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Patient specific cutting guides versus an imageless, computer-assisted surgery system in total knee arthroplasty

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ABSTRACT

Background: Patient specific cutting guides (PSC) in total knee arthroplasty (TKA) have recently been introduced, in which preoperative 3-dimensional imaging is used to manufacture disposable cutting blocks specific to a patient's anatomy. The purpose of this study was to compare the alignment accuracy of PSC to an imageless CAS system in TKA.
Methods: Thirty-seven patients (41 knees), received a TKA using an imageless CAS system. Subsequently, 38 patients (41 knees), received a TKA using a MRI-based, PSC system.
Postoperatively, standing AP hip-to-ankle radiographs were obtained, from which the lower extremity mechanical axis, tibial component varus/valgus, and femoral component varus/valgus mechanical alignment were digitally measured. Each measurement was performed by two blinded, independent observers, and interclass correlations were calculated. A student's two-tailed *t* test was used to compare the two cohorts (p-value < 0.05 = significant).
Results: In the PSC cohort, 70.7% of patients had an overall alignment within 3° of a neutral mechanical axis (vs. 92.7% with CAS, p = 0.02), 87.8% had a tibial component alignment within 2° of perpendicular to the tibial mechanical axis (vs. 100% with CAS, p = 0.04), and 90.2% had a femoral component alignment within 2° of perpendicular to the femoral mechanical axis (vs. 100% with CAS, p = 0.2). Interclass correlation coefficients were good to excellent for all radiographic measurements.
Conclusion: While PSC techniques appear sound in principle, this study did not demonstrate patient specific cutting guides to obtain the same degree of overall mechanical and tibial component alignment accuracy as a CAS technique.
Level of evidence: III: Retrospective cohort study.

1. Introduction

Despite the clinical success of total knee arthroplasty (TKA) in the management of degenerative joint disease, concerns remain regarding the accuracy of tibial and femoral component alignment, as implant malpositioning has been shown to increase the odds of aseptic failure [1,2]. While a recent study has questioned the significance of overall postoperative mechanical alignment on implant survivorship [3], the vast majority of studies still demonstrate alignment to be a crucial factor in the clinical success of TKA, and surgeons continue to aim for a neutral mechanical alignment, postoperatively. Ritter et al., in a review of 6070 TKAs, noted the risk of aseptic failure to significantly increase if the orientation of the tibial component was less than 90° relative to the tibial axis, and the orientation of the femoral component was in greater than 8° of valgus (failure rate 8.7%) [2]. With the increasing prevalence of total joint replacements performed in the United States, and a projected increase in revision TKAs of 412% by the year 2030, improved surgical techniques to prevent malalignment may prove cost-effective [4].

Computer-assisted surgery (CAS) techniques have been developed to improve the precision and accuracy of implant positioning in TKA, and numerous comparative studies have demonstrated improved component alignment with these techniques when compared to conventional intramedullary (IM) and extramedullary (EM) alignment guides [5–9]. Mason et al. performed a meta-analysis of 29 studies comparing CAS to conventional alignment techniques, and demonstrated an overall mechanical axis malalignment of greater than 3° in only 9.0% of CAS versus 31.8% of conventional TKA patients [7]. However, increased capital costs, operative times, and the associated learning curve with the use of CAS techniques have continued to limit its widespread acceptance in the United States, as less than 3% of TKAs are performed using computer navigation [5].

Recently, patient specific cutting guides (PSC) for TKA has been introduced, in which preoperative 3-dimensional imaging is used to manufacture disposable, cutting guides specific to a patient's anatomy. Proposed benefits of this technology include a decrease in operative time, instrument trays required, and improvement in postoperative

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mechanical alignment when compared to conventional EM and IM alignment guides. However, early results regarding the accuracy of this technology have been mixed [10–13]. The purpose of this study was to determine the accuracy of overall lower extremity, femoral, and tibial component alignment obtained when using patient specific cutting guides (Signature™, Biomet Orthopaedics, Warsaw, IN), and compare these results to a large console, imageless CAS system (Praxim, Omnilife Sciences, East Taunton, MA). Our hypothesis is that PSC in TKA will not achieve the same degree of overall mechanical, and component alignment accuracy seen with the use of an imageless CAS system.

2. Materials and methods

This study is a non-randomized, retrospective review of the radiographic results of a single surgeon (ADP) from an IRB-approved database. From September 2010 to May 2011, 37 consecutive patients (10 male, 27 female) received a TKA using the Praxim, imageless CAS system. Four patients underwent bilateral TKAs for a total of 41 knees in the CAS cohort (19 right, 22 left). Adjustable cutting blocks were used, in which screws on the cutting guide allow the surgeon to alter the orientation of the cutting guide slot relative to the fixation base, after the base has been provisionally pinned to the bone. Real-time feedback from the computer console indicates when the cutting guide is within 0.5°/mm of the planned target [14].

From June 2011 to February 2012, 38 consecutive patients (15 males, 23 females) received a TKA using a magnetic resonance imaging (MRI)-based, PSC system (Signature™, Biomet Orthopaedics, Warsaw, IN) to perform the proximal tibial, distal femoral, and femoral chamfer resections. Three patients underwent bilateral TKAs for a total of 41 knees in the PSC cohort (21 right, 20 left). In this PSC system, select MRIs are performed of the hip, knee, and ankle, from which a preoperative 3-dimensional image of the knee is generated (Fig. 1). The optimal size, position, and alignment of the implants are templated, and once approved by the surgeon, rapid prototyping technology is used to fabricate disposable, custom cutting guides. These guides are intended to fit the patient's specific anatomy. In this cohort, after the proximal tibial resection was performed, a tibial flat plate with an extramedullary alignment rod was used to check the resection. If deemed necessary, a modification of the initial tibial resection was performed. Inclusion criteria for this study were patients with a history of osteoarthritis, rheumatoid arthritis, or post-traumatic arthritis who received a primary, posterior stabilized total knee arthroplasty. Patients were excluded if they had a distal femoral or proximal tibial defect requiring a metal or allograft augment, received a unicondylar or patellofemoral arthroplasty, or required the use of either femoral or tibial stem extensions.

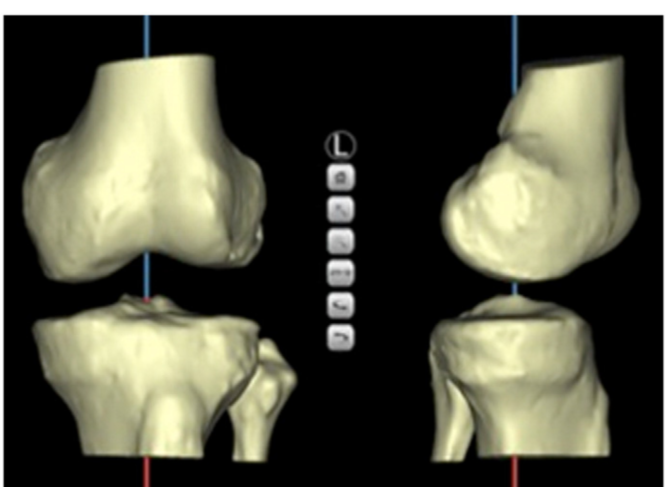

Fig. 1. 3-dimensional model of the patient's anatomy, created using magnetic resonance imaging, for templating of the optimal bony resections.

Preoperatively, standing anteroposterior (AP) hip-to-ankle radiographs were obtained for each patient, from which the lower extremity mechanical axis was measured (in degrees). For convention, a positive value for all radiographic measurements in this study represents a varus alignment, while negative values represent a valgus alignment. At each patient's first postoperative clinic visit (approximately 6 weeks postoperatively), standing AP hip-to-ankle radiographs were obtained, from which the lower extremity mechanical axis, tibial component varus/valgus alignment, and femoral component varus/valgus alignment were digitally measured.

The methods for measuring tibial and femoral component varus/valgus alignment have previously been described [15,16]. Briefly, tibial component varus/valgus alignment was determined in the following manner. First, a line was drawn connecting the most medial and lateral points of the subchondral talar surface, and the midpoint was marked. Next, a second line was drawn connecting the most medial and lateral points of the tibial plateau beneath the tibial implant, and the midpoint was marked. A line connecting the two, previous midpoints represented the tibial mechanical axis in the coronal plane. The angle between the tibial mechanical axis, and a tangential line on the inferior surface of the tibial tray, formed the mechanical varus/valgus alignment of the tibial component (Fig. 2). Femoral varus/valgus alignment was determined in the following manner. The center of the femoral head was determined using a best-fit circle, and a line was drawn from center of the femoral head to the intercondylar notch of the implant, which represented the femoral mechanical axis. The angle between the femoral mechanical axis, and a line tangential to the most distal aspects of the medial and lateral femoral condyles, formed the mechanical varus/valgus alignment of the femoral component (Fig. 3). For both the tibial and femoral component measurements, the difference between the measured angle and 90° was recorded, with negative values representing valgus alignment (i.e. −0.4° represents a tibial component in 0.4° of valgus relative to the mechanical axis). Each radiographic measurement was performed by two independent observers, blinded to the surgical technique. Interclass correlation coefficients were calculated for each, respective measurement.

The goal for all TKAs in this study was 0° each for overall mechanical, tibial, and femoral component alignment. This correlates with the tibial and femoral components being perpendicular to each, respective mechanical axis. The accuracy of both the CAS and PSC systems was determined by measuring the difference between the postoperative radiographic measurements for each component, and the intraoperative goal, and the overall mean absolute difference was calculated. The accuracy in obtaining an overall lower extremity alignment within 3° of neutral, and femoral and tibial component alignments within 2° of neutral, was also calculated.

2.1. Statistical methods

All data was collected and analyzed utilizing Microsoft Excel software (Microsoft Corporation, Redmond, WA). Statistical comparisons between the two cohorts regarding alignment were performed using a Student's two-tailed t test. Statistical significance was set at a p-value <0.05. Interclass correlation coefficients for postoperative radiographic measurements were graded using previously described semi-quantitative criteria: excellent for $0.9 \leq p \leq 1.0$, good for $0.7 \leq p \leq 0.89$, fair/moderate for $0.5 \leq p \leq 0.69$, low for $0.25 \leq p \leq 0.49$, and poor for $0.0 \leq p \leq 0.24$ [17].

3. Results

There were no statistically significant differences with regards to the preoperative patient age, body mass index, or preoperative alignment for valgus knees, when comparing the CAS and PSC cohorts (Table 1). However, patients in the CAS cohort with a

Fig. 2. Anteroposterior radiograph demonstrating measurement of the tibial component varus/valgus alignment relative to the coronal mechanical axis. This component was measured to be in 0.4° of valgus.

Fig. 3. Anteroposterior radiograph demonstrating measurement of the femoral component varus/valgus alignment relative to the coronal mechanical axis. This component was measured to be in 0.4° of valgus.

preoperative varus alignment did have a significantly greater degree of deformity compared to varus knees in the PSC cohort (9.0° ± 5.0° vs. 7.5 ± 5.0°, p = 0.02).

3.1. Overall lower extremity mechanical alignment

Postoperatively, the average lower extremity mechanical alignment in the CAS cohort was 1.0° ± 1.9° in those patients with a preoperative varus deformity, and 0.6° ± 1.7° in those with a preoperative valgus deformity. Overall, the mean postoperative lower extremity alignment was 0.8° ± 1.9°, with 92.7% of patients having an alignment within 3° of a neutral mechanical axis.

In comparison, in the PSC cohort, the average lower extremity mechanical alignment was 0.8° ± 2.9° in those patients with a preoperative varus deformity (p = 0.46), and 0.8° ± 2.8° (p = 0.85) in those with a preoperative valgus deformity. Overall, the mean postoperative lower extremity alignment was 0.8° ± 2.9°, with 70.7% of patients having an alignment within 3° of a neutral mechanical axis, which was statistically significant compared to the CAS cohort (p = 0.02).

Table 1
Preoperative demographics and mechanical alignment.

	CAS	PSC	p-value
Age (year)	67.0 ± 9.9	67.5 ± 7.9	0.51
BMI (kg/m^2)	312 ± 4.9	33.9 ± 6.9	0.09
Preoperative mechanical alignment (valgus, °)	9.1 ± 5.0	7.5 ± 5.0	0.02
Preoperative mechanical alignment (valgus, °)	−6.7 ± 4.3	− 6.4 ± 6.0	0.8
Tourniquet time (min)	69.9 ± 10.7	65.7 ± 12.6	0.41

3.2. Tibial component mechanical alignment

Postoperatively, in the CAS cohort, the mean tibial component alignment was 0.5° ± 0.9° in those patients with a preoperative varus deformity, and 0.3° ± 1.1° in those patients with a preoperative valgus deformity. Overall, the mean tibial component alignment was 0.5° ± 0.9°, with 100% of patients having an alignment within 2° of perpendicular to the coronal mechanical axis of the tibia. The mean absolute difference between the intraoperative goal and the postoperative alignment was 0.8° ± 0.6° in the CAS cohort.

In the PSC cohort, the mean tibial component alignment was 0.5° ± 2.7° in those patients with a preoperative varus deformity ($p = 0.8$), and 0.4° ± 1.5° in those patients with a preoperative valgus deformity ($p = 0.8$). Overall, the mean tibial component alignment was 0.4° ± 1.6°, with 87.8% of patients having an alignment within 2° of perpendicular to the coronal mechanical axis of the tibia, which was statistically significant compared to the CAS cohort ($p = 0.04$). The mean absolute difference between the intraoperative goal and the postoperative alignment was 1.3° ± 1.0° in the PSC cohort, which was also statistically significant ($p = 0.02$).

3.3. Femoral component mechanical alignment

Postoperatively, in the CAS cohort, the mean femoral component alignment was 0.3° ± 1.2° in those patients with a preoperative varus deformity, and 0.1° ± 1.4° in those patients with a preoperative valgus deformity. Overall, the mean femoral component alignment was 0.2° ± 1.1°, with 100% of patients having an alignment within 2° of perpendicular to the coronal mechanical axis of the femur. The mean absolute difference between the intraoperative goal and the postoperative alignment was 0.9° ± 0.6° in the CAS cohort.

In the PSC cohort, the mean femoral component alignment was 0.1° ± 1.6° in those patients with a preoperative varus deformity ($p = 0.2$), and −0.1° ± 1.6° in those patients with a preoperative valgus deformity ($p = 0.7$). Overall, the mean femoral component alignment was 0.1° ± 1.5°, with 90.2% of patients having an alignment within 2° of perpendicular to the coronal mechanical axis of the femur ($p = 0.2$). The mean absolute difference between the intraoperative goal and the postoperative alignment was 1.2° ± 0.8° in the PSC cohort ($p = 0.2$).

A summary of the radiographic results comparing the CAS and PSC cohorts is provided in Table 2.

3.4. Interclass correlation measurements

The interclass correlation coefficient for measurement of the postoperative tibial component alignment was excellent, with a value of 0.90, as was the interclass correlation coefficient for measurement of the lower extremity mechanical axis (0.91). The interclass correlation coefficient for measurement of the postoperative femoral component alignment was good, with a value of 0.88.

4. Discussion

The purpose of this study was to compare the accuracy of overall lower extremity, femoral, and tibial component coronal alignment obtained when using patient specific instrumentation, compared to an imageless CAS system in total knee arthroplasty. This study demonstrates PSC to be comparably accurate with regards to femoral component positioning, however, it is not able to reproduce the same degree of tibial component, or overall lower extremity alignment accuracy as with CAS techniques.

CAS systems were developed with the goal of improving component alignment accuracy in TKA. Most commonly, they consist of a large computer console, with the use of additional pins in the tibia and femur for placement of tracking arrays (as was used in this study). Numerous comparative studies have demonstrated improved precision and accuracy of implant positioning in TKA when compared to conventional techniques, with a significant decrease in the number of "outliers" (typically defined as greater than 3° outside of a neutral mechanical axis) [5–7]. However, despite these improvements, CAS systems have not become a panacea, as concerns regarding the increased capital costs, operative times, extra pin sites, and the associated learning curve have continued to limit its widespread acceptance.

Table 2
Comparison of component and overall mechanical alignment in the computer assisted surgery and patient specific cutting guide cohorts.

	Computer assisted surgery	Patient specific cutting guides	p-value
Tibial varus/valgus: % within 2°of neutral	100%	87.85	0.04
Femoral varus/valgus: % within 2°of neutral	100%	90.2%	0.2
Overall mechanical axis: % within 3° of neutral	92.7%	70.7%	0.02

Patient specific cutting guides have been developed with the goal of combining the accuracy and precision of CAS techniques, while eliminating its aforementioned disadvantages [18]. Proposed benefits of PSC technology include a decrease in operative times and instrument trays required, improved overall operating room efficiency, and the ability to preoperatively plan a patient's component size, position, and alignment. In essence, navigation of the surgery is moved into the preoperative period, as 3-D models of the patient's anatomy are used to fabricate cutting blocks specific to the patient's anatomy, that once placed will set the appropriate alignment. However, concerns regarding PSC technology do exist, including the effect of preoperative deformities of the knee that may distort the accuracy of the preoperative MRI or CT scan [19,20]. Therefore, points digitized during creation of the 3D model may be compromised, and their accuracy remains susceptible to human error. In addition, the use of PSC technology does not allow the surgeon to intraoperatively assess the alignment of their resections as with CAS techniques, and if adjustments are required, additional instrument trays must be utilized. Lastly, several studies have questioned the proposed cost-efficiency of PSC, as it remains unclear whether the suggested increase in operating room efficiency will offset the costs of additional preoperative imaging and fabrication of the cutting blocks [10,21,22].

In addition, it remains unclear whether the postoperative alignment obtained using PSC systems are as accurate as CAS techniques. Nunley et al. performed a retrospective review of 50 TKAs in which PSC was used to obtain a neutral mechanical axis, and compared their results to a cohort of 50 TKAs in which conventional instrumentation was used. They found that the percentage of outliers was similar between the two groups (32% in PSC versus 40% in conventional), and that PSC failed to improve postoperative component alignment [11]. In contrast, in the largest series reported in the literature, Ng et al. retrospectively reviewed 569 TKAs performed with patient specific cutting guides, and noted 91% of knees to be aligned within 3° of a neutral mechanical axis, concluding that this technology can improve a surgeon's ability to obtain a neutral mechanical axis [12]. However, as this is a relatively new technology, the data regarding postoperative radiographic alignment remains limited, and to our knowledge, no studies have been performed directly comparing the results of PSI and CAS techniques.

Based on this study, the MRI-based, PSC system utilized was not able to obtain the same degree of accuracy as the CAS system, with respect to both the tibial component and overall lower extremity axis. There were a concerning number of outliers in the PSC cohort, with only 70.7% of the patients having an alignment within 3° of a neutral mechanical axis. While this value is comparable to most reports of TKAs performed using conventional intramedullary and extramedullary alignment methods, it falls far below the accuracy reported with CAS techniques [7]. However, this study does possess several limitations. First, this is a non-randomized, retrospective review of two cohorts of patients, and thus selection bias remains a concern. However, the preoperative demographic variables were similar between the two cohorts, and the increase in preoperative varus deformity in the CAS cohort should have made achieving a neutral axis in this cohort more difficult. In addition, the sizes of each cohort in this study were relatively small, and thus the presence of only a few outliers can greatly affect the results. Lastly, while standing AP hip-to-ankle and lateral knee-to-ankle radiographs were used to measure component alignment, it could be argued that computed tomography may more accurately determine component positioning. However, computed tomography has disadvantages, as it subjects patients to increased doses of radiation, it is costly, interpretation is subject to artifact around the implant, and it is not used for routine follow-up in the clinical setting. The radiographic analysis performed in the present study utilized acceptable axes that reproducibly depict the alignment of the tibial components in both the coronal and sagittal plane, as demonstrated by the good to excellent interobserver correlation coefficients seen in all of the radiographic measurements. In conclusion, while PSC techniques appear sound in principle, this study did not demonstrate patient specific cutting guides to obtain the same degree of overall mechanical and tibial component alignment accuracy as a CAS technique.

Conflict of interest

One of the authors of this study (ADP) has stock options in Bluebelt technologies. None of the other authors have any relationships to disclose.

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