The Journal of Arthroplasty 29 (2014) 1705–1708

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

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

Benjamin M. Stronach, MD [a], Christopher E. Pelt, MD [b], Jill A. Erickson, PA [b], Christopher L. Peters, MD [b]

[a] Department of Orthopaedic Surgery, University of Mississippi Medical Center, Jackson, Mississippi
[b] University of Utah, University Orthopaedic Center, Salt Lake City, Utah

ARTICLE INFO

Article history:
Received 19 February 2014
Accepted 20 April 2014

Keywords:
patient-specific instrumentation
total knee arthroplasty
femoral component alignment
tibial component alignment
MRI

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 range 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.

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 arthroplasty is a novel technology aiming to increase the accuracy of component sizing, rotation and alignment without the associated risks of computer navigation. The potential benefits include: decreased operative time, decreased instrumentation, no intramedullary entry and increased 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 postoperative 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. We also compared the accuracy of PSI to TI for obtaining the surgeon's preferred implant alignment. Operative variables were recorded for both groups to include tourniquet time and estimated blood loss.

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.

This work was performed at the University of Utah, Salt Lake City, UT, USA.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2014.04.025.

Reprint requests: C. L. Peters, MD, University of Utah, University Orthopaedic Center, 590 Wakara Way, Salt Lake City, UT 84108.

http://dx.doi.org/10.1016/j.arth.2014.04.025
0883-5403/

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 primary surgeon (CLP) performed 30 PSI surgeries prior to the initiation of the study in an effort to minimize any resultant bias from the learning curve of a new technology. 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° to the mechanical axis, and femoral component sagittal alignment 3° of flexion with 9-mm distal medial resection. The tibial default alignment was 0° rotation to the AP axis, coronal alignment was 90° to the mechanical axis, and sagittal alignment was 3° 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. 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 postoperative radiographs were obtained at the 6 week postoperative 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.

Table 1
Demographics of the PSI and TI Groups.

	PSI (95% CI)	TI (95% CI)	*P*-Value
Age, m (years)	63 (60–65)	63 (60–65)	0.98
Height, m (cm)	168 (166–171)	168 (166–171)	0.98
Weight, m (kg)	89 (83–94)	90 (84–95)	0.84
BMI, m (kg/m^2)	31.3 (29.5–33.0)	31.4 (29.8–33.1)	0.86
Gender			
Male, n (%)	23 (40%)	18 (29%)	0.22
Female, n (%)	35 (60%)	44 (71%)	

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 are 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

Table 2
Mean Component Sizes and Bearing Types Between the PSI and TI Groups.

	Femur Size	Tibial Size	Poly Thickness	CR Bearing	AS Bearing
PSI	64	71	12	36%	64%
TI	63	70	12	39%	61%
P-value	0.31	0.25	0.73	0.78	

CR = Cruciate retaining, AS = Anterior Stabilized.