Implant Positioning in TKA: Comparison Between Conventional and Patient-Specific Instrumentation

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Abstract

The number of total knee arthroplasty (TKA) procedures continuously increases, with good to excellent results. In the last few years, new surgical techniques have been developed to improve prosthesis positioning. In this context, patient-specific instrumentation is included. The goal of this study was to compare the perioperative parameters and the spatial positioning of prosthetic components in TKA procedures performed with patient-specific instrumentation vs traditional TKA. In this prospective comparative randomized study, 15 patients underwent TKA with 3-dimensional magnetic resonance imaging (MRI) preoperative planning (patient-specific instrumentation group) and 15 patients underwent traditional TKA (non-patient-specific instrumentation group). All patients underwent postoperative computed tomography (CT) examination. In the patient-specific instrumentation group, preoperative data planning regarding femoral and tibial bone resection was correlated with intraoperative measurements. Surgical time, length of hospitalization, and intraoperative and postoperative bleeding were compared between the 2 groups. Positioning of implants on postoperative CT was assessed for both groups. Data planned with 3-dimensional MRI regarding the depth of bone cuts showed good to excellent correlation with intraoperative measurements. The patient-specific instrumentation group showed better perioperative outcomes and good correlation between the spatial positioning of prosthetic components planned preoperatively and that seen on postoperative CT. Less variability was found in the patient-specific instrumentation group than in the non-patient-specific instrumentation group in spatial orientation of prosthetic components. Preoperative planning with 3-dimensional MRI in TKA has a better perioperative outcome compared with the traditional method. Use of patient-specific instrumentation can also improve the spatial positioning of both prosthetic components. [Orthopedics. 2015; 38(4):e271-e280.]
Osteoarthritis is 1 of the most important causes of disability in the elderly. Over the past few decades, total knee arthroplasty (TKA) has been established as a reliable and cost-effective treatment to alleviate pain and restore physical function in patients with severe arthritis. With the aging of the population, there will be a continued increase in the number of total knee replacement interventions.

The development of strategies to improve the accuracy and reproducibility of TKA is a principal goal of contemporary orthopedic research. Correct alignment of components has been cited as one of the most important features of successful TKA, and implant malpositioning leads to patellofemoral problems, knee instability, stiffness, early wear and loosening of components, and inferior functional performance. In contrast, good alignment of prosthetic components correlates with reduced pain, better knee function, faster rehabilitation, and improved quality of life.

Conventional instrumentation is suspected to have limited accuracy in determining the key landmarks needed to achieve optimal alignment of components. Furthermore, weight-bearing radiographs of the knee, generally used for preoperative planning of conventional TKA, have several limitations because of the inherent inaccuracy of a 2-dimensional technique, influenced by variable magnification and rotation factors. As a result, implant malpositioning with conventional instrumentation can reach a rate of 20% to 40%, even at most experienced centers.

Computer-assisted navigation systems limit implant malpositioning, reducing the number of outliers. However, potential disadvantages include difficulty with registration of intraoperative landmarks, longer operative time, increased costs, pin loosening and pin-site fractures, a long learning curve, and poor accuracy in determining the rotational alignment of implants. Patient-specific instrumentation has been introduced as a means to improve implant positioning in all 3 planes of space.

Use of ancillary instrumentation with custom-made tibial and femoral cutting guides or blocks, constructed on the basis of a 3-dimensional model of the knee, is the most recent technique used for TKA. Data provided by computed tomography (CT) or magnetic resonance imaging (MRI) allow perfect conformity of custom prostheses to patient anatomy. In addition to potential disadvantages of increased costs and the use of ionizing radiation in CT-based methods, there are limited and contradictory results in the literature about the orientation of components obtained with patient-specific instrumentation, particularly regarding rotational alignment.

It was the authors’ hypothesis that an accurate depiction of the anatomic landmarks of the knee, as allowed by 3-dimensional MRI preoperative planning, could improve the spatial orientation of prosthetic components. The authors compared perioperative parameters and spatial positioning on postoperative CT of TKA procedures implanted with patient-specific instrumentation and with the traditional method.

**Materials and Methods**

In this prospective randomized study, 30 patients presenting with severe osteoarthritis underwent total knee replacement surgery at the authors’ institution between June and November 2012. Patient inclusion criteria were primary knee osteoarthritis, age 50 to 85 years, failure of nonoperative treatments, no contraindications to surgery, acceptance of a relatively new method, and willingness to wait an additional 7 to 8 weeks required for the instrumentation to be prepared. Patient exclusion criteria included previous surgery or trauma of the limb to be treated, coronal deformity (>10° deviation), and general contraindications to MRI examination. The study protocol (including the use of patient-specific instrumentation and postoperative radiologic evaluation) was approved by the authors’ institutional review board. Written consent forms were obtained from all patients.

Patients were randomized into 2 groups by the informatics department of the authors’ hospital, using a systematic sampling method. The randomization protocol was not revealed to the authors, who received information about patient group assignments in numbered and sealed envelopes. Patients were matched for sex, age within 5 years, pathologic condition, body mass index, and side treated. All patients were implanted with a cemented posterior stabilized prosthesis, sacrificing the cruciate ligaments (NexGen LPS; Zimmer, Warsaw, Indiana), by the same surgeon (V.D., with more than 10 years of experience in TKA). Patients were treated under general anesthesia. Fifteen patients (9 women and 6 men; mean age, 75.3±6.7 years; range, 65-85 years; body mass index, 28.4±3.6 kg/m²) underwent total knee replacement surgery (9 right and 6 left knees) with the use of custom-made surgical cutting guides designed on the basis of 3-dimensional MRI preoperative planning (patient-specific instrumentation group). The other 15 patients (8 women and 7 men; mean age, 74.5±7.2 years; range, 63-85 years; body mass index, 28.1±3.8 kg/m²) underwent TKA (8 right and 7 left knees) with the traditional method (non–patient-specific instrumentation group).

For all patients, preoperative assessment included full-length weight-bearing radiographs of both lower limbs. Exclusively in patients in the non–patient-specific instrumentation group, a mediolateral projection and a skyline view at 45° flexion of the knee to be implanted were also performed. For patients in the patient-specific instrumentation group, MRI was performed 7 to 8 weeks before surgery with a 1.5 T unit (Achieva; Philips Healthcare, Best, The Netherlands).
according to a standardized protocol consisting of 3 consecutive sequences of the knee, hip, and ankle, respectively (Figures 1A-C). Fat saturated T1-weighted high-resolution images of the knee were obtained to visualize adequately the residual articular cartilage (Figure 1D). The most important factor influencing image quality, complete immobility of the patient, was achieved through the supervision of a radiologist (N.M., with more than 15 years of experience in musculoskeletal imaging). Patients were scanned in the supine position, with the feet placed parallel to each other and the toes pointing upward, to reconstruct as closely as possible the mechanical axis of the lower limbs in non–weight-bearing conditions.

For the femur, the mechanical axis was defined as a line connecting the center of the femoral head with the middle point of the intercondylar notch, whereas for the tibia it passed through the talar dome and the intercondylar eminence. These lines, together with the transepicondylar axis (connecting the medial and lateral femoral epicondyles), Whiteside’s line (passing through the middle and the most anterior point of the intercondylar notch), and the maximum anteroposterior and mediolateral diameters of the tibial bone tray, constituted the virtual coordinate system adopted in TKA planning.

The images were sent to the manufacturer (Materialise, Leuven, Belgium) through an online management system at least 28 days before the date of surgery. Images were anonymized on receipt, and a unique patient identifier was assigned to every case throughout its entire life cycle to protect sensitive data. A quality check of images was performed to exclude artifacts, implying the need to repeat MRI acquisition. Afterward, software (Materialise) was used to create a 3-dimensional model of the knee on which engineers performed default TKA planning.

Therefore, the surgeon, integrating the data acquired from preoperative clinical and radiologic evaluation, controlled and eventually adjusted to each patient this default alignment protocol by choosing the distal and posterior bone resections of the femoral condyles as well as the proximal bone resection of the tibial plates. Assessment of the coronal orientation of the tibial mechanical axis with respect to the femoral axis was preliminarily performed (Figure 2A). The depth of the distal femoral and proximal tibial bone cuts was calculated parallel to their corresponding presumed mechanical axes, whereas the posterior femoral bone cuts were determined perpendicularly to both the femoral mechanical axis and the transepicondylar axis (Figure 2B). The thickness of the residual articular cartilage and of the surgical saw blade was always included in the measurements.

Other parameters taken into consideration were the sagittal orientation of the distal femoral bone cut, associated with the anteroposterior shift of the anterior cutting plane, and the tibial slope (Figure 2B). Care was taken to avoid allowing the anterior cutting plane to exit the femoral cortical bone to prevent the formation of a notch (Figure 2C). The rotational alignment of the tibial component was established with the maximum anteroposterior and mediolateral diameters of the tibial bone tray used for reference, ensuring that the implant was best suited to the anterior tibial cortical bone (Figure 2D). For each TKA, it was also possible to choose the size of both prosthetic components. After planning approval was obtained, patient-specific instrumentation jigs perfectly conforming to the patient anatomy were created with computer-assisted manufacturing.

In the patient-specific instrumentation group, all prostheses were implanted according to a standardized technique, with instrumentation with just 9 tools. Each knee was exposed with an anteromedial approach and then patient-specific instrumentation guides were carefully positioned over the articular surfaces that were previously cleaned and dried, ensuring an accurate fit. Drill holes and pins were placed in the bone under the guidance of patient-specific instrumentation jigs (Figure 3) to orient the standard cutting blocks. No cartilage or osteophytes were removed, nor was the patella resurfaced. The depth of the femoral distal and posterior and proximal tibial bone cuts was measured with a caliper. The values recorded were compared with the corresponding preoperative data. In the non–patient-specific instrumentation group, TKA procedures were performed with an extramedullar guide for the tibia and an intramedullar guide for the femur.

In both groups, the following parameters were assessed: surgical or ischemia time (calculated from positioning to the release of a tourniquet at the root of the thigh), intraoperative blood loss (calcu-
lated from elastic bandage release to skin closure, postoperative blood loss (amount of blood collected during the intervention by an autotransfusion device, then reinfused to the patient in the first 2 to 4 hours after surgery, plus that collected by drains removed on the second postoperative day), and hospitalization time (from admission to discharge). The same rehabilitation protocol was used for all patients.

For each patient, CT examination was carried out 6 to 8 weeks after surgery with a 64-slice scanner (Lightspeed VCT 64; GE Healthcare, Waukesha, Wisconsin), after an acquisition protocol of the knee, hip, and ankle similar to that used for preoperative MRI. Images were transferred to a workstation (Advantage Windows 4.4; GE Healthcare) for postprocessing, including multiplanar reconstructions and maximum intensity projections. Another radiologist (F.F., with more than 5 years of experience in musculoskeletal imaging), blinded to the type of operative technique used (patient-specific instrumentation vs non–patient-specific instrumentation), evaluated the positioning of both prosthetic components in the 3 planes of space. In more detail, after the presumed mechanical axis of the femur and tibia for each lower limb was drawn, the coronal orientation of the tibial axis with respect to the femoral axis was calculated. Positive values of the measured angles were attributed to valgus deviation, and negative values were attributed to varus (Figure 4A). With each corresponding mechanical axis used for reference, the coronal and sagittal orientations of both the femoral and tibial components were assessed. Positive values of the measured angles were attributed to flexion and valgus deviation, whereas negative values were attributed to extension and varus (Figures 4B-C). Finally, the transepicondylar axis and a line connecting the anterior tuberosity with the geometric center of the tibial bone tray were used as a reference for determining the rotational alignment of the femoral and tibial components, respectively. Positive values of the measured angles

Figure 2: Comprehensive view of the magnetic resonance imaging (MRI)-derived mechanical axis of the femur and tibia (red lines), with the coronal orientation of the second with respect to the first also indicated (A). Adapted graphic user interface showing the data necessary for total knee arthroplasty preoperative planning: the distal and posterior cutting planes for the femur together with the sagittal orientation of the first (yellow lines, top), and the proximal cutting plane for the tibia together with its slope (yellow lines, bottom). The selected size of implants together with a 3-dimensional anatomic model, including cutting bone surfaces covered by implant overlays, is also seen. Red lines represent the mechanical axis of the femur and tibia and, for the femur, also the transepicondylar axis (B). The software provided a warning if the anterior cutting plane exited the femoral cortical bone (C) or if tibial overhang occurred (D). For the femur (C), yellow lines represent the anterior and distal cutting planes, whereas the red line represents the mechanical axis. For the tibia (D), the yellow circle represents the superimposed prosthetic component, whereas the red lines represent the maximum anteroposterior and mediolateral diameters of the tibial bone tray.

Figure 3: Femoral and tibial custom-made jigs (A) used for guidance in placing cutting guides on the patient knee (B, C).
indicated extrarotation, and negative values indicated intrarotation (Figure 4D). These postoperative CT measurements were compared with the corresponding preoperative MRI parameters (Figures 4E-F).

Statistical Analysis
Continuous data were presented as mean±SD. The Kolmogorov-Smirnov test was used to verify the normality of data distribution. Bland-Altman plots were constructed to compare preoperative MRI parameters concerning the depth of surgical bone cuts and the spatial positioning of implants with the corresponding intraoperative measurements and postoperative CT values, respectively. The differences between each set of methods were always plotted against the preoperative MRI parameters. Outliers were identified as measurements differing from the corresponding preoperative values beyond the limits of agreement, or ±1.96 times the standard deviation of differences. Pearson r coefficients were used to assess the correlation of both the intraoperative measurements of the depth of bone cuts and the postoperative CT values of the sagittal orientation of components with the corresponding preoperative MRI parameters. The F test was used to compare the variances of distribution between the 2 groups for all values concerning the spatial positioning of the femoral and tibial components. P<.05 was considered significant. MedCalc version 12.5.0.0 software (MedCalc Software, Mariakerke, Belgium) was used for inferential statistics.

RESULTS
Except for 1 case characterized by motion artifacts, high-resolution MRI of the knee adhered to the standards required. Acquisition time for MRI was 19.2±1.5 minutes. No patient-specific instrumentation technique was converted to a traditional technique, and there was no need to make intraoperative changes in the depth of the femoral or tibial bone cuts. In the patient-specific instrumentation group, the size of the femoral and tibial prosthetic components, hypothesized at preoperative planning, was confirmed in the operating room. The Kolmogorov-Smirnov test showed all data to have a normal distribution. Good to excellent correlation was found between the data on the depth of the femoral and tibial bone cuts, hypothesized at preoperative planning, and the corresponding intraoperative measurements (Table 1). Only 2 outliers were detected among the values measured in the operating room, concerning the thickness of distal resection of a lateral condyle (11 mm) and that of proximal resection of a medial condyle (6 mm).

Mean tourniquet time was shorter in the patient-specific instrumentation group vs the non–patient-specific instrumentation group (51.9±12.3 minutes vs 74.2±7.9 minutes, P<.01). Less intraoperative bleeding occurred in the patient-specific instrumentation group compared with the non–patient-specific instrumentation group (140±56.7 mL vs 290±112.5 mL, P<.01). Otherwise, postoperative blood loss was not significantly different between the 2 groups, although it was slightly lower in the patient-specific instrumentation group (968±225 mL vs 1084±318 mL, P=.03). The decrease observed in the hemoglobin value before surgery and on the first postoperative day was smaller in the patient-specific instrumentation group compared with the non–patient-specific instrumen-
Transfusion of heterologous concentrated erythrocytes was needed in 2 cases in the patient-specific instrumentation group and in 4 cases in the non–patient-specific instrumentation group. Finally, mean length of hospitalization was shorter in the patient-specific instrumentation group compared with the non–patient-specific instrumentation group (3.0±0.7 days vs 3.8±0.8 days, \( P < .01 \)).

In the patient-specific instrumentation group, a good match was found between the values planned preoperatively and those measured on postoperative CT for the sagittal orientation of the femoral (\( r = 0.72; 95\% \text{ CI}, 0.34-0.90; P < .01 \)) and tibial components (\( r = 0.88; 95\% \text{ CI}, 0.68-0.96; P < .01 \)).

A significant difference between the patient-specific instrumentation and non–patient-specific instrumentation groups was observed for variance of distribution for sagittal orientation (3.6°±1.0° vs 1.5°±2.0°, \( P = .01 \)) and rotational alignment (0.3°±0.8° vs -0.9°±2.0°, \( P < .01 \)) of the femoral component as well as for the tibial slope (5.9°±0.7° vs 7.0°±1.6°, \( P < .01 \)), indicating greater variability of traditional preoperative planning with respect to that based on 3-dimensional MRI. No difference was found between the patient-specific instrumentation and non–patient-specific instrumentation groups regarding the variances of distribution for the coronal orientation of each component, taking the corresponding mechanical axis as a reference.

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### Table 1

Comparison Between Preoperative Magnetic Resonance Imaging Data on Depth of Femoral and Tibial Bone Cuts and Corresponding Intraoperative Measurements

<table>
<thead>
<tr>
<th>Component/Cut</th>
<th>Preoperative Magnetic Resonance Imaging Data</th>
<th>Intraoperative Measurement</th>
<th>Mean Difference</th>
<th>Limits of Agreement (±1.6 SD)</th>
<th>No. of Outliers</th>
<th>Correlation Coefficient</th>
<th>95% Confidence Interval</th>
<th>( P )</th>
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<tbody>
<tr>
<td>Femoral condyle</td>
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<tr>
<td>Medial</td>
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<tr>
<td>Distal</td>
<td>9.4±0.6</td>
<td>8.4±1.4</td>
<td>1.0</td>
<td>-1.2 to 3.1</td>
<td>0</td>
<td>0.68</td>
<td>0.26-0.89</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Posterior</td>
<td>11.9±1.5</td>
<td>10.4±1.9</td>
<td>1.5</td>
<td>-0.8 to 3.8</td>
<td>1</td>
<td>0.83</td>
<td>0.55-0.94</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Lateral</td>
<td>8.9±1.6</td>
<td>8.6±1.7</td>
<td>0.3</td>
<td>-2.0 to 2.5</td>
<td>1</td>
<td>0.75</td>
<td>0.39-0.91</td>
<td>&lt;.01</td>
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<tr>
<td>Posterior</td>
<td>10.2±2.5</td>
<td>8.5±2.3</td>
<td>0.7</td>
<td>-1.5 to 2.9</td>
<td>0</td>
<td>0.89</td>
<td>0.70-0.96</td>
<td>&lt;.01</td>
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<td>Tibial plate</td>
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<tr>
<td>Medial</td>
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<tr>
<td>Proximal</td>
<td>4.9±2.2</td>
<td>4.7±2.4</td>
<td>0.3</td>
<td>-1.1 to 1.6</td>
<td>0</td>
<td>0.95</td>
<td>0.88-0.99</td>
<td>&lt;.01</td>
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<tr>
<td>Lateral</td>
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<tr>
<td>Proximal</td>
<td>9.7±0.7</td>
<td>8.6±1.5</td>
<td>1</td>
<td>-1.3 to 3.4</td>
<td>0</td>
<td>0.64</td>
<td>0.18-0.87</td>
<td>.01</td>
</tr>
</tbody>
</table>

*Unless otherwise indicated, data are expressed in millimeters and reported as mean±SD.*
ence (0.3°±1.6° vs 0.2°±1.7°, P=.86 for the femoral and 0.0°±1.0° vs -0.1°±1.3°, P=.37 for the tibial component). This indicated the usefulness of performing preoperative radiographs of both lower limbs in weight-bearing conditions for all patients. Variability that was comparable between the 2 groups was observed also for rotational alignment of the prosthetic tibial tray (-11.8°±3.2° vs -8.7°±3.6°, P=.60). This parameter was not considered in the preoperative MRI planning.

**DISCUSSION**

The goals of total knee replacement surgery are correct restoration of the mechanical axis, gap equality preservation (flexion-extension matching), and proper femoropatellar alignment. The long-term success of TKA depends on patient characteristics, the type of implant, the operative technique adopted, and accurate positioning of the prosthetic components, especially rotational alignment. Proper cutting of the femoral condyles and tibial plates is an extremely time-consuming phase of TKA that attempts to perform in the operating room what was previously established in preoperative planning. This is necessary to obtain correct positioning of implants. Unlike conventional radiographs, which are necessarily less accurate in the reproduction of bone size because of the projective magnification of anatomic structures, second-level imaging techniques such as CT and MRI can provide volumetric depiction of tissues with different characteristics, including the articular cartilage. As a result, recently, the use of 3-dimensional models for simulation of surgical interventions and manufacturing of custom blocks has experienced exponential growth.

Many studies have evaluated the spatial positioning of prostheses implanted using patient-specific instrumentation, with contradictory results, as shown in a recent review of the literature by Con-
In the authors’ study, the only value that showed great variability in the patient-specific instrumentation group, comparable to that reported for the traditional method, was the rotational alignment of the prosthetic component. These results are justified by both the difficulty of defining correct landmarks on the anterior tuberosity during surgery\(^29\) and the fact that the rotational alignment of the tibial component is the less predictable parameter obtainable with 3-dimensional MRI preoperative planning because of a limitation of the software.\(^18\) The authors believe that more work should be carried out to limit the poor accuracy of a parameter that can potentially determine prosthesis malfunction.

The tibial slope affects the anteroposterior stability of an implant, its range of motion, and the contact pressure within the femorotibial joint.\(^30\) An inappropriate proximal tibial bone cut results in polyethylene wear and loosening of components.\(^31\) Conventional radiographs are of limited value in planning an adequate tibial cutting angle because of the rotation and projective magnification of the tibia in the mediolateral view. In contrast, measurements based on 3-dimensional imaging are substantially more accurate,\(^32\) as evidenced in the authors’ study.

For a correct cinematic of TKA, the fulcrum of each articulation involved (hip, knee, and ankle) should ideally be aligned along the same axis so that the coronal orientation of each component coincides with the loading axis of the lower limb.\(^33\) Coronal deviation greater than 3 degrees is frequently associated with a high rate of surgical revisions and poor long-term results.\(^34\) A recent study by Bali et al.\(^35\) confirmed the effectiveness of patient-specific instrumentation in restoring the mechanical axis of the lower limb. In agreement with other reports in the literature,\(^36\) the authors restored the loading axis of the lower limb in all patients in their series. In their opinion, 3-dimensional imaging performed in the supine position provides only an indicative reconstruction of the mechanical axis of the lower limb, which should necessarily be integrated with information derived from full-length weight-bearing radiographs.

Preoperative planning was modified based on the authors’ previous experience with patient-specific instrumentation and adapted to the needs of the surgeon. Therefore, there was no need to perform significant changes in the operating room, as reported elsewhere.\(^37\) Yaffe et al.\(^38\) concluded that patient-specific instrumentation was more accurate than computer-assisted navigation in predicting the size of the femoral component (89% vs 43%), whereas Chen et al.\(^39\) reported predictability of 100% for the size of implants. In contrast with previous reports,\(^40\) their study confirmed good correspondence between the values hypothesized at 3-dimensional MRI preoperative planning and those verified in the operating room regarding both the depth of surgical bone cuts and the size of components.

The advantages offered by patient-specific instrumentation in TKA compared with the traditional method include reduced surgical time, length of hospitalization, rate of complications, and number of tools used. A study by Bali et al.\(^35\) showed less intraoperative blood loss during total knee replacements based on custom-made cutting guides compared with conventional surgery, whereas Nunley et al.\(^42\) reported a substantial decrease in tourniquet time. Also, the authors’ study suggested some advantages associated with the use of MRI preoperative planning, such as the reduction in surgical time, length of hospitalization, and intra- and postoperative blood loss, reflected by the smaller number of transfusions needed. The reason is that there is less trauma to the bone as a result of less invasive surgery.

**Limitations**

The authors acknowledge some limitations of their study. First, the authors included a relatively small sample of pa-
tients, although this was partially compensated for by the study design. Second, a single experienced orthopedic surgeon performed all of the procedures and all preoperative and intraoperative measurements, so it was not possible to analyze interobserver variability. This study is not representative of a low-volume center or an inexperienced surgeon using this technology. Long-term survival of an accurately positioned implant can only be presumed to be good in this study but cannot be proven. However, the goal of the analysis was to evaluate the positioning of implants by comparing the values planned preoperatively with those obtained both intraoperatively and on postoperative CT.

CONCLUSION
This study showed the usefulness of preoperative planning with 3-dimensional MRI in TKA, indicating greater reliability of this technique in providing the correct spatial positioning of prosthetic components as well as better perioperative outcomes compared with traditional surgery. Further research with a larger number of patients and evaluation of long-term results is needed to confirm the findings of this preliminary study.

REFERENCES


