



## Results of an Initial Experience with Custom-fit Positioning Total Knee Arthroplasty in a Series of 48 Patients

By Stephen M. Howell, MD; Kyle Kuznik, BS; Maury L. Hull, PhD; Robert A. Siston, PhD  
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The custom-fit approach to total knee arthroplasty in conjunction with removal of osteophytes and preservation of ligaments rapidly returned function; restored motion, stability, and postoperative mechanical axis alignment; effected high patient satisfaction; and had an acceptable clinical outcome.

Total knee arthroplasty (TKA) restores a significant degree of function, especially for the low-demand activities of daily living. However, improvements are needed to restore motion closer to normal and to allow performance of physically demanding activities that more active patients consider important.<sup>1</sup>

Errors in surgical technique and small changes in component positioning compromise postoperative performance.<sup>2-4</sup> Optimal component placement may not be possible when a patient presents a bone geometry that differs from that assumed by the instrument designer.<sup>5</sup> The use of computer-assisted surgical systems<sup>5</sup> has improved mechanical axis alignment,<sup>6-9</sup> but 6-month and 2-year active range of motion and Knee Society scores with computer-assisted techniques are not better than the conventional technique,<sup>10-12</sup> and the use of the computer increases operative time by approximately 10 to 20 minutes.<sup>13</sup> Conventional and computer-assisted approaches to TKA are not designed to restore the natural prearthritic alignment of the limb, but instead use standard cuts or a 0° mechanical axis that necessitates soft-tissue releases to restore motion and balance the knee.<sup>3,14</sup>

Disregard for the patient's natural alignment and the similar clinical outcomes of the conventional and computer-assisted techniques suggest the need for a new surgical approach with a different alignment principle. One approach is to apply the natural alignment principle of the mobile-bearing unicompartamental knee to TKA. The mobile-bearing unicompartamental knee restores natural alignment by removing marginal osteophytes, preserving ligaments, and filling the worn area with components. The restoration of natural alignment with preservation of ligaments may explain why the function, range of movement, speed of recovery, and kinematics of the mobile-bearing unicompartamental knee replacement are better than conventional and computer-assisted TKA.<sup>15-18</sup>

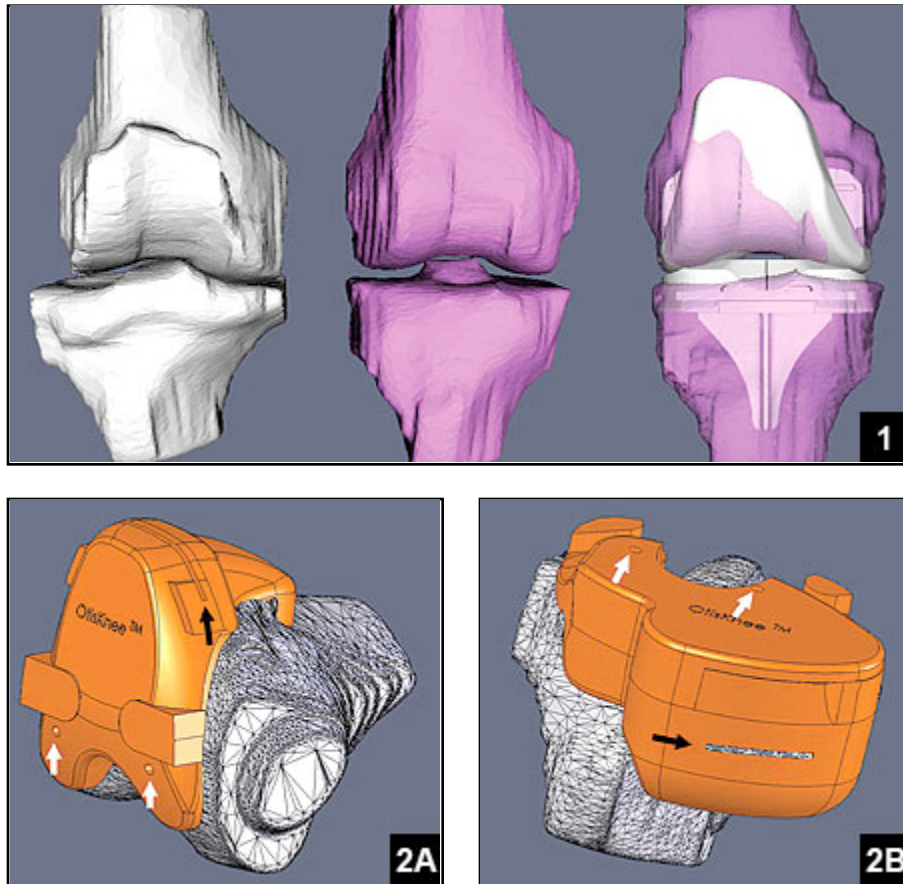
This article introduces a new custom-fit technique designed to restore the natural prearthritic alignment of the limb and normal kinematics through the use of custom-made tibial and femoral cutting guides constructed from a 3D model of the arthritic knee. While other researchers have proposed the development of patient-specific alignment guides,<sup>17,19</sup> to our knowledge the present study is the first to report on the intraoperative use of custom-fit guides to restore natural alignment and early postoperative results. This article evaluates the adverse events, perioperative experience, early functional outcomes, and mechanical axis alignment in the coronal plane of the custom-fit technique.

### Materials and Methods

#### Patients

Forty-eight consecutive patients (41 women and 7 men) treated from August 15 to December 1, 2006, were included in this prospective study. Institutional review board approval was obtained for the study. The inclusion criterion was the presence of primary arthritis of the knee with or without prior open or arthroscopic meniscectomy. Patients with osteotomies, malaligned shaft fractures of the femur and tibia, and arthroplasties were excluded. Preoperatively, the age and body mass index (BMI) of each patient were documented. Patients with a preoperative hemoglobin <12.0

g/dL were given the option to donate blood; 1 patient donated 1 unit, and 1 patient donated 2 units.



**Figure 1:** Side-by-side comparison showing a 3D model of an arthritic knee (left) and a 3-D model of a naturally aligned knee (center). The best-fitting femoral and tibial components are shape-fit to the articular surface of the 3D model of the naturally aligned knee (right). **Figure 2:** Six degree-of-freedom femoral (A) and tibial (B) cutting guides are shown referencing the arthritic model of the femur and tibia. The saw slot (black arrows) sets proximal/distal, flexion/extension, and varus/valgus. The 2 holes (white arrows) are set at internal/external rotation, anteroposterior, and mediolateral.

### Preoperative Computerized Planning

A sagittal magnetic resonance imaging (MRI) scan of the treated knee was obtained using a high-field scanner with a dedicated knee coil. The general scanning parameters included a 16-cm field of view centered at the joint line of the knee, 256 matrix, 2-mm slice thickness, and alignment of the coronal and axial slice planes perpendicular to the cortical-cancellous junction of the distal and posterior femur, respectively. We used the following sequence for the 1.5T General Electric scanner (GE Medical Systems, Milwaukee, Wisconsin): 2D FRFSE PD, 26 to 35 TE, 2400 to 3500 TR, 31.25 Hz bandwidth, and 2 excitations. In 2 patients with pacemakers, a computed tomography (CT) arthrogram was used to acquire sagittal images, reformatted from axial images, with the same general scanning parameters as MRI.

From the sagittal slices, the femur, tibia, articular cartilage, and osteophytes were segmented, and a 3D arthritic model was generated using proprietary software. The arthritic knee model was transformed into what we term a “naturally aligned” normal knee model by filling articular defects, removing osteophytes, and approximating the joint surface to restore the natural prearthritic alignment. For preoperative planning, the normal knee model and surface models of the femoral and tibial components were imported into software where proprietary routines shape-matched the femoral and tibial components to the knee, which aligned the flexion-extension rotational axis of the femur and femoral component (Figure 1). The cut planes corresponding to the position of the tibial and femoral components

were transferred to the arthritic model. Custom-made femoral and tibial cutting guides were machined using a biocompatible plastic (Delrin; DuPont, Wilmington, Delaware) to fit the arthritic knee (Figure 2). The saw slot in the guides set the proximal/distal translation and the flexion/extension and varus/valgus rotations of the femoral and tibial components. The 2 holes in the distal surface of the femoral guide and the proximal surface of the tibial guide were used to drill reference holes for seating the femoral chamfer guide and the tibial positioning guide, which set the anteroposterior and mediolateral translations and the internal/external rotation. Hence, each guide determined the size and position of the femoral and tibial components in all 6 degrees of freedom.

### **Operative Procedure**

All patients received an unconstrained TKA (Vanguard, Biomet Inc, Warsaw, Indiana) that was implanted with cement. The posterior cruciate ligament (PCL) was retained and the patella was resurfaced in all cases. The operations were performed with use of a tourniquet after a single injection of antibiotics (1 g of cephazolin and 1 g of vancomycin).

The range of motion and magnitude of deformity was measured under anesthesia. The knee was then exposed through a midvastus approach without patella eversion. The custom-fit femoral guide was seated on the anterior cortex, trochlear groove, and distal femur. The fit of the femoral guide was considered stable if it repeatedly seated in the same location when compressed along the longitudinal axis of the femur and rotated internally and externally. The guide was secured with 2 distal and 2 anterior pins. The medial and then lateral distal pins were sequentially removed as the distal cut was made. The chamfer guide corresponding to the size of the femoral component was inserted in the distal pin holes and the chamfer cuts were made. An intramedullary alignment rod was not used. The tibia was dislocated anteriorly, preserving the insertion of the PCL.

The custom-fit tibial guide was seated on the articular surface and the anteromedial cortex of the tibia. The fit of the tibial guide was considered stable if it repeatedly seated in the same location when compressed along the longitudinal axis of the tibia and rotated internally and externally. The guide was secured with 2 proximal and 2 anterior pins. The medial and then lateral proximal pins were sequentially removed as the tibial cut was made. The trial femoral component was centered on the femur and the lug holes were drilled.

A trial reduction was performed with the tibial liner that gave the best fit. Range of flexion/extension, varus/valgus stability from maximum extension to maximum flexion, and anterior subluxation of the tibia at 90° were checked. Any loss of extension was treated by removal of posterior osteophytes. Any medial and or lateral tightness during passive flexion/extension or during varus/valgus laxity was treated by removal of medial or lateral osteophytes until the knee was balanced throughout the motion arc. There were no releases of the deep medial collateral ligament, nor any of the lateral ligaments. The tibial positioning guide corresponding to the size of the tibial component was superimposed over the proximal pin holes, which set internal/external rotation. Small 1- to 2-mm mediolateral and anteroposterior adjustments in the location of the tibial positioning guide were made to center the tibial component while maintaining internal/external rotation. The placement of the patella button was medialized and tracking of the patella was stable without the need for a lateral retinacular release. A long-alignment rod was not used to check the varus/valgus orientation of the tibial cut.

In addition to the range of motion and deformity, we collected the following data during the operative procedure: 1) whether the fit of the femoral guide was stable, 2) whether the fit of the tibial guide was stable, 3) whether osteophytes on the anterior femur or tibia had to be removed to improve the fit of the guides, 4) whether the femoral or tibial cut had to be redone, 5) whether the size of the implanted femoral and tibial component matched the plan, 6) the thickness of the tibial liner, and 7) whether soft-tissue releases were required. The operative duration was from tourniquet inflation to release at the time of dressing application.

### **Postoperative Procedure**

Postoperatively, drains and peripheral nerve blocks were not used. Discomfort was managed with an intra-articular injection of 20 to 30 cc of 0.5% bupivacaine with epinephrine, patient-controlled analgesia overnight (morphine sulphate or meperidine), and oral analgesics until discharge. Continuous passive motion from 0° to 70° was started in the recovery room and continued during the day during the hospital stay. Pulmonary embolism prophylaxis included asymmetric compression stockings during surgery and the hospital stay and low-dose warfarin started on the evening of surgery and continued for 21 days. Length of stay, use of transfusions, hemoglobin at discharge, and postoperative complications were recorded.

Postoperatively, long-leg coronal alignment was determined by CT. In accordance with a standard protocol, we acquired a coronal scout scan that included the hip joint to the ankle. Internal-external rotation of the limb was controlled by accepting scans in which the 2 holes in the posterior condyles designed to receive augments were at least partially visible on either side of the flange of the femoral component. We defined the femoral mechanical axis as the line between the center of the femoral head and the center of the knee with use of screen measurement software (Iconico Inc, New York, New York). The tibial mechanical axis was defined as the line between the center of the knee and the center of the ankle. The angular deviation of the mechanical axis was the angle formed by the intersection of the femoral and tibial mechanical axes (varus [+ ] or valgus [-]).

At 3 months postoperatively, return to function indices, knee motion, and Knee Society score were measured.

## Results

No adverse events occurred with the custom-fit technique. No patients required reoperation or rehospitalization, and there were no hematomas, superficial or deep wound infections, symptomatic deep vein thrombosis, or pulmonary embolisms. One patient required a knee manipulation for stiffness.

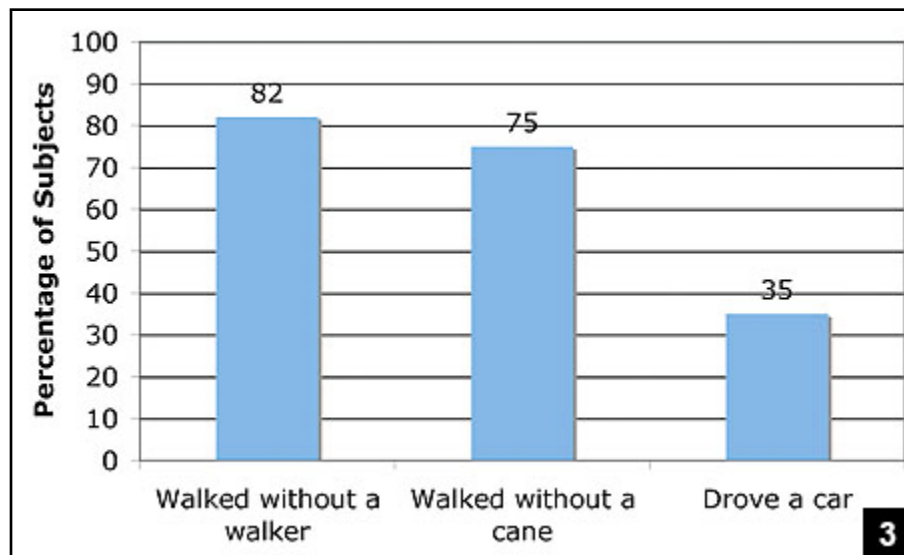
The preoperative varus/valgus deformities at the time of surgery included 40% (19 of 48) patients with a varus deformity ( $4.5 \pm 5.0$ , maximum 15.0) and 60% (29 of 48) with a valgus deformity ( $-6.3 \pm 3.0$ , maximum -14.0). The preoperative extension/flexion deformities at the time of surgery included 67% (32 of 48) with an extension loss ( $7.5^\circ \pm 6.2^\circ$ ; range,  $2^\circ$  hyperextension to  $27^\circ$  flexion), and flexion averaged  $116.3^\circ \pm 8.6^\circ$  (range,  $87^\circ$ - $135^\circ$ ) as measured with a long-arm goniometer. The intraoperative postoperative extension averaged  $0.9^\circ \pm 2.5^\circ$  (range,  $4^\circ$  hyperextension to  $9^\circ$  flexion) and flexion averaged  $123.0^\circ \pm 7.4^\circ$  (range  $108^\circ$ - $136^\circ$ ).

The average postoperative mechanical axis derived from the long-leg CT scan was  $-1.4^\circ \pm 2.8^\circ$  valgus.

The perioperative experience with the custom-fit technique was positive. The average tourniquet time was  $52 \pm 8$  minutes. Forty-five of 48 of the femoral guides and 45 of 48 of the tibial guides had a stable feel. Anterior osteophytes were removed in 7 femurs and 2 tibias to improve the fit of the guides. No femoral cuts had to be redone, and 1 tibial cut had to be redone to remove an additional 2 mm of the tibia to make room for the liner. The size of the planned femoral and tibial component matched the implanted size in every knee. The implanted thickness of the tibial liner was 10 mm in 47%, 12 mm in 45%, and 14 mm in 8% of the patients. The PCL inadvertently detached in 2 of the knees that required a 14-mm liner, suggesting that a more conservative tibial cut might have preserved the insertion of the ligament. The knee was balanced by removing marginal osteophytes, which indirectly lengthened tight ligaments. No knees required a release of a collateral ligament, posterior cruciate ligament, or lateral release.

With regard to hospital stay, 7% of patients were discharged the day after surgery, 42% 2 days after surgery, 42% 3 days after surgery, and 9% 4 days after surgery. No patients received donor blood, and only 3 units of autologous blood were transfused. The average hemoglobin at discharge was  $9.9 \pm 1.7$  g/dL.

With regard to postoperative recovery, 75% of patients walked independently and one-third drove their cars 1 month postoperatively (Figure 3). At 3 months postoperatively, 35% of patients judged their knee as "normal" and 60% "nearly normal." Patient demographics, operative duration, use of blood transfusion, active range of motion, and Knee Society scores are listed in the Table.



**Figure 3:** Column graph showing the percentage of patients in the custom-fit group who walked without a walker or cane and drove a car 1 month postoperatively.

## Discussion

This study evaluated a new custom-fit technique for performing TKA, focusing on adverse events, perioperative experience, early functional outcomes, and mechanical axis alignment. The most important finding of the study is that the new custom-fit technique for implanting a TKA did not have any adverse effects. Other equally important findings are that the custom-fit technique had short operative duration, few blood transfusions, a high return of function and motion, and high patient satisfaction at 1- and 3-month follow-up, and it reliably aligned the limb.

There is evidence that the arthritic and the prearthritic naturally aligned 3D knee models from the MRI were accurate enough to plan and execute the surgery. The intraoperative fit of the femoral and tibial guides was consistent, and the implanted size of the femoral and tibial components matched the shape-fitted size. The 2 thinnest tibial liners (10 and 12 mm) were implanted in 92% of the knees, indicating that the tibial cut plane was set correctly and the amount of bone removal was conservative.

No knees required a collateral ligament release. Like the mobile-bearing unicompartmental knee, the custom-fit technique restores balance and motion by removing medial, lateral, and posterior femoral and tibial osteophytes and shape-matching the components. Indirect lengthening of the ligaments through osteophyte removal is preferred because soft-tissue releases cause an abrupt lengthening with a gross increase in angular alignment<sup>20-22</sup> that imbalances the knee, causing lift-off and premature wear.<sup>23,24</sup> The excellent restoration of intraoperative and 3-month motion and the acceptable alignment of the mechanical axis suggest that the ligament preservation principle of the custom-fit technique was successful.

One explanation for the complete absence of collateral ligament and lateral retinacular releases is that the custom-fit technique resurfaces the knee. The goal of the shape-matching technology is to place the femoral component with the same internal/external, varus/valgus, flexion/extension, proximal/distal, anteroposterior orientation as the prearthritic articular surface of the femur. Matching the internal/external rotation of the femoral component to the prearthritic articular surface of the femur maintains normal ligament balance through mid and late flexion, which is rarely achieved with the highly variable computer-assisted technique and traditional techniques that reference the transepicondylar axis, Whiteside's line, or a posterior referencing line, or uses the surgeon's own method.<sup>25</sup> Shape-matching also seeks to restore the normal kinematic axes of the tibia and patella throughout the full motion arc by striving to align the flexion-extension rotational axis of the femoral component coincident with the flexion-extension rotational axis of the femur.

Coincident alignment of the axes of the femoral component and femur is the sine quo non for restoring normal kinematics to the knee because the flexion-extension axis of the patella is parallel to the flexion-extension axis of the

femur and the internal/external rotational axis of the tibia is perpendicular to the flexion-extension axes of the femur and patella.<sup>26</sup> Not aligning the flexion-extension rotational axes of the femoral component coincident with the femur malaligns the tibia and patella, requiring collateral ligament and lateral retinacular releases in an attempt to restore motion and patella tracking. These releases may have penalties, as they alter knee kinematics and destabilize the knee.<sup>14,26</sup>

The perioperative data suggests that the custom-fit technique may lessen the surgical stress experienced by the patient. The average operative duration of 53 minutes is less than the average reported operative times for conventional (73 minutes) and computer-assisted (90 minutes) approaches.<sup>27</sup> Transfusions were infrequent (3 units of autologous blood in 48 patients), and there were no documented fat emboli. The use of custom-fit guides lessens operative time, reduces blood loss, and eliminates the possibility of fat emboli because the surgery is performed through a smaller surgical incision, with fewer surgical steps, without soft-tissue releases, and without an intramedullary rod.

Another advantage of the custom-fit technique is the economies that are gained because the size of the femoral and tibial components is known prior to surgery, which means fewer instruments are needed to perform the surgery. One customized tray of instruments is used instead of the 6 to 8 trays needed with traditional and computer-assisted techniques. The use of 1 tray shortens the set-up time (approximately 30 minutes) and lowers the cost and time needed for cleaning and sterilizing the instruments. Consignment costs are less since only the femoral and tibial component, the 3 thinnest tibial liners, and patella buttons are needed for a case. Collectively, these economies allow more cases to be accomplished in the same time period, especially in hospitals with limited sterilization equipment.

Table	
Custom-fit Total Knee Arthroplasty <sup>a</sup>	
Age (y)	67 ± 10 (47-89)
Body mass index (kg/m <sup>2</sup> )	30.4 ± 6.3 (19.1-47.8)
Operative duration (min)	53 ± 8 (39-71)
Units of blood transfused	3 units autoblood
Active range of motion (°)	114 ± 11 (92-134) <sup>b</sup>
Knee score (points)	94 ± 6 (72-100) <sup>b</sup>
Function score (points)	87 ± 15 (45-100) <sup>b</sup>
Pain score (points)	47 ± 5 (30-50) <sup>b</sup>
Combined Knee Society score (points)	171 ± 19 (130-200) <sup>b</sup>
<sup>a</sup> n=48.	
<sup>b</sup> At 3 months.	

A retrospective analysis was undertaken to determine why 3 of 48 (3%) of the tibial guides and 3 of 48 (3%) femoral guides did not fit securely. The cause of the poor fit was a random error by the technician when aligning the MRI. The fit of the guides and positioning of the components has since been improved by the development of a protocol for aligning the MRI and for checking the alignment after the knee has been scanned. This protocol was instituted in December 2006 after closure of the present study and has prevented the technician from malaligning the MRI.

It is important to discuss whether the alignment of the custom-fit technique is compatible with a low rate of wear. It must be emphasized that the natural alignment aim and restoration of the 3 kinematic axes of rotation of the custom-fit technique is similar to the mobile-bearing unicompartmental knee technique. The unicompartmental technique does not attempt to restore a straight-line mechanical axis, and therefore a wider variability of the deviation of the mechanical axis is possible. Furthermore, any outliers with natural anatomic alignment should be considered normal, as they reflect the wide variability of the mechanical axis in normal knees as shown by Eckhoff et

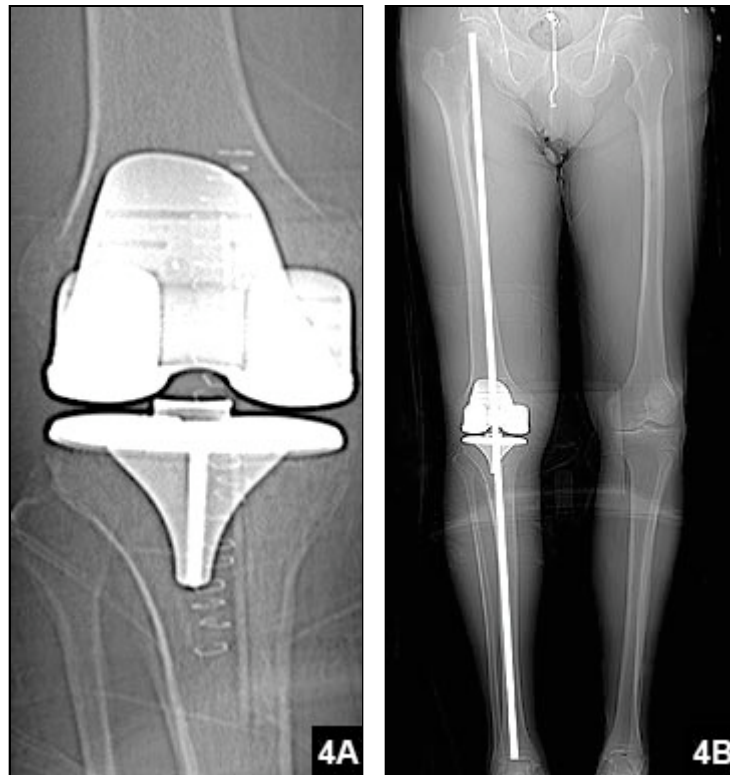
al.<sup>14</sup> Although achieving a 0° mechanical axis alignment is not the aim of this technique, the average alignment in the present study was in slight valgus ( $-1.4^\circ \pm 2.8^\circ$ ) and within the  $\pm 3^\circ$  window of mechanical axis alignment, which has been suggested to prevent component loosening and wear.<sup>3,28-31</sup>

The long-leg alignment in the present study of slight valgus and within the  $\pm 3^\circ$  window of a 0° mechanical axis does not agree with a cursory report of a small case series of custom-fit knees (n=4).<sup>32</sup> The cases in this series were performed at the request of an implant company as a pilot study to evaluate the first-time use of their knee component with the custom-fit guides before commercial release. The authors of that pilot study suggested that the custom-fit knees were malaligned, which is not the experience of the present study. A retrospective review of those cases revealed that the technician malaligned the MRI in 2 of the 4 knees in their pilot study, which was not a known problem at the time the surgeries were performed. Their observation of a malaligned leg might have been due to poor fitting of the guides that affect the position of the components because of an MRI alignment error.

A recent study of the survivorship of modern implants in 395 knees showed that factors other than the mechanical axis are more important for determining survivorship at 15 years, and suggested that the surgical goal of restoring a 0° mechanical axis should be revisited.<sup>33</sup> The founding principle of conventional TKA, which is that a 0° mechanical axis might reduce wear, is based on only 1 publication of a knee implant (Denham, Biomet Inc) that is substantially different from modern designs.<sup>3</sup> The recent study of the modern implant showed that the 25% of patients who were outliers ( $>3^\circ$  varus or valgus) had better survivorship at 15 years than the 75% aligned within the  $3^\circ$  window, which is in contrast from the study of the Denham knee.<sup>33</sup> The better survivorship of outliers might be due to better balancing of the knee and restoring normal kinematics. One aim of the custom-fit technique is to balance the knee by removing osteophytes, filling defects, and reapposing the joint surface to restore normal leg alignment and not by releasing the collateral ligaments. Another aim of the custom-fit technique is to restore normal kinematics by shape-fitting the components to align the flexion-extension axis of the femoral component coincident with the femur, thereby reestablishing the 3 kinematic axes of the knee. Irrespective of this debate, long-term studies of the custom-fit technique are required to determine whether it provides at least the same long-term, low-wear rate as conventional TKA.

We recommend caution when using a short radiograph of the knee to assess alignment of the components and the leg, as the alignment of the knee on a short radiograph does not predict the mechanical alignment of the leg. Figure 4 shows a short radiograph of the knee in which the tibial component appears in varus. However, a long-leg CT scout scan shows the mechanical axis is neutral and the plane of the joint line of the knee and ankle are parallel to each other and parallel to the floor, which are acceptable for long-term wear and survivability. Accordingly, we no longer use the short radiograph to check leg and component alignment because the long-leg alignment is unrelated to the alignment on the short radiograph of the knee.





**Figure 4:** Short AP view of the knee (A) showing that the alignment of the knee and component on the short view are not predictive of the long-leg alignment (B). The short view suggests that the knee and tibial component are aligned in varus. However, the long-leg view shows the mechanical axis of the leg is neutral, the plane of the knee and ankle are parallel to each other and parallel to the floor, and the varus/valgus inclination of the knee is similar to the contralateral knee. The inconsistency between the alignment of the knee and components on the short- and long-leg view suggests that alignment should be assessed with the long-leg view and not the short view of the knee.

## Conclusion

The present case-controlled study did not detect any adverse effects or long-leg malalignment that would preclude the use of the custom-fit technique. Custom-fit placement in conjunction with removal of osteophytes and preservation of ligaments rapidly returned to function; restored motion, stability, and postoperative mechanical axis alignment; effected high patient satisfaction; and had an acceptable clinical outcome at 3 months. The consistent sizing of the implants, secure fit of the femoral and tibial guides, short operative duration, low transfusion rate, and lack of fat emboli suggest that continued use of the custom-fit technique is warranted. Although encouraged by these promising results, we recognize the need for additional studies to determine whether the custom-fit technique restores more normal 3D kinematics, reduces long-term wear, and provides better long-term function than conventional and computer-assisted techniques.

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## Authors

Drs Howell and Hull are from the Department of Mechanical Engineering, University of California at Davis, and Mr Kuznik is from OtisMed Corporation, Alameda, California; and Dr Siston is from the Departments of Mechanical Engineering and Orthopedics, The Ohio State University, Columbus, Ohio.

Dr Howell is an unpaid consultant and founder of OtisMed Corporation. Dr Howell owns stock in OtisMed Corporation. Mr Kuznik is employed by OtisMed Corporation. Drs Hull and Siston have no relevant financial relationships to disclose.

Correspondence should be addressed to: Stephen M. Howell, MD, 8100 Timberlake, Ste F, Sacramento, CA 95823.

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