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Patient-specific implants with custom cutting blocks better approximate natural knee kinematics than standard TKA without custom cutting blocks

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ABSTRACT

Background: Nearly 14% to 39% TKA patients report dissatisfaction causing incomplete return of function. We proposed that the kinematics of knees implanted with patient-specific prostheses using patient-specific cutting guides would be closer to normal.
Methods: Eighteen matched cadaver lower limbs were randomly assigned to two groups: group A was implanted with patient-specific implants using patient-specific cutting guides; group B, the contralateral knee, was implanted with a standard design using intramedullary alignment cutting guides. Knee kinematics were measured on a dynamic closed-kinetic-chain Oxford knee rig, simulating a deep knee bend and in a passive rig testing varus–valgus laxity.
Results: The difference from normal kinematics was lower for group A compared to group B for active femoral rollback, active tibiofemoral adduction, and for passive varus–valgus laxity.
Conclusions: Our results support the hypothesis that knees with patient-specific implants generate kinematics more closely resembling normal knee kinematics than standard knee designs.
Clinical Relevance: Restoring normal kinematics may improve function and patient satisfaction after total knee arthroplasty.

1. Introduction

Despite greater than 95% survivorship of total knee arthroplasty (TKA) over the long term, patient satisfaction is less compelling with anywhere from 14% to 39% of patients reporting dissatisfaction with their TKA result [1–5]. Causes for dissatisfaction are due in part to anterior knee pain, mid-flexion instability, reduction in range of flexion, and incomplete return of function [6–10]. The changing demographics and higher expectations of the target recipients of TKA place greater demands on surgical technique and implant design.

Studies of knee anatomy have revealed distinct anatomical differences in gender and race. This variation in anatomic sizes can lead to compromises during the surgery, as it is impossible to maintain implant inventories that precisely match every individual. Through the use of varying size and design rationales, implant manufacturers have tried to achieve a better fit at the bone–implant interface. However, the potentially adverse events such as femoral component overhang or tibial component under coverage still occur.

In a study conducted by Mahoney et al. [11], it was found that 40% of men and 68% of women experienced greater than three millimeters of femoral overhang, which resulted in a two-fold increase in knee pain. Equally important, reports in the use of these standard, off-the-shelf designs have not shown any success in restoring the kinematics of the implanted knee to its native, healthy condition [12]. In fact, standard off-the-shelf knee implants often lead to compromises during implantation that require surgeons to decide between optimal fit on the tibial side or restoring rotational alignment, as well as necessitating external rotation of femoral implants to close on the lateral gap and improving patellar tracking, all of which can result in kinematic compromises and disadvantages. These issues have led to the development of patient-specific implant designs with the goals of not only improving the fit of the implant to the patient but also restoring normal or near normal kinematics for each patient.

Improvements in imaging and image processing technology coupled with rapid prototyping allow for manufacturing of not only patient-specific cutting guides but also patient-specific femoral and tibial components. The goals are to maximize bony coverage and have articulating surfaces that closely approximate the subjects' natural anatomy, corrected for any underlying deformity. The current study was designed to evaluate the kinematics of a patient-specific prosthesis implanted using patient-specific cutting guides and to compare the results to the

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kinematics of the normal knee, as well as to those of an off-the-shelf implant placed in the contralateral knee of the same subject. We tested the hypothesis that restoring the articular surface including the patient's normal medial, lateral, and trochlear J-curve and maintaining the medial/lateral femoral condylar offset and the articular geometry of the implanted knee to that of the joint before implantation would also restore knee kinematics to normal.

2. Materials and methods

2.1. Study design

Preoperative computed tomography (CT) scans were obtained from 18 paired human cadaveric knees (nine left; nine right) and screened to rule out arthritis or anatomic deformity. One knee of each pair was randomly assigned to one of two groups. The first group was implanted with a standard off-the-shelf posterior cruciate-retaining implant design with multiradius sagittal femoral geometry (PFC Sigma® CR, DePuy, Warsaw, IN). The paired contralateral knee was implanted with patient-specific implants designed and manufactured from the preoperative CT scans (ConforMIS iTotal G1®, Bedford, MA) (Fig. 1). Implantation of the PFC Sigma components was done by one surgeon and that of the iTOTAL was done by another surgeon.

The patient-specific implants were generated using proprietary software, whereby the mechanical axis of the knee was restored to normal alignment (180°). Femoral and tibial implant rotation was set to zero during the computer aided design (CAD) design process and maintained in both the patient-specific implants as well as the patient-specific jigs to avoid any postoperative implant malrotation. The software generated three patient-specific J-curves for the medial condyle, the lateral condyle and the trochlea each corrected for arthritic deformity, to restore the normal, pre-arthritic articular geometry of each patient. These femoral J-curves were paired with patient-specific polyethylene inserts that had a perimeter that was matched to the individual patient's tibial plateau and restored the distal medial–lateral offset of the patient's femoral condyles through patient-specific insert heights that reflect the condylar offset while maintaining a normal mechanical axis alignment. The inserts also had patient-specific sagittal radii derived from the sagittal J-curves of the patient's femoral condyles using proprietary algorithms.

2.2. Specimen preparation

Each cadaver specimen was implanted with nine fiducial markers; titanium screws were placed in the femur, tibia, and patella to aid in digitization of the specimens. An active infrared surgical navigation system was used to establish the mechanical axis of the knee using the center of the femoral head, the center of the ankle, and the center of the knee (tibial attachment of the anterior cruciate ligament). Threaded rods were cemented into the proximal femoral and distal tibial canals. A nylon strap was sutured to the quadriceps tendon; infra-red navigation trackers were rigidly fixed to the femoral and tibial shafts (Fig. 2)

2.3. Measurement of knee kinematics

Tibiofemoral kinematics were recorded using the active infrared surgical navigation system. Anatomic landmarks were digitized on each knee to generate embedded coordinate systems in the femur, the tibia, and the patella. The midpoint of the transepicondylar line was used as the center of the femoral coordinate system; the midpoint of

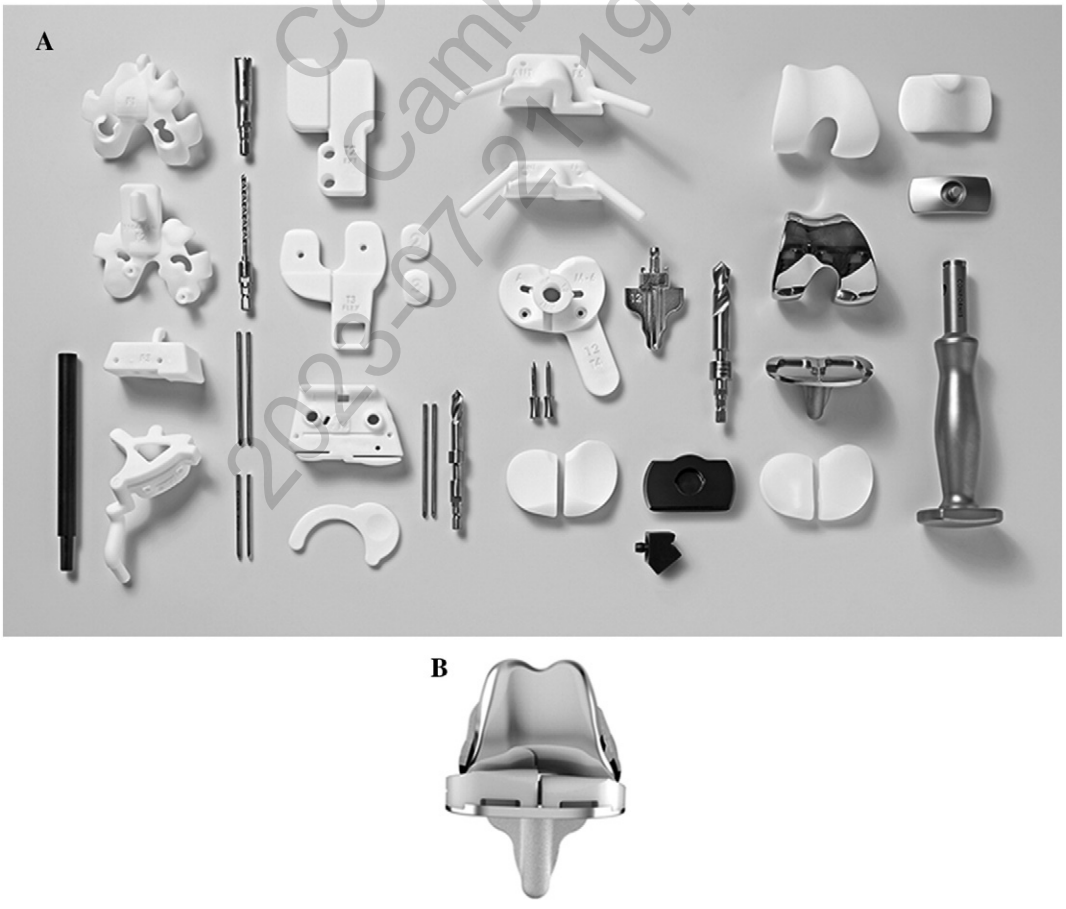

Fig. 1. A: Photograph of patient-specific cutting guides. B: Photograph of patient-specific implant.

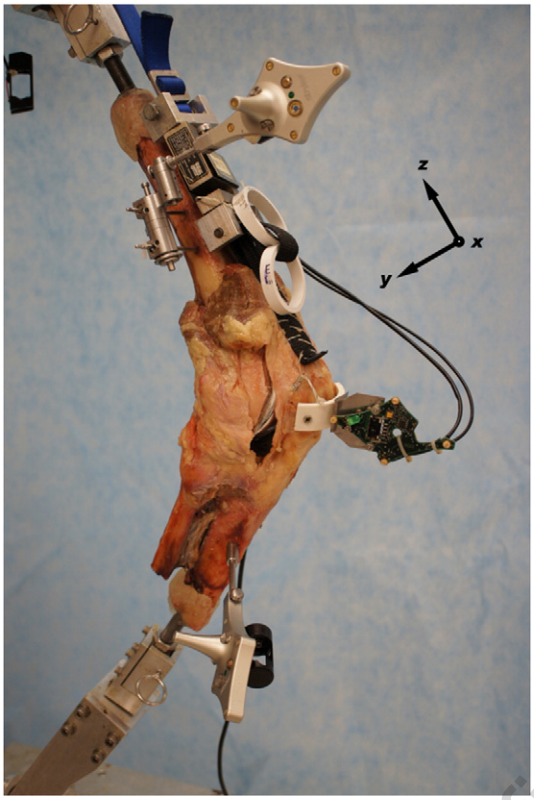

Fig. 2. Placement of the active infrared surgical navigation trackers and the tibiofemoral coordinate system.

the tibial plateau was used as the center of the tibial system. Knee kinematics were recorded between 0° and 130° of knee flexion. Tibial flexion was measured about the femoral transverse axis (the femoral transepicondylar axis) X; tibiofemoral internal and external rotation about the bone-embedded tibial shaft axis Z; and tibiofemoral varus and valgus about a floating axis Y perpendicular to the femoral X and tibial Z axes. Femoral rollback was recorded as the posterior translation of the center of the transepicondylar line of the femur relative to the center of the tibial coordinate system (Fig. 2).

2.4. Active kinematic testing

To simulate a deep knee bend, the knees were mounted on a dynamic, quadriceps driven, closed-kinetic-chain knee simulator based on the Oxford knee rig design, which has been previously described (Fig. 3A, [13]). The tibial rod was mounted on the ankle-joint assembly on the rig, which had three degrees of rotational freedom but was constrained in translation. The femoral rod was mounted on the hip-joint assembly on the rig. The hip-joint assembly was allowed freedom in flexion–extension and varus–valgus angulations, with vertical motion guided by two parallel cylindrical bars. The location of the hip joint was offset laterally to account for a nominal anatomic valgus of five degrees at the knee. The quadriceps tendon was attached to an electric motor via a nylon strap sutured to the quadriceps tendon. Flexion moment at the knee was generated by applying vertical load at the hip. The hip load was adjusted to generate a peak moment of approximately 40 Nm, which was close to that reported in vivo for stair climbing [14,15]. The motor pulling on the quadriceps tendon generated an active extension moment, controlling concentric and eccentric "contraction" of the quadriceps, resulting in closed-kinetic-chain knee flexion–extension.

This arrangement permitted six degrees of freedom at the knee, which was constrained only by articular geometry and surrounding soft tissues [16]. Active knee kinematics were recorded for the following conditions: Intact knee (Normal) and after implantation (TKA). The kinematics of each pre-implantation knee were used as a control for the post-implantation stage and considered as 'Normal'.

2.5. Passive kinematic testing

Passive knee kinematics were recorded on a custom rig, which passively flexed the knee joint under gravitational force (Fig. 3B). The femur was mounted on a jig that controlled the flexion. A constant force was applied to the quadriceps tendon. A constant varus or valgus

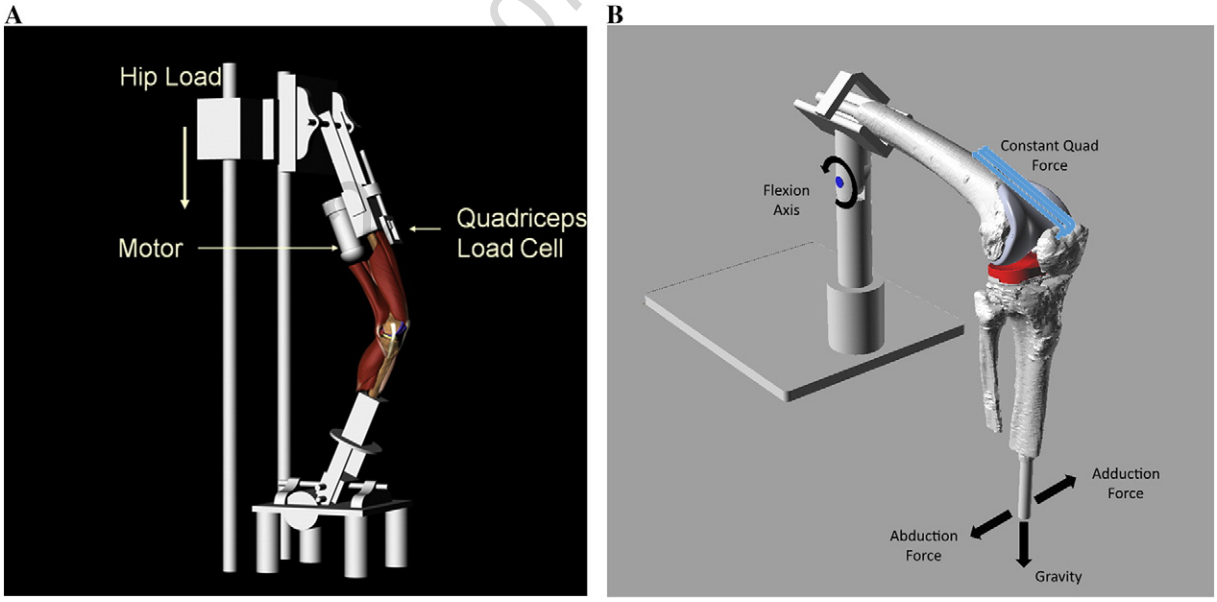

Fig. 3. A: Active knee kinematics were recorded on an Oxford knee rig. The knee was extended by applying tension through the quadriceps tendon while a load representing body weight was applied at the "hip joint". B: Passive knee kinematics were recorded on a custom knee rig. The femur was mounted on a hinge joint. By flexing the femur, the knee was passively flexed and extended under gravity. A pulley system was used to apply a constant adduction or abduction moment (arrows).

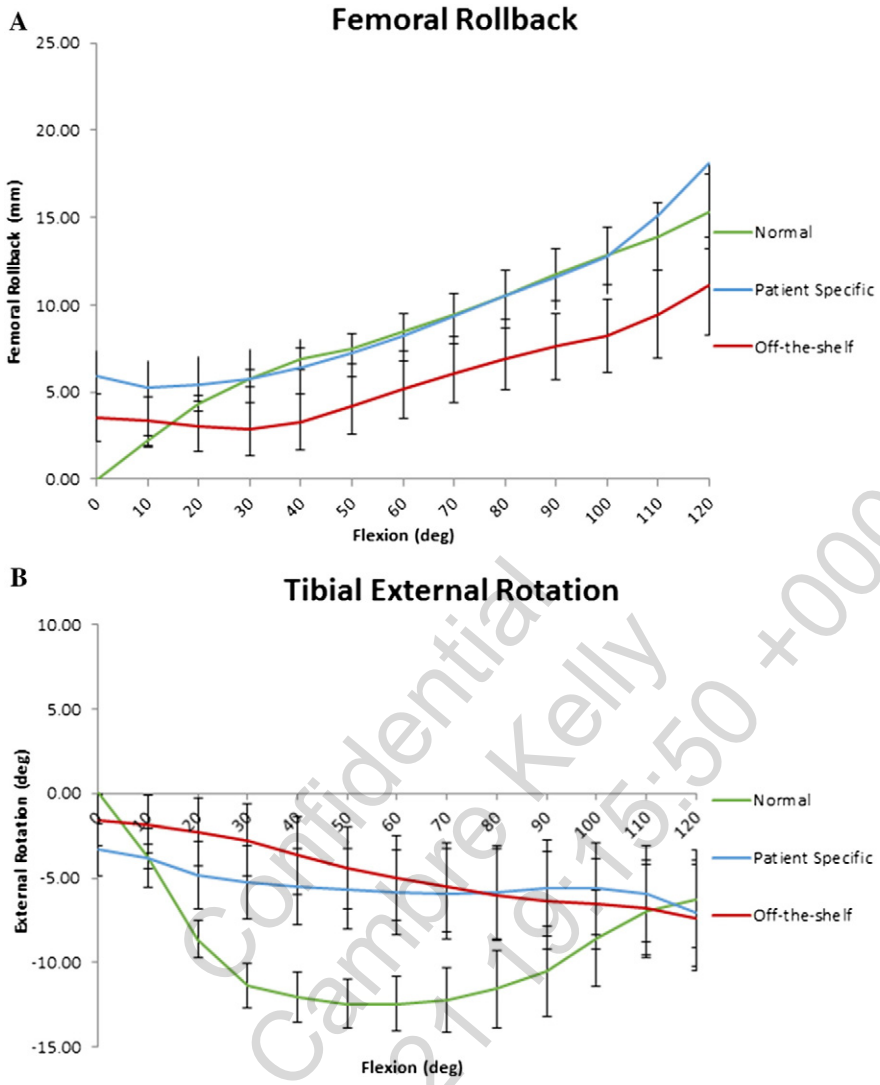

Fig. 4. Comparison of kinematic measures in the patient-specific design, and the off-the-shelf design for A: active femoral rollback. B: active tibial external rotation.

nominal moment of 5.5 Nm was applied to the tibia via weights using a pulley system.

2.6. Data collection and analysis

The following active knee kinematics for each condition were recorded over the range of knee flexion: tibiofemoral flexion, adduction, and axial rotation; femoral rollback (Fig. 4). The following passive knee kinematics were recorded: tibiofemoral adduction and rotation over the range of knee flexion under passive varus or valgus moment. To account for the effect of patient-specific variability in knee kinematics among cadaveric specimens, we used a paired analysis to compute the change in kinematics from the intact knee to the implanted knee: comparing this change between the off-the-shelf and patient-specific designs. First, the change in each kinematic measure was quantified as the absolute difference between the kinematic measure recorded in the normal knee and the same measure after implantation, which generated a "delta" curve representing the difference from normal over the range of flexion. Next, the cumulative difference from normal kinematics was calculated by summing the area beneath the curve to yield one "delta-sum" value for each implanted knee. Paired t-tests (Table 1, one-tailed) were performed to assess the statistical significance of the differences in the delta-sum between off-the-shelf and patient-specific conditions for each kinematic measure, with a P value of 0.05 chosen as a threshold in determining statistical differences between the two groups tested.

Table 1
Average (± standard deviation) of the cumulative difference from normal kinematics.

Kinematics	Patient-specific	Off-the-shelf	P value*
Femoral rollback	343 ± 213	590 ± 255	0.036
Tibial adduction	241 ± 93	406 ± 240	0.045
Tibial external rotation	650 ± 284	664 ± 381	0.466
Passive varus–valgus	175 ± 67	505 ± 399	0.016

* One-tailed paired t-test.

3. Results

3.1. Active kinematics

The kinematics of the knees implanted with the patient-specific design visually more closely approximated normal femoral rollback and tibial adduction than the knees implanted with the off-the-shelf design. The cumulative difference in these kinematics from normal (delta-sum) was statistically lower for the patient-specific group compared to the off-the-shelf group for all kinematic measures except for tibial external rotation (Fig. 5, paired t-test).

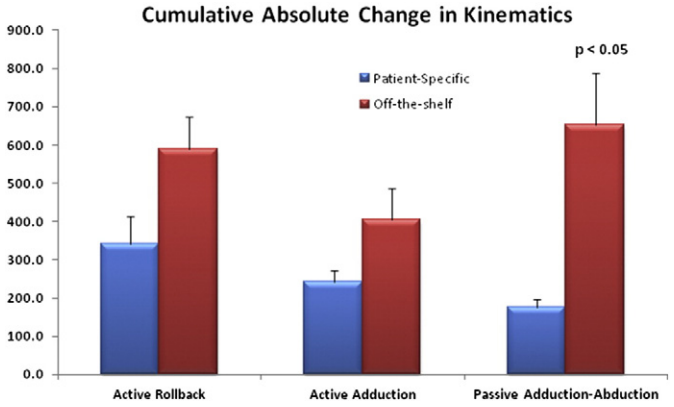

Fig. 5. Cumulative difference from normal for active and passive kinematics.

3.2. Passive kinematics

The kinematics of the patient-specific design were not significantly different from the off-the-shelf design for rollback and tibial rotation. However, the difference from normal in passive range of total varus–valgus laxity with the patient-specific design was significantly less than that with the off-the-shelf design. Also, the net variation of total varus–valgus laxity between individual patient-specific TKAs was lower than that seen in the off-the-shelf group (Fig. 5)

4. Discussion

Despite major advances in TKA implant design, restoration of function and especially normal kinematics are still elusive. This issue is in part due to the altered geometry of the articular surfaces, resection of the anterior cruciate ligament, variation in implant alignment, and differences in soft-tissue balance after surgery. Patient-specific cutting guides have shown promise in reducing the variation in implant alignment. However, the articular surfaces of a standard off-the-shelf implant do not correspond to those of the patient's native anatomy. Patient-specific implants, customized to the patient's geometry have been proposed in an attempt to better match the size and shape of the patient's knee and to restore articular surface geometry. In our study, the objective was to determine whether patient-specific implants would restore the normal knee kinematics.

Femoral rollback is an important feature of healthy kinematics and was qualitatively and quantitatively significantly closer to the normal knee in the specimens implanted with the patient-specific design (Fig. 4A; Table 1). A more posterior position of the femur in flexion lengthens the extensor lever arm and improves the mechanical efficiency of the knee during activities such as stair climbing and rising from a chair. On the other hand, paradoxical rollback (femur sliding forward with flexion) has been reported clinically after TKA and is thought to increase the risk for polyethylene wear [17,18]. In our study, neither implant design generated paradoxical rollback. However, the femoral rollback with the patient-specific implant was significantly closer to normal than with the standard, off-the-shelf implant. Tibial rotation is also important and is thought to improve range of flexion since the normal tibia rotates internally with flexion. In both implant designs the tibia rotated internally with flexion (Fig. 4B).

Tibial adduction–abduction is often linked to soft-tissue balance. During standard TKA surgery with off-the-shelf implants, the asymmetric femoral and tibial condylar geometry is replaced by an articulation which is symmetric with respect to the femoral and or tibial components. This can often result in a trapezoidal gap between the femoral and tibial cuts and in a mismatch between the joint gap with the knee in extension compared to the gap in flexion. The rationale behind the patient-specific implants is that restoration of the anatomic J-curves of the knee, together with respecting the geometry of the articular surfaces and natural medial/lateral condylar offset of the knee, would result in more normal balance and preclude the need for soft-tissue releases. The patient-specific group more closely approximated normal tibial adduction under active loading, indicating that component alignment and articular surfaces were closer to that of the normal knee. Additionally, the significantly smaller deviation in passive varus–valgus laxity in the patient-specific group indicated that coronal ligament balance was better restored. Importantly, the standard deviations and ranges revealed that the standard, off-the-shelf knee implants had a greater variability in active tibial adduction and varus–valgus laxity.

Other factors, such as implant sizing and alignment may contribute to more normal kinematics. The sizes of off-the-shelf implant designs are based on statistical averages of anatomic measures. However, there is a substantial difference in the anteroposterior to mediolateral aspect ratio and articular morphology between genders, races and, most importantly, between patients. Surgeons often have to choose between an implant that is too large or one that is too small for a particular patient. Increasing sizes to address the full range of interpatient variability results in a major increase in implant inventory and fails to address all patients. A patient-specific design that directly addresses interpatient variation, restores normal articular geometry, and maintains alignment results in normal kinematics.

One weakness of the study was that we measured kinematics in cadaver knees without significant arthritic pathology. This allowed us to compare kinematics after TKA with those of an intact pre-arthritic knee. In arthritic patients undergoing TKA, patient-specific implants may restore preoperative pain free kinematics. Another weakness of this study was that it was not possible to test the patient-specific design and the off-the-shelf design in the same knee. We therefore used paired cadaver knees from the same subject and compared postimplantation kinematics to pre-implanted kinematics of each knee.

This study tested a single off-the-shelf design against the patient-specific design. While the tested design cannot be representative of all the available knee designs, it has been shown in multiple in-vivo studies of multiple designs using fluoroscopy, gait laboratory systems and other analyses that the kinematic patterns after TKA differ considerably from the normal knee. Specifically, the rollback in pre-implantation knees often exhibit a paradoxical movement in the opposite direction after cruciate-retaining TKA implantation [19,20]. Finally, we only tested one activity simulating a deep knee bend, because this activity is relevant to stair climbing and rising from a chair and is a standard activity studied in in vitro biomechanical and in vivo fluoroscopic analyses. Knee kinematics during other activities may be different.

The results of this study show that the patient-specific implants generate kinematics that more closely resemble normal knee kinematics than standard, off-the-shelf knee implants. More normal kinematics achieved with the patient-specific implants may result in improvements in many of the clinical problems observed with standard, off-the-shelf knee implants such as anterior knee pain, mid-flexion instability, reduction in range of flexion, and incomplete return of function. Clinical outcome studies are necessary to determine if these cadaver study results will translate into better clinical and functional outcomes for patients.

Conflict of interest statement

Darryl D. D'Lima, MD, PhD, has received research support from ConforMIS.

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