

Review Article

Patient-Specific Instrumentation in Total Knee Arthroplasty: Alignment Accuracy and Clinical Scores

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Abstract

Background: Patient-specific instrumentation (PSI) uses preoperative CT or MRI to manufacture single-use cutting guides for total knee arthroplasty (TKA), promising more accurate alignment and lower instrumentation burden than conventional technique.

Objective: To synthesise comparative evidence on PSI accuracy, efficiency, cost, and outcomes relative to conventional instrumentation and navigated/robotic TKA.

Methods: Narrative review of randomised trials, comparative series, and systematic reviews/meta-analyses.

Findings: Individual series report fewer coronal outliers with PSI (9-13% versus 22-29% for conventional), but pooled meta-analyses find no significant difference in outliers, operative time, blood loss, or Oxford/WOMAC/KSS scores; navigation and robotics achieve more consistent alignment than PSI.

Conclusions: PSI offers workflow convenience but no demonstrated accuracy or outcome advantage over conventional instrumentation, and is outperformed by robotic/navigated techniques on alignment precision.

Keywords: Patient-specific instrumentation; Total knee arthroplasty; Mechanical alignment; Outliers; Knee Society Score; Robotic surgery

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Introduction

Total knee arthroplasty (TKA) volumes have grown steadily, with United States projections estimating a several-fold increase in primary procedures by 2030, intensifying interest in technologies that might improve implant positioning while streamlining operating-room workflow [1]. Malalignment of the femoral and tibial components outside a target mechanical axis window has long been associated with accelerated polyethylene wear and inferior implant survivorship, motivating instrumentation strategies intended to reduce outliers beyond conventional intramedullary and extramedullary jigs [2]. Patient-specific instrumentation (PSI) emerged as one such strategy: preoperative computed tomography

(CT) or magnetic resonance imaging (MRI) is used to generate a three-dimensional bone model from which single-use, patient-matched cutting blocks are manufactured, in principle transferring a virtual preoperative plan directly to the femur and tibia without intramedullary or extramedullary guide rods [3]. Early industry-sponsored series reported fewer coronal-plane outliers and shorter surgical time with PSI [2,4], generating rapid clinical uptake before independent, methodologically rigorous comparative data accumulated.

This review synthesises the published comparative literature on PSI in TKA: coronal and rotational alignment accuracy against conventional instrumentation, the consistency of outlier reduction across study designs, operative time, blood loss and cost, how PSI compares with computer-navigated and robotic-arm-assisted TKA, and clinical/patient-reported outcome scores (Knee Society Score [KSS], Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC], and Oxford Knee Score [OKS]) at short- and mid-term follow-up.

Rationale, Workflow and Comparative Study Landscape

PSI removes intramedullary canal violation, theoretically lowering fat-embolism risk and blood loss, and reduces the instrument-tray burden processed per case [5,6]. The workflow requires a preoperative CT or MRI scan several weeks before surgery, from which a manufacturer generates a segmented three-dimensional bone model, a proposed component position, and single-use guides milled or three-dimensionally printed to seat uniquely on the patient's distal femur and proximal tibia; the surgeon reviews and can adjust the virtual plan before manufacture, then executes the bone cuts intraoperatively using the guides rather than intramedullary rods or extramedullary alignment jigs [3]. A substantial body of randomised controlled trials, large single- and

multi-surgeon comparative series, and pooled meta-analyses has since examined whether these theoretical advantages translate into measurable accuracy or clinical benefit (Table 1). Designs range from small early single-centre randomised trials of around 40-100 knees [7,8] to large registry-scale comparative radiographic series exceeding 1,000 TKAs [9,10], and multicentre pragmatic trials designed to test PSI's value within routine healthcare-system practice [11,12]. Sample size, target alignment philosophy (mechanical versus kinematic), implant system, and surgeon PSI experience all vary across this body of work, plausibly contributing to the discordant findings summarised below.

Table 1: Representative comparative studies of patient-specific instrumentation (PSI) versus conventional instrumentation in total knee arthroplasty [7,8,11,14,9,10].			
Study	Design	N (knees)	Key alignment finding
Chareancholvanich 2013	RCT	80	Small tibial-alignment difference favouring PSI; not clinically meaningful
Yan 2015	RCT (PSI vs conventional vs navigation)	78	Navigation, not PSI, achieved most consistent alignment
Teeter 2019	Multicentre RCT	146	No advantage of PSI in alignment or patient-reported outcomes
Kosse 2018	RCT	80	Stability and alignment not improved by PSI
Pauzenberger 2019	Large comparative radiographic series	1257	PSI reduced 3D deviations and eliminated severe (>5 degrees) outliers
Gaukel 2022	Comparative series	>700	CT-based single-use PSI as accurate as standard instruments

Coronal and Rotational Alignment Accuracy

Findings on alignment accuracy diverge by study design. Ng et al. reported the mechanical axis fell within the

central third of the knee more often with PSI (88%) than manual instrumentation (78%) in a large comparative series [2], and a subsequent 1,257-TKA comparative radiographic analysis found significantly lower mean three-dimensional component-positioning deviations with PSI than conventional instrumentation, with PSI eliminating severe (>5°) outliers altogether [9]. A CT-based series of over 700 cases similarly found single-use PSI as accurate as standard instruments [10], and refined tibial-guide designs have further improved coronal and axial tibial accuracy over earlier PSI iterations [13]. Conversely, randomised trials have generally failed to reproduce a clear advantage: Chareancholvanich et al. found only a small, arguably clinically irrelevant difference in tibial component alignment [7]; Kosse et al. found stability and alignment were not improved by PSI [14]; and Barrack et al. found coronal alignment equivalent between PSI and conventional groups [5]. Pooled across the randomised literature, a meta-analysis of fifteen studies (916 PSI, 998 conventional TKAs) found no significant difference in mechanical-axis deviation (weighted mean difference 0.07°) and no protective effect of PSI against hip-knee-ankle (HKA) angle outliers [15], a conclusion echoed by a JBJS-published systematic review and meta-analysis [16] and by a further meta-analysis restricted to osteoarthritis populations [17]. Cavaignac et al. also noted a non-significant trend toward fewer femoral outliers with PSI but the opposite trend for the tibial component, and in a minority of cases surgeons abandoned the PSI plan intraoperatively because the guide did not match the exposed bone surface [15].

Alignment Outliers Across Study Designs

Because outlier proportion (rather than mean deviation) is most clinically relevant, Figure 1 juxtaposes coronal HKA outlier rates reported for PSI versus conventional instrumentation in three representative comparative series [2,4,9]. All three individually favour PSI, with outlier

rates roughly halved (9-13% versus 22-29%); yet this pattern is not reproduced when randomised trials are pooled; the Cavaignac meta-analysis reported a risk ratio for HKA outliers of 0.88 (95% CI 0.68-1.13), and a further systematic review and meta-analysis of PSI's efficacy and safety in primary TKA likewise found no consistent accuracy advantage over conventional guides [18]. This divergence likely reflects publication and selection effects favouring single-centre PSI series, surgeon learning curves, and heterogeneity in implant systems and imaging modality across pooled trials [19]; series from the centres that pioneered a technology, often against historical cohorts, warrant more cautious interpretation than independently conducted randomised trials.

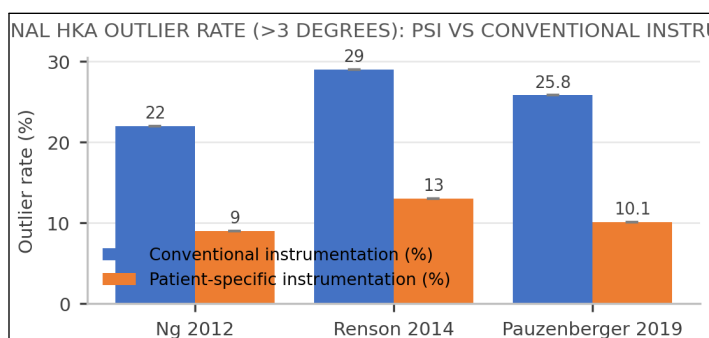


Figure 1: Coronal hip-knee-ankle (HKA) outlier rates (>3 degrees from neutral) reported for patient-specific instrumentation versus conventional instrumentation in three representative comparative series [2,4,9].

Operative Time, Blood Loss and Cost

PSI's practical appeal rests partly on anticipated efficiency gains. Renson et al. found PSI reduced total surgical time by roughly 8.9 minutes and OR time by 8.6 minutes, alongside a six-tray reduction in instrumentation [4], and Chareancholvanich et al. reported a smaller but significant 5.1-minute reduction in total operating time [7]. Figure 2 contrasts these single-centre efficiency gains with the pooled meta-analytic estimate, in which Kizaki et al. found no significant overall reduction in surgical time (mean difference -3.09 minutes, 95% CI -6.73 to 0.55) [17], though blood loss was modestly lower with PSI

(haemoglobin reduction difference 0.4 g/dL) with no difference in transfusion rate or composite complications [17]. Cost-effectiveness analyses have been unfavourable: Nunley et al. found the roughly \$322 in operative-time and processing savings from PSI was substantially outweighed by the added cost (~\$1,500) of preoperative imaging and guide manufacture, concluding PSI did not demonstrate added value [6,5]. A multicentre resource-use study likewise found no consistent improvement in OR efficiency or outcome with PSI [12]. PSI's economic case therefore depends heavily on local sterile-processing costs and scan reimbursement [6].

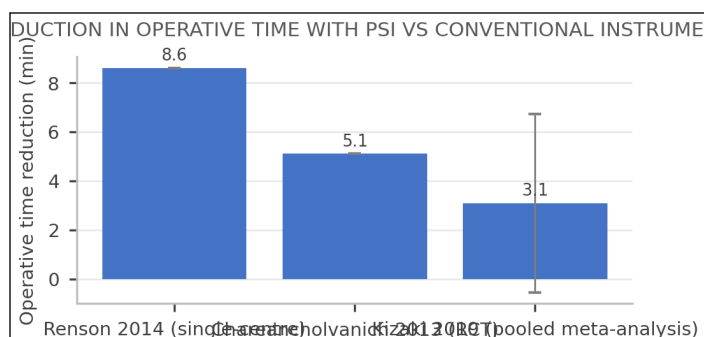


Figure 2: Mean reduction in operative time attributed to patient-specific instrumentation, contrasting single-centre and randomised-trial estimates with the pooled meta-analytic (non-significant) estimate [4,7,17].

Comparison with Computer Navigation and Robotic-Assisted TKA

Placed alongside computer-navigated and robotic-arm-assisted TKA, PSI's relative accuracy advantage narrows further (Table 2). In a randomised trial comparing PSI, conventional instrumentation and computer navigation, Yan et al. found navigation, not PSI, achieved the most consistent alignment [8]. A network meta-analysis of 73 randomised trials (4,209 TKAs) found surgical robots and computer navigation produced significantly better alignment accuracy than PSI or conventional instruments, although postoperative clinical scores were similar across all four technique groups, with navigation associated with modestly higher medium- and

long-term KSS scores [20]. A separate network meta-analysis of navigated, robotic, patient-specific and standard-cutting-guide TKA reached a concordant conclusion regarding accuracy hierarchy, without demonstrating superior functional outcome scores for any single technology [21]. Robotic-arm-assisted TKA has independently been associated with improved early functional recovery and reduced hospital stay compared with conventional jig-based TKA [22], and a simultaneous bilateral randomised comparison found more precise mechanical-axis restoration with the robotic knee [23] — reinforcing that navigation and robotics, not PSI, deliver the most reproducible alignment, likely because they allow real-time intraoperative verification, whereas PSI commits the surgeon to a fixed preoperative plan that cannot compensate for cartilage loss or soft-tissue balancing discovered only after exposure.

Table 2: Systematic reviews, meta-analyses and network meta-analyses comparing PSI with conventional, navigated and robotic total knee arthroplasty [19,15,17,24,20,21,18].		
Source	Comparisons pooled	Key finding
Voleti 2014	PSI vs conventional (meta-analysis)	Data do not support routine PSI use
Cavaignac 2015	PSI vs conventional, 15 studies/1914 TKAs	No significant difference in mechanical-axis deviation or outliers
Kizaki 2019	PSI vs conventional, 38 studies/3487 patients	No significant difference in surgical time or PROMs; modestly lower blood loss
Rudran 2022	PSI vs conventional, prospective studies	No significant difference in functional outcome scores
Lei 2022	Navigation, robotics, PSI, conventional (network meta-analysis, 73 RCTs)	Navigation/robotics more accurate than PSI; similar clinical scores
Bouche 2020	Navigation, robotics, PSI, standard guides (network meta-analysis)	Accuracy hierarchy favours navigation/robotics; no PROM advantage for any technique
Hinloopen 2023	PSI vs conventional (systematic review/meta-analysis)	No consistent efficacy or safety advantage for PSI

Clinical and Patient-Reported Outcome Scores

Despite differences in radiographic alignment, most comparative studies converge on similar clinical and patient-reported outcomes. A systematic review and meta-analysis of prospective studies found no significant difference between PSI and conventional instrumentation in functional outcome scores at short- or mid-term follow-up [24], consistent with the pooled Oxford Knee Score (mean difference 0.48) and WOMAC (mean difference 0.25) estimates reported by Kizaki et al. for follow-up under and over one year respectively [17]. A large Canadian health-system randomised trial similarly found PSI conferred no meaningful advantage in patient-reported outcomes or implant migration relative to conventional instrumentation [11], and Voleti et al.'s review concluded available data do not support routine PSI adoption on either radiographic or clinical grounds [19]. Collectively, KSS, WOMAC and OKS scores at the follow-up intervals studied to date have not tracked radiographic alignment differences into a clinically detectable functional advantage for PSI [16], a dissociation that mirrors a wider theme in TKA outcomes research where soft-tissue balance and pain phenotype often explain more score variance than small alignment differences, and argues for outcome-focused rather than purely radiographic evaluation of instrumentation technologies.

Imaging Modality: MRI- versus CT-Based Guides

Because PSI depends on preoperative imaging, the choice between MRI- and CT-derived guides has itself been studied. Schotanus et al. reported favourable alignment outcomes with MRI-based PSI [25], while a direct comparison of MRI- and CT-based systems found broadly comparable accuracy between the two imaging pathways, with modality-specific trade-offs in cost, radiation exposure and soft-tissue visualisation rather than a clear accuracy winner [26]. Imaging-modality choice for PSI manufacture is therefore best guided by institutional

workflow, cost, and radiation considerations rather than expected differences in final alignment accuracy [27]: CT is faster and cheaper but exposes patients to ionising radiation, while MRI avoids radiation and better delineates cartilage for surface registration at the expense of longer, costlier scans.

Conclusion

Across two decades of comparative study, patient-specific instrumentation in TKA has consistently reduced instrument-tray burden and, in several large single- and multi-surgeon series, alignment outliers, but pooled randomised evidence has not confirmed a reproducible advantage over conventional jig-based instrumentation in mechanical-axis accuracy, operative time, blood loss, cost, or KSS/WOMAC/OKS outcomes [15,16,17,24]. Computer navigation and robotic-arm-assisted TKA now achieve more consistent alignment than PSI without yet translating into superior patient-reported outcomes at the follow-up intervals studied [20,21,22]. PSI therefore remains a workflow-convenience option rather than an evidence-based means of improving alignment accuracy or clinical scores, and future comparative work should prioritise longer-term functional and survivorship endpoints across all three instrumentation strategies.

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