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KNEE ARTHROPLASTY

Patient-specific instrumentation development in TKA: 1st and 2nd generation designs in comparison with conventional instrumentation

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Abstract
Introduction This study was conducted to determine if the difference in magnetic resonance imaging (MRI)-based 2nd generation patient-specific instrumentation (PSI) design affects post-operative restoration of neutral mechanical alignment in total knee arthroplasty (TKA) compared with the 1st generation PSI design and conventional surgical techniques. In addition, it is aimed at elucidating whether PSI improves surgical efficiency with respect to operating room time, estimated blood loss and the number of instrument trays used intra-operatively.
Materials and methods We report our experience in TKA using PSI techniques in 234 patients from August 2012 to March 2015. The patients were divided into 1st ($n = 64$) and 2nd ($n = 70$) generation PSI design. The control group ($n = 100$) underwent TKA with the conventional instrument technique.
Results The mean surgical time was significantly shorter in the 2nd generation PSI design (62.1 ± 12.1 min) than in the control group (80.6 ± 21.7 min; $P < 0.001$). A mechanical axis malalignment of >3° of the lower limb was observed in 5.7% of the patients in 2nd generation PSI design compared with 26.0% of the control group ($P = 0.006$). No significant difference in mechanical alignment on post-operative long alignment radiography was found between 20.3% of the patients in 1st generation PSI design and the control group ($P = 0.584$).
Conclusion The 1st generation PSI design did not have a shorter surgical time or improved alignment compared with conventional instrumentation (CI). However, the use of the perfectly fitted 2nd generation PSI design was associated with improvements in both of these measurements. This study emphasizes the importance of PSI design in intra-operative and post-operative outcomes of TKA.

Keywords Design improvement · Patient-specific instrument · Total knee arthroplasty

Introduction

Since the concept of knee replacement using ivory implants was introduced by Gluck in the 19th century [1], total knee arthroplasty (TKA) has become a reliable treatment for knee osteoarthritis. Axial alignment of the limb and mechanical axis restoration are determinants of surgical outcomes [2]. Several studies have suggested that alignment errors of >3° are associated with more rapid failure and less satisfactory functional results [3, 4].

Alignment accuracy depends on surgical technique precision and computer-assisted surgery (CAS) was developed to improve surgical accuracy and avoid outliers. Numerous CAS studies have demonstrated improved accuracy in coronal implant positioning in TKA [5–7]. However, the increased cost, surgery time, complications and steep learning curve have hindered widespread acceptance of this technique [8, 9].

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Patient-specific instrumentation (PSI) was designed with similar goals as to computer navigation (limb alignment and absence of morbidity related to intramedullary instrumentation) and to simplify the procedure. The advantages of PSI include improving operating room (OR) time management, reducing preoperative costs, and improving component alignment, when compared with conventional instrumentation (CI), although these advantages have not been confirmed in published literature to date [10, 11]. Whether PSI is effective in TKA operation prognosis compared with the primary CI technique remains controversial [12]. Both surgeons and manufacturers have suggested that operative time can be reduced by eliminating CI, which may translate into cost savings for the health system and increased volume capacity for surgeons. However, discussions about operative time are conflicting [11, 13, 14].In addition, whether PSI improves the accuracy of post-operative mechanical alignment is controversial [15–17].

Therefore, the purpose of this comparative and retrospective study was (1) to examine magnetic resonance imaging (MRI)-based 2nd generation PSI design scans with respect to OR time, estimated blood loss, and number of instrument trays used intra-operatively, and (2) to evaluate the effect of the 2nd generation PSI designs with respect to post-operative restoration of the mechanical axis using radiography, in comparison with the results from the 1st generation PSI designs and the CI technique. It was hypothesized that the design changes of the 2nd generation PSI design would translate into improvement in accuracy for mechanical alignment in TKA.

Materials and methods

Patient enrollment

This retrospective study (Level of Evidence III) was approved by the Institutional Review Board of Yonsei Sarang Hospital, Seoul, Republic of Korea (Protocol No. PSI-2.0). For this study, 234 patients with end-stage knee osteoarthritis scheduled to undergo TKA in a single institution between August 2012 and March 2015 were included in the study. The exclusion criteria were defined as patients with rheumatoid arthritis, previous osteotomy, infections, fractures, retained hardware in the limb, or claustrophobia. The inclusion criteria were defined as diagnosis of primary knee osteoarthritis and ability to undergo MRI at our facility. Moreover, patients with defects on the distal femoral or proximal tibial regions who required metal or allograft augmentation, or either femoral or tibial stem extensions were excluded because of its influence to the radiographic interpretation for alignment achieved using each surgical technique. All eligible patients were offered to choose between operative options of TKA using PSI and TKA using CI. They were not recommended any particular surgical technique over the other by surgeons. No significant differences in preoperative demographic characteristics and clinical and radiographic data were found between the groups (Table 1).

MRI scans were acquired using a 1.5T MRI scanner (Achieva 1.5T; Philips Healthcare, the Netherlands). The MRI scans were obtained in 2-mm slice thickness on the sagittal plane for the tibiofemoral knee joint and in 5-mm slice thickness on the axial plane for the hip and ankle joints. For the non-fat saturation condition, the MRI consisted of an axial proton-density (PD) sequence. A high resolution setting was used for the spectral presaturation inversion recovery sequence (TE: 25.0 ms, TR: 3,590.8 ms, acquisition-matrix: 512 × 512 pixels, NEX: 2.0, field-of view: 140 × 140 mm).

Pre-surgical TKA techniques and PSI design methods

Three-dimensional (3D) data can be acquired from MRI scans. Data were transferred via a digital imaging and communications in medicine (DICOM) and the 3D reconstruction processes were performed with Mimics software (version 17.0; Materialise, Leuven, Belgium). Femoral and tibial bony structures and articular cartilage were manually segmented. 3D model was developed using the sectional slices of MRI scan followed by masking via smart expand function. Using Mimics, the 3D images were converted to standard tessellation language (STL) files and loaded into the digital CAD software 3-Matic (Materialise). 3-Matic allows the user to combine the geometry from mixed sources into one project. PSI guides were designed in the 3-Matic commercial software (version 9.0; Materialise). Using 3-Matic, the geometry of each patient's femur and tibia was regenerated from wrapping function. The 1st generation PSI design that was assigned to group 1 was similar to the products that were currently used in PSI-TKA [10, 18–20]. The potential problem in 1st generation PSI design could be intra-operative instability in translation and rotation [18, 21].

Based on the learning curve, a 2nd generation PSI design was created. 2nd generation PSI differed in movement prevention during drilling using a perfect fit between the bone and the femur PSI guides (Fig. 1). The femoral guide in 2nd generation PSI was designed to be perfectly fitted to the anterior flange. The modified design for the femoral anterior flange region in 2nd generation PSI design allowed the expansion of the contact area, which resulted in rotational stability improvement of the femoral PSI guide. The only contact points in the tibial guide are at the proximal tibia and tibial tuberosity in 1st generation PSI

Table 1 Patient demographics

	1st generation ($n = 64$)	2nd generation ($n = 70$)	Control group ($n = 100$)	*P* value (1st generation: control group)	*P* value (2nd generation: control group)
Age	70 ± 6.8	71 ± 7.3	72 ± 8.8	0.104	0.420
Gender (F/M)	58/6	63/7	91/9	N/A	N/A
BMI	28.3 ± 4.5	27.8 ± 5.1	28.1 ± 5.2	0.794	0.709
Mechanical tibiofemoral angle	Varus	Varus	Varus	0.820	0.639
	8.9 ± 4.8	9.1 ± 4.7	8.7 ± 6.4		

N/A not available, *BMI* body mass index

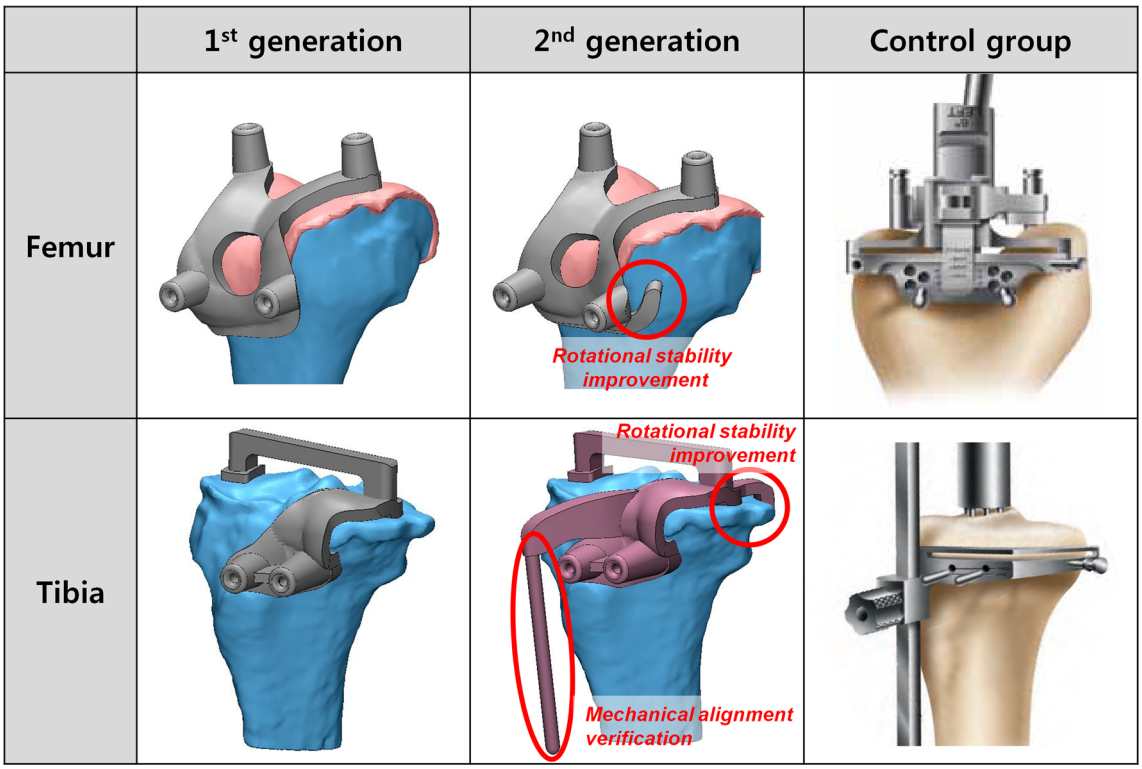

Fig. 1 The PSI guides in each group. *PSI* patient-specific instrumentation

design. Therefore, the tibial guide in 2nd generation PSI design has an additional contact point on the posterior proximal tibia and includes the alignment checker rod after pinning (Fig. 1). In the control group, a CI system was applied using an extramedullary guidance rod for the tibia, and an intramedullary guidance rod for the femur and spacer blocks [21].

All TKA operations based on the surgical pre-planning were performed by an experienced surgeon (the first author), and the design and manufacturing were conducted by co-author and biomedical engineer. In addition, for the research purpose, it was approved by Ministry of Food and Drug Safety, Republic of Korea. Furthermore, it was also approved by Smith & Nephew Korea to use their product in this study, and our hospital designed and manufactured the own patient-specific surgical guides using a newly developed software for the PSI.

A computer-generated preoperative plan was created according to the following surgical preferences: the default alignment for the femoral component rotation was parallel to the surgical epicondylar axis, the femoral component coronal alignment was 90° to the mechanical axis, and the femoral component sagittal alignment was 3° of flexion with 9.5 mm distal medial resection. All the patients received a posterior-stabilized, fixed-bearing implant. The operation was performed using an anteromedial parapatellar approach, without everting the patella. Cement fixation was used in all the patients. The LEGION Total Knee System (Smith & Nephew, Inc., Memphis, TN, USA) was used as an implant.

Intra-operative and post-operative analysis

Surgical time, OR time, number of instrument trays used, blood loss, and knee alignment outcomes were compared between the PSI and CI groups. Blood loss was estimated based on the amount of blood in sponges, drapes, and the suction canister at the completion of closure and verified by the anesthesiologist and surgeon [22].

The mean values of the individual measurements provided the final calculation for each variable measured in terms of operative efficiency parameters. Post-operative radiography was compared to determine changes in knee alignment (mechanical axis), and the angular position of the femoral and tibial components was measured. All the assessments were performed by two different authors who were not directly involved in the surgical procedures. Each measurement was performed three times at different time points, and the readers were blinded to the name of the patient and the treating surgeon. Calculations and measurements were performed on digitized images using previously validated commercial software from Materialise [23, 24]. Post-operative alignment of the femoral component was based on a mechanical axis on the frontal plane, a distal anatomical axis on the sagittal plane, and a surgical epicondylar axis on the axial plane in the three groups. For frontal mechanical alignment, the hip–knee–ankle angle (HKA) was measured on long-leg radiographs. The varus/valgus position of the femoral and tibial components was determined by measuring the femoral coronal angle (FCA) and tibial coronal angle (TCA) relative to the mechanical axis. Femoral component flexion was measured as the femoral sagittal angle (FSA), and the tibial component posterior slope was measured as the tibial sagittal angle (TSA) on standard lateral radiographs, according to techniques described in Fig. 2 [25]. Femoral rotation angle (FRA) was assessed on post-operative computed tomography (CT) (Fig. 2). The femoral component rotation was measured as described in a recent publication [26], following a technique proposed for CT scans by Berger et al. [27]. The femoral component rotation was determined by connecting the lateral epicondylar prominence and the middle sulcus of the prosthetic dorsal condylar surfaces.

To analyze the accuracy of the mechanical axis restoration and 3D-component positioning between the PSI

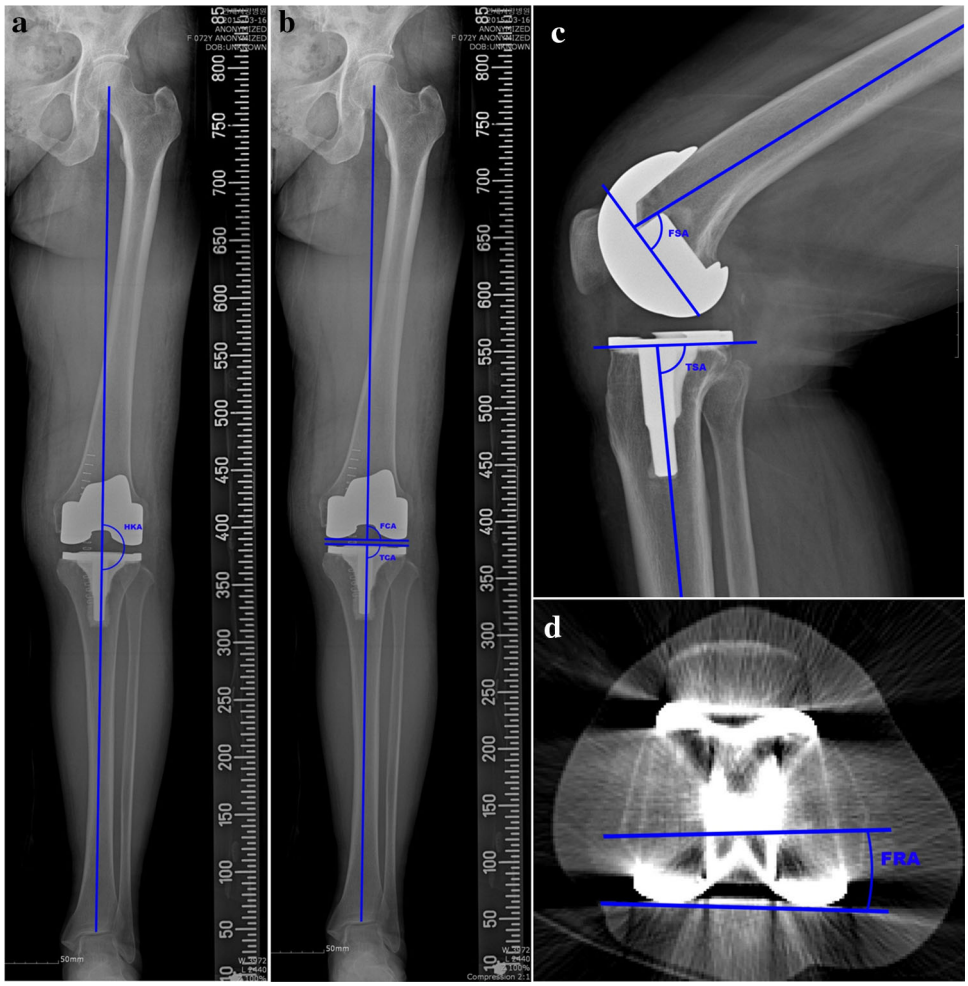

Fig. 2 Alignment of the knee: **a** HKA (HKA, hip–knee–ankle angle); **b** FCA, TCA (*FCA* femoral coronal angle, *TCA* tibial coronal angle); **c** FSA, TSA [*FSA* femoral sagittal angle (femoral flexion/extension angle), *TSA* tibial sagittal angle (tibial posterior slope angle)]; **d** FRA (*FRA* femoral rotation angle)

and CI groups, deviations from the neutral mechanical alignment and targeted 3D-component positioning in degrees were calculated in degrees. Outliers were defined as deviations from the intra-operative goals (HKA, ±3°; FCA, ±2°; TCA, ±2°; FSA, ±2°; TSA, ±2°; FRA, ±2°) [16]. All the alignment parameters were recorded preoperatively and at the standard 3-month follow-up. Finally, the increase in the contact area due to the design improvement in 2nd generation PSI design was compared with the results in 1st generation PSI design.

Statistical analysis

Continuous data were presented as mean and standard deviation (SD). All the statistical analyses were performed in SPSS (version 20.0; IBM SPSS Statistics, Chicago, IL, USA). The two-sample *t* test was used to assess differences in operating time between the groups. Chi-square or Fisher's exact tests were used to test for significant differences in alignment (proportions) between the groups. Statistical significance was set at $P < 0.05$.

Results

Reductions in surgical and OR time were observed according to the design type of the patient-specific guides compared with the control group (Table 2). Compared with the patients in the control group, those in the 2nd generation PSI design had remarkably 18.5 min ($P < 0.001$) and 26.7 min ($P < 0.001$) shorter mean surgical and OR times, respectively. There was no statistically significant improvement in surgical time between the standard PSI cohort in 1st generation PSI design and the control group (5.1 min saved; $P = 0.093$) but observed a significant improvement in the total time in the OR (10.7 min saved; $P = 0.005$). The median number of surgical trays opened for both the standard and optimum PSI group procedures was 5 (range 3–5), compared with 11 (range 10–12) for the control group, which represented a significant reduction of 55% ($P < 0.001$). No statistically significant differences in estimated intra-operative blood loss were found between both 1st and 2nd generation PSI design and the control group.

Table 3 summarizes the radiological evaluation results that show significant reductions in the outliers and statistical comparisons between the study groups for the limb mechanical axes, femoral and tibial component varus/valgus alignments, femoral flexion and rotation angles, and posterior slopes of the tibial component. The proportion of patients with HKA malalignment of >3° in the post-operative analysis of frontal alignment was 26.0% among the CI patients, 20.3% in the 1st generation PSI design, and 5.7% in the 2nd generation PSI group 2. The differences in FCA and TCA alignments between 1st generation PSI design and the control group were not significant ($P = 0.835$ and $P = 0.828$, respectively). However, the FCA in 2nd generation PSI design was statistically significant ($P = 0.031$) and statistically to that in the control group. The differences in FSA between groups 1st generation PSI design and the control group were not statistically significant in comparison ($P = 0.642$).

TSA also decreased in 2nd generation PSI design compared with that in the control group, and this reduction in 2nd generation PSI design was believed to be due to the intra-operative differences in the increase in the contact points between the PSI guide and bone surface, and not due to the significant variations in the outliers. Significantly, more cases of femoral rotation of >2° were found in the control group (22.0%) than in 1st generation PSI design (9.4%) and 2nd generation PSI design (4.3%). No significant differences were found between 1st generation PSI design and the control group. Contact areas for the femoral and tibial PSI in 2nd generation PSI design increased by 139.95 ± 32 and 116.01 ± 21 mm^2, respectively, compared with those in 1st generation PSI design.

Table 2 Comparison of surgical time, OR time, number of tray, and blood loss from each group

	1st generation ($n = 64$)	2nd generation ($n = 70$)	Control group ($n = 100$)	*P* value (1st generation: control group)	*P* value (2nd generation: control group)
Surgical time (min)[a]	75.5 ± 16.8	62.1 ± 12.1	80.6 ± 21.7	0.093	<0.001
OR time (min)[a]	114.2 ± 23.3	98.2 ± 16.9	124.9 ± 24.2	0.005	<0.001
Number of tray[b]	5 (4, 5)	5 (4, 5)	11 (11)	<0.001	<0.001
Estimated blood loss (mL)[a]	115.2 ± 57.6	107.9 ± 64.2	126.4 ± 87.5	0.324	0.113

OR operating room

[a] Mean ± standard deviation

[b] Median (interquartile range)

Table 3 Comparison of outliers and statistical analysis between PSI versus CI after total knee arthroplasty

	1st generation ($n = 64$)		2nd generation ($n = 70$)		Control group ($n = 100$)
		P value (1st generation: control group)		P value (2nd generation: control group)	
HKA	20.3% ($n = 13$)	0.584	5.7% ($n = 4$)	0.006	26.0% ($n = 26$)
FCA	15.6% ($n = 10$)	0.835	4.3% ($n = 3$)	0.031	18.0% ($n = 18$)
TCA	14.1% ($n = 9$)	0.828	2.9% ($n = 2$)	0.025	16.0% ($n = 16$)
FSA	10.9% ($n = 7$)	0.642	2.9% ($n = 2$)	0.034	15.0% ($n = 15$)
TSA	17.2% ($n = 11$)	N/A	2.9% ($n = 2$)	0.018	17.0% ($n = 17$)
FRA	9.4% ($n = 6$)	0.090	4.3% ($n = 3$)	0.009	22.0% ($n = 22$)

PSI patient-specific instrumentation, *CI* conventional instrumentation, *HKA* hip–knee–ankle angle, *FCA* femoral coronal angle, *TCA* tibial coronal angle, *FSA* femoral sagittal angle (femoral flexion/extension angle), *TSA* tibial sagittal angle (tibial posterior slope angle), *FRA* femoral rotation angle, *N/A* not available

Discussion

It was hypothesized that a perfect shape-matched design and the absence of an alignment checker rod can reduce surgical and OR times, and that improvement in femoral and tibial guide stabilities leads to enhanced mechanical alignment in TKA.

With the increasing demand for TKA [1, 28], the orthopedic community is investigating techniques to provide high quality and efficient patient care at a reasonable cost. Recent studies have reported inconsistent findings on whether PSI is the best approach for this issue [10, 12, 13]. Computer-navigated and robotic systems require an additional stage of registration, which can be time-consuming and costly, and PSI systems are advantageous because they eliminate these steps. In addition, they can be cost effective by reducing the operating time and number of trays required during surgery [12, 19, 29, 30]. In addition, the PSI guide can be customized using the patient's anatomy for a more accurate and precise bone resection. However, opinions on these issues are conflicting, especially regarding shortened surgical time and post-operative TKA results [11, 13–16].

The pre-planning and design processes were conducted using previously validated commercial software from Materialise [21, 22]. PSI is designed such that the 3D reconstruction of bone is a key step. Thus, this interobserver study was completed by two authors (second and third authors) using the rule-based protocol suggested by Koo et al. for cartilage reconstruction in MRI scans [31].

In this study, the design used in 2nd generation PSI design improved the rotation stability in the femoral guide and the alignment checker rod function in the tibial guide. The tibia alignment checker rod does not require additional bony exposure at the tibial site. The most important finding of this study was the remarkable difference in surgical and OR times with the use of the PSI guide designs. The number of trays used in the OR was also reduced with the PSI system. Reduced surgical and OR times lead to a considerable difference in cost. During surgery, the surgeons used the patient's anatomy to determine the PSI guide position with the bone model. Once it was fitted to the bony surface, the surgeon drilled the cutting block. This process reduces surgical time using a fit design and a tibial alignment checker rod to allow the surgeon to ensure proper alignment with the proximal tibial cut. Ultimately, the 2nd generation PSI design with an alignment checker rod had significantly shorter surgical times. However, using the PSI design without an alignment checker rod in 1st generation PSI design required alignment confirmation with an extramedullary rod after tibial drilling, which could be the reason for the absence of statistically significant in surgical and OR times in the comparisons with the control group.

Knee alignment results indicated that all of the results from 2nd generation PSI design showed better restoration of the mechanical axis than those from the control group. All of the mechanical axis alignment results in this study were all superior to those reported in previous studies. Victor et al. [19] reported a similar rate of 25%, and Nunley et al. [10] reported a much higher rate, with 37% of patients diagnosed as having malalignment. However, the results for mechanical alignment restoration in 2nd generation PSI design showed improvement compared with results from the previous studies because it prevented to problem caused by intra-operative instability due to the translation and rotation movement in femoral and tibial PSI guides, and it also provided alignment checker rod in tibial PSI guide.

Furthermore, Hommel et al. reported that the novel surgical technique is allowed to lead femoral alignment based on ligament tension in TKA with PSI, which had been verified to be safe in clinical and radiological examinations [32]. In addition, Hommel and Perka reported that

the gap-balancing technique was successfully performed in 25 patients using PSI. The balancer device allows consideration of individual soft-tissue tension and is beneficial to surgeons who prefer the gap-balancing technique [33]. In other words, the post-operative outcome in PSI surgery is mainly dependent on the surgeons surgical experiences and accumulation of know-how. They have already treated 500 cases of TKA with PSI.

In the FRA from the control group 22 outliers were >2°. To date, no technology has been proven effective in reducing positional outliers of the component rotation following TKA. PSI was effective in significantly reducing outliers of optimal rotational femoral component alignment, compared with CI for TKA [34]. In the 2nd generation PSI design, femoral rotation was defined with an anatomical epicondylar axis and it could lead to good post-operative outcomes after drilling owing to the improvement in femoral PSI rotational stability. In addition, Heyse and Tibesku recently reported the improvement of the tibial component rotation in TKA using PSI [35].

This study had some limitations. First, a single experienced surgeon conducted all of the pre-planning. Confusion can be reduced if the planning work is conducted by one surgeon rather than by with multiple surgeons [22]. Considering his previous surgical experience, the results are also not representative of a low volume or inexperienced knee surgeon applying this technology. A future study with multiple surgeons would provide a more comprehensive representation of this technology based on surgeon experience. Second, the present study had a non-randomized design as group allocation was based on patient preference. Third, the study lacks long-term clinical outcomes. Fourth, the estimation of blood loss was inaccurate and it should have been evaluated using the formulas for blood loss calculation reported in the previous studies [36]. Fifth, the difference in tibial rotation between 1st and 2nd generation PSI design was not evaluated. Sixth, although 2nd generation PSI design led to shorten operation time compared to 1st generation PSI design, the number of patients for PSI has been progressively collected, thus the learning curve could have influenced to reduce the operation time in retrospective study. Finally, the comparisons of operating times and medical image measurements were only included to determine cost-utility, but not factor in clinical results or patient satisfaction scores.

In conclusion, this retrospective study measured pre-operative differences between normal and optimum PSIs, and CI in TKA. Significant improvements in surgical times and mechanical alignment restoration were not observed when the normal PSI designs were used in comparison with the CI techniques, but they were all enhanced with the optimum PSI designs. This study emphasized the importance of PSI design in post-operative clinical outcomes. Further studies should be conducted with larger cohorts and longer follow-up periods.

Compliance with ethical standards

Conflict of interest The authors received no funding for this study and report no conflicts of interest.

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