Patient-Specific Instrumentation in Total Knee Arthroplasty Provides No Improvement in Component Alignment

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Brief Title: PSI in TKA Provides No Improvement in Component Alignment.

Abstract

Improved component alignment in TKA remains a commonly cited benefit of MRI based patient-specific instrumentation (PSI). We hypothesized that PSI would lead to improved alignment versus traditional instrumentation (TI) during primary TKA. Fifty-eight knees (54 patients) that underwent TKA with PSI were compared to 62 knees that had previously undergone TKA with TI. Radiographs were evaluated for mechanical axis and alignment of the femoral and tibial components. Alignment was similar between the groups. However, the PSI group showed fewer knees in the target range for posterior tibial slope (PSI 38% vs. TI 61%, p=0.01) in addition to a trend for fewer knees in target for femoral flexion (PSI 40% vs. TI 56%, p=0.07). This study demonstrated no improvement in overall alignment and perhaps a worsening of the tibial slope.

Key Words: Patient-Specific Instrumentation, Total Knee Arthroplasty, Femoral Component Alignment, Tibial Component Alignment and MRI

Introduction

It is generally accepted that coronal alignment following total knee arthroplasty (TKA) should approximate the mechanical axis. A higher failure rate has been reported in knees that were not aligned in proximity to the mechanical axis [1-3]. However, this remains a topic of controversy with one recent report showing no increase in failure rate of knees falling outside the accepted range for appropriate alignment [4].

To achieve alignment, traditional instrumentation (TI) uses a series of jigs to provide bone resections when performing TKA. This has been the primary method of alignment since the advent of this surgery and was the only option available for guiding surgical resections until recently. Potential drawbacks of TI include instrumentation of the femoral canal, the need for multiple surgical trays, human error with setting the guides, and the potential for inaccurate alignment based on surgeon technique.

An entire industry has been developed to increase the accuracy of implant alignment to include the use of robotics and computer navigation. Computer navigation is an effective method for improving accuracy[5-9], but comes with potential problems [5, 10-14] in comparison to TI that include pin site fracture and increased operative time. There has also been no proven benefit in terms of long-term patient outcomes with the use of this technology.

The use of patient specific instrumentation (PSI) for knee replacement is a novel technology aiming to increase the accuracy of component sizing and alignment without the associated risks of computer navigation. The potential benefits include: decreased operative time, decreased instrumentation, no intramedullary entry and increased

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accuracy of component alignment. Multiple manufacturers offer this technology and there are variations in the methodology with each system. The algorithms used to render imaging and determine alignment remain proprietary, making comparisons between products difficult. Initial reports on the use of PSI were conflicting with some supporting the technology [15-18] while others abandoned the use of PSI with concern for component mal-alignment [19]. Component alignment has been evaluated using several different systems and no advantage in alignment in comparison to traditional instrumentation or computer navigation has yet been shown [20-23]. Patient specific instrumentation is being provided by seven implant manufacturers and was used for an estimated 82,556 total knee arthroplasties worldwide in 2012 [24] despite no proven clinical benefit and minimal literature available to support its use.

The purpose of this study was to evaluate the accuracy of implant alignment with the use of Biomet Signature (Biomet, Warsaw, IN, USA) MRI based PSI technology in comparison to TI for TKA in regards to sagittal and coronal implant alignment and overall mechanical axis. More specifically, we sought to compare the post-operative alignment of TKAs performed with PSI to TI in regards to overall mechanical alignment and sagittal and coronal alignment of the femoral and tibial components, the accuracy of PSI in comparison to TI for obtaining the surgeon's preferred implant alignment and operative variables to include tourniquet time and estimated blood loss in comparison to TI.

Materials and Methods

We retrospectively reviewed data on a consecutive series of 63 patients who were followed prospectively and had undergone 69 TKAs using an MRI based PSI system in a

nonrandomized fashion from September 2010 to April 2011. The inclusion criteria were diagnosis of primary knee osteoarthritis and the ability to undergo MRI at our facility. We excluded 3 patients who had metal in proximity to the knee or received CT for guide production. Additionally, we abandoned the PSI technique in 8 knees (6 patients) and therefore removed these patients from the analysis. This resulted in 58 knees in 54 patients. We compared these knees with a historical control group of 62 consecutive primary TKAs using TI performed immediately before the use of PSI from March 2010 to September 2010.

All patients received Biomet Vanguard (Warsaw, IN, USA) components. The study group underwent TKA with the Biomet Signature PSI technology. This process began with a preoperative MRI scanogram of the operative hip, knee, and ankle obtained at our facility per the manufacturer protocol. Imaging data were then provided to Materialise (Leuven, Belgium) and uploaded into proprietary software, generating a three-dimensional model of the arthritic knee. A computer-generated preoperative plan was created according to the following surgeon preferences: default alignment for femoral component rotation was parallel to the epicondylar axis, femoral component coronal alignment 90^{o} to the mechanical axis, and femoral component sagittal alignment 3^{o} of flexion with 9-mm distal medial resection. The tibial default alignment was 0^{o} rotation to the AP axis, coronal alignment was 90^{o} to the mechanical axis, and sagittal alignment was 3^{o} of posterior slope with 8-mm resection below the highest point of the lateral plateau. The surgeon assessed each preoperative plan with the option to change multiple variables including implant size, alignment, and resection level. We retained the default plan when it appeared appropriate.

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Once the plan was approved, femoral and tibial guides were manufactured (Materialise Leuven, Belgium) to fit each patient's unique anatomy and to guide surgical bone resections. The values chosen for alignment with PSI were based on our alignment goals that were also used in the TI group.

For all participants, we recorded intra-operative variables to include tourniquet time, estimated blood loss, and implant sizes. The tourniquet was inflated directly prior to skin incision and deflated before closure at a consistent time point (12 minutes after cementation). Blood loss was estimated by the amount of blood present on sponges, drapes, and the suction canister at the completion of closure and verified by the anesthesiologist and surgeon. Implant sizes were recorded to include femoral and tibial components and tibial polyethylene thickness.

Anteroposterior (AP), lateral, and AP long-standing post-operative radiographs were obtained at the 6 week post-operative visit in all patients with 100% follow up obtained. One author (BMS) reviewed all radiographs with measurements recorded. An internal validation to ensure minimal intra-observer variability was performed for a randomly selected group of patients with all measures within 1° of the initial measurement. These were evaluated for specific measurements that can be clearly determined on radiographs to include coronal and sagittal alignment of the femoral and tibial components and mechanical axis of the leg in both groups. Goal alignment was within +/- 2° of planned femoral flexion of 3°, posterior tibial slope of 3°, mechanical axis of 0°, femoral valgus of 5°, and tibial varus of 0°.

Descriptive statistics to include mean and confidence intervals were used to present all continuous variables. An independent samples T-test was used for comparison between

the groups (PSI v. TI). The Chi-square test was used to compare all binary variables. Statistical analysis was performed using STATA v.13 (College Station, Texas, USA) and values less than p=0.05 were considered significant.

Results

Demographics were similar among the groups, (TABLE 1). Additionally, there was no difference between tourniquet times with 58.8 minutes (95% CI 56.5 – 61.1) in the PSI group and 57.0 minutes (95%CI 53.6 – 60.3) in the TI group (p=0.34). Estimated blood loss was also similar, with 111 ml (95% CI 95 – 127) in the PSI group and 114 ml (95% CI 102 – 125) in the TI group (p=0.75). Femoral component size, tibial component size and tibial polyethylene thickness were also similar between the groups (TABLE 2). There was no statistically significant difference in component alignment for femoral flexion, femoral valgus angle, tibial varus angle, mechanical axis alignment or absolute posterior tibial slope between the two groups (TABLE 3). There was also no difference in the accuracy of achieving the goal alignment between the two groups for femoral flexion, femoral valgus angle, tibial varus angle, and mechanical axis alignment. There was decreased accuracy with the use of PSI for tibial slope (38% PSI vs. 61% TI, p = 0.01) (TABLE 4).

Discussion

Patient-specific instrumentation technology is being used increasingly for TKA with multiple potential benefits to include improved implant alignment but there is minimal data to support its use. The rationale of this study was to determine if this technology could consistently reproduce the component alignment of TI when used by a single, experienced surgeon. We evaluated 1) the post-operative alignment of TKAs performed with PSI in

comparison to TI to include overall mechanical alignment and sagittal and coronal alignment of the femoral and tibial components 2) the accuracy of PSI in comparison to TI for obtaining the surgeon's preferred implant alignment and 3) operative variables to include tourniquet time and estimated blood loss.

There were limitations to our study. First, we radiographically evaluated only a subset of overall implant alignment including sagittal and coronal femoral and tibial alignment along with sizing. The use of postoperative CT could have been used to evaluate component rotation and provide a more comprehensive understanding of the alignment provided by this technology. As a result of time, expense, and radiation exposure concerns, we elected to not include CT in this analysis. Second, we only evaluated PSI from one manufacturer using MRI. There are multiple manufacturers of this technology for TKA with variations in the computer algorithms and the functionality of the cutting guides. Our results may represent specific findings for only one manufacturer and may not be representative of the overall technology. Third, this was not a randomized control trial but was a retrospective study performed on data collected in a prospective fashion. Potential confounding factors such as time to treatment, medical comorbidities and preoperative deformity were not included. We found similarities between the two groups based on the data available and this allowed us to evaluate our routine implantation practices in comparison to a novel technology. Fourth, a single experienced surgeon made intra-operative changes to the alignment and implant sizing proposed by PSI if the proposed resections or sizes were not appropriate. These changes have previously been reported [25] and the surgeon improved alignment in 82 of these 95 measurable changes (86%). These surgeon-directed changes likely minimized the malalignment of the implants placed with PSI and we could have

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potentially found more differences in alignment if the implants were placed as the guides had directed. A future study using computer navigation to evaluate the alignment of the PSI blocks could be performed in which the proposed resections could be documented without having to make a potentially incorrect resection.

There is not a great deal of literature available on the Biomet Signature system despite its use in over 20,000 knee replacements in 2012 [24]. We have previously evaluated this technology and found frequent intra-operative changes were required to obtain the surgeon's preferred component sizing and alignment [25]. Lombardi et al. [17] evaluated the Biomet PSI technology in 54 knees with overall satisfactory alignment and component position in all cases with no complications or reoperations reported. A recent study by Nunley et al. [26] used the Biomet Signature technology as one of the study groups and found similar mechanical axis and number of outliers between TI and the Biomet Signature technology. Roh et al. [27] used the Biomet Signature guides manufactured with pre-operative CT and found no difference in alignment compared to TI but abandoned PSI guides in 16% of the cases due to malalignment. They found excessive external rotation of the femur in 12% of the PSI cases, which is similar to our previous findings in which the proposed femoral resection appeared too externally rotated in 18% of cases. Interestingly, they recognized a concern for decreased posterior tibial slope while the present study found increased tibial slope.

Multiple systems have been evaluated with mixed results in relation to implant alignment. Vundelinckx et al. performed a randomized trial between PSI and TI with the Smith and Nephew System and found similar alignment between the two groups with improved tibial slope seen in the PSI group [23]. Lustig et al. [22] utilized computer navigation to evaluate

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the same system and found that PSI did not improve accuracy and required frequent modification or abandonment, which was a similar to our experience. The mechanical axis alignment for the Depuy TruMatch system has been evaluated and was found similar in comparison to TI [21].

There is difficulty in making comparisons amongst the different implant manufacturers as several manufacturers are using a third party company such as Materialise, as is the case with the Biomet system, while other companies have developed the technology and produced the guides without using a third party vendor. The algorithms used for modeling and rendering the images, determining the virtual resections and setting the alignment and implant sizing is proprietary and does not allow the end user to have a full understanding of how the end product comes into existence. There is the opportunity for the surgeon to pre-operatively evaluate the implant sizing and alignment but concerns have been raised that the pre-operative plan is not reproduced in the operative setting [25, 28]. Victor et al. [29]compared component and mechanical axis alignment of PSI to TI and found more outliers in the sagittal and coronal alignment of the tibial component with the use of PSI in comparison to conventional instrumentation. They also compared 4 different manufacturers of PSI with no difference in outliers of alignment for multiple measures across the manufacturers except for improved sagittal alignment of the femoral component for the Smith and Nephew system in comparison to the others.

In conclusion, we found no improvement in alignment with the use of PSI and found an increased posterior slope with decreased accuracy of sagittal plane alignment of the tibial component. The body of literature concerning this technology is increasing but there is still insufficient data supporting its use with no proven benefit to offset the increased cost.

Multiple studies have found a high rate of guide abandonment due to improper fit or recommended resection. We recommend caution if using this technology as surgeon intervention is often required to obtain the desired implant alignment.

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