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Primary Knee

Patient-Specific Instrumentation Versus Standard of Care in Total Knee Arthroplasty in an Obese Population: Minimum 5-year Follow-Up

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ABSTRACT

Background: Patient-specific instrumentation (PSI) in total knee arthroplasty (TKA) was developed to improve alignment accuracy by using custom cutting guides. Obese patients pose unique technical challenges, and enhanced alignment methods may be especially beneficial. This study compared PSI with standard of care (SOC) using conventional instrumentation in obese patients undergoing primary TKA.
Methods: Patients who had a body mass index greater than 30 and undergoing primary TKA were randomized to SOC or PSI. Patients were followed for five years postoperatively. Patient-reported outcome measures, surgical information, postoperative lower extremity alignment, complications, and revision rates were recorded. There were 158 patients included (80 in PSI and 78 in SOC).
Results: The primary radiographic outcome, medial proximal tibial angle, showed a statistically significant, but not clinically meaningful, difference between the groups (PSI = 88.2 ± 2.2, SOC = 88.7 ± 1.8, $P = 0.02$). No significant differences were observed in the anatomic femoral-tibial angle ($P = 0.075$) or lateral distal femoral angle ($P = 0.53$). Patient-reported outcomes, including Western Ontario and McMaster Universities Arthritis Index (PSI: 82.5 ± 18.7, SOC: 83.2 ± 15.9, $P = 0.83$), 12-Item Short-Form Survey physical and mental composite scores ($P = 0.35$ and $P = 0.40$), and Knee Society Score total scores (PSI: 177.3 ± 24.3, SOC: 168.2 ± 31.2, $P = 0.08$), were similar between the groups. A higher rate of deviation from the preoperative surgical plan was observed in the PSI group (30.2%) compared to SOC (5.1%). Complication and revision rates were comparable between the groups.
Conclusions: Use of PSI in primary TKA did not result in clinically relevant improvements in radiographic alignment compared to SOC. Despite increased preoperative planning, intraoperative deviations from the PSI surgical plan were common. There were no differences in patient-reported outcome measures, complications, or revision rates observed at five years.

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This study was registered at www.ClinicalTrials.gov (NCT02177227).

Ethical Review Statement: This study was approved by the Institutional Review Board of London Health Science Center, University of Western Ontario, London, Ontario, Canada.

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Successful total knee arthroplasty (TKA) depends on knee alignment, soft tissue balancing, and appropriate component position. Multiple factors can increase the technical complexity of TKA, including the patient's anatomy and significant preoperative deformity. Failure to achieve a successful result in TKA can lead to residual pain and functional limitations [1]. Implant malalignment has been shown to be a cause of failure [2,3]. In addition, implant malalignment has been demonstrated to lead to poorer patient-reported outcomes [4].

Multiple techniques have been developed to improve the accuracy of implant positioning and alignment [5–7]. Patient-specific instrumentation (PSI) has been introduced in TKA with the goal of increased accuracy by creating custom-fit cutting guides to match the patient's bony anatomy. These guides are thought to increase the accuracy of component positioning and alignment [8–11]. A systematic review and meta-analysis demonstrated that the overall risk of mechanical axis malalignment was significantly lower in PSI compared to standard instrumentation, with a pooled relative risk of 0.79 ($P = 0.013$) [9].

Obese patients undergoing TKA can present as particularly challenging cases due to increased soft tissue envelope, leading to difficulty achieving accurate implant positioning [12]. Obese patients have demonstrated equal functional outcomes compared to nonobese patients [12–17]. They do, however, face a higher rate of complications and failures compared to the general population [12,17–20]. Implant malalignment has been considered a possible mode of TKA failure in obese patients [20]. Literature has demonstrated an increase in malalignment in obese patients compared to nonobese patients [13,20]. There was one such study that demonstrated a 29% rate of deviation greater than three degrees from the mechanical axis compared to 10% in nonobese patients [21]. Malalignment in obese patients may have further detrimental effects due to the increased contact pressures on the joint. In a study of the failure of tibial components, Berend et al. [18] demonstrated that a body mass index (BMI) greater than 33.7 and varus alignment have been shown to have a higher risk of TKA failure. In a study examining the effect of BMI and alignment on failure in TKA, patients who had a BMI of greater than 41 were associated with an increased failure rate with all types of malalignment compared to malalignment in patients who had a BMI of 23 to 26 [20]. Thus, the potential for PSI in obese patients to increase accuracy in alignment and implant position would be of particular importance to improve outcomes and prevent failure.

The purpose of the current study was to determine, using a prospective, randomized trial, the clinical results of PSI compared to standard of care (SOC) for TKA in an obese patient population with respect to patient-reported outcome measures (PROMs) and radiographic TKA alignment parameters. Secondary outcome measures included surgical characteristics and adverse events.

Materials and Methods

A prospective, randomized trial was conducted, including patients undergoing surgery between January 1, 2015, and January 31, 2018. Patients were randomized to one of the following two groups: (1) PSI, TRUMATCH Personalized Solutions Resection Guide (DePuy Synthes, Warsaw, Indiana) or (2) SOC for implanting ATTUNE Total Knee Implants (DePuy Synthes). This study was conducted at a single center. All surgeries were performed by fellowship-trained arthroplasty surgeons. The study was approved by the institutional research ethics board and registered at www.ClinicalTrials.gov (NCT02177227).

Selection Criteria

Participants were included if they were scheduled to undergo primary TKA, between the ages of 20 and 70 years, had a BMI greater than 30, had symptomatic osteoarthritis, and were English-speaking. Participants were excluded if they had previously had open knee surgery, infection, or a history of trauma to the affected knee; were scheduled to undergo simultaneous bilateral TKA; and had underlying dementia or cognitive delay, inflammatory arthritis, chronic pain syndrome, or fibromyalgia.

Sample Size

This study was powered to detect a difference in radiographic alignment between the groups. We selected an effect size of 0.45 to determine our sample size. Using an alpha of 0.05, 80% power, and a two-tailed test resulted in a sample size of 80 patients per group. We then inflated our sample to account for an attrition rate of approximately 20% for a total of 97 patients per group or 194 patients overall.

Randomization

Patients were randomized at the time of consultation for surgery. Randomization was stratified by surgeon, and participants were allocated in a one-to-one ratio to either PSI or SOC for their TKA using a computer-generated randomization scheme.

Participants

There were 194 patients randomized into the study. There were three participants who failed screening (one PSI and two SOC). Also, 17 patients withdrew at or before surgery. There were 158 patients included in the analysis at the 5-year postoperative time point, with 80 patients in the PSI and 78 in the SOC (Figure 1).

Intervention

Participants randomized to the PSI arm underwent a computed tomography (CT) scan of the surgical limb performed six to 12 weeks before surgery using the PSI system's scanning protocol. The treating surgeon reviewed the surgical plan online before surgery and made any required modifications in conjunction with the planning engineers. The personalized resection guides were then manufactured using three-dimensional printing and shipped in sterile packaging to the site. Surgeons utilized a midline incision and medial parapatellar arthrotomy. The femoral and tibial cuts were made using the PSI resection guides.

All patients undergoing SOC were treated with posterior-stabilized TKA implants. Preoperative radiographs included antero-posterior, lateral, and skyline views of the surgical knee as well as a three-foot standing film. A midline incision and medial parapatellar arthrotomy were utilized. All bony cuts were made using conventional instrumentation targeting a neutral mechanical alignment.

Apart from the instrumentation utilized for bony resections, the procedures and postoperative protocols, rehabilitation, and follow-up were standardized between groups. Primary patella resurfacing was not routinely performed and was reserved for cases with intraoperative evidence of maltracking.

Outcome Measures

Participants completed baseline assessments before surgery, and outcome measures were also collected at six weeks; three, six,

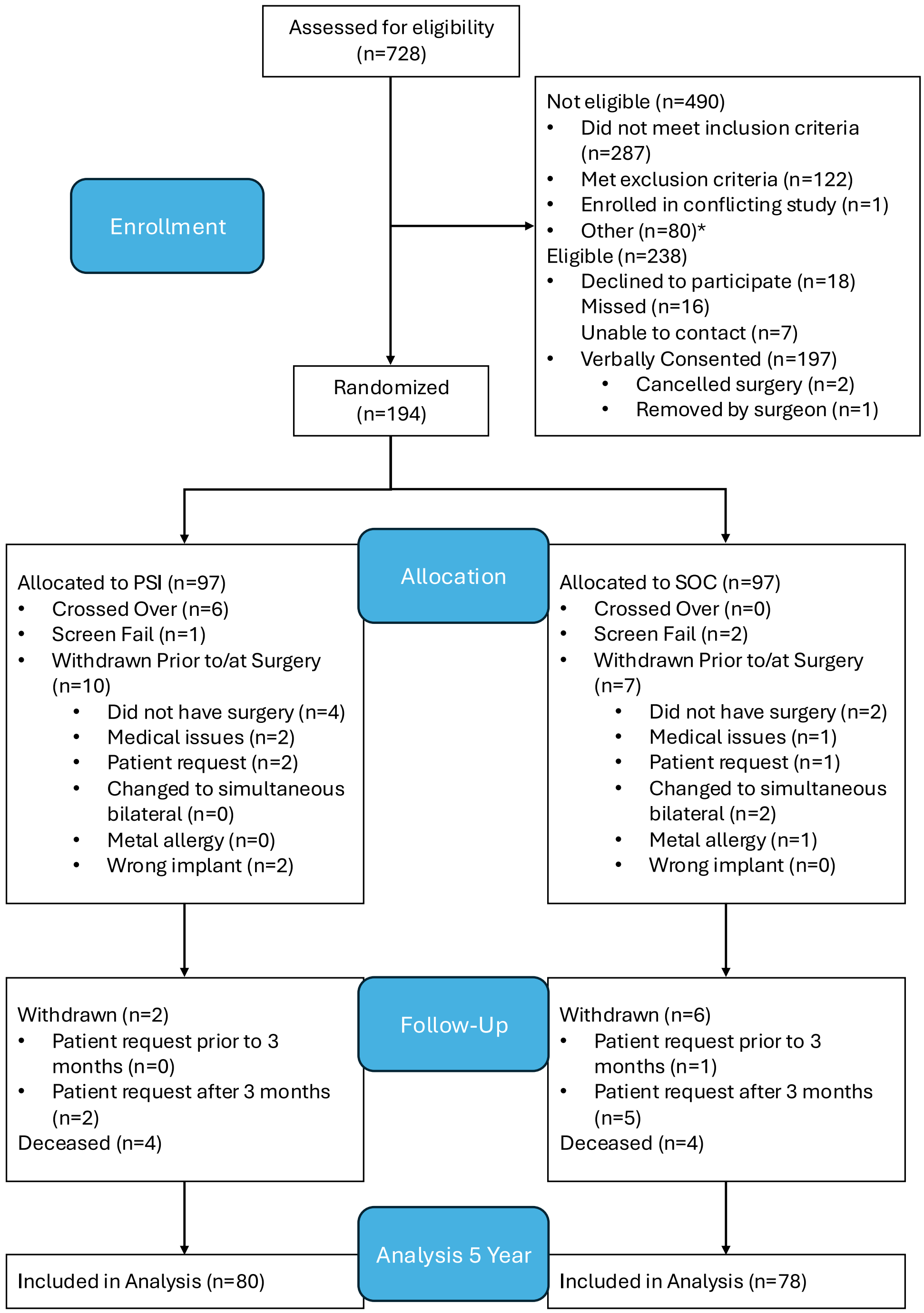

Figure 1. CONSORT diagram of participant flow through the study. *Other: changed surgeons (n = 1), canceled/postponed surgery (n = 9), amputee (n = 2), acromegaly (n = 1), other medical issues (n = 2), lives too far from study site (n = 65). CONSORT, Consolidated Standards of Reporting Trials; PSI, patient-specific instrumentation; SOC, standard of care.

nine, and 12 months; and 5 years postsurgery. The PROMs collected included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Knee Society Score (KSS), and 12-Item Short Form Survey (SF-12). Lower extremity alignment was measured using 6-week postoperative radiographs. Alignment measurements included the anatomic femoral-tibial angle, anatomic lateral distal femoral angle, and the medial proximal tibial angle (MPTA). Surgical information, including deviation from surgical plan, procedure time, tourniquet time, lengths of stay, and adverse events, was also recorded. Deviations from the surgical plan were defined as intraoperative changes from the preoperative PSI-based plan and included modifications to bone resection depths or angles (e.g., increased distal or posterior femoral cuts and increased tibial resection), changes in component sizing (upsizing or downsizing of femoral or tibial components), or alterations in alignment (e.g., increased femoral external rotation). All deviations were recorded intraoperatively and categorized by the operating surgeon at the time of surgery.

Table 1
Patient Demographics.

Characteristic	PSI (n = 80)	SOC (n = 78)	*P*-Value
Age ±SD, years	61 ± 9.8	62 ± 5.8	0.70
Sex (women), n (%)	56 (70)	52 (67)	0.78
Height ±SD, cm	167.6 ± 9.3	166.2 ± 8.9	0.34
Weight ±SD, kg	108.8 ± 19.2	110.5 ± 23.3	0.62
BMI ±SD, n (%)	39.1 ± 6.1	39.8 ± 6.5	0.49
<35	23 (29)	21 (27)	
35 to 40	28 (35)	26 (33)	
40 to 45	11 (14)	15 (19)	
>45	18 (22)	16 (21)	
Contralateral knee symptoms, n (%)	42 (52)	47 (60)	0.41
Contralateral TKA, n (%)	15 (19)	19 (24)	0.51
Smoker, n (%)	43 (54)	43 (55)	0.99
ASA score, n (%)			0.82
2	24 (30)	27 (35)	
3	51 (64)	46 (59)	
4	5 (6)	5 (6)	
Charlson Comorbidity Index, n (%)			0.39
0	40 (50)	36 (46)	
1	26 (33)	27 (35)	
2	6 (8)	11 (14)	
3+	8 (9)	4 (5)	

SOC, standard of care instrumentation; PSI, patient-specific instrumentation; BMI, body mass index; TKA, total knee arthroplasty; ASA, American Society of Anesthesiologists.

Demographics

Demographics were similar between groups (Table 1). The mean age for the PSI group was 61 ± 9.8 years. The mean age for the SOC group was 62 ± 5.8 years. There were 70% women in the PSI group and 67% women in the SOC group. The BMI was 39.1 ± 6.1 and 39.8 ± 6.5 for the PSI and SOC groups, respectively. Stratification of BMI was similar between groups as well. The American Society of Anesthesiologists and Charlson Comorbidity scores were also similar between groups.

Data Analyses

Statistical Package for Social Sciences statistical software (version 29; IBM Corporation, New York) was used to complete the analysis according to the intention-to-treat principle. Descriptive statistics were used to present the demographic and surgical characteristics of the groups using proportions for nominal variables and means and SDs for continuous variables.

The PROMs were compared between the groups using linear regression with group as the predictor. For the analyses of postoperative scores, baseline scores were included as a covariate. All comparisons were presented with 95% confidence intervals around the mean difference.

Results

Radiological Evaluations

There was no significant difference in the anatomic femoral-tibial angle (PSI = 177.2 ± 1.8, SOC = 176.8 ± 1.9, *P* = 0.075) or the anatomic lateral distal femoral angle (PSI = 86.0 ± 2.0, SOC = 86.2 ± 2.1, *P* = 0.53) between groups. The MPTA did demonstrate a statistically significant difference, but not a clinically relevant difference between groups (PSI = 88.2 ± 2.2, SOC = 88.7 ± 1.8, *P* = 0.02), Table 2.

Table 2
Radiographic Alignment.

Outcome	PSI (n = 80)	SOC (n = 78)	Mean Difference (95% CI)	*P*-Value
FTA ± SD, °	177.2 ± 1.8	176.8 ± 1.9	−0.34 (−0.91, 0.24)	0.075
LDFA ± SD, °	86.0 ± 2.0	86.2 ± 2.1	0.18 (−0.53, 0.88)	0.53
MPTA ± SD, °	88.2 ± 2.2	88.7 ± 1.8	0.47 (−0.16, 1.12)	0.02

FTA, femoral-tibial angle; LDFA, lateral distal femoral angle; MPTA, medial proximal tibial angle; PSI, patient-specific instrumentation; SOC, standard of care; CI, confidence interval.

Patient-Reported Outcome Measures

The PROMs are reported in Table 3. There were no differences between PSI and SOC in SF-12 mental composite score or physical composite score at five years postoperatively (*P* = 0.50 and 0.35, respectively). There was no significant difference between groups at any postoperative time point for WOMAC score when comparing the PSI to the SOC group for pain, stiffness, function, or total scores. Both groups had an overall increase in WOMAC score at 5-year follow-up. Mean total WOMAC scores for PSI and SOC were 44.6 ± 15.2 and 48.0 ± 15.2 at baseline, respectively (*P* = 0.19). Mean total WOMAC scores for PSI and SOC were 82.5 ± 18.7 and 83.2 ± 15.9 at 5-year follow-up, respectively (*P* = 0.83). There were no significant differences between groups at any postoperative time point for KSS score when comparing the PSI to the SOC group for symptoms, satisfaction, or function. Baseline KSS total score for PSI was 99.5 ± 15.6 and 98.1 ± 14.4 for the SOC group (*P* = 0.60). The mean total KSS scores at 5 years were 177.3 ± 24.3 for the PSI group and 168.2 ± 31.2 for the SOC group (*P* = 0.08).

Surgical Information

Surgical and tourniquet times were comparable between groups (Table 4). Surgical and tourniquet times for PSI were 59.5 ± 14.0 and 58.0 ± 13.4 min, respectively. For the SOC group, procedure time was 60.6 ± 11.9 minutes, and tourniquet time was 60.0 ± 12.1 minutes. There was a higher rate of deviation from the surgical plan in the PSI group (30.2%) compared to the SOC group (5.1%). Deviation from the surgical plan in the PSI group varied significantly by surgeon. Surgeon 1 had a 44% rate of deviation, surgeon 2 had a 7% rate of deviation, and surgeon 3 had a 71% rate of deviation. Table 5 displays the reasons for deviation of surgical plans in the PSI group with the respective changes. Lengths of stay in hospital were similar between groups, with 2.5 ± 1.3 days for PSI and 2.6 ± 1.7 days for SOC.

Complications and Revision Rates

There were no significant differences in the overall 5-year rate of revision (*P* = 0.44). There were five total revisions in the PSI group (one infection, two revisions for patella resurfacing, one for aseptic loosening, and one for tibial component failure). Superficial infections were treated nonoperatively with prolonged antibiotic treatment, and these patients achieved full recovery. There were two total revisions in the SOC group (one infection and one tibial component failure), Table 6.

Discussion

Results of this study suggest that there is no statistically significant difference in radiographic alignment outcomes or PROMs for PSI in TKA compared to SOC at 5-year follow-up. No significant differences were observed in WOMAC, KSS, or SF-12 scores, and

Table 3
Clinical and Functional Outcomes, Patient-Reported Outcome Measures.

Outcome	Time Point	PSI (n = 80)	SOC (n = 78)	Mean Difference (95% CI)	*P*-Value
SF-12 MSC ± SD	Baseline	53.1 ± 10.3	54.2 ± 9.4	1.12 (−2.16, 4.40)	0.50
	5-Years FU	52.2 ± 9.9	53.7 ± 8.9	1.55 (−1.70, 4.81)	0.35
SF-12 PCS ± SD	Baseline	29.6 ± 7.3	30.3 ± 7.4	0.72 (−1.75, 3.18)	0.57
	5-Years FU	44.5 ± 10.8	42.9 ± 10.8	−1.59 (−5.33, 2.14)	0.40
KSS total ± SD	Baseline	99.5 ± 15.6	98.1 ± 14.4	−1.37 (−6.56, 3.82)	0.60
	5-Years FU	177.3 ± 24.3	168.2 ± 31.2	−9.12 (−19.51, 1.26)	0.08
WOMAC total ± SD	Baseline	44.6 ± 15.2	48.0 ± 15.2	3.35 (−1.65, 8.35)	0.19
	5-Years FU	82.5 ± 18.7	83.2 ± 15.9	0.63 (−5.25, 6.51)	0.83

PSI, patient-specific instrumentation; SOC, standard of care; FU, follow-up; SF-12, 12-Item Short Form Survey; MSC, mental composite score; PSC, physical composite score; KSS, Knee Society Score; WOMAC, Western Ontario and McMaster Universities Arthritis Index; CI, confidence interval.

although the MPTA showed a statistically significant difference, it was not clinically meaningful. In addition, surgical characteristics were similar between groups, with comparable rates of complications and revisions.

The current study demonstrates that both PSI and SOC with conventional instrumentation achieve an acceptable alignment with no significant deviation from the target mechanical alignment goal. There was a statistically significant difference between groups for the MPTA (PSI = 88.2 ± 2.2, SOC = 88.7 ± 1.8, *P* = 0.02). We do not believe that this is clinically significant, although the difference between groups is less than 0.5 degrees, and both fall within the target margin of 87 to 93 degrees.

Recent literature highlights that alignment variations within a reasonable range may not significantly affect clinical outcomes. Kaneko et al. [22] demonstrated that robotic-assisted TKA resulted in a variety of alignment phenotypes without affecting PROMs, suggesting that slight coronal plane deviations do not necessarily translate to poorer functional outcomes. Similarly, Schelker et al. [23] found no significant differences in PROMs or revision rates between knees aligned within ±3° and those considered outliers, challenging the traditional “safe zone” concept for mechanical alignment. These findings align with our study, where a statistically significant, but clinically not meaningful, difference in MPTA did not translate into differences in PROMs or revision rates.

Moreover, although PSI aims to improve component positioning and alignment, these benefits have not been definitively linked to superior clinical outcomes. Moret et al. [24] reported that PSI reduces alignment outliers and improves implant fit compared to standard implants, but these radiographic improvements have not yet demonstrated long-term advantages in implant survival.

Taken together, these results reinforce that although PSI achieves acceptable alignment, its slight radiographic differences from SOC do not translate into meaningful clinical benefits. This supports the growing evidence suggesting that alignment targets in TKA should be individualized rather than strictly adhering to traditional mechanical alignment goals [25].

Despite the complexities associated with TKA in the obese population, these patients experience clinically important improvements postsurgery. A TKA in the obese population has been previously shown to have similar improvements in PROMs as compared to the general population. Our study demonstrates an increase in PROMs for both the PSI and SOC groups. Previous studies have demonstrated significant improvements in WOMAC scores from 25.3 to 29 after TKA in the obese population [15,26,27]. The current study demonstrated an improvement in the mean WOMAC total scores in both groups, with baseline scores for PSI and SOC improving from 44.6 ± 15.2 and 48.0 ± 15.2, respectively (*P* = 0.19), to 82.5 ± 18.7 and 83.2 ± 15.9, respectively, at 5-year follow-up (*P* = 0.83).

Use of PSI in TKA has been developed to improve implant placement and alignment. These improvements, however, have not been shown to be of major benefit to PROMs in the literature [26,28–30]. The results of our comparison between PSI and SOC are in keeping with previous literature. Anderl et al. [28] demonstrated that despite improved alignment in PSI, the PROM data demonstrated no difference at 2-year follow-up with WOMAC and Oxford Knee Scores. The WOMAC scores for the SOC and PSI groups at 2-year follow-up in their study were 85.7 ± 17.9 versus 86.7 ± 15.4, respectively. The mean BMI in their study was 29 and was lower in comparison to our patient cohort (BMI 39). Our study in the obese population demonstrated slightly higher WOMAC scores at 5-year follow-up. Similarly, meta-analyses examining studies comparing PSI and SOC have shown no difference between groups. A study examining randomized controlled trials (RCTs) only demonstrated no significant difference in KSS, Knee Injury and Osteoarthritis Outcome Score for Joint , or SF-12 scores between PSI and SOC. The follow-up for this study was limited to three and six months post-TKA [29]. Another meta-analysis including both RCTs and non-RCT studies demonstrated no difference in PROMs when they grouped studies with less than one year and more than one year follow-up for WOMAC, KSS, or Knee Injury and Osteoarthritis Outcome Score [30].

Total knee arthroplasty using PSI requires increased preoperative imaging and planning. Despite the added planning required for PSI, both preoperative and intraoperative changes are often required. There was a high rate of deviation from the preoperative surgical plan observed in the PSI group (30.2%) compared to the SOC group (5.1%). Victor et al. [31] demonstrated a similar rate of modification at 28% in their study of PSI in TKA. Stronach et al. [32] found a much higher rate of intraoperative deviation from the surgical plan, with approximately 2.4 changes required per knee. They also reported that 85% of these changes prevented

Table 4
Procedure-Related Characteristics.

Characteristic	PSI (n = 80)	SOC (n = 78)	Mean Difference (95% CI)	*P*-Value
Length of stay ±SD, days	2.5 ± 1.3	2.6 ± 1.7	−0.1 (−0.6, 0.4)	0.63
Procedure time ±SD, minutes	59.5 ± 14.0	60.6 ± 11.9	−1.1 (−4.7, 2.5)	0.55
Tourniquet time ±SD, minutes	58.0 ± 13.4	60.0 ± 12.1	−1.9 (−5.6, 1.7)	0.31
OR time ±SD, minutes	86.5 ± 17.5	90.3 ± 18.8	−3.8 (−9.1, 1.4)	0.15
Surgical trays ±SD, n	5.6 ± 0.9	5.8 ± 0.6	−0.1 (−0.3, <0.1)	0.12

PSI, patient-specific instrumentation; SOC, standard of care instrumentation; CI, confidence interval; OR, operating room.

Table 5
Reasons for Deviation From Surgical Plan.

Deviation Category	Changes	PSI (n = 80) N (%)
Resection		
Femoral	Increased distal cut	3 (12.5)
	Increased posterior cut	1 (4.2)
	Increased anterior cut	1 (4.2)
Tibial	Increased varus	1 (4.2)
	Increased cut	3 (12.5)
Component size		
Femoral	Downsized	4 (16.7)
	Upsized	1 (4.2)
Tibial	Downsized	14 (58.3)
	Upsized	1 (4.2)
Alignment	Increased femoral external rotation	2 (8.3)

PSI, patient-specific instrumentation.

malalignment that was intended to be avoided by PSI. All changes occurred intraoperatively in the current study. In many cases, the surgical plan was changed to adjust component size (18.6% of the total 30.2%). There was a major variation in the amount of deviation per surgeon (range, 7 to 71%). This demonstrates differing levels of comfort with the PSI system. Despite the initially high deviation rate from the PSI surgical plan (30.2%), most modifications involved tibial component sizing rather than femoral adjustments. Downsizing the tibial component, which accounted for the majority of changes, does not markedly impact knee alignment or balance, as it primarily affects tibial coverage rather than flexion or extension gaps. In contrast, femoral modifications, such as changes in resection level or component size, could directly alter joint balance and flexion-extension gaps, suggesting potential inaccuracies in the PSI preoperative plan or deviations from intraoperative findings. That suggests that although PSI-guided surgery necessitated intraoperative changes, most deviations did not compromise the intended knee balance or alignment. Other studies, however, demonstrated high rates of abandonment of the PSI technique altogether (16 to 32%) [31,33,34]. Again, once abandoned, studies reported that surgeons achieved acceptable alignment in these cases. Patient-specific instrumentation guides were never abandoned altogether in the current study. This data suggest that PSI fails to achieve the goal of improved alignment inherent to its design. These studies were not specific to the obese population.

Although TKA in obese patients is often associated with increased technical complexity and a higher risk of complications, recent large-scale registry data suggest that these challenges can be effectively addressed in high-volume, specialized centers. Quayle et al. [35] demonstrated that although operative time increases with BMI, this effect is markedly attenuated among high-volume surgeons, underscoring the value of surgical experience in managing this patient population. Our results align with these findings; despite the high BMI of our cohort, we observed no significant differences between the PSI and SOC groups in procedure time, tourniquet time, or total operating room time. These outcomes support the premise that, within experienced centers, the technical demands of TKA in obese patients, including those related to PSI, can be successfully managed without prolonging operative duration or compromising perioperative care. Complications observed in our study were similar to those seen in the literature previously. An increased risk of infection in obese patients has been well described [12,36]. Jamsen et al. [36] reported infection rates for obese patients increased with higher BMI categories, from 0.9% for BMI 30 to 34 up to 4.7% for BMI ≥ 40 in the first year after joint arthroplasty. The overall infection rate reported in the current study was 1.3% (two of 158). The rate of superficial infections of 4.4% (seven of 158) in the current study is lower than that reported by Ponnusamy et al. [37], who reported rates greater than 6.2% within the first 90 days postsurgery for patients who had a BMI greater than 30. Winiarsky et al. [12] reported a rate of 26% superficial infections and wound complications. Increased severity of obesity has been shown to increase the complication rate [38]. In the current study, there was no statistically significant difference between groups when it came to revision rate at five years ($P = 0.44$). The reoperation rate was 6.3% (n = 5) for the PSI group and 2.6% (n = 2) in the SOC ($P = 0.44$).

Strengths of our study include the inclusion of PROMs in the obese population. To our knowledge, there is only one study in the literature that examines PSI in the obese population [39]. The previous study comparing TKA with PSI to SOC in an obese population examined alignment, surgical data, and revision rates. Although these outcomes are important, they do not demonstrate the impact of PSI on patient satisfaction and quality of life.

Potential limitations of the current study include the lack of blinding to group allocation. It was not possible to blind any of the persons involved in the study to group allocation due to the required preoperative CT scan and additional instrumentation associated with the PSI group allocation. Furthermore, from the perspective of cost and radiation exposure, a preoperative CT scan for the SOC group was not a feasible option. Another limitation of the study was the number of participants who withdrew from the study before undergoing surgery. While waiting for surgery, a few enrolled participants developed health concerns that either needed to be addressed before surgery, thus delaying their surgery, or permanently changed their health status, such that surgery was no longer appropriate. Dropout numbers and demographics between groups, however, remained well balanced; thus we do not believe this affected the results of the current study. Another potential limitation of this study is that the final analysis included 80 and 78 patients in each group, respectively, after an initial inclusion of 97 patients per group. Although intention-to-treat principles were followed for initial allocation, exclusions during the follow-up period, as well as preoperative withdrawals and reassignments, reduced the final cohort size. However, given that the study was powered based on the initially allocated groups and the final sample sizes remain robust, the overall findings and conclusions remain valid despite not reaching the full 80 patients per group in the final analysis. In addition, the current study was appropriately powered to account for a 20% rate of attrition.

Table 6
Reasons for Revision.

Specific Cause of Revision	PSI (n = 80)	SOC (n = 78)	*P*-Value
Revisions, n (%)	5 (6.3)	2 (2.6)	0.44
Deep Infection, n (%)	1 (1.3)	1 (1.3)	
Patellar resurfacing, n (%)	2 (2.5)	0 (0)	
Aseptic loosening, n (%)	1 (1.3)	0 (0)	
Varus tibial component, n (%)	1 (1.3)	1 (1.3)	

PSI, patient-specific instrumentation; SOC, standard of care.

Conclusions

The current study suggests that although a statistically significant difference in radiographic alignment was observed for the MPTA, this difference was not clinically meaningful. There were no significant differences in other radiographic parameters, PROMs, surgical characteristics, or revision rates at five years of follow-up in obese patients undergoing primary TKA with PSI or SOC. Both techniques demonstrate a safe and reproducible approach in this patient population.

CRediT authorship contribution statement

Sebastian Braun: Writing – review & editing, Writing – original draft, Validation, Investigation, Formal analysis, Data curation, Conceptualization. **James Allen:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation. **Lyndsay Somerville:** Writing – review & editing, Validation, Supervision, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **James L. Howard:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Investigation, Funding acquisition. **Brent A. Lanting:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Funding acquisition, Conceptualization. **Edward M. Vasarhelyi:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Investigation, Funding acquisition, Conceptualization.

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