

# Patient-Specific Implants and Cutting Guides Better Approximate Natural Kinematics than Standard Total Knee Arthroplasty.

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## INTRODUCTION

Despite the over 95% survivorship of total knee arthroplasty (TKA) over the long term, patient satisfaction is less compelling with anywhere from 14–39% of patients reporting dissatisfaction with their TKA result [1–4]. Causes for dissatisfaction are due in part to anterior knee pain, mid-flexion instability, reduction in range of flexion, and incomplete return of function [5–9]. While many knee implants are available based on various design rationales, none have been reported to be successful in restoring the knee to its native condition.

Patient-specific cutting guides coupled with individualized femoral and tibial implants maximize bony coverage and have articulating surfaces that more closely approximate the subjects' natural anatomy. We hypothesized that restoring the articular surface and maintaining the medial and lateral condylar offset and geometry of the implanted knee to that of the joint before implantation would also restore the normal knee kinematics.

## METHOD

Preoperative CT scans were obtained from 9 matched pairs of human cadaveric knees (average age 74.3, range 56–88). 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 using standard cutting guides based on intra-medullary alignment. The contralateral knee was implanted with patient-specific implants (Fig 1) using patient-specific cutting guides, both manufactured from the preoperative CT scans. The implants were first generated using proprietary software, whereby the mechanical axis was restored to normal alignment (180°). Then, femoral and tibial implant rotation was set to zero and maintained in both the patient-specific implants as well as the patient-specific jigs in order to avoid any postoperative implant malrotation. The software generates 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.

The knees were tested on a dynamic, quadriceps-driven, closed-kinetic-chain oxford knee rig, which simulated a deep knee bend from full extension to a 120° flexion. Each knee was tested preoperatively as an intact, normal knee, and postoperatively after implantation with either the standard or patient-specific implant. The kinematics were recorded using an active infrared tracking system. Ligament balance was also determined by measuring the range of passive adduction-abduction under a nominal external adduction-abduction moment of 5.5 N-m.



Figure 1A. Patient-Specific Implant showing anatomical matching of condylar geometry.



Figure 1B. Patient-Specific Implant restoring the articular surfaces and showing the medial and lateral condylar offset.

## RESULTS

The kinematics of the knees implanted with the patient-specific design more closely approximated normal femoral rollback (Fig 2), and tibial adduction than the knees implanted with the standard design. To reduce the effect of variability among the cadaveric specimens, the change in each kinematic measure was quantified as the absolute difference between the normal kinematic measure and the same measure after implantation (at 10° flexion increments) for each knee. The cumulative difference from normal kinematics was calculated by summing the area beneath the curve (Fig 3). The cumulative difference in kinematics from normal was statistically lower for the patient-specific group compared to the standard group for all kinematic measures except for patellar shift (Fig 3, paired one-tailed *t*-test).

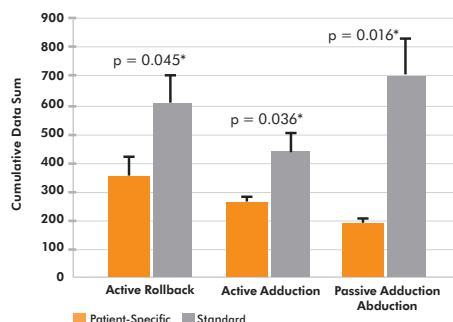


Figure 3. Cumulative absolute change in kinematics after implantation: \*Differences were statistically significant.

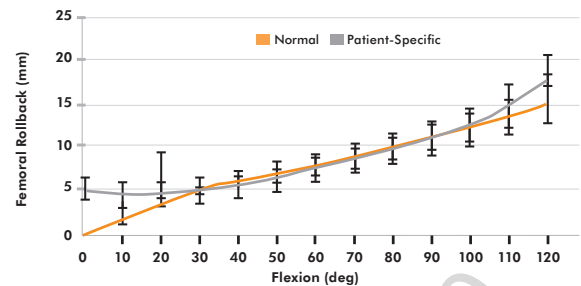


Figure 2A. Average femoral rollback (mm) for the patient-specific design.

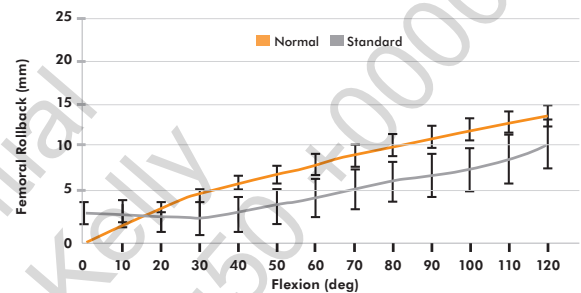


Figure 2B. Average femoral rollback (mm) for the standard design.

## DISCUSSION

Femoral rollback is an important feature of healthy kinematics and is significantly closer to the normal knee in the specimens implanted with the patient-specific design (Figs 2, 3). Rollback lengthens the extensor lever arm and improves the mechanical efficiency of the knee in deep flexion. On the other hand, paradoxical rollback (femur sliding forward with flexion) is thought to increase the risk for polyethylene wear. In our study, neither design generated paradoxical rollback. The patient-specific group more closely approximated normal tibial adduction (Fig 3) suggesting that ligament balance is better restored. Importantly, the standard deviations and ranges show that the standard knee implants also have a higher degree of variability than do the normal knees preoperatively or patient-specific knees postoperatively.

Ligament balance is another important variable that has been implicated in several complications including instability, restricted motion, and increased wear. A patient-specific implant that restores articular geometry is likely to result in a more stable knee. On passive testing of the range of adduction-abduction, the patient-specific implant resulted in varus-valgus laxity that was significantly closer to the normal knee compared to the standard implant.

Other factors, such as implant sizing and alignment, may contribute to more normal kinematics. The sizes of standard implant designs are based on statistical averages of anatomic measures. Even with an increased range of sizes, it will not be possible to address the full range of inter-patient variability, in particular with regard to articular geometry and associated kinematics. A patient-specific design that removes this variation, restores normal articular geometry and maintains alignment is more likely to result in normal kinematics.

One weakness of this study was that the anterior cruciate ligament was intact for the pre-implantation condition and was transected for the implanted condition. It is possible that loss of the anterior cruciate ligament was responsible for residual differences in implanted versus pre-implantation kinematics, especially in femoral rollback and tibial adduction. Nevertheless, these results support our hypothesis that knees implanted with patient-specific implants generate kinematics that more closely resemble normal knee kinematics than a standard knee design. Clinical outcome studies are necessary to determine if these cadaveric results translate into better outcomes.

## SIGNIFICANCE

Patient dissatisfaction and lack of return to normal kinematics are major issues affecting total knee arthroplasty. Patient-specific cutting guides coupled with individualized femoral and tibial implants that better approximate normal kinematics have the potential to address this deficiency.

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