

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

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5 Benjamin M. Stronach MD, Christopher E. Pelt MD, Jill Erickson PA, Christopher L. Peters  
6 MD

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9 B. M. Stronach

10 Department of Orthopaedic Surgery, University of Mississippi Medical Center, Jackson, MS,  
11 USA

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13 C. E. Pelt, J. Erickson, C. L. Peters

14 University of Utah, University Orthopaedic Center, Salt Lake City, UT, USA

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

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

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22 C. L. Peters \*

23 University of Utah

24 University Orthopaedic Center

25 590 Wakara Way

26 Salt Lake City, UT 84108, USA

27 e-mail: [chris.peters@hsc.utah.edu](mailto:chris.peters@hsc.utah.edu)

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

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

34  
35 **Abstract**

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

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

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51 **Introduction**

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

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

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

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

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

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

## 92 **Materials and Methods**

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

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

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

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

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

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

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

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

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## 145 **Results**

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

## 158 **Discussion**

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

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

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

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

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

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

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

214 There is difficulty in making comparisons amongst the different implant manufacturers as  
215 several manufacturers are using a third party company such as Materialise, as is the case  
216 with the Biomet system, while other companies have developed the technology and  
217 produced the guides without using a third party vendor. The algorithms used for modeling  
218 and rendering the images, determining the virtual resections and setting the alignment and  
219 implant sizing is proprietary and does not allow the end user to have a full understanding  
220 of how the end product comes into existence. There is the opportunity for the surgeon to  
221 pre-operatively evaluate the implant sizing and alignment but concerns have been raised  
222 that the pre-operative plan is not reproduced in the operative setting [25, 28]. Victor et al.  
223 [29] compared component and mechanical axis alignment of PSI to TI and found more  
224 outliers in the sagittal and coronal alignment of the tibial component with the use of PSI in  
225 comparison to conventional instrumentation. They also compared 4 different  
226 manufacturers of PSI with no difference in outliers of alignment for multiple measures  
227 across the manufacturers except for improved sagittal alignment of the femoral component  
228 for the Smith and Nephew system in comparison to the others.

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

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

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