Reliability of Templating with Patient-Specific Instrumentation in Total Knee Arthroplasty

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Abstract

Magnetic resonance imaging (MRI) or computed tomography–based patient-specific instrumentation (PSI) may allow for reliable alignment and fewer outliers when compared with conventionally instrumented total knee arthroplasty (TKA). However, some authors have suggested that frequent intraoperative surgeon-directed changes may still be required. This study evaluated the accuracy of PSI to predict component sizing and alignment during TKA. A total of 84 patients (89 knees) who underwent a TKA using a PSI system were evaluated. An MRI-based preoperative plan of every knee was provided and approved by the surgeons. This demonstrated the proposed prosthetic component alignment, as well as the femoral, tibial, and bearing insert component size and position. Intraoperative changes to these components were prospectively recorded and compared with the computerized preoperative plan. *Major changes* were defined as any changes in femoral or tibial resection, size, and position of the components. Minor changes were defined as any change in the size of the polyethylene bearing insert. The preoperative plan was able to correctly predict the size of the implanted tibial and femoral component in 93 and 95.5% of the cases, respectively. Thirteen major intraoperative changes were made. In one knee, the proposed femoral resection was not acceptable (because of the presence of significant amount of osteophytes) and was abandoned in favor of a manual extramedullary guide. In another patient, the proposed femoral and tibial components were upsized. In two other patients, the femoral components were downsized, in four patients, the tibial components were downsized, and in another patient, it was upsized. There were also 16 minor changes, which included 2-mm upsizing of the polyethylene liner in 13 knees and 4-mm upsizing in 3 knees. Surgical experience is necessary to recognize improper component size, incorrect surgical resection, or nonideal alignment when performing TKA using PSI. The authors believe that the design and manufacture of PSI combined with a comprehensive templating resulted in excellent intraoperative concordance of the preoperative plan at the default settings with minimal changes.

Keywords
- total knee arthroplasty
- patient-specific instrumentation

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Primary total knee arthroplasty (TKA) is a reliable and cost-effective procedure to successfully treat end-stage knee arthritis in patients who have failed nonoperative management.[1–4] However, the success of this procedure may be affected by poor postoperative components alignment, which has been associated with increased stiffness, instability, wear, and implant loosening.[5–17] Alignment using conventional instrumentation has been reported to result in radiographic outliers in approximately 28% (range, 0 to 70%) of the knees studied.[18–31] Thus, new technologies that can reliably improve overall limb alignment may potentially improve clinical outcomes, implant survivorship, and patient satisfaction.

Magnetic resonance imaging (MRI)– or computed tomography (CT)–based patient-specific instrumentation (PSI) may potentially achieve more reliable alignment parameters, decrease operative time, blood loss, and increase efficiency when compared with conventionally instrumented TKA.[18,32–37] However, a previous report[38] suggested that frequent intraoperative surgeon-directed changes may still be required. Thus, there is a need for more evidence-based data that evaluate and quantify the accuracy and reliability of PSI.

Because of the paucity of templating reports with PSI in TKA, we undertook this study to evaluate whether preoperative planning was reliable and reproducible in predicting the actual intraoperative outcomes. Specifically, we asked the following questions: (1) What percentage of times was the preoperative plan able to accurately predict the actual size of the implanted femoral or tibial components? (2) What was the total number of changes that were being made and what were the underlying reasons for these changes? (3) What percentage of knees were implanted without any changes? And (4) what were the complications?

Methods

A consecutive cohort of 84 patients who had undergone 89 primary TKAs using PSI and cutting blocks between 2011 and 2012 was prospectively evaluated. All procedures were performed by four experienced, fellowship-trained adult reconstructive surgeons (A.R., A.L.M., M.A.M., and V.K.M.) at three high-volume institutions. All cases were performed without any previous learning curve. There were 53 women and 31 men who had a mean age of 60 years (range, 41 to 82 years). All patients had end-stage knee arthritis and had failed nonoperative management before their index arthroplasty procedure. Appropriate review board approval for the study of these patients was obtained.

All patients underwent a knee MRI according to the manufacturer's established protocol. A computer-generated preoperative plan on the basis of MRI findings of every knee was provided to each surgeon that demonstrated the proposed prosthetic component alignment, as well as the femoral, tibial, and bearing insert component size and position. All preoperative plans were carefully reviewed by the surgeons and approved either at the default settings or after proposed changes to improve the limb alignment. In all cases, ideal neutral mechanical coronal limb alignment (0-degree alignment from mechanical axis) was followed. The reported margin of error from the manufacturer was ± 1-degree valgus or varus, and the quality control measure was usually less than ± 0.3 degrees.

All TKAs were performed using a standard medial parapatellar ($n = 51$) approach or subvastus approach ($n = 28$). The cemented femoral and tibial components (Triathlon Stryker Orthopedics, Mahwah, NJ) and patient-specific femoral and tibial cutting guides (ShapeMatch Stryker Orthopedics, Mahwah, NJ) were used on all knees. Intraoperative changes compared with the preoperative plan were recorded. *Major changes* were defined as any changes in femoral or tibial resection, orientation, size, and position of the components. *Minor changes* were defined as any change in the size of the polyethylene-bearing insert.

Postoperative, erect-leg X-rays obtained during patients' office visits were used to analyze knee alignment parameters such as hip-knee-ankle angle, number of outlier alignment, zone of mechanical axis, etc. These findings are subject to a separate report. However, no patient had failed their primary surgery or required revision for any septic or aseptic reason.

Using an Excel spread sheet (Microsoft Corporation, Redmond, WA), all data were recorded prospectively. All statistical calculations were analysis was performed by using an SPSS (version 17, Armonk, NY).

Results

The preoperative plan was able to correctly predict the size of the implanted tibial component in 93% ($n = 83$ of 89), femoral component in 95.5% ($n = 85$ of 89), and the polyethylene insert in 82% ($n = 73$ of 89) of the cases (►**Fig. 1**).

A total of 29 intraoperative changes were made compared with the preoperative plan (mean, 0.3 changes per knee), which included 13 major (14.5%) and 16 minor intraoperative changes (18%) (►**Table 1**). Major changes included a patient whose proposed femoral resection was not acceptable because of the presence of significant amount of osteophytes that precluded a close fit for the cutting guide and necessitated the use of a manual extramedullary guide. In another patient, the proposed femoral and tibial components were upsized to avoid undercoverage of the components mediolaterally. In two other patients (two knees), the femoral components were downsized because of insufficient anterior resection. In four other patients (four knees), the tibial components were downsized to avoid overcoverage of the tibial plateau and component overhang. In one knee, the tibial component was upsized to provide appropriate tibial coverage. In addition, orientations of the tibial components relative to drill holes were changed in three knees (including two tibial components that were externally rotated further and one tibial component that was lateralized). Minor changes included 2-mm upsizing of the polyethylene-bearing insert in 13 knees (14.5%) and 4-mm upsizing of the polyethylene-bearing insert in 3 knees (3%).

Of the total of 89 TKAs, 65 knees (73%) were implanted without any further changes in the resection, orientation, size

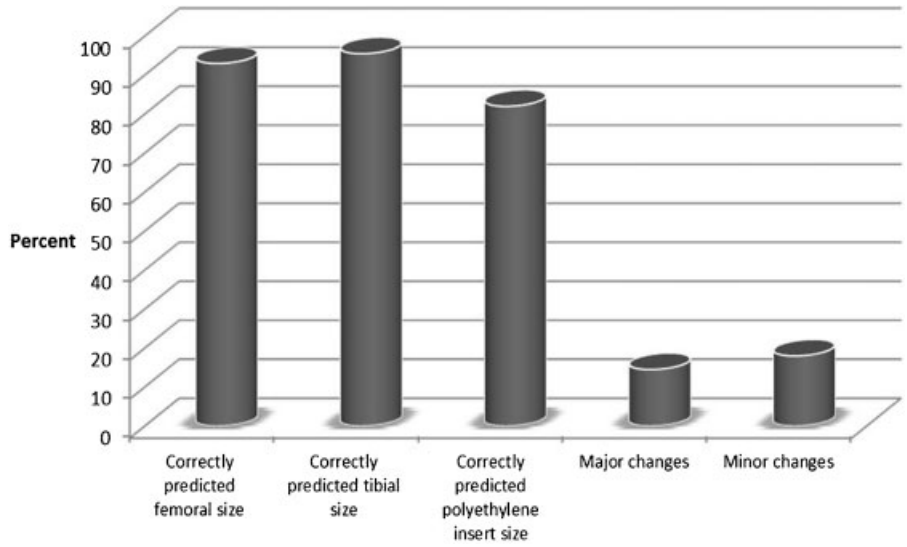

Fig. 1 Accuracy of preoperative templating with patient-specific instrumentation in primary total knee arthroplasty.

of the femoral or tibial components, or the size of the polyethylene-bearing inserts.

There were no surgical perioperative complications,[39] including bleeding, wound complications, arterial or venous thromboembolic disease, vascular injury, neural deficit, ligament injury, instability, stiffness, fracture, infection, osteolysis, or implant loosening during any of the cases.

Discussion

PSI has been introduced as an alternative technology to conventional-instrumentation or computer navigation with the potential purpose of improving overall component sizing, alignment, and reducing outliers. However, a previous report has suggested that frequent intraoperative surgeon-directed changes may still be required.[38] Thus, orthopedic surgeons may benefit from further evidence-based data that attempt to evaluate and quantify the accuracy and reliability of such plans to set realistic expectations as well as prepare for potential intraoperative modifications of the plan. The purpose of this study was to evaluate the accuracy of MRI-based preoperative templating in patient-specific TKA. We found excellent reproducible results using the preoperative plan at the default settings with minimal changes.

Table 1 Summary of our Templating Outcomes with Patient-specific Instrumentation in Primary Total Knee Arthroplasty

Metric	Outcome	Percent
Total number of changes	29	32.5
Number of major changes	13	14.5
Number of minor changes	16	18
Changes involving the femoral component	4	4.5
Changes involving the tibial component	9	10
Number of knees implanted without any change	65	73

There were several limitations of this report including the small sample size. This was not a randomized study, which could have reduced potential biases. We only evaluated PSI from one manufacturer and thus these outcomes may not be applied to other manufactures, and thus, not a representative of the overall technology. Nevertheless, the authors believe that the outcomes are valuable because there is a paucity of reports on the templating outcomes with this technology.

Outcomes of our study are in contrast with a previous report that demonstrated frequent intraoperative surgeon-directed changes compared with the preoperative plan.[38] Stronach et al[38] prospectively evaluated the MRI-based templating outcomes in 60 patients who had a mean age of 62 years (range, 59 to 64.5 years) and had undergone 66 primary TKAs with a type of PSI system (Biomet Signature Warsaw, IN). They reported that overall 161 intraoperative changes were made with an approximate mean of 2.4 changes per each knee. The predetermined implant size was able to predict the exact size of the implanted tibial and femoral components in 47 and 23% of cases, respectively. They also reported that the femoral guide did not fit securely in eight cases (12%) requiring traditional intramedullary instrumentation in three cases. The tibial guide did not fit securely in three cases (5%) and was abandoned for traditional instrumentation in five cases, mainly because of inaccurate proposed resections.

Potential differences in PSI templating outcomes can be explained by differences in the type and manufacture of patient-specific cutting blocks, margin of error of the different manufacturer, different types of MRI-or CT-based protocols and their resolution, variation in the computer algorithms and the preoperative plan, functionality of the cutting guides, the need for removal of PSI guides before

making cuts, the need for a learning curve, and single-surgeon experience.

To summarize, we found excellent outcomes using preoperative templating with PSI in patients who had undergone a primary TKA. Preoperative plan was able to accurately predict the size of the implanted tibial and femoral components in 93 and 95.5% of the cases. Intraoperative changes included 13 major and 16 minor changes with 73% of the knees being implanted without any changes. Although, surgical experience is necessary to recognize improper component size, incorrect surgical resection, or nonideal alignment, and excellent outcomes at the default settings were obtained. The authors believe that the design and manufacture of PSI combined with a comprehensive preoperative plan, which was reviewed and approved by the treating surgeons, resulted in intraoperative concordance of the preoperative plan with minimal changes. Further prospective, randomized, and multicenter studies are necessary to better evaluate these outcomes.

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