoral component, and internal-external rotation and AP location were set by externally rotating 3 degrees about the center of the femoral component with respect to the posterior cartilage surface of the femur such that the thinner resection was equal to the thickness of the femoral component. For both alignments, the flexion-extension rotation of the femoral component was set parallel to the sagittal projection of the mechanical axis of the femur, and the medial-lateral (ML) location was set by centering the femoral component. Femoral components were downsized when ML overhang was 1 mm or greater.

Differences in the ML and radial locations and sulcus angle of the groove from native were determined for KA and MA. The best-fitting of a cylinder to the cartilage surface of the medial and lateral femoral condyles of the 3D femur-cartilage model established a cylindrical coordinate system (►Fig. 2). Eleven cross-sections of the 3D femur-cartilage model were constructed at 10% increments along the arc length of the native trochlear groove by rotating about the cylindrical axis (►Fig. 3). These cross-sections were propagated onto the KA and MA prosthetic trochlea. At each cross-section, a polynomial function fit a line to all points coincident to the articular surface creating a tracing of the native and prosthetic trochlea (►Fig. 4). The deepest point represented the groove, and the two highest points on the medial and lateral facets represented the boundary of the sulcus.

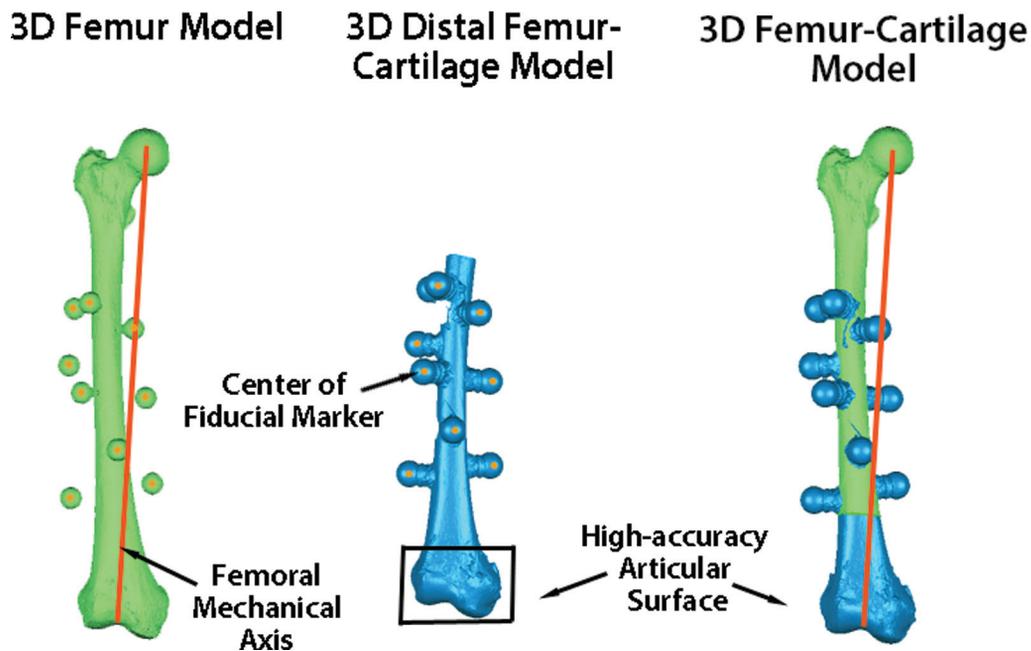


Fig. 1 Images showing (left to right) the 3D femur model created from CT scanning, the 3D distal femur-cartilage model created from laser scanning, and the 3D femur-cartilage model created by best-fitting the centers of the fiducial markers (dots). 3D, three-dimensional; CT, computed tomography.

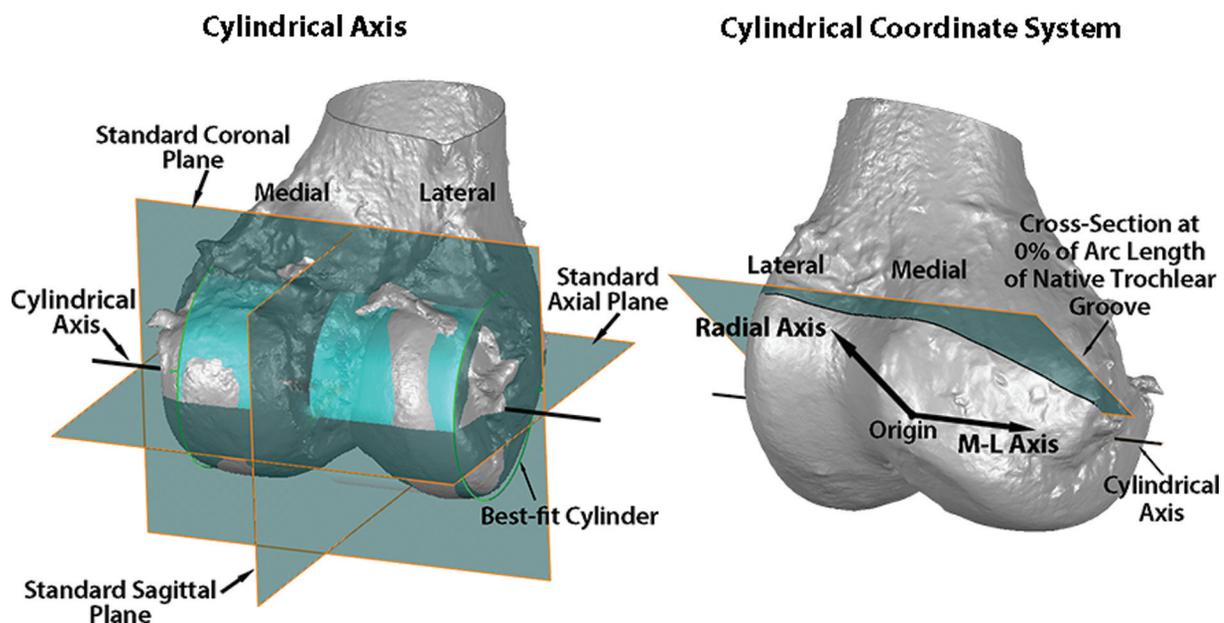


Fig. 2 Images showing the standard planes and the relationship of the cylindrical axis with respect to the standard planes on a posterior oblique view of the 3D femur-cartilage model (left), and the origin, medial-lateral (M-L) axis, radial axis, and reference plane of the cylindrical coordinate system on an anterior oblique view of the 3D femur-cartilage model (right). The cylindrical axis (black line) passes through the center of a cylinder (green) best-fit to the central third of the cartilage on each femoral condyle (left). The origin of the cylindrical coordinate system (black dot) was on the M-L axis (i.e., cylindrical axis) midway between the most medial and lateral points on the femoral condyles (right). A radial axis set at the proximal edge of the groove of the native trochlea defined the plane of the 0% cross-section along the arc length of the native trochlear groove. The relationship of the cylindrical axis and coordinate system to the prosthetic trochlea is not shown.

These three points served to determine the three dependent variables of interest (→ Fig. 4).

For KA and MA, the differences in the ML and radial locations of the groove and sulcus angle of the trochlea between the prosthetic minus native were computed at each percent of arc length of the native trochlear groove.

Based on making five measurements of each of the dependent variables on five different specimens, the precisions in the differences in the ML and radial locations of the groove were 2.5 and 2.0 mm, respectively, while the precision in the difference in the sulcus angle of the trochlea was 6.2 degrees.¹³

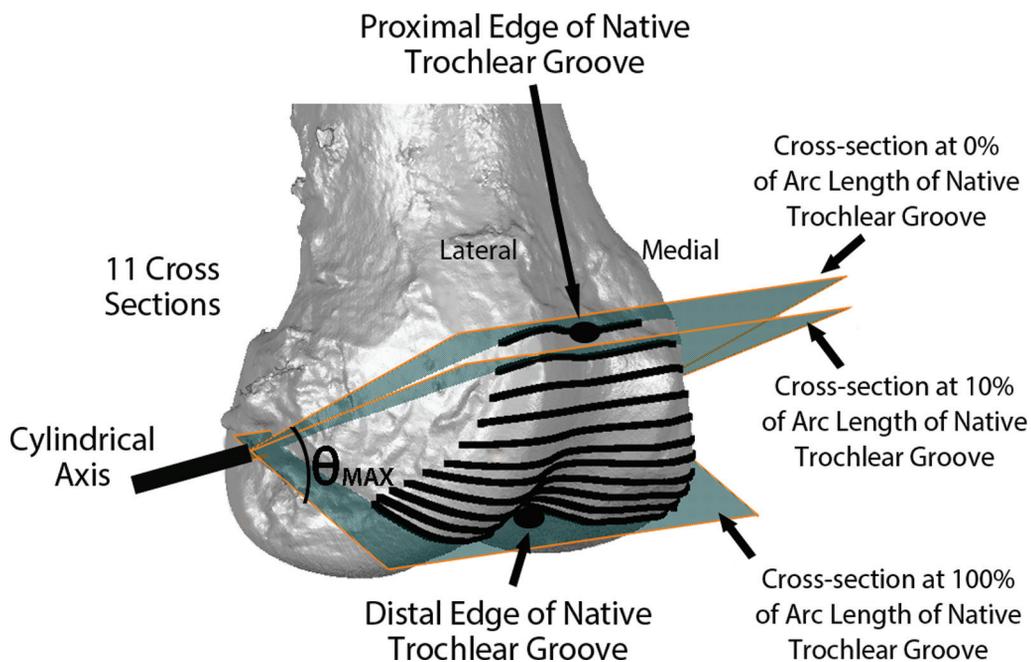


Fig. 3 Image showing the relationship of eleven cross-sections along the arc length of the native trochlear groove with respect to the cylindrical axis on an oblique view of the 3D femur-cartilage model. The 0% cross-section was set coincident to the proximal edge of the trochlear groove, and the 100% cross-section was set at the most distal edge. Not shown are the projections of the cross-sections on the KA and MA prosthetic trochleas. 3D, three-dimensional; KA, kinematic alignment; MA, mechanical alignment.

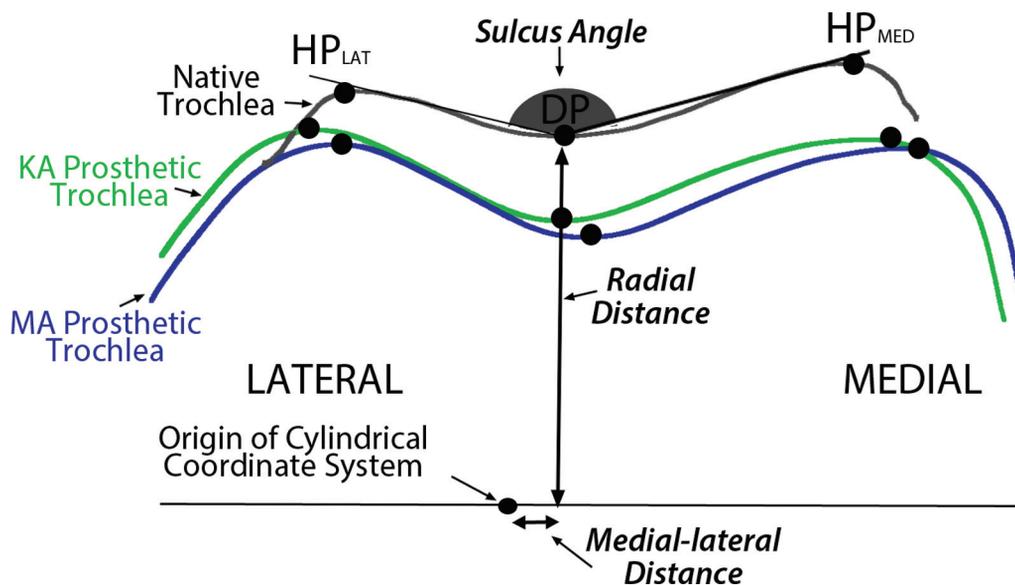


Fig. 4 Diagram of a representative cross section of the distal femur showing the relationship between tracings of the articular surface of the native trochlea (gray), KA prosthetic trochlea (green), and MA prosthetic trochlea (blue). The landmarks of the deepest point (DP) of the groove and the highest point (HP) of the medial and lateral facets (only shown on the native trochlea) were used to determine the medial-lateral and radial distances of the groove and the sulcus angle of the trochlea for the native and prosthetic femurs. The medial-lateral distance was positive in the medial direction. KA, kinematic alignment; MA, mechanical alignment.

Following University of California policies, this study did not require Institutional Review Board approval because de-identified cadaveric specimens were used.

Statistical Analysis

Differences between prosthetic and native were expressed as the mean ± standard deviation. Because significant and important interactions between the factors of alignment method

and percent of arc length were evident, paired Student’s *t*-tests were performed at each percent of arc length. To determine whether differences between KA and native were significant and to determine whether differences between MA and native were significant, paired *t*-tests were performed for prosthetic minus native for the ML and radial locations and for the sulcus angle for KA and for MA. To determine whether KA differed from MA, paired *t*-tests also were performed at each percent of

arc length using the paired differences of the prosthetic values. A p -value of < 0.05 indicated the difference was significant.

A power analysis confirmed that with ten femurs, differences in groove locations between alignment methods of 2 mm, which do not cause adverse mechanical effects,^{16,17} could be detected with $\alpha = 0.05$ and $(1 - \beta) \geq 0.80$ using standard deviations of the differences in groove locations between alignment methods of 1.9 mm. This value was obtained from the present study based on measurements from five specimens and subsequently checked with measurements from all ten specimens.

The ICC values for repeatability (i.e., intraobserver) and reproducibility (i.e., interobserver) for both KA and MA were determined previously¹³ and were ≥ 0.95 for all three dependent variables except for the radial distance for MA which were 0.89 for both. Hence the repeatability and

reproducibility of both alignment methods were rated generally as excellent.

Results

Mean ML locations of the prosthetic trochlear groove differed significantly from native for KA over the arc length range from 40 to 90% where the groove was medial to native (**Fig. 5**; **Table 1**). For MA, significant differences occurred in the arc length ranges from 0 to 10% where the groove was lateral to native and from 60 to 80% where the groove was medial to native. Absolute mean differences from native were confined to approximately 1.5 mm at most for KA and approximately 3.5 mm at most for MA (**Fig. 5**). Mean differences between KA and MA were significant over the arc length range of 0 to 50% where KA was closer to native in the

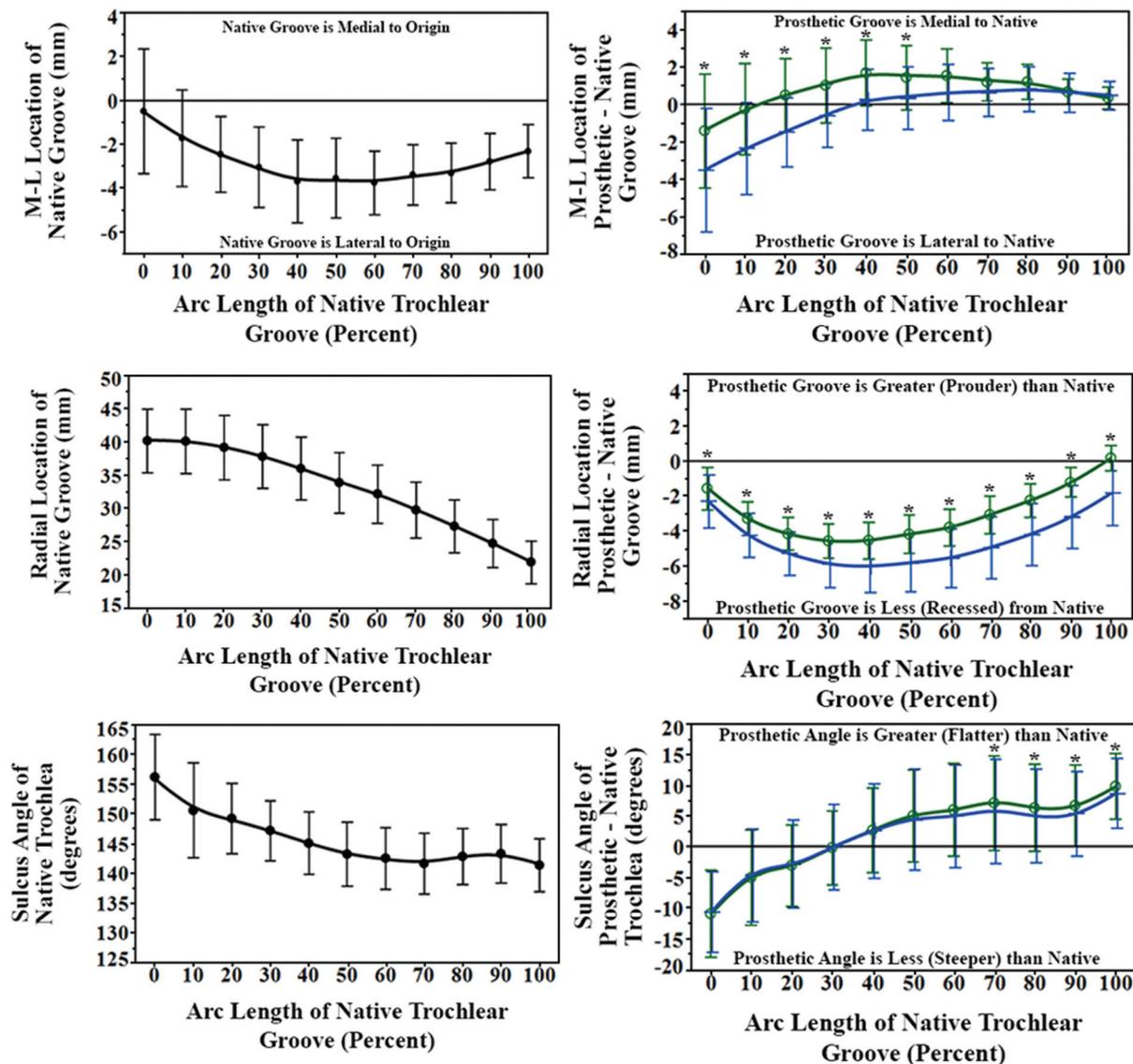


Fig. 5 Series of graphs showing the mean \pm one standard deviation for the native knee and the differences between prosthetic and native for KA (green lines) and MA (blue lines) in the medial-lateral and radial locations of the groove and sulcus angle of the trochlea at intervals from 0 to 100% of normalized arc length of the native trochlear groove for the femoral component which interfaces with an anatomical patellar prosthesis. The horizontal lines at 0 mm and 0 degrees represent the baseline for no difference from native. The values denoted by an * indicate significant differences between KA and MA ($p < 0.05$). KA, kinematic alignment; MA, mechanical alignment.

Table 1 Summary of *p*-values from paired *t*-tests to determine differences in KA from native and in MA from native at each % of arc length

ML location			Radial location			Sulcus angle		
% Arc length	KA	MA	% Arc length	KA	MA	% Arc length	KA	MA
0	0.1461	0.0014 ^a	0	0.0031 ^a	0.0011 ^a	0	0.0009 ^a	0.0006 ^a
10	0.8605	0.0104 ^a	10	<0.0001 ^a	<0.0001 ^a	10	0.0742	0.0895
20	0.2857	0.059	20	<0.0001 ^a	<0.0001 ^a	20	0.1891	0.255
30	0.0585	0.5432	30	<0.0001 ^a	<0.0001 ^a	30	0.9554	0.9805
40	0.0045 ^a	0.2781	40	<0.0001 ^a	<0.0001 ^a	40	0.2364	0.3056
50	0.0103 ^a	0.1895	50	<0.0001 ^a	<0.0001 ^a	50	0.0615	0.1215
60	0.0013 ^a	0.0372 ^a	60	<0.0001 ^a	<0.0001 ^a	60	0.0319 ^a	0.0883
70	0.0012 ^a	0.0339 ^a	70	<0.0001 ^a	<0.0001 ^a	70	0.0164 ^a	0.059
80	0.0031 ^a	0.0196 ^a	80	<0.0001 ^a	<0.0001 ^a	80	0.0191 ^a	0.0669
90	0.0076 ^a	0.0608	90	0.0013 ^a	0.0003 ^a	90	0.0107 ^a	0.0341 ^a
100	0.1878	0.1367	100	0.4673	0.0118 ^a	100	0.0003 ^a	0.0009 ^a

Abbreviations: KA, kinematic alignment; MA, mechanical alignment.

^a*p*-values <0.05.

arc length range 0 to 20% and MA was closer to native in the arc length range from 30 to 50% (►Fig. 5; ►Table 2).

Mean radial locations of the prosthetic trochlear groove differed significantly from native over the entire arc length for both KA and MA except at 100% for KA such that the prosthetic groove was understuffed (►Fig. 5; ►Table 1). The greatest absolute mean difference for KA approached 5 mm in the 30 to 40% range of the arc length and for MA was 6 mm at 40% arc length. Mean differences between KA and MA were significant over the entire arc length with KA being closer to native than MA (►Fig. 5; ►Table 2).

The prosthetic sulcus angle was approximately 10 degrees steeper than native at 0% arc length gradually flattening to approximately 10 degrees flatter than native at 100% of arc length.

Table 2 Summary of *p*-values from paired *t*-tests to determine differences between KA and MA

% Arc length	M-L location	Radial location	Sulcus angle
0	0.0177 ^a	0.0228 ^a	0.4297
10	0.0031 ^a	0.0136 ^a	0.1781
20	0.0022 ^a	0.0108 ^a	0.3727
30	0.0073 ^a	0.0088 ^a	0.8988
40	0.0141 ^a	0.0066 ^a	0.7774
50	0.0440 ^a	0.0055 ^a	0.2825
60	0.0958	0.0047 ^a	0.1286
70	0.241	0.0039 ^a	0.0456 ^a
80	0.4013	0.0034 ^a	0.0380 ^a
90	0.8789	0.0030 ^a	0.0170 ^a
100	0.5406	0.0024 ^a	0.0154 ^a

Abbreviations: KA, kinematic alignment; MA, mechanical alignment.

^a*p*-values <0.05.

length so that the prosthetic sulcus angle differed significantly from native for both KA and MA at the extremes of arc length (►Fig. 5; ►Table 1). The mean differences in the sulcus angle between KA and MA were minimal over the full arc length yet still the mean differences were statistically significant in the range 70 to 100% of arc length with the sulcus angle for MA being closer to native than KA (►Fig. 5; ►Table 2).

Discussion

For a femoral component which interfaces with an anatomical patellar prosthesis, the finding, that the mean ML location of the prosthetic trochlear groove was significantly more lateral than that of the native groove over a relatively smaller region of arc length from 0 to 10% for MA but was more medial for a somewhat larger portion of the arc length from 60 to 80%, was unexpected (►Table 1). This is because literature of the manufacturer indicates that the trochlear groove by design was shifted 2 mm laterally for the femoral component of interest (<https://media.medacta.com/media/gmk-sphere-leaflet-99-26-sphere-11-rev02.pdf>). Accordingly, the expectation was that the ML location of the prosthetic trochlear groove would be shifted laterally from the native groove over a larger region of the native arc length. Since the details as to how the reference trochlear groove was determined by the manufacturer are unknown, it is difficult to offer a reason for this unexpected result.

The largest discrepancy in the ML location of the prosthetic groove between KA and MA was confined to 0 to 30% range of the native arc length (►Fig. 5). The difference in the varus-valgus rotation of the two alignment methods and not the difference in internal-external rotation explains this finding. The MA prosthetic groove was 2 mm more lateral than the KA prosthetic groove at the 0% cross-section because MA set the femoral component in approximately 5 degrees more varus from the native distal femoral joint line than KA.¹³ The more lateral location of the MA prosthetic groove than the native

groove at the 0% cross-section is nonanatomical making the prosthetic groove oblique to the native groove as can be discerned from the positive slope with the ML location becoming more medial with increasing arc length in the 0 to 30% range (► **Fig. 5**).

A methodological issue relevant to the ML location of the patellar groove was the method used to set the ML location of the femoral component which involved centering the component. The clinical practice recommended by the manufacturer is to best-fit the largest anatomical tibial component on the tibial resection, which centers the ML location of the baseplate and insert. Because the medial compartment functions as a ball and socket, the ML location of the femoral component likewise should be centered on the distal femoral resection to properly align the medial femoral condyle with the socket on the tibial insert. The design of the femoral component (GMK Sphere, Medacta, Inc.) provides a range of 13 femoral sizes that change in 2 mm increments in the ML and AP dimensions. This robust range enables the surgeon to select a femoral component that best-fits a broad spectrum of anatomical profiles of the native distal femur without the need to shift the ML location from center.

The mean radial location of the prosthetic groove was recessed with respect to the native groove and the KA prosthetic groove was 1 to 2 mm less recessed than MA, which is consistent with other studies.^{13,18,19} On average, the deviation of the radial location of the KA prosthetic groove from the native groove ranged from 0 mm to approximately 5 mm throughout the arc length of the native trochlea with the greatest deviations confined to the 20 to 60% range of arc length (► **Fig. 5**). Small adjustments of 1 to 5 mm in the radial location of the prosthetic groove is a strategy for enabling KA to better restore the native trochlear groove. If the patella is not resurfaced, then more closely restoring the radial location of the prosthetic groove to native might have the biomechanical advantage of increasing the moment arm of the quadriceps muscle force by radially translating the patella farther away from the center of rotation of the knee, which lowers the quadriceps muscle force needed to develop an extension moment and decreases the patellofemoral joint compression force. However overstuffing the prosthetic patellofemoral joint should be avoided since this can lead to complications such as decreased flexion¹⁷ and patellar maltracking.²⁰ The patellar prosthesis, which interfaces with the femoral component used herein, is anatomical and perhaps designed so that the prosthetic femur-prosthetic patellar system creates the proper balance between biomechanical advantage of the quadriceps without risk of complications due to overstuffing.

Although the prosthetic sulcus angles compared closely between MA and KA, the prosthetic sulcus angles differed from native substantively (► **Fig. 5**). Accordingly, these differences in the prosthetic sulcus angle from native are likely due to the differences in the design of the components per se rather than any effect of the alignment technique. The prosthetic sulcus angle was steepest at the 0% cross-section and gradually got flatter with increasing arc length. This feature would promote stronger engagement of the patella

early in flexion which might be important to prevent patellar subluxation/dislocation for a prosthetic in which the groove is recessed relative to the native groove.

In comparing the results for the femoral component design used herein to those generated previously for three other designs which interface with modified dome patellar prostheses,¹³ the overall findings and patterns of mean differences in prosthetic trochlear minus native were similar. None of the three designs restored the prosthetic trochlea to native but KA better restored the prosthetic trochlea to native than MA. For the ML and radial distances, the patterns of the mean differences for prosthetic minus native (► **Fig. 5**) were similar to those patterns for the three other designs. For the sulcus angle, while the pattern of the mean difference in the prosthetic trochlea minus native (► **Fig. 5**) was similar to those for all three designs with the angle becoming increasingly flatter relative to native with increasing arc length, a distinct shift in the pattern was evident with the mean prosthetic minus native angle being generally steeper over much of the arc length. This may be a consequence of the differences in shapes of the prosthetic articular surfaces of the patella; the articular surface of the prosthetic patella interfaced with the femoral component design in this study is anatomical as noted above whereas the shapes for other three designs are modified domes.²¹ In any case, the overall similarities in differences from native observed for all four femoral component designs including three fundamentally different femoral component designs from the world's largest manufacturer highlight the need to reassess the design of trochlea on the part of multiple manufacturers worldwide.

A formidable challenge in the design of prosthetic trochleae is insuring patellofemoral joint function without complications in the face of large variability in the ML location (i.e., path) of the native trochlear groove (► **Fig. 5**), high variability in the rectus femoris Q-angle which ranges 26 degrees for 95% of the population,²² and high patellar contact forces¹⁰ leading to high material stresses.^{23,24} On the one hand, if the groove is too medial in valgus knees with large Q-angles, then lateral patellar subluxation looms as a potential complication.^{25,26} On the other hand, if the groove is too lateral for varus knees with small Q-angles, then early wear of the medial articular surface of the prosthetic patella due to high contact stresses is a foreseeable complication.²⁶

Manufacturers seem to have addressed lowering the risk of lateral patellar subluxation in preference over lowering the risk of early wear of the medial articular surface. This is because a distinct similarity in all four femoral components is a flange which extends several centimeters superior to the most proximal cross section of the native groove so that the groove on the flange starts well superior to the groove on the native femur as well.¹³ Further, when set in MA, the path of the prosthetic groove is oblique to the native groove being oriented more lateral proximally.¹³ This extension of the flange and groove would promote early engagement of the patella with the groove and a more lateral location of the groove would avoid a tendency for lateral patellar subluxation particularly in valgus knees with large Q-angles, which is a relatively common complication.²⁵ To reduce the risk of other

complications such as early wear, however, it would appear that a single trochlea design for a particular femoral component may not be adequate and that manufacturers should consider offering femoral components with different paths of the trochlear groove particularly for femoral components which interface with anatomical patellar prostheses where alignment is more critical. Also, since femoral components set in KA are aligned in 5 degrees less varus than femoral components set in MA as noted above, achieving the same path of the trochlear groove in KA as that achieved with MA will require femoral components designed specifically for use in KA.

Several limitations should be discussed. First, the level of restoration of the native trochlea reported for the femoral component design used herein does not apply to other femoral component designs as a quantitative comparison to three other designs would indicate. Second, the present study did not determine whether the relatively small differences between ML and radial locations and the sulcus angle of the prosthetic from those of the native trochlea for KA and MA are large enough to be clinically important. Third, the effects of the morphology of the prosthetic trochlea on the biomechanics of the tibiofemoral and patellofemoral joints depend on whether the patella is resurfaced or nonresurfaced, and the patellofemoral interaction was not studied. Finally, a single method for setting the rotation of the femoral component was studied with MA whereas multiple methods are used clinically.^{12,27}

Conclusion

Our results add new information regarding the trochlear morphology of existing femoral component designs and their ability to mimic the native trochlea in KA and MA. The groove location and sulcus angle of the prosthetic trochlea using a femoral component design which interfaces with an anatomical patellar prosthesis differed from native for both KA and MA. Generally KA more closely restored the ML and radial groove locations closer to those of the native trochlea than MA with absolute mean differences being limited to approximately 1.5 and 4 mm, respectively, for KA so that radial locations were understuffed over the full arc length. Mean differences in sulcus angles compared closely for KA and MA but absolute mean differences from native were as high as 10 degrees occurring at the extremes of arc length being steeper at 0% arc length and being flatter at 100% arc length. The general consistency in differences from native observed for the femoral component design used herein with those differences for three other fundamentally different femoral component designs from the world's largest manufacturer highlights the need to reassess the design of trochlea on the part of multiple manufacturers worldwide.

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Conflict of Interest

M.L.H. reports grants from Medacta, Inc. during the conduct of the study; grants from Zimmer Biomet outside

the submitted work. S.M.H. reports grants from Zimmer Biomet and Medacta, Inc during the conduct of the study; personal fees from THINK Surgical, personal fees from Zimmer Biomet, personal fees from Medacta, Inc outside the submitted work.

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