Component Alignment During Total Knee Arthroplasty with Use of Standard or Custom Instrumentation

A Randomized Clinical Trial Using Computed Tomography for Postoperative Alignment Measurement

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Background: Patient-specific femoral and tibial cutting blocks produced with use of data from preoperative computed tomography (CT) or magnetic resonance imaging (MRI) scans have been employed recently to optimize component alignment in total knee arthroplasty. We report the results of a randomized controlled trial in which CT scans were used to compare postoperative component alignment between patients treated with custom instruments and those managed with traditional instruments.

Methods: The in-hospital data and early clinical outcomes, including Knee Society scores, were determined in a randomized clinical trial of forty-seven patients who had undergone a total of forty-eight primary total knee arthroplasties with patient-specific instruments (twenty-two knees) or standard instruments (twenty-six knees). Orientation of the implants was compared by using three-dimensional CT data.

Results: No significant differences were found between the study and control groups with respect to any clinical outcome after a minimum of six months of follow-up. The patient-specific tibial cutting block was abandoned in favor of a standard external alignment jig in seven of the twenty-two study knees because of possible malalignment. A detailed analysis of intent-to-treat and per-protocol groups of study and control knees did not show any significant improvement in component alignment, including femoral component rotation in the axial plane, in the patients treated with the custom instruments. The percentage of outliers—defined as less than −3° or more than 3° from the correct orientation of the tibial slope—was significantly higher in the group treated with use of patient-specific blocks than it was in the control group, in both the intent-to-treat (32% versus 8%, p = 0.032) and the per-protocol (47% versus 6%, p = 0.0008) analysis.

Conclusions: There were no significant improvements in clinical outcomes or knee component alignment in patients treated with patient-specific cutting blocks as compared with those treated with standard instruments. The group treated with patient-specific cutting blocks had a significantly higher prevalence of malalignment in terms of tibial component slope than the knees treated with standard instruments.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.
Recently, there have been reports of favorable results from the use of patient-specific cutting blocks for total knee arthroplasty. These custom cutting blocks are fabricated for individual patients on the basis of magnetic resonance imaging (MRI) or computed tomography (CT) scans. It has been reported that these guides improve the accuracy of component placement; however, to our knowledge, all of the authors of these reports used two-dimensional radiographs of the knee to determine the postoperative alignment resulting from this new technique.

Those advocating the use of patient-specific cutting blocks have suggested that they can reduce surgical procedure time. Others have claimed that eliminating the use of an intramedullary femoral alignment rod by employing a patient-specific cutting block can reduce blood loss as well as the amount of embolic fat during knee arthroplasty. However, other authors have reported that there is no cost benefit from this technology and that the results of procedures performed with patient-specific cutting blocks are not superior to those in which standard instruments are used.

This study was conducted to assess whether utilization of custom instruments derived with use of preoperative three-dimensional CT data would improve clinical outcomes and component alignment as compared with results obtained with a standard instrument system of intramedullary femoral and external tibial cutting guides.

**Materials and Methods**

Patients who had arthritis of the knee and were scheduled to undergo primary total knee arthroplasty at our Veterans Administration hospital were asked to participate in this institutional review board-approved study to evaluate any difference between clinical outcomes and component alignment between patients treated with patient-specific instruments and those treated with standard instruments. This trial was registered at ClinicalTrials.gov (04061991).

A sample size of thirty patients in each group was chosen in reference to a recently published study that showed that computer navigation had some significant benefits when compared with standard instrumentation. Our study was conducted from December 2010 to May 2012. All patients who agreed to participate in this randomized controlled trial signed consent forms and were randomly assigned to a treatment group through the use of sealed envelopes. Figure 1 summarizes the data on the participants in the study. All patients had either degenerative or posttraumatic arthritis as a preoperative diagnosis, and all were male. One of us (S.T.W.) performed all of the procedures using the same cemented posterior-cruciate-substituting prosthesis with patellar resurfacing. Forty-seven patients had a total of forty-eight arthroplasties, with twenty-two knees treated with patient-specific cutting blocks and twenty-six, with standard instruments. One patient who had bilateral knee arthroplasty was randomized to have one knee arthroplasty with each type of block. There were no significant differences between groups based on the values for any preoperative parameter (see Appendix).

In the control patients, the procedures were performed with a standard instrument system with intramedullary femoral and extramedullary tibial alignment cutting guides. The femoral cutting guide was set to align the femoral component in 5° of valgus, and the tibial component was aligned perpendicular to the mechanical axis in the coronal plane with 3° of posterior slope. Axial rotation of the femoral component was referenced to a plane parallel to the posterior femoral condyles or to the transepicondylar line.

Study patients had a preoperative CT scan from the hip to the ankle performed according to the manufacturer's patient-specific-instrument protocol. After a preoperative plan was formulated on the basis of three-dimensional images of the bone, and reviewed online and approved by the surgeon, custom cutting blocks were manufactured (TruMatch; DePuy, Warsaw, Indiana). Both of the patient-specific cutting blocks (femoral and tibial) were designed to align the implants in the coronal plane parallel to the mechanical axis. The resection levels determined by the custom cutting blocks were planned by the manufacturer to allow for a wider extension space (2 mm) if the patient had a fixed preoperative knee flexion contracture. None of the preoperative online plans were modified by the surgeon other than by increasing either the distal femoral and/or the proximal tibial resection for patients who had a flexion contracture, since all of the plans appeared to result in a neutral coronal mechanical axis. The patient-specific femoral cutting block was placed on the distal part of the femur and pinned with use of two anterior and two distal pins. The distal femoral osteotomy was then made through the slot on the cutting block. The distal femoral pin-site holes were localized to determine placement of a second femoral cutting block for the anterior and posterior condylar bone cuts.

The proximal tibial osteotomy was performed after the cutting block was pinned to the tibia. The alignment of the planned proximal tibial osteotomy was visually checked by attaching a guide rod to the cutting slot on the
cutting block to ensure that the guide was in alignment with the tibia prior to the osteotomy. After the osteotomies were made, the extension and flexion spaces were checked and, if necessary, were adjusted by ligament releases and/or cutting more bone from the femur and/or tibia without changing the alignment of the cut(s). A soft-tissue release of the medial collateral ligament was performed in all patients who had any fixed varus deformity.

The surgical time, the need for postoperative transfusion, and the length of the hospital stay were recorded, as was the hematocrit on postoperative day two or three. Patients were followed for a minimum of six months and Knee Society scores were recorded preoperatively and at the final six-month follow-up examination.

Postoperative Three-Dimensional Alignment

All patients underwent a postoperative CT scan from the hip to the ankle to determine alignment of the femoral component in the coronal and axial planes with reference to the center of the femoral head and the transepicondylar line and the tibial component alignment in the coronal and sagittal planes with respect to the center of the ankle joint, with use of a method similar to that described by Matziolis et al. and Hirschmann et al. An independent observer (N.J.G.) who was blinded to the method of component alignment evaluated each postoperative scan and manually identified fifteen key points (Fig. 2) using OsiriX (version 3.5.1, 64 bit). A custom program was written with use of MATLAB (MathWorks, Natick, Massachusetts) to calculate separate orthonormal femoral and tibial reference coordinate systems from a subset of the key points defined in OsiriX. The remaining key points were used to define the orientations of the tibial and femoral components in their respective reference systems.

Statistical Analysis

Separate intent-to-treat and per-protocol analyses were performed. In the intent-to-treat analysis, patients were divided according to whether they had been randomized to the patient-specific cutting-block group, regardless of whether the custom blocks had actually been used. In the per-protocol analysis the patients were divided according to whether the patient-specific cutting blocks were used to make both the femoral and tibial cuts in all planes. Because some of the study patients had patient-specific cutting blocks used for some of the bone cuts and standard instruments used for other bone cuts, the numbers of patients in each of the per-protocol groups was not uniform. Per-protocol analysis tables are provided in the Appendix.

In the primary intent-to-treat analysis, a Welch two-sample t test and a 95% confidence interval for the difference in means between the two conditions was calculated. Then, the proportion of outliers (defined as less than −3° or more than 3° from the normal value) was compared between the treatment...
groups by using a test of independent proportions. An alpha of 0.05 was used for all tests. Finally, we conducted a sensitivity analysis in which we repeated the tests described above on the per-protocol sample.

Source of Funding
Both the preoperative and postoperative CT scans and the patient-specific cutting blocks were funded by the manufacturer; however, none of the authors received other research funds and none were consultants to the manufacturer.

Results
Intraoperative Findings
Use of the patient-specific tibial cutting blocks was unsuccessful in seven (32%) of the twenty-two knees. In three knees, the surgeon abandoned (removed) the block before he made the proximal tibial cut because, after visually checking the proposed cut with an alignment rod, he judged that the cut would be malaligned if he used the custom block. In four knees, the proximal tibial osteotomy that had been made with a patient-specific cutting block was recut because malalignment (with regard to tibial slope in two, in the coronal plane in one, and in both planes in another) was noted after the osteotomy had been made. In these seven knees, the final proximal tibial cut was made with a standard extramedullary alignment guide.

An insufficient extension space was created by the distal femoral and proximal tibial cuts made with patient-specific cutting blocks in eight knees, and more distal femoral bone (2 to 4 mm) was resected from those knees. More proximal tibial bone (2 to 4 mm) was removed from eight knees because of an inadequate extension and flexion space. Four knees had resection of more bone on both the femoral and the tibial side. Thus, in twelve (55%) of the twenty-two study knees, the

<table>
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<th>TABLE I Comparison of Clinical Outcomes Between Control and Study Groups</th>
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<th>TABLE II Alignment of Knee Components in Intent-to-Treat Control and Study Groups</th>
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<td>Average (95% Confidence Interval)* (deg)</td>
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<td>Coronal mechanical axis</td>
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<td>Coronal femoral</td>
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<td>Axial femoral (femoral rotation)</td>
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*A minus sign indicates varus.
surgeon adjusted the extension space by increasing the amount of femoral or tibial bone, or both. Less distal femoral bone than planned was resected from one study knee when it appeared that excessive bone would have been resected with use of the patient-specific femoral cutting block.

During the procedure, the patient-specific preoperative plan with regard to the size of the component was changed in nine study knees (41%). This change consisted of using a femoral component (three knees) or a tibial component (four knees), or both components (two knees), that was larger or smaller than the size that had been predicted preoperatively. Five (23%) of the twenty-two femoral components were downsized one or two sizes and six (27%) of the twenty-two tibial components were either downsized or increased in size (three each).

In six knees (23%) in the control group, more bone (2 to 4 mm) was resected, from the distal part of the femur in three and from the proximal part of the tibia in three, after the initial cuts were made because of an inadequate extension space. Intraoperatively, none of the knees had malalignment of the proximal tibial or distal femoral osteotomy that required re-cutting. One control patient, however, had excessive resection of bone requiring a 17.5-mm polyethylene insert and, because of this, the standard cruciate-sacrificing implant was not used; a more constrained implant was substituted for more stability.

Clinical Results
There was no significant difference between the study and control groups with regard to the mean surgical time, postoperative hematocrit, length of hospital stay, Knee Society rating or function score, or improvement in the Knee Society score (Table I). The patient who had bilateral knee arthroplasty required two autologous units of blood. One control patient had a reoperation three weeks postoperatively because of dehiscence of the fascial repair with patellar subluxation but had no subsequent sequelae. Another control patient developed tibial component loosening at fourteen months and was scheduled for revision at the time of writing. Two patients (one in the control group and one in the study group) died, at three and four months postoperatively, of causes unrelated to the arthroplasty. All other patients were followed for a minimum of six months.

Component Orientation Demonstrated by CT Data
In the intent-to-treat analysis, the control and study groups were similar with regard to the mean mechanical axes and number of outliers (Tables II and III). The analysis of the per-protocol groups showed no difference between the control and study groups with regard to the mean deviations from the mechanical axis or the percentage of outliers in each group (see Appendix).

Similarly, there were no differences between the study and control groups, in either the intent-to-treat or per-protocol analysis, with respect to the coronal or rotational alignment of the femoral component (Tables II and III and Appendix). Although there was no difference in the coronal alignment of the tibial component between the study and control groups in the intent-to-treat analysis, there was a trend (p = 0.08) for more tibial implants in the study group to be outside a 3° tolerance in the per-protocol analysis (see Appendix). There was no significant difference in the mean sagittal alignment (slope) of the tibial component between the study and control groups in either the intent-to-treat or per-protocol analyses, but both analyses showed a significant increase in the number of outliers (tibial slope, $< 0^\circ$ or $> 6^\circ$ posterior) in the study group ($p = 0.32$ and 0.0008, respectively). In the per-protocol analysis, the study group had a much higher percentage of outliers for tibial slope than the control knees (47% and 6%, respectively).

Discussion
The potential advantages of patient-specific cutting guides are improved component alignment, reduction in surgical time, less blood loss, and cost reductions due to a decreased number of sterile surgical instrument trays. However, the disadvantages of a custom instrument system include a considerable increased cost for the preoperative scan ($300 US [2010] in our study) and production of the cutting blocks (as much as $1500 US [2013] as a list price for these particular custom personalized instruments) as well as a six-week delay in the surgery because of the need for planning and production of the custom blocks. The use of custom instruments produced on the basis of CT data subjects patients to greater radiation exposure than they would receive from radiographs.

| TABLE III Percentage of Alignment Outliers in Intent-to-Treat Control and Study Groups |
|---------------------------------|---------------------------------|
| Percentage (No. of Outliers/No. of Knees) | [95% Confidence Interval] |
| Control Group | Study Group |
| Coronal mechanical axis | 38 (10/26) [21 to 59] | 41 (9/22) [21 to 63] |
| Coronal femoral | 23 (6/26) [10 to 44] | 23 (5/22) [9 to 46] |
| Axial femoral (femoral rotation) | 46 (12/26) [27 to 66] | 27 (6/22) [11 to 50] |
| Coronal tibial | 4 (1/26) [0.2 to 22] | 14 (3/22) [3.5 to 36] |
| Sagittal tibial (slope) | 8* (2/26) [1 to 27] | 32* (7/22) [14 to 55] |

*P = 0.032.
To justify the use of custom instruments to improve patient outcomes, patient-specific cutting blocks would have to provide more accurate alignment than standard instrument systems in randomized clinical trials. Because orientation of the femoral component in the axial plane (femoral component rotation) is impossible to determine from radiographs and because assessment of component alignment on standing radiographs may lead to error\textsuperscript{15}, we used a postoperative CT scan as the gold standard imaging test to compare alignment data between our study and control groups.

We were unable to find a difference in the early clinical outcomes between the study and control groups within a six-month follow-up period. The follow-up was short because the main outcome measure was alignment. Although at the time of writing two control patients had undergone, or were scheduled to undergo, a reoperation, both had components that were aligned within a 3° tolerance window.

Intraoperatively, a high percentage of study patients (41%; nine of twenty-two) had deviations from the customized surgical plan, as they required a femoral and/or tibial component of a different size than planned. Resection of more or less bone from the distal part of the femur or proximal part of the tibia to provide an adequate extension and/or flexion space was necessary in more than twice the number of knees in the study group than in the control group, indicating that the surgeon’s estimation of the amount of bone resection to correct a flexion contracture was more accurate than a preoperative planning protocol.

We expected to see more precise rotational femoral alignment with the use of patient-specific instruments, as was found by Heyse and Tibesku\textsuperscript{5}, but we did not. In fact, the patient-specific proximal tibial cutting block was unreliable in a third (seven) of the twenty-two cases and often resulted in cutting errors in the sagittal plane because placement of the custom block on the tibia resulted in an anterior slope of the tibial component in several patients. Five knees in the patient-specific-instrument group had an anterior, rather than a posterior, slope, and this number would have been higher had the custom block been used in more knees. We do not know the reason for these tibial cutting block failures but assume that it was a combination of the preoperative planning and the surgeon’s inability to place the block securely on the tibia using the three points on the custom block that correspond to the medial tibial cortex and both tibial plateaus.

This prospective randomized, controlled, observer-blinded study of procedures performed by one surgeon provides additional information on the accuracy of patient-specific cutting blocks for knee arthroplasty. We believe that this is the first study in which this was assessed with CT for measuring alignment. However, our study had shortcomings. First, the number of patients in each group was lower than we intended to recruit. Because of these low numbers, we reported the 95% confidence intervals rather than p values. However, given the trends in the data that we obtained, it is unlikely that we would have found improved alignment with patient-specific cutting blocks if we had studied more patients, as any non-significant trends favored the standard instrumentation group. Second, it could be argued that additional experience with patient-specific cutting blocks would have resulted in improved performance. However, we do not think that more practice using the cutting blocks would be likely to result in different outcomes, as the surgeon’s ability to position the blocks correctly did not appear to improve after twenty cases had been performed. Again, we are not sure whether the inaccuracies associated with use of the patient-specific tibial cutting block were due to the surgeon’s inability to place the custom block onto the bone accurately or whether the block was not designed correctly. The manufacturer has made changes to its technique for designing the tibial cutting block that were not utilized for the blocks used in these patients, but we do not have information regarding the results of these changes. Several other recent publications on patient-specific instruments have also reported no improvement in component alignment\textsuperscript{16-18}, and Stronach et al.\textsuperscript{19} found that 50% to 70% of components were not sized accurately with use of an MRI-based system.

In summary, we found no improvement in any clinical or radiographic measure with the use of CT-based patient-specific cutting blocks for primary total knee arthroplasty. This is in contrast to a report by Ng et al.\textsuperscript{1} that showed fewer outliers in alignment with MRI-based patient-specific cutting blocks. However, Ng et al. used radiographs, which are not as accurate as CT, to measure alignment. Although we did not find that use of this type of patient-specific femoral cutting block provided better accuracy than a standard intramedullary instrument system, we did find equal accuracy in coronal alignment and fewer (although not significantly fewer) outliers for malrotation of the femoral component. Thus, we believe that this instrumentation can be used safely for aligning the femoral component in knee arthroplasties for which it is not possible to use an intramedullary femoral alignment rod. However, because the tibial patient-specific instrument was less accurate than a standard extramedullary guide, that CT-based instrumentation system cannot be recommended for uncomplicated cases in its present form.

Appendix

Tables showing alignment of knee components in the per-protocol control and study groups, the percentage of knee-alignment outliers in the per-protocol control and study groups, and a comparison of patient demographics between the control and study groups are available with the online version of this article as a data supplement at jbjs.org.

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