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Intra-Operative Experience using Magnetic Resonance Imaging (MRI) Based Patient Specific Cutting Guides during Total Knee Arthroplasty

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ABSTRACT

Background. The incidence of malalignment in total knee arthroplasty (TKA) using conventional instrument has been reported as high as 25%. A relatively new TKA system involves the use of a preoperative magnetic resonance image (MRI) to obtain accurate implant placement more consistently. For broad acceptance of this new technique, it is crucial to analyze the initial intra-operative experience. The specific aim of this study was to evaluate the initial intra-operative experience of a single surgeon using this new technique.

Methods. A total of 15 knees (12 patients: 6 female and 6 male) were reviewed from TKA procedures using the selected manufacturer's patient specific cutting guides between January 2011 and April 2013 at a single institution. Patient demographic and specific parameters and intra-operative alterations of component positioning were recorded and evaluated.

Results. The preoperative plan was able to predict correctly the size of the implanted femoral component in 87% (n = 13) and tibial component in 80% (n = 12) of the cases. However, 60% (n = 9) of cases required additional intra-operative corrections on femoral resection, and 73% (n = 11) required an additional 2 - 4 mm correction on the tibial proximal resection. Twenty percent (n = 3) required additional tibial varus/valgus correction, but there were no tibial slope corrections for any of the 15 cases.

Conclusions. The initial intra-operative experience of a single surgeon using current patient specific cutting guides for a selected manufacturer to align femoral and tibial components during TKA has raised some concerns. We agreed with previous studies that caution should be taken when using patient specific cutting guides without supportive data. The findings of this study provided additional evidence to contest the accuracy of patient specific cutting guides with respect to the initial experience of an orthopaedic surgeon who is trained in total joint replacement. The results provided more evidence to assist orthopaedic surgeons in the decision of whether to use these patient specific systems versus conventional TKA methods. *KS J Med 2016;9(2):22-26.*

INTRODUCTION

Total knee arthroplasty (TKA) is one of the most common orthopaedic procedures performed and repeatedly has been associated with highly successful outcomes.[1-3] Post-operative knee function and knee pain scores have improved substantially following TKA.[4-10] Surgical techniques and component designs continue to expose inherent limitations that affect long-term outcomes and implant survival. Many elements have been implicated in influencing the long-term success of any TKA procedure. Proper mechanical alignment and stability of femoral and tibial components are two of these critical factors.[11-15] Varus/valgus alignment within 3° of neutral is necessary to prevent abnormal stresses across the weight bearing surfaces of the implants.[16-20] Thus, accuracy of component alignment and component sizing in TKA are essential for the longevity of a joint replacement.

The incidence of malalignment has been reported as high as 25%, even in facilities that are considered high volume centers.[21-22] Therefore, there exists a demand for innovation in TKA to obtain accurate implant placement more consistently. The use of patient specific cutting guides is one of the newer technologies being utilized during TKA procedures. This technique utilizes preoperative magnetic resonance imaging (MRI) to analyze both the normal and abnormal anatomy to construct a three-dimensional representation of the knee. These data are used to produce custom patient specific cutting guides for both the femur and tibia. These cutting guides are designed to result in more accurate bone cuts for acceptable mechanical alignment and soft tissue balancing without the intra-operative reliance on fixed anatomical landmarks that often are distorted secondary to chronic arthritic changes (i.e., osteophytes). Additionally, the MRI-based system allows the predetermination of implant sizes for both the femur and tibia prior to the operation. Decreased cost, blood loss, operative time and total amount of required instrumentation also have been reported as proposed benefits.[23-29]

Several studies have reported controversial experiences and variable outcomes when utilizing this technique.[24,25,30-33] For broad acceptance of this new technique in TKA procedures, it is crucial to analyze the initial intra-operative experience of using patient specific cutting guides in TKA. Therefore, the specific aim of this study was to evaluate the initial intra-operative experience of a single surgeon using the selected manufacturer's patient specific cutting guides to align femoral and tibial components during TKA.

METHODS

Institutional Review Board approval was obtained for the study. This retrospective study reviewed the initial intra-operative experience of a single surgeon (the principal investigator) during a consecutive series of TKA performed using a single manufacturer's (BioMet, Inc, Warsaw, IN) patient specific cutting guides. Preoperative assessment included documentation of gender, age, body mass index (BMI), and deformities in the knee. A total of 15 knee arthroplasties (12 consecutive patients: 6 female and 6 male) who had the procedure performed between January 2011 and April 2013 by the principal investigator in a single institution were included.

The inclusion criterion was the principal diagnosis of osteoarthritis undergoing primary TKA. Patients with a history of trauma and/or a history of surgery on the operative knee were included as long as there was no retained hardware. Since the production of the patient specific cutting guides is dependent on the quality of the preoperative MRI, it was determined that the presence of hardware may interfere with the generation of accurate guides. The exclusion criterion was pre-operative planning where patient specific cutting guides were not utilized in any manner.

Preoperative planning for the MRI technique was performed as described by the manufacturer's protocol. Prior to surgery, each patient obtained a sagittal MRI of the operative lower extremity from the hip to the ankle. The MRI imaging data was provided to the cutting guide manufacturer who was responsible for the custom fabrication of the femoral and tibial cutting guides. The surgeon was provided with a virtual three-dimensional representation model of each patient's arthritic knee and the specialized computer software necessary for preoperative planning. The cutting guide manufacturer generated specialized disposable cutting guides for each patient (Figure 1). These cutting guides are used to determine accurate pin placement with standard resection instrumentation. Scheduling of the operation was made once the patient specific cutting guides were provided by the manufacturer.

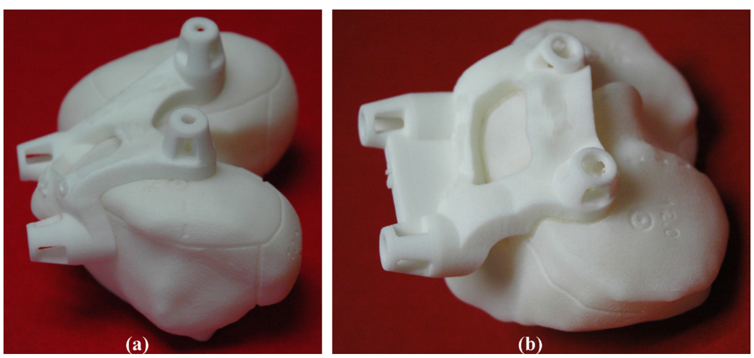

Figure 1. Custom cutting guides: (a) femoral cutting guide, (b) tibial cutting guide.

Each surgery was performed through a traditional medial parapatellar approach under tourniquet control. Once bony exposures were achieved and prior to any revision or resection of bone, the patient specific cutting guides were placed as manufacturer guidelines direct. The manufacturer stated that the placement of the guide should achieve a "glove fit" (i.e., the guide perfectly matches the contour of the bone). The guide was pinned after appropriate placement (Figure 2b). These initial steps were performed in similar fashion for both the femur and the tibia. In each of the operations, the femur was addressed first. After the femoral patient-specific cutting guide was pinned in place, the guide was removed and replaced with the conventional cutting guide (Figure 2c). Then, all cuts of the distal femur were performed in the standard fashion of a conventional TKA technique. Next, the surgeon evaluated femoral component size, femoral anterior-posterior translation, femoral proximal-distal translation, and femoral component rotation. A record was made of any bony cuts that had to be redone after the initial cut with the customized cutting guide. The size of the implanted components for both the femur and tibia also were recorded.

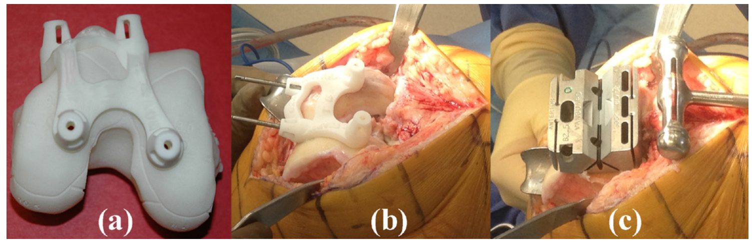

Figure 2. Femoral cutting procedure: (a) femoral cutting guide model, (b) placement of femoral cutting guide, (c) placement of conventional cutting guide.

With respect to femoral anterior-posterior translation and femoral proximal-distal translation, a revision of the initial cuts of 2 mm or greater was defined and recorded. The absolute amount of the revision cut was recorded. When evaluating femoral rotation, a revision was required if the rotation was not within the accepted literature value of greater than 3° of neutral mechanical axis.[34-37] The absolute amount of the revision was recorded.

A similar procedure was performed on the tibia as described for the femur, including placement of patient specific cutting guide, pinning, and replacement of the cutting guide with the conventional tibial cutting block. Following completion of the initial bone cuts, the tibial trial component was placed. Component placement was evaluated for appropriate tibial component size, tibial slope, tibial rotation, and tibial proximal-distal translation. With respect to tibial proximal-distal translation, a revision of the initial cut of 2 mm or greater was defined and recorded. A record was made of any bony cut that had to be revised after the initial cut, as determined by the placement of the patient specific cutting guide. The absolute amount of the revision cut was recorded.

After completion of revision bone cuts, both the femoral and tibial trial components were placed. Soft tissue balancing of the knee was evaluated. The femoral and tibial component sizes selected were recorded and compared to the component sizes determined by the preoperative MRI. Procedural blood loss and tourniquet time were recorded.

Data collection involved a chart review of the preoperative, operative, and postoperative notes documented by the orthopaedic surgeon, specifically in regards to the component sizes, revision cuts, and intra-operative complications, to evaluate the initial intra-operative experience with these patient specific cutting guides to align femoral and tibial components during TKA.

RESULTS

A total of 15 knees (12 patients) met the inclusion criteria, 8 knees (53%) were in females and 7 knees were in males (47%). Table 1 summarizes the demographic profile of the patients. The mean age was 58 years (range: 43 - 72 years) and the mean BMI was 32.4 kg/m2 (range: 19.8 - 42.0 kg/m2). The average tourniquet time was 56 ± 9 minutes, and the mean blood loss was 88 ± 34 mL.

Table 1. Profile of the twelve patients.

	Mean	SD	Range
Age (years)	58	9.8	43-72
Weight (kg)	91.8	24.5	47.6-127.5
Height (cm)	167.6	10.6	154.9-182.9
BMI (kg/m^2)	32.4	7.4	19.8-42.0
Tourniguet time (minutes)	56	9	42-70
Estimated blood loss (mL)	88	34	50-150

The preoperative plan correctly predicted the size of the implanted femoral component in 87% (13 of 15) and the tibial component in 80% (12 of 15) of the cases. However, a total of 9 (60%) of the 15 cases required additional corrections on femoral resection: four (27%) of the cases the femoral distal cut had to be redone to remove an additional 3 mm of femur, five (33%) of the cases the femoral rotation had to be redone to rotate 2 - 5° externally, and two (13%) of the cases required a femoral anterior-posterior correction of an additional 2 mm (one of the knees required both femoral rotation correction and femoral anterior-posterior correction, and one of the knees required both femoral distal cut correction and femoral rotation correction; Table 2). Of the total 15 TKAs, 11 (73%) cutting guides proposed for tibial proximal resections were not acceptable and had to be corrected by the removal of an additional 2 - 4 mm of bone. Only three knees (20%) required tibial varus/valgus correction, and there were no tibial slope corrections in all 15 cases (Table 2).

There were no surgical intra-operative complications 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.[38]

DISCUSSION

The use of patient specific cutting guides that utilize preoperative MRI to align femoral and tibial components during TKA was introduced as an alternative technology with the potential benefit of improving overall component sizing, alignment, and reducing outliers.[39-41] These patient specific cutting guides are designed to promote more accurate bone cuts for acceptable mechanical alignment and soft tissue balancing. These cutting guides also diminish the intra-operative reliance on fixed anatomical landmarks that are often distorted secondary to chronic arthritic changes (i.e., osteophytes). Decreased costs, blood loss, incidence of fat embolism, and operative time also have been reported as proposed benefits.

Table 2. Inaccuracy of patient specific cutting guides in TKA.

	Femur				Tibia			
Subject #	Distal Cut	Rotation	Anterior-Posterior	Size	Proximal Cut	Varus/ Valgus	Slope	Size
1								
2					X			X
3	X							X
4					X			
5	X				X			
6		X			X			
7					X			X
8					X			
9	X				X			
10			X			X		
11		X		X	X			
12					X			
13		X	X	X	X			
14		X				X		
15	X	X			X	X		
Total	4 (27%)	5 (33%)	2 (13%)	2 (13%)	11 (73%)	3 (20%)	0 (0%)	3 (20%)
Overall correction	9 (60%)				14 (93%)			

Unlike the conventional system, the custom-fit TKA does not require the use of intramedullary alignment rods.[39-41] One of the other proposed benefits of this system includes the ability to plan a patient's component size preoperatively which decreases the number of instrument trays required and improved overall operating room efficiency. Concerns regarding this technology, however, exist. It does not allow the surgeon to intra-operatively assess the alignment of their resections, nor check the accuracy of the bone cuts for acceptable mechanical alignment and soft tissue balancing. If adjustments are required, additional instrument trays must be utilized.

Several studies have questioned the proposed cost-efficiency of this technology as to whether the suggested increase in operating room efficiency will offset the costs of additional preoperative imaging and fabrication of the cutting blocks.[26,42,43] Certainly, this is a legitimate concern for which this study does not provide an answer. The main objective of this study was to illustrate the initial experience of an experienced surgeon with a selected manufacturer's patient specific cutting guides during TKA. The results demonstrated that these custom-fit devices were not able to provide accurate implant placement, which is in contrast with the body of literature concerning the use of these custom-fit devices.

Bali and colleagues[30] prospectively studied 32 TKAs performed in 29 patients with MRI-based custom cutting guides. The system they used, however, provided slotted cutting guides that do not require the use of standard instrumentation. Their results showed that 29 of the 32 knees had a mechanical axis restored to within 3° of neutral, and they concluded that this technology can be used safely in most cases of osteoarthritis of the knee. Our findings did not agree with their results. The cause of this discrepancy may lie in differences in the design of the custom cutting guides. Depending on the manufacturer, most recent guides can be used to determine pin placement for use with standard resection instrumentation, or may serve as the actual cutting guides slots. Although these different guide systems were not compared side-by-side, these differences in the design of patient specific cutting guides could potentially create the discrepancies in the accuracy of component alignment and sizing. Each patient specific system is either Computed Tomography (CT) or MRI-based. Proponents of CT-based systems claim component alignment is achieved more accurately with CT-based systems since CT technology generally is considered superior to MRI in regards to evaluating bony anatomy.[44] Recently, however, a CT-based system developed by a major orthopaedic implant company was recalled for general use, contributing to the uncertainty of which of these patient specific systems should be advocated.

Ng and colleagues[23] retrospectively reviewed 569 TKAs performed with patient-specific positioning guides and 155 with manual instrumentation by two surgeons. They used the same patient specific guide system as in this study, and reviewed long leg radiographs to evaluate mechanical alignment. Their results revealed that 91% of knees were aligned within 3° of a neutral mechanical axis and concluded that this technology can improve a surgeon's ability to obtain a neutral mechanical axis. Two of the authors, however, were consultants for and have research funded by the manufacturer which could serve as a potential for bias.

On the other hand, Nam and colleagues[45] performed a non-randomized retrospective review of 41 knees (37 patients) who received a TKA using an imageless computer-assisted surgery (CAS) system, and 41 knees (38 patients) who received a TKA using the same MRI based systems as this study. Their results demonstrated that patient specific cutting guides did not obtain the same degree of overall mechanical and tibial component alignment accuracy as a CAS technique.

There are limitations to this study including the small sample size, which prevented applying tests of significance due to a low power. The low number of procedures performed was unavoidable because the primary surgeon abandoned this specific system as the early outcomes were not satisfactory. In addition, only one selected patient specific system was evaluated, thus these outcomes may not be applied to other systems. Nevertheless, the outcomes were valuable because this study contributed to the available literature on the initial experience with one particular patient specific guide system. We also did not attempt to address the cost of this custom-fit technique, but rather evaluated our initial experience for total knee replacements. Furthermore, we did not determine long-term functional outcome, as the primary surgeon corrected all resections intra-operatively using the conventional instrument.

CONCLUSION

The overall findings of this study illustrated the concerns encountered during the initial intra-operative experience of a single surgeon with a selected manufacturer's patient specific cutting guides to align femoral and tibial components during TKA. This study demonstrated that one current patient specific cutting guide did not provide the proper alignment for femoral and tibial components during TKA. This study agreed with Stronach and colleagues[46] that caution should be taken when using the selected manufacturer's patient specific cutting guides without supportive data.

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CONFLICT OF INTEREST STATEMENT

This study did not receive any external support for this research project. The authors did not receive any payments, other personal benefit, or commitments or agreements that were related to the research. No benefits of any form were received directly or indirectly.

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