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REVIEW

Patient-specific instrumentation in total knee arthroplasty

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ABSTRACT

Introduction: Total knee arthroplasty (TKA) is one of the most commonly performed orthopedic procedures. During the past decade, patient-specific instrumentation (PSI) has been commercially introduced in order to simplify and make TKA surgery more effective, precise and efficient than conventional mechanical instrumentation (CI) and computer-assisted surgery (CAS). Nevertheless, there are critical arguments against PSI for routine use. The aim of the current manuscript is to describe advantages and limitations of PSI for primary TKA.

Areas covered: By means of a description of the available literature different aspects are discussed (accuracy, clinical and functional outcomes, operative time, blood loss, efficiency and costs).

Expert opinion: Most publications do not claim a significant increase in PSI accuracy over CI, but they also do not postulate PSIs accuracy is worse either. Regarding clinical aspects, PSI did not appear to give any advantage over standard techniques although, equally, it did not appear to show any disadvantages. PSI seems to reduce operative time, could reduce perioperative blood loss and provides logistical benefits in the operation room. Further studies will be required to more thoroughly assess all the advantages and disadvantages of this promising technology as an alternative to CI and CAS.

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Patient-specific instrumentation (PSI); total knee arthroplasty (TKA); total knee replacement (TKR); knee

1. Introduction

Total knee arthroplasty (TKA) is an effective option for patients suffering from disabling knee osteoarthritis and has demonstrated excellent outcomes, with 10 to 15 year implant survivorship rates approaching 95% [1–5]. Infection is the most common failure mechanism for early revision, and aseptic loosening is the most common reason for late revision [6–8]. It has long been suggested that restoration of a neutral mechanical axis improves durability following TKA [9–13]. The understanding of the replaced knees has improved significantly in the last years, and recent studies have reported no significant difference in survivorship among aligned TKA in the traditionally held safe zone of 180º ± 3º and cases outside this zone [14–18]. It had also been reported better or at least not worse clinical and functional outcome scores in those patients considered outliers (e.g. a slight undercorrection following TKA in native varus knees) [19–21]. Despite this, evidence is still insufficient and currently we have as many doubts as certainties [22–24]. We lack a predictive mathematical model among the preoperative alignment and the optimal postoperative alignment. Furthermore, alignment in the coronal plane is only one aspect, and we need to take the component alignment in the sagittal and transverse plane into consideration as well. In addition, this predictive model could become even more complicated if we take into account the dynamic condition of the joint, the movement [25,26]. Surely, in the future, through the integration of Data Mining and Big Data, we will be able to analyze sets of data to identify meaningful relationships, and use these relationships to make better decisions. However, until additional data can be generated to accurately determine the ideal individual postoperative limb alignment, a neutral mechanical axis remains a reasonable target [14]. It has been widely accepted that any malalignment may increase the wear due to off-axis loading, by shear forces or not homogeneous distribution of pressure between the femoral component and the insert and thus compromise the long-term results, regardless of clinical outcomes [21]. The incidence of malalignment with conventional mechanical instrumentation (CI) can be as high as 30% [27,28]. The limited accuracy of CI technique [29,30] has provided an incentive for the development of newer technologies to improve the accuracy of surgery whilst also increasing operative efficiency.

2. Computer-assisted navigation

In order to improve the implant position during TKA, computer-assisted surgery (CAS) was introduced. It has been extensively reported that CAS significantly improves alignment, accuracy and prosthesis positioning, and reduces the number of outliers greater than 3º, as compared to CI TKA [31,32]. CAS allows for a more accurate ligament balancing, component sizing, kinematics evaluation, reduction of blood loss and for a reduction in the incidence of embolic events [33–35]. Nevertheless, several limitations of CAS have been reported such as longer operation times, higher costs, errors on landmark registration, pin loosening and fractures [36]. Additionally, there are still no long-term results available to

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Article highlights

- The limited accuracy of conventional mechanical surgical technique (CI) has provided an incentive for the development of newer technologies to improve the accuracy of surgery whilst also increasing operative efficiency. Computer-assisted surgery (CAS) and patient-specific instrumentation (PSI) were introduced.
- Although the importance of a neutral mechanical axis to the success of TKA has been questioned, a neutral mechanical axis still remains a reasonable target for most surgeons performing TKA. Most publications do not claim a statistically significant increase in PSI accuracy over CI but, in general terms, they do not claim that accuracy with PSI is worse either.
- Regarding clinical aspects, PSI did not appear to give any advantages over standard techniques although, equally, it did not appear to show any disadvantage. PSI seems to reduce operative time, could reduce perioperative blood loss and provides logistical advantages in the operation room.
- Further studies will be required to more thoroughly assess all the advantages and disadvantages of this technology as an alternative to CI and CAS.

draw a conclusion about clinical and functional outcomes, survivorship and cost-effectiveness following CAS [32,37–39].

3. Patient-specific instrumentation

Patient-specific instrumentation (PSI) was developed to streamline the operative process in the day-by-day practice and to increase cutting accuracy. One of the aims of the development of this technology was to take profit from the advantages of CAS and avoid its disadvantages. PSI involves the use of preoperative advanced three-dimensional imaging techniques starting from computed tomography (CT) scan or magnetic resonance imaging (MRI) and full-length standing anteroposterior radiograph images. The 3D models are constructed from the images obtained and predetermined anatomic landmarks are identified. The specific algorithms of each manufacturer are applied in order to determine bony resections, implant position, rotation, and sizes before surgery with the use of an interactive, computer-based planning tool. This preoperative plan is sent to the surgeon for approval, and any appropriate modifications are made. Once the surgeon has confirmed the preoperative plan, the engineers design cutting blocks (devices that allow the surgeon to cut directly through the custom block) or positioning templates (the surgeon uses a standard cutting block based on the pin placement from the patient-specific guides) that fit on the patient's native anatomy, which are manufactured by means of rapid prototyping technology. The jigs are delivered for the surgical procedure. In some cases, they arrive at the hospital sterilized and ready to be opened at the time of surgery. In others, they are sterilized by the hospital before the surgical procedure.

3.1. Surgical technique with PSI

After incision according to the surgical approach, the tibia is exposed and the custom tibial guide is positioned, taking care to remove soft tissue but without altering the osteophytes, because they are necessary for positioning the guide. In cases of guides designed from images by MRI, it is not necessary to remove cartilage in the support areas of the guide. If a CT-scan has been used as an image acquisition system, it is necessary to remove the cartilage from those support areas of the block since the references will be exclusively osseous. With the tibial guide, the surgeon is able to determine tibial alignment, level of bone resection, tibial slope, and rotational placement of the tibial component, eliminating several steps from the conventional procedure. If the PSI system is a pin-positioner type, it will be used to place the pins. Standard cutting block will be placed on them. If it is a cutting block type, once it is placed, the tibial osteotomy will be performed directly through the slot of the cutting block (Figure 1). After tibial preparation, the soft tissue is cleared from the femur. Osteophytes should also not be removed because they help to determine the proper orientation of the cutting guides and favor a stable positioning of the blocks. The guide is placed on the distal femur and secured with pins (Figure 2). With the femoral guide, the surgeon is able to determine femoral alignment, level of bone resection, sagittal alignment, rotational placement and

Figure 1. View of the customized tibial cutting block in place for the proximal tibial resection.

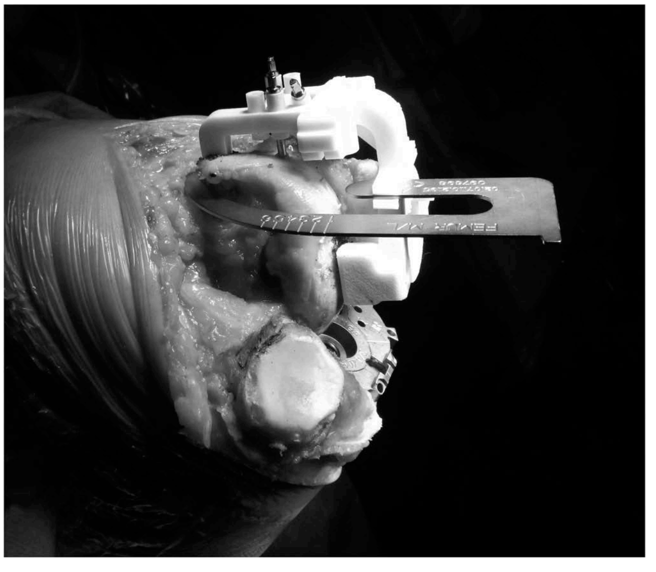

Figure 2. View of the customized femoral cutting block in place for the distal femoral resection.

size of the femoral component, eliminating, as well, several steps from the conventional procedure. The femoral distal osteotomy is performed after marking references for the femoral external rotation, and the remainder femoral resections are performed using the standard cutting guide for the anterior, posterior and chamfer cuts, based on the preoperatively determined size. Cutting blocks or positioning jigs are used only as an aid to the standard technique for component placement and for the bone osteotomies, and do not replace careful and appropriate balancing of the soft tissues [40–43].

3.2. PSI and accuracy

Although the importance of a neutral mechanical axis to the long-term success of TKA has been questioned [14–18,44,45], a neutral mechanical axis still remains a reasonable target for most surgeons performing TKA [14,21]. Several studies, systematic reviews and meta-analysis [46–59] have been published examining the efficacy of PSI in accurately reproducing a neutral mechanical axis. The first publication referring to alignment precision belongs to Klatt et al. [60] and is desolating, as it states that 'the custom cutting jigs have the potential to place the components outside of the accepted range of alignment and even place the limb out of the accepted alignment range'. Subsequently, several studies were published on this topic. We will confine the description on this issue to randomized controlled trials (RCTs) with a minimum score of 4 in the Jadad Rating Scale. Boonen and colleagues [61,62] evaluated in a prospective, double-blind, controlled trial 180 patients randomized for PSI or conventional TKA. There was no statistically significant difference in mean mechanical axis or percentage of outliers in mechanical axis between groups. No statistically significant difference was found for the alignment of the individual components in the frontal plane, nor for the percentages of outliers. The authors concluded that the results in terms of obtaining a neutral mechanical axis and a correct position of the prosthesis components did not differ between groups. Chareancholvanich et al. [63] compared the accuracy of limb alignment and component positioning after TKA performed using PSI or CI. No significant difference was observed between the groups in terms of tibio-femoral angle or femoral component alignment. Their study showed that both PSI and CI restore limb alignment and locate the components with similar accuracy. Hamilton et al. [64] did not find a significant difference (p 0.77) in mechanical alignment between PSI and CI on postoperative long axis X-rays. Parratte et al. [65] hypothesized that PSI can improve the accuracy of the rotational alignment in TKA. The position of the implants was compared in two groups of 40 patients on standard radiographs, and the rotational position was analyzed on post-operative CT-scan. Mean HKA was 179° in the PSI group with four outliers and 178.3° with two outliers in the control group. No difference was observed between the two groups concerning the frontal and sagittal position of the implants on the radiographs. Mean tibial rotation was 8° of internal rotation in the PSI group and 15° of internal rotation in the standard group (not significant). Roh and colleagues [66] evaluated the accuracy of PSI TKA by comparing the incidence of outliers in postoperative alignment among PSI (50 cases) and CI (50 cases). Outliers in the HKA angle were comparable between groups (12% in the PSI group and 10% in the CI group). Other parameters such as sagittal alignment and femoral component rotation did not differ in terms of outliers. So the authors concluded that accuracy was comparable between PSI and CI. Vundelinckx et al. [67] compared 31 patients, operated with PSI, to an equal control group for different radiographic outcome parameters. Between both groups, no statistical significant difference could be found in radiographic alignment and precision of bone cuts. Kotela et al. [68,69] compared radiological results of TKA performed with PSI CT-based instrumentation (52 cases) and CI (60 cases). They did not obtain statistically significant differences between groups with respect to coronal and sagittal component positioning and overall coronal alignment, except for frontal tibial component positioning. For this parameter, better results were obtained in the control group, with borderline statistical significance. Their study did not reveal superiority of the CT-based PSI system over CI. Silva et al. [70] compared the femoral and tibial components rotational alignment in TKA performed either with CI or with PSI. The femoral component rotation was 0.0° (−0.25, 1.0) in CI group, and 0.0° (0.0, 1.0) in PSI group. The tibial component rotation was −16.0° (−18.5, 11.8) in CI group, and −16.0° (−19.0, −14.0) in PSI group. There were no significant differences between the two groups in tibial and femoral components rotation and a smaller chance of internal malrotation of the tibial component with the PSI system used. Victor et al. [71] compared three-planar component alignment and overall coronal mechanical alignment between PSI and CI (both groups with 64 patients). In his study, the PSI and CI cohorts showed similar numbers of outliers in overall coronal alignment (25% vs 28%; $p = 0.69$), femoral coronal alignment (7% vs 14%; $p = 0.24$) and femoral axial alignment (23% vs 17%; $p = 0.50$). There were more outliers in tibial coronal (15% vs 3%; $p = 0.03$) and sagittal (21% vs 3%; $p = 0.002$) alignment in the PSI group than in the CI group. Woolson and colleagues [72] report the results of a RCT in which CT-scans were used to compare postoperative component alignment between patients treated with PSI and those managed with CI. A detailed analysis of intent-to-treat and per-protocol groups of study and control knees did not show any significant improvement in component alignment, including femoral component rotation in the axial plane, in the patients treated with PSI. Abane et al. [73] published after a multicentre randomized controlled trial a mean HKA angle of 178.9° (172.5 to 183.4°) in the CI group and 178.2° (172.4 to 183.4°) in the PSI group ($p = 0.34$). In this study, outliers were identified in 22 of 67 knees (32.8%) in the CI group and 19 of 59 knees (32.2%) in the PSI group ($p = 0.99$). The authors concluded that the use of PSI in primary TKA did not reduce the proportion of outliers as measured by postoperative coronal alignment. Gan et al. [74] compared component alignment evaluated using CT-scan and radiographs among PSI and CI (both groups with 35 patients). Overall, the PSI method showed a high degree of accuracy. Yan and colleagues [75] randomized in 1:1:1 ratio into CI, CAS and PSI groups to receive TKA. In this study, CI and PSI were more likely to result in an excessively flexed femoral component ($p = 0.001$) compared to CAS. Number of outliers in postoperative alignment and components positions in the coronal and sagittal plane showed no statistically significant difference. Huijbregts et al. [76] conducted a RCT to assess the accuracy of positioning and alignment of the components in TKA, comparing those undertaken using CI (64 cases) and those with PSI (69 cases). In this paper there were 22% HKA-angle outliers in the CI group and 13% in the PSI group ($p = 0.251$), so the authors concluded that the accuracy of alignment, and the proportion of outliers was not different in the two groups. De Vloo et al. [77] assessed the accuracy of 3D component placement in TKA with PSI compared to CI using virtual 3D bone models. Postoperative CT images were converted to 3D models and aligned to the planned, preoperative models and implant orientation. In this study, PSI allowed significantly more accurate varus/valgus placement for the femoral component ($p < 0.05$), but more slope was introduced ($p < 0.05$). Less variability in positioning accuracy for femoral flexion angle and tibial rotation was found with PSI, indicating a result closer to the planned position, but no significant differences in positioning accuracy were found. Vide et al. [78] analyzed 95 of 100 randomized patients eligible for TKA. PSI was performed in 47 patients, while 48 patients received CI. CI had a higher number of outliers in the coronal alignment with a relative risk of 3.015, compared to PSI. Kosse and colleagues [79] examined the alignment after TKA using PSI and CI. No significant differences were found between the two groups regarding HKA angle and rotational alignment. Maus et al. [80] implemented a multicenter RCT with 59 patients in the PSI group and 66 in the CI group. The absolute number of outliers outside the ± 3º target neutral mechanical leg alignment was compared between the groups with a Chi-square test and the authors concluded that the use of PSI did not significantly reduce the number of outliers in comparison with CI. Van Leeuwen et al. [81] compared radiological alignment among TKA performed with the use of PSI and CI. A statistically significant difference was found for the frontal femoral and tibial component angles and for the tibial alignment in the sagittal plane. The proportions of outliers were similar between the groups as well as the HKA angle. Details of the studies dealing with precision are displayed in Table 1.

Several meta-analyses [46–59] have been published that examine the accuracy of the PSI to reproduce a neutral mechanical axis. Russell et al. [53] published after an analysis of seven studies evaluating 559 patients undergoing TKA that PSI does not significantly improve the postoperative mechanical alignment of the limb and does not decrease the number of outliers compared with CI. Thienpont et al. [57] concluded that PSI does not improve the accuracy of alignment of the components in TKA compared with CI, after an analysis of 16 studies that fulfilled the eligibility criteria. Voleti and colleagues [59] stated that PSI demonstrated improved accuracy in femoro-tibial angle, while standard instrumentation demonstrated improved accuracy in HKA angle regarding to coronal alignment, with no differences between treatment groups in the percentages of outliers and in the sagittal alignment. Cavaignac et al. [47] found no evidence of PSI superior accuracy during TKA after an analysis of 15 articles (916 TKA cases in the PSI group and 998 in the CI group). Fu and colleagues [48] reviewed 10 RCTs involving 837 knees comparing outcomes of PSI TKAs with CI TKAs and concluded that PSI appeared not to be superior to CI in terms of the postoperative mechanical axis of the limb or femoral component placement and for the tibial component outliers in the coronal plane occurred at a higher frequency in the PSI group. Mannan et al. [51] stated that PSI does not confer increased accuracy in reconstituting the postoperative mechanical axis in the aftermath of an analysis of 26 studies, reporting a total of 1792 knees. Sharareh et al. [55] reported no significant difference among PSI and CI in terms of postoperative coronal alignment in its review of 12 studies comparing PSI with CI. Shen et al. [56] stated that the use of PSI compared with CI was not likely to improve the accuracy of component alignment of TKA. Huijbregts et al. [50] analyzed 21 RCTs involving 1587 TKAs. PSI resulted in slightly more accurate HKA angle, coronal

Table 1. Accuracy in the coronal plane: conventional instrumentation (CI) versus patient-specific instrumentation (PSI). CAS: computer-assisted surgery. CT: computed tomography. MRI: magnetic resonance imaging. LLR: full-leg standing radiographs. Signature® Biomet, Inc., Warsaw, IN, USA. Zimmer® Patient Specific Instrumentation (PSI), Zimmer, Warsaw, IN, USA. TruMatch® DePuy Orthopaedics, Warsaw, IN, USA. Visionaire Smith & Nephew, Memphis, TN, USA. Stryker, Mahwah, NJ, USA. Imprint® Aesculap, Tuttlingen, Germany. SD: standard deviation. n.s: not significant. * intention-to-treat. ** CAS.

		Valid cases				Percentage of outliers > 3º (%)		
	Initial n (CI/PSI)	CI	PSI	Imaging techniques	PSI system	CI	PSI	p value
Boonen et al., [61]	180 (90/90)	82	86	MRI	Signature	18	30	n.s
Chareancholvanich et al., [63]	80 (40/40)	40	40	MRI	Zimmer PSI	7.5	2.5	n.s
Hamilton et al., [64]	52 (26/26)	26	26	CT	Trumatch	31	35	n.s
Parratte et al., [65]	40 (20/20)	20	20	MRI	Zimmer PSI	10	20	n.s
Roh et al., [66]	100 (50/50)	48	42	CT	Signature	10	12	n.s
Kotela A. and Kotela I., [68]	112 (60/52)	46	49	CT	Signature	30	49	n.s
Victor et al., [71]	128 (64/64)	64	61	MRI CT MRI + LLR MRI	Signature Trumatch Visionaire Zimmer PSI	28	25	n.s
Woolson et al., [72]	60 (30/30)	26	22*	CT	Trumatch	38	41	n.s
Abane et al., [73]	140 (70/70)	67	59	MRI + LLR	Visionaire	32	33	n.s
Gan et al., [74]	70 (35/35)	35	35	CT	Stryker	23	3	< 0.001
Yan et al., [75]	90 (30/30/30**)	30	30	MRI	Zimmer PSI	43	27	n.s
Huijbregts et al., [76]	140 (65/75)	64	69	MRI + LLR	Visionaire	22	13	n.s
Vide et al., [78]	100 (50/50)	48	47	MRI + LLR	Visionaire	35	13	0.011
Maus et al., [80]	157 (78/79)	66	59	MRI	Imprint	12	26	0.04
Van Leeuwen et al., [81]	94 (50/44)	49	42	MRI	Signature	22	26	n.s

femoral alignment, tibial slope, and femoral component rotation. No significance was found for other radiographic measures. They, therefore, concluded that PSI does not result in a clinically meaningful improvement in alignment. Mannan and colleagues [52] performed a systematic review and meta-analysis of all relevant literature between 2000 and 2014 and demonstrated favorable femoral rotational alignment outcomes in PSI TKA. Alcelik et al. [46] suggested that PSI is not superior to CI in primary TKA. Thienpont et al. [58] conducted a meta-analysis in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement assessing a total of 44 studies, which included 2866 knees that underwent surgery with PSI and 2956 knees that underwent surgery with CI. They concluded that PSI improves the accuracy of femoral component alignment and global mechanical alignment, but at the cost of an increased risk of outliers for the tibial component alignment. Finally, Gong and colleagues [49] analyzed a total of 23 RCTs involving 2058 knees. For these authors, PSI has advantages in axial alignment of the femoral component but they did not find any differences between PSI and CI with respect to any other parameter. Several limitations should be outlined in the published meta-analysis, since they combine accuracy outcomes from different PSI systems. There are differences depending on whether the image is acquired with MRI or CT-scan [49,82–88], on the software used for the planning phase, on whether a pin-positioner or a cutting block is designed. Therefore, the individual surgical technique as well as the specific PSI technique from one certain manufacturer may not be representative for all different custom-fit technologies available. In an own retrospective unpublished study of 243 TKAs performed by the same surgeon (72 cases operated with CI, 68 cases with CAS (iMNS system – Medacta Navigation System) and 103 cases operated employing PSI (MyKnee® system, Medacta International SA, Castel San Pietro, Switzerland) we obtained a postoperative alignment (HKA angle) in the range of 180º ± 3º of 73.4% with CI, 90.2% with CAS and 88.6% with PSI (with a mean out-of-range deviation of 1.98º ± 1.73º, for the PSI cases). Our coronal alignment with PSI is comparable to other authors, using the same PSI system (Koch et al. 87.6% [89], Anderl et al. 90.4% [90] and Helmy et al. 81.4% [91]).

Most publications do not claim a statistically significant increase in PSI accuracy over CI. But, in general terms, they do not claim that accuracy with PSI is worse either. Overall, studies describing better component positioning, particularly in the sagittal plane and less outliers in the mechanical axis prevail. The trend is changing and from the first pessimistic articles with the precision of PSI we are shifting to the publication of more favorable results. Another advantageous aspect to consider regarding PSI or CAS versus CI (i.e. CI will not achieve the exact perpendicularity to the femoral sagittal mechanical axis) is the flexibility to adapt to the surgeon's preferences regarding the different alignment philosophies (mechanical, anatomical, kinematic, adjusted mechanical or restricted kinematic alignments).

3.3. PSI and clinical and functional outcomes

A few systematic reviews and meta-analyses [50,92–94] have assessed clinical and functional results evaluated through different Patient Reported Outcome Measures (PROMs) such as Knee Society, Oxford Knee, WOMAC, KOOS, UCLA activity or SF-12 scores. In some works, postoperative range of motion (ROM) or Visual Analogue Scale score for pain (VAS) has been taken into account. Details of the systematic reviews and meta-analyses concerning clinical and functional outcomes are shown in Table 2.

Goyal and colleagues [92] included five RCTs [67,69,75,95,96] involving 379 TKA in its meta-analysis. No significant improvement in short-term functional outcomes was seen after using PSI compared to the control in terms of PROMs or VAS. However, the authors concluded that current literature is insufficient to address whether there is a benefit of PSI in TKA in terms of improvement in functional outcomes. Huijbregts et al. [50] analyzed randomized and quasi-randomized controlled trials (RCTs) comparing PSI and CI in TKA. From the analysis of those concerning clinical or functional outcomes [67,72,75,76,95,97], the authors concluded that

Table 2. Clinical and functional outcomes: Conventional instrumentation (CI) versus patient-specific instrumentation (PSI). KSKS: Knee Society Knee Score. KSFS: Knee Society Function Score. KSS 2011: new version of the Knee Society Score. KOOS: Knee injury and Osteoarthritis Outcome Score. OKS: Oxford Knee Score. SF-12: Short Form 12 Health Survey. WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index. VAS: Visual Analogue (for pain) Scale. ROM: range of movement.

	Included studies	Functional scores analyzed	Differences among CI and PSI
Goyal et al., [92]	5 [67,69,75,95,96]	KSKS	n.s
		KSFS	n.s
		WOMAC	n.s
		OKS	n.s
		KOOS	n.s
		VAS	n.s
Huijbregts et al., [50]	6 [67,72,75,76,95,97]	KSKS	n.s
		KSFS	n.s
		OKS	n.s
		KSS 2011	n.s
		KOOS	n.s
		SF-12	n.s
Mannan et al., [93]	8 [69,72,73,75,85,90,98,99]	KSKS	n.s
		KSFS	n.s
		ROM	n.s
		OKS	n.s
		WOMAC	n.s
Woon et al., [94]	4 [96,100–102]	WOMAC	n.s
		KSKS	n.s
		KSFS	n.s

PSI does not result in a clinically meaningful improvement in early PROMs. Mannan et al. [93] searched levels 1 [72,73,75,85] and 2 [69,90,98,99] studies comparing functional outcomes of PSI versus CI. In their systematic review and meta-analysis, no conclusive evidence for or against PSI was demonstrated when considering short-term functional outcomes. Woon and colleagues [94] recently published a collaborative study that combined raw data from RCTs [96,100–102], with the aim of comparing functional outcomes among kinematic alignment using PSI and traditional neutral mechanical alignment using CI, and whether any subgroup of patients may benefit more from the kinematic alignment. The authors concluded that PROMs following TKA using PSI kinematic alignment are similar to mechanical alignment using CI. No identifiable subgroups benefited more from kinematic alignment, and long-term results remain unknown. Other articles not reviewed in the previous publications [50,92–94] are, for instance, the papers of Zhu et al. [103] which states that no significant clinical benefit could be demonstrated in using PSI over CI after 24 months, and routine use of PSI is not recommended in non-complicated TKA. Stone et al. [104] retrospectively reviewed a total of 85 PSI procedures, and these were compared with a matched cohort of 85 TKAs using CI with the conclusion that functional outcomes are equivalent for both groups. Finally, Nam and colleagues [105] reported in a retrospective study clinical outcomes at 2 years follow-up as measured by UCLA activity, SF-12, and Oxford knee scores among 95 patients operated with PSI and 95 patients operated with CI. They did not obtain significant differences between the two cohorts for ROM and for PROMs.

There is, therefore, enough agreement among the published studies to affirm that there is no difference in clinical and functional results in the short and mid-term between patients operated with PSI and those operated with CI. PSI did not appear to give any clinical advantages over standard techniques although, equally, it did not appear to show any disadvantages. Possibly the type of instrumentation used to perform TKA surgery does not influence the early clinical outcome, and this parameter is more a reflection of clinical conditions (e.g. worse preoperative PROMs, worse mental well-being, body mass index greater than 35 kg/m^2, worse preoperative ROM, higher American Society of Anesthesiologists grade, presence of comorbidities and history of previous knee surgery) than a direct result of the surgical technology used. Articles reviewing clinical outcomes when CAS is used, also point in this direction [32,37–39].

3.4. PSI and operative time

Each type of instrumentation (CI, CAS or PSI) involves a different sequence of surgical steps, so that the intervention can be more or less prolonged. PSI should reduce the operative time due to simplification of the operative procedures. Details of the systematic reviews and meta-analyses including operative time are presented in Table 3.

Voleti and colleagues [59] affirm after carrying out a systematic query that operative time was not significantly reduced in the PSI group (193 knees) compared to the standard instrumentation group (192 knees) ($p = 0.1$). In the article by Fu et al. [48], among the seven studies that reported results on surgical time [61,63,64,95,106–108], five reported that the operative time was significantly shorter for the PSI group than for the CI group [61,63,95,106,108]. The studies from Hamilton et al. [64] and Ng et al. [107] reached the opposite conclusion. The meta-analysis conducted by Fu et al. [48] showed that the duration was significantly longer in the CI group than in the PSI group ($p < 0.00001$). Sharareh and colleagues [55] reviewed five studies [64,109–112] comparing PSI with CI for TKA and concluded no significant difference in terms of operation time. Shen et al. [56] conducted a meta-analysis to compare the performance of PSI to CI in TKA. Regarding operative time, data from seven studies [61,64,106,110,113–115] could be pooled. Meta-analysis showed no significant difference between PSI and CI ($p = 0.19$). In the article by Huijbregts et al. [50] data for total operation time of 12 papers [61,63,64,66,72,75,76,95,106–108,113] could be pooled. Using a random-effects model, total operation time was not shorter in the PSI group. Tourniquet time [75,107,116] was scarcely shorter for PSI. For the analysis of operative time, Thienpont et al. [58] pooled data from 26 studies [61,63,64,66,72,73,75,78,95,99,103,106,108–112,114,115,117–123] with a total of 3480 knees. The difference in mean total operative time favored PSI ($p = 0.002$), but with substantial heterogeneity among studies ($I^2 = 93.5\%$). For tourniquet time, nine studies with 1313 knees were pooled [69,75,111,114–116,120,121,124]. No significant difference was found ($p = 0.597$). Based on the results, by the most recently published analysis of nine papers of Gong and colleagues [49,61,63,72,74–76,78,80,95], PSI reduced operative time by a mean of 7 min compared with CI ($p < 0.0001$, $I^2 = 78\%$). Our own experience (article in press), a retrospective analysis with assessment of the skin-to-skin and tourniquet time of 243 TKAs performed by the same surgeon (72 CI, 68 CAS and 103 PSI) revealed a significant difference between PSI and the other instrumentation systems (CI 87.85 ± 11.86 min, CAS 123.46 ± 11.27 min and PSI 78.69 ± 13.06 min; $p = 0.000$).

3.5. PSI and blood loss

Estimates of average blood loss after TKA have reached as high as 1500 ml [122]. Postoperative anemia has been linked with medical complications, and there are also risks associated with transfusion. The femoral and tibial intramedullary canal, breached in the CI in order to allow passage of an intramedullary rod, is sources of bleeding during TKA. PSI is hypothesized to decrease perioperative blood loss. Voleti et al. [59]

Table 3. Operative time: conventional instrumentation (CI) versus patient-specific instrumentation (PSI). n.s: not significant.

	Included studies	Operative time	*p* Value
Fu et al., [48]	7 [61,63,64,95,106–108]	CI 3.51 min > PSI	<0.00001
Sharareh et al., [55]	5 [64,109–112]	CI 2.2 min > PSI	n.s
Shen et al., [56]	7 [61,64,106,110,113–115]	CI ≈ PSI	n.s
Huijbregts et al. [50]	12 [61,63,64,66,72,75,76,95,106–108,113]	CI 1.25 min > PSI	n.s
Thienpont et al., [58]	26 [61,63,64,66,72,73,75,78,95,99,103,106,108–112,114,115,117–123]	CI 4.4 min > PSI	0.002
Gong et al., [49]	9 [61,63,72,74–76,78,80,95]	CI 7 min > PSI	<0.00001

asserted that blood loss was similar between treatment groups. The mean intraoperative blood loss was 371 mL for the PSI group vs 384 mL for the CI group (p 0.2). The percentage of patients requiring blood transfusion was 10.1% for the PSI group and 14.1% for the CI group ($p = 0.1$). In the article by Fu et al. [48], among the five studies that reported results on blood loss [61,63,95,106,108], two reported that there was significantly less blood loss in the PSI group than in the CI group [61,95]. The remaining studies reported no significant difference. Four studies revised by Shen et al. [56] could not pool data for mean differences in mean total blood loss because only means were reported in the revised studies [61,63,66,106]. According to the article by Shen and colleagues [56], Boonen et al. [61] reported that blood loss was significantly less in the PSI group than in the CI group. However, the other three studies [63,66,106] detected no difference between the groups. Huijbregts and colleagues [50] divided blood loss in intraoperative blood loss, blood loss by 48-hour drain and hemoglobin loss on day 3 of the analyzed studies [61,63,67,95,108,116]. Using random-effects models, total blood loss was reduced by 44 mL and intraoperative blood loss by 68 mL for PSI. 48-hour drain production was reduced by 194 mL in the PSI group. Hemoglobin loss was similar in both groups. Blood transfusion risk ratio was 0.71 for PSI. Thienpont et al. [58] pooled data from 12 studies [63,69,95,106,108,109,116–118,120,122,124] for blood loss analysis. PSI was associated with a slight reduction in blood loss with a difference between means of −37.9 mL ($p = 0.015$), but there was substantial heterogeneity among studies (I^2 = 91.2%). PSI was also associated with a lower relative risk of transfusion (0.61; p 0.004). After the analysis of five RCTs [63,69,74,80,95], Gong et al. [49] concluded that PSI could reduce the perioperative blood loss by approximately 90 mL compared to CI because PSI avoids invasion of the femoral medullary cavity and shortens the operative time. Other published studies have reported analogous outcomes [125–127]. In our own experience in a retrospective cohort study [125], PSI reduces blood loss and the risk of transfusion when compared to both CAS and CI TKA performed with use of a tourniquet. The calculated total blood loss was significantly different among groups with values of 442 ± 160, 750 ± 375 and 700 ± 401 mL for PSI, CAS, and CI, respectively ($p < 0.001$).

3.6. *PSI: efficiency and costs*

One of the claimed benefits of PSI is an increase in efficiency and thereby a decrease in costs; however, published reports have so far shown mixed results. Voleti et al. [59] wanted to perform in their systematic review and meta-analysis of the evidence comparing CI to PSI for TKA an analysis of perioperative cost, but they claim that only one study presented data regarding perioperative cost [128]. That study reported a total savings of $322 per case with PSI versus CI as a result of decreased operative time and sterilization time with PSI. However, once the cost of generating the custom cutting guide and the cost of the preoperative MRI were taken into account, it was determined that PSI was more expensive than CI. Fu et al. [48] analyzed the duration of the hospital stay published in four articles [61,63,107,108]. Ng et al. [107] and Noble et al. [108] and reported a significantly shorter hospital stay for the PSI group. But in the article from Fu et al. [48] emphasis is placed in the complexity of comparing the duration of hospital stay among studies because this parameter is more a reflection of medical or economic conditions than a direct result of the surgical technology used and therefore, a straightforward comparison is neither possible nor beneficial. Only two publications [61,63] are referred to in the article by Shen and colleagues [56]. Neither study reported significant differences between the CI and the PSI groups. According to the meta-analysis by Huijbregts et al. [50] hospital stay was approximately 8 h (95% CI: 3.1–12.5) shorter in the PSI group (507 TKAs, I^2 = 47%) [61,63,67,72,107,108,116] and 2 pooled studies [64,108] involving 81 TKAs (I^2 = 89%) had a reduction of 4 surgical trays sterilized (95% CI: 2.48–5.61) in the PSI group. So Huijbregts et al. [50] concluded that efficiency is improved. Gong et al. [49] refer to seven studies [61,63,67,69,72,78,80] that reported the length of hospital stay as the mean and standard deviation. For the authors [49] no significant differences were observed between PSI and CI with respect to the length of hospital stay ($p = 0.29$, I2 = 19%). In a recent multicenter randomized prospective study [81] not included in the aforementioned meta-analyses, no statistically significant differences were found for the length of stay between the groups. In studies without the characteristics of RCTs, length of hospital stay, efficiency and cost are also reflected upon. Boonen et al. [61], Abane et al. [73] and Klasan et al. [129] postulate that the duration of hospital stay was not significantly reduced. Nunley et al. [111] performed a patient cohort study of 2 groups of 57 matched patients who underwent TKA using either CI or PSI. The PSI group used four trays less per surgery and the technique removed 5 to 6 steps per procedure. Overall, the tourniquet time was 5 min faster with PSI, and the overall time in the operating room was 12 min faster. After the determination of all these parameters the overall estimated cost savings per PSI case were only $291. Nunley et al. [111] concluded that this did not outweigh the costs of the blocks and extra imaging and therefore may not be cost-effective. Duffy [130] stated that the use of PSI in his practice led to a decrease in operative time, and an increase in the turnover and overall number of procedures he was able to perform in one day. At Lionberger et al. [131] institution, the PSI cases were 1.45 times more profitable than CAS and the use of PSI allowed for one additional surgery to be performed per day compared with the CAS group.

Regarding the economic aspect, Watters et al. [132] published a comparison of costs and efficiency among CI, CAS, and PSI, from the health care provider perspective. They stated that on a cost-per-case basis, PSI TKA is more costly than CI technique but less costly than CAS. In the opposite direction, Tibesku et al. [133] applied an Activity Based Costing (ABC) model and determined that TKA with PSI is economically effective, provided that the time savings are effectively used to perform additional procedures. Slover et al. [134] used a Markov decision model to analyze the cost-effectiveness of routine use of PSI. Given the increased costs associated with advanced imaging and fabrication of the custom jigs, they concluded that this technology would not be cost-effective unless it decreased revision rate over time and postulated that longer term follow-up is needed to see whether this becomes true in the future.

In general terms, there is an inverse relationship between efficiency and cost, since an increase in efficiency results in an overall decrease in costs or an increase in productivity. Some studies point in the direction of increased efficiency of PSI [107,108,111,130,131] but the literature to support its cost-effectiveness is lacking. In our experience, PSI creates efficiency by reducing the time it takes to perform the surgery, simplifying the workflow, reducing the number of required instrument trays and contributing to decrease the volume of tibial and femoral implant stock required in the operating room, by anticipating sizes needed for the procedure. We believe that PSI would be cost-effective if applied in the setting of routine day-to-day use. Prospective studies methodologically designed to demonstrate this hypothesis will be needed.

3.7. PSI: better CT-scan or MRI?

Controversy exists regarding the differences in outcomes among MRI- and CT-based PSI for TKA. The first publication to compare the accuracy of MRI and CT imaging for the manufacture of PSI for TKA was developed in an experimental sheep model by White et al. [83] from the University of Leeds. The authors argued that bone models generated from MRI-scans were dimensionally less accurate than those generated from CT-scans. Furthermore, the bone models generated from MRI-scans were visibly inferior to those generated from the CT-scans. Only three meta-analyses [54,82,88] refer to comparative studies between MRI- and CT-based PSI. An et al. [82] extracted data from the text, tables, and figures of seven studies [70,84,136–138] and concluded that MRI-based PSI produced a lower proportion of outliers in the overall coronal alignment of the limb compared to CT-scan modalities. However, there was no difference between the two in terms of femoral and tibial components placement in the sagittal and coronal planes, and in terms of the axial rotation of the femoral component. Wu and colleagues [88] compared six studies [84–87,136,138] with a total of 336 knees meeting the eligibility criteria, and four trials [84–86,136] were included in the final meta-analysis. The authors [88] suggested that MRI-based PSI systems are associated with lower incidence of outliers of coronal overall limb alignment, and smaller angular errors of coronal overall limb alignment as compared to CT-based PSI systems. Schotanus and colleagues [54] performed a systematic literature review and meta-analysis studying the differences in alignment outliers between CT- and MRI-based PSI for TKA. Twelve RCTs, studying 841 knees, were eligible for data extraction and meta-analysis. These studies on PSI TKA consisted of six CT-based [64,66,68,72,85,106] and six MRI-based [61,63,65,75,116,139] PSI TKA groups in which PSI was compared to conventional instrumentation. The most important finding of the study by Schotanus et al. [54] was that alignment with MRI-based PSI is at least as good as, if not better than, that with CT-based PSI. Up to date, only three studies have compared MRI- and CT-scan modalities for the production of PSI from the same manufacturer [86,87,137]. Frye et al. [137] found a significantly higher number of outliers for the HKA angle when CT-based PSI was used, with the Signature™ system (Biomet, Inc., Warsaw, IN, USA). Silva et al. [87] concluded that MRI may be more accurate than CT using the Signature™ system when planning the surgical guides for TKA, with fewer patients with malrotation of the tibial component. Schotanus et al. [86] carried out a prospective, randomized, controlled noninferiority trial in 137 patients (67 in the MRI- and 70 in the CT-based PSI group) also with the Signature™ system and concluded that the postoperative HKA angle was comparable in the MRI- and CT-based PSI groups, but there were significantly more outliers for the posterior slope in the CT-based PSI group. Three studies have compared CT-based to MRI-based PSI systems from different manufacturers [71,85,137]. Victor et al. [71] compared three-planar component alignment and overall coronal mechanical alignment between PSI (61 cases) and CI (64 cases). Four subgroups were established in the PSI group. In subgroup 1, Signature® (Biomet Inc, Warsaw,IN, USA) MRI-based PSI was used. In subgroup 2, TruMatch® (DePuy Inc, Warsaw, IN, USA) CT-based PSI was used. In subgroup 3, Visionaire® (Smith & Nephew Inc, Memphis, TN, USA) MRI/RX-ray-based PSI was used. And in subgroup 4, Patient-Specific Instruments® (PSI) (Zimmer Inc, Warsaw, IN, USA) MRI-based PSI was used. No significant differences were noted in deviation from target alignment among subgroups 1 to 4, except for sagittal alignment of the femoral component, which was significantly better for subgroup 3 ($p = 0.02$). Pfitzner and colleagues [85] compared the accuracy of MRI/X-ray-based (Visionaire®), CT-based (TruMatch®) PSI and CI in TKAs. The comparison between PSI groups for alignment showed only small and not significant differences. The authors found a reduction in surgery duration of in the MRI-based PSI group compared with the CT-based PSI group. Finally, Ensini et al. [136] compare the accuracy of a CT-based system (MyKnee®, Medacta International SA, Castel San Pietro, Switzerland) versus a MRI/X-ray-based system (Visionaire®, Smith & Nephew Inc, Memphis, TN, USA) both intraoperatively for bone preparation and postoperatively for final component alignment. The authors [136] concluded that both PSI systems showed good alignments in the coronal plane in all stages. For sagittal alignment, a better performance was observed in the MRI/X-ray-based system than in the CT-based system.

The different published studies have not sufficiently clarified the controversy between CT-based and MRI-based PSI systems. It will be necessary to extend studies that take into account accuracy (both intraoperative and postoperative), direct and indirect costs and cost-benefit ratio, surgical time consumption, requested effective radiation dose, et cetera.

4. Expert opinion: PSI, an option for the future?

The value of any new medical technology depends on its potential to improve clinical outcomes with respect to technologies already established. Any new technology must be evaluated in terms of efficacy, effectiveness, utility, and benefit and must demonstrate either increased efficacy compared to existing technology or equivalent outcomes with reduced cost. However, new technologies also provide practical advantages that can be difficult to objectify. PSI offers numerous theoretical advantages that make it an attractive alternative both to CI and CAS for TKA surgery.

In general terms, most publications do not claim that outcomes with PSI are either better or worse than with other technologies. In our experience, we have achieved better outcomes than with CI and similar to those obtained with CAS in terms of alignment, with noticeable less time consumption and less bleeding. PSI has been especially useful in bilateral surgery in a single time from the point of view of operating room efficiency.

Another advantage that PSI offers is the possibility of planning before surgery with a computer-aided design virtual 3D model. This allows the optimization of decisions not only in the coronal plane, but also in the sagittal and transverse planes, the familiarization with each knee individually (the absolute customization of each TKA) and the reduction of the unexpected during surgery. This added value is a practical utility that cannot be demonstrated through RCTs.

It is obvious that PSI is especially useful in complex cases (extra-articular deformities, presence of hardware, complex distal femur or tibial plateau fractures healed with a malalignment or severe tibial and femoral bone loss). These cases present a considerable difficulty for preoperative planning and some intra-operative technical difficulties can occur, such as the use of intra-medullar rods. In these selected cases PSI can be of considerable usefulness.

What is the future and applicability of this technology? There is no clear answer and the body of literature remains limited. Further studies, especially in the form of unbiased RCTs, will be required to more thoroughly assess all the advantages and disadvantages of this technology. It will also be necessary to clearly establish what type of Orthopaedic Surgery Departments and Surgeons can benefit most from this technology. Further work is needed to define more clearly the role of PSI in TKA for low- and high-volume surgeons. In addition, studies with long-term follow-up and larger sample sizes will be necessary to determine whether the proposed benefits of improved radiographic alignment accuracy and decreased outliers will lead to improved clinical and functional outcomes, increased patient satisfaction, increased implant survival, and decreased revision rate. One of the postulated advantages of PSI is the reduction of surgical time and overall process costs. Although most studies describe a reduction in operating time, a reduction in the number of instruments and trays used, and faster turnover of the operation room, the cost-effectiveness of this procedure has not yet been demonstrated. This may be because the overall cost reduction can be outweighed by the costs of preoperative imaging and template fabrication. However, this factor varies considerably from country to country. On the other hand, we must not forget that an increase in the operating room efficiency and therefore in the volume of surgeries per session can offset the increased cost of preoperative imaging and template manufacture. Perhaps efficiency and cost-effectiveness will increase with a complete set of disposable instruments that would include cutting blocks, trials, and polyethylene inserts for each case providing significant logistical benefits, but the potential financial advantages of single-use instrumentation in primary TKA will require further investigation as no favorable cost-effectiveness has been demonstrated to date [140].

Surely, the future of PSI is to increase its usefulness in combination with single-use instruments by improving surgeon's workflow in the operating room or sensor-assisted or portable accelerometer-based surgical navigation systems to determine during surgery dynamically throughout the range of motion the balance of the knee by means of quantified load data or ligament elongations data which allow individualized dynamic modeling of the knee. In addition, the indication for the use of PSI will surely be extended to revision surgery of unicompartmental knee prosthesis and TKA.

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