Systematic Review of Patient-specific Instrumentation in Total Knee Arthroplasty: New but Not Improved

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Abstract

Background Patient-specific cutting blocks have been touted as a more efficient and reliable means of achieving neutral mechanical alignment during TKA with the proposed downstream effect of improved clinical outcomes. However, it is not clear to what degree published studies support these assumptions.

Questions/purposes We asked: (1) Do patient-specific cutting blocks achieve neutral mechanical alignment more reliably during TKA when compared with conventional methods? (2) Does patient-specific instrumentation (PSI) provide financial benefit through improved surgical efficiency? (3) Does the use of patient-specific cutting blocks

translate to improved clinical results after TKA when compared with conventional instrumentation?

Methods We performed a systematic review in accordance with Cochrane guidelines of controlled studies (prospective and retrospective) in MEDLINE® and EMBASE® with respect to patient-specific cutting blocks and their effect on alignment, cost, operative time, clinical outcome scores, complications, and survivorship. Sixteen studies (Level I–III on the levels of evidence rubric) were identified and used in addressing the first question, 13 (Level I–III) for the second question, and two (Level III) for the third question. Qualitative assessment of the selected Level I studies was performed using the modified Jadad score; Level II and III studies were rated based on the Newcastle-Ottawa scoring system.

Results The majority of studies did not show an improvement in overall limb alignment when PSI was compared with standard instrumentation. Mixed results were seen across studies with regard to the prevalence of alignment outliers when PSI was compared with conventional cutting blocks with some studies demonstrating no difference, some showing an improvement with PSI, and a single study showing worse results with PSI. The studies demonstrated mixed results regarding the influence of PSI on operative times. Decreased operative times were not uniformly observed, and when noted, they were found to be of minimal clinical or financial significance. PSI did reliably reduce the number of instrument trays required for processing perioperatively. The accuracy of the preoperative plan, generated by the PSI manufacturers, was found lacking, often leading to multiple intraoperative changes, thereby disrupting the flow of the operation and negatively impacting efficiency. Limited data exist with regard to the effect of PSI on postoperative function, improvement in pain, and patient

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satisfaction. Neither of the two studies we identified provided strong evidence to support an advantage favoring the use of PSI. No identified studies addressed survivorship of components placed with PSI compared with those placed with standard instrumentation.

Conclusions PSI for TKA has not reliably demonstrated improvement of postoperative limb or component alignment when compared with standard instrumentation. Although decisive evidence exists to support that PSI requires fewer surgical trays, PSI has not clearly been shown to improve overall surgical efficiency or the cost-effectiveness of TKA. Mid- and long-term data regarding PSI's effect on functional outcomes and component survivorship do not exist and short-term data are scarce. Limited available literature does not clearly support any improvement of postoperative pain, activity, function, or ROM when PSI is compared with traditional instrumentation.

Introduction

Although a recent study has called into question the importance of mechanical alignment on the survivorship of TKA [26], many studies support the idea that neutral mechanical alignment is critical in the overall success of the surgical procedure [4, 12, 28]. The majority of orthopaedic surgeons continue to strive for neutral, postoperative mechanical alignment; however, this objective remains elusive with conventional intramedullary and extramedullary cutting guides demonstrating difficulty in reproducing this target reliably [9, 17, 18, 24].

Two technologic advancements have emerged that seek to improve the likelihood of achieving neutral TKA alignment: computer-assisted navigation and patient-specific instrumentation (PSI). A recent systematic review of computer-assisted TKA demonstrated that although many studies support the idea that this technology can improve TKA alignment, there has been a paucity of documented gains in function, patient satisfaction, or survivorship [6]. This review addresses a similar set of questions applied to PSI.

PSI is generated from preoperative three-dimensional imaging in the form of a CT scan or an MR image. These imaging modalities help construct a preoperative surgical plan with respect to the bone resection depths and angles, and from this plan, disposable cutting blocks are fabricated to match and conform to the patient's anatomy. The anticipated benefits of this technology are that neutral postoperative alignment would be more reproducible, surgical time would be decreased, and the entire procedure would be more efficient and cost-effective.

The degree to which this technology achieves those benefits remains controversial. We therefore conducted a systematic literature review to answer three questions: (1) Do patient-specific cutting blocks achieve neutral mechanical alignment more reliably during TKA when compared with conventional methods? (2) Does PSI provide financial benefit through improved surgical efficiency? (3) Does the use of patient-specific cutting blocks translate to improved clinical results after TKA when compared with conventional instrumentation?

Search Strategy and Criteria

We performed a systematic review of controlled studies (prospective and retrospective) related to the use of PSI in TKA using MEDLINE® and EMBASE® databases. Relevant reports within this body of literature were identified using the search headings: “total knee arthroplasty”, “patient-specific instrumentation”, “patient-specific cutting guides”, and “patient-matched instrumentation”. A literature search, performed in January 2014, using the headings “total knee arthroplasty” and “patient-specific instrumentation” found 117 articles using MEDLINE®, which were then limited to 101 articles published in the last 10 years in the English language. The abstracts of these articles were reviewed to determine their relevance to the study questions and ensure a level of evidence of between Levels I and III. Twenty studies were identified in this fashion. A similar search in EMBASE®, performed in June 2014, restricted to articles and articles in press, found 23 papers of which 11 were applicable to our study. All 11 of these had been identified in the MEDLINE® search. Additionally, a second search was performed using the terms “total knee arthroplasty” and “patient-matched instrumentation”, which yielded 11 studies on MEDLINE®. Only two of these met inclusion criteria, were relevant, and not previously identified by the first search. The EMBASE® search using this second set of terms generated five studies. Four of these met inclusion criteria; however, they had all been identified by the previous MEDLINE® searches. The lead author performed both searches and the results were agreed on by a consensus of the other authors. The bibliographies of the selected studies were not searched additionally. Furthermore, conference proceedings or abstracts were not used because they had yet to vetted through a traditional peer review process. Of the 22 total studies identified, three were Level I, nine were Level II, and 10 were Level III studies based on evidence rubric. Sixteen studies addressed our first study question [1–3, 5, 7, 8, 11, 13, 14, 19, 20, 22, 25, 30, 32, 33], 14 addressed our second study question [1–3, 5, 7, 8, 10, 13, 15, 20, 21, 27, 29, 31], and two addressed our third study question [32, 33].

Table 1. Summary of the data regarding the first study question: Do patient-specific cutting blocks achieve neutral mechanical alignment more reliably during TKA when compared with conventional methods?

Study	Total number of patients	Level of evidence	Conclusion
Chareancholvanich et al. [7]	80	I	No difference in overall alignment, no difference in femoral component alignment, small difference in tibial component alignment unlikely to be significant (89.8° versus 90.5°)
Hamilton et al. [13]	52	I	No difference in mechanical alignment with PSI
Noble et al. [20]	29	I	Mechanical alignment closer to neutral with PSI (1.7° versus 2.8°)
Barrack et al. [2]	200	II	Equivalent coronal plane alignment
Barrett et al. [3]	66	II	Mechanical alignment comparable between groups
Chen et al. [8]	60	II	Increased rate of mechanical axis outliers ($\pm 3^\circ$) with PSI
Silva et al. [30]	45	II	Decreased rate of tibial component internal rotation with PSI
Parratte et al. [25]	40	II	PSI does not improve component rotation in TKA
Daniilidis and Tibesku [11]	170	II	Overall mechanical alignment equivalent, fewer outliers ($\pm 3^\circ$) with PSI
Ng et al. [19]	724 (160*)	III	Overall mechanical alignment equivalent, fewer outliers ($\pm 3^\circ$) with PSI
Nunley et al. [22]	150	III	Equivalent number of mechanical axis outliers with standard instrumentation and PSI
Yaffe et al. [33]	122	III	No difference in mechanical alignment with PSI
Heyse and Tibesku [14]	94	III	PSI reduced the number of femoral component rotation outliers
Barke et al. [1]	89	III	No difference in mechanical alignment with PSI
Vundelinckx et al. [32]	62	III	No difference in mechanical alignment, posterior slope of tibial component more accurate with PSI
Boonen et al. [5]	40	III	Overall mechanical alignment equivalent, fewer outliers ($\pm 3^\circ$) with PSI

* Only 160 patients of the total patients had data pertaining to mechanical alignment; PSI = patient-specific instrumentation.

Of the 16 studies investigating whether PSI achieved neutral mechanical alignment more readily than conventional instrumentation, three provided Level I evidence, five supplied Level II evidence, and eight supplied Level III evidence (Table 1). Of the 14 studies investigating whether PSI led to financial gains via improved surgical efficiency, three provided Level I evidence, seven provided Level II evidence, and four provided Level III evidence (Table 2). The two studies investigating clinical results pertaining to postoperative pain, function, or ROM as they relate to the use of PSI compared with standard instrumentation were both Level III (Table 3).

Studies reviewed varied with respect to their levels of evidence, ranging between Level I and III. Reports were weighted based on the level of evidence that they provided, with emphasis placed on randomized controlled trials, registry studies, and meta-analyses. Additionally the strength of the three randomized control trials was verified using the modified Jadad scoring system [16], whereas the retrospective studies were evaluated with the Newcastle-Ottawa grading system [23]. Preference was shown to conclusions derived from studies with stronger levels of evidence. This was done under the assumption that studies with higher strength of evidence would have less inherent bias and thus generate less of a downstream effect in this systematic review. The selected reports were reviewed and their conclusions synthesized with respect to our study questions. A consensus was reached

between the authors before formulating overall conclusions based on the literature review.

The outcome measures for our first study question included coronal, sagittal, and rotational limb alignment. The second study question outcomes included cost of preoperative imaging and fabrication of the cutting guides, hospital cost, time in the operating room, number of instrument trays used per procedure, and fidelity of the predetermined surgical plan with the implemented surgical plan as measures of procedure efficiency. ROM, knee function, clinical outcome scores, implant survivorship, and patient satisfaction were used as outcomes measures for the third study question.

Because the population of studies incorporated in this review was heterogeneous and included a large proportion of nonrandomized studies, data pooling (meta-analysis) was not appropriate and, thus, not performed.

Results

Do Patient-specific Cutting Blocks Achieve Neutral Mechanical Alignment More Reliably During TKA When Compared With Conventional Methods?

Although there were some discrepancies among the studies we included that addressed this question, the

Table 2. Summary of the data regarding second study question: Does PSI provide financial benefit through improved surgical efficiency?

Study	Total number of patients	Level of evidence	Conclusion
Chareancholvanich et al. [7]	80	I	PSI decreased OR time by 5 minutes
Hamilton et al. [13]	52	I	PSI was 4 minutes longer than standard instrumentation but decreased number of instrument trays
Noble et al. [20]	29	I	PSI decreased OR time by 7 minutes and decreased instrument trays
Barrack et al. [2]	200	II	PSI decreased OR time and instrument processing time, overall increase in cost of procedure after accounting for preoperative scan and cutting guide
Issa et al. [15]	89	II	Minimal changes required to the preoperative plan generated by PSI
Barrett et al. [3]	66	II	No difference in operative time
Stronach et al. [31]	66	II	No difference in operative time, multiple changes to preoperative plan required intraoperatively
Chen et al. [8]	60	II	No difference in operative time
Scholes et al. [29]	30	II	PSI-directed cuts do not always match the preoperative plan and should be checked carefully intraoperatively
Conteduca et al. [10]	12	II	PSI-directed cuts do not always match the preoperative plan and should be checked carefully intraoperatively
Nunley et al. [21]	114	III	No difference in tourniquet time but decreased total time in OR by 12 minutes
Barke et al. [1]	89	III	No difference in operative time
Pietsch et al. [27]	50	III	Changes in the technician plan needed preoperatively to generate an accurate preoperative plan
Boonen et al. [5]	40	III	PSI decreased OR time by 10 minutes

PSI = patient-specific instrumentation; OR = operating room.

Table 3. Summary of the data regarding third study question: Does the use of patient-specific cutting blocks translate to improved clinical results after TKA when compared with conventional methods?

Study	Total number of patients	Level of evidence	Conclusion
Yaffe et al. [33]	122	3	No difference in pain, motion, Knee Society knee scores; PSI had higher Knee Society function scores pre- and postoperatively
Vunderlinckx et al. [32]	62	3	No difference in pain, patient satisfaction, or functional outcomes (KOOS, Lysholm score)

PSI = patient-specific instrumentation; KOOS = Knee Injury and Osteoarthritis Outcome Score.

preponderance of the stronger evidence evaluated failed to show an association between PSI and more reliable achievement of neutral mechanical axis when compared with conventional cutting blocks. One of the three Level I studies demonstrated no difference in postoperative mechanical alignment [13]. Another Level I study demonstrated no difference in tibiofemoral or femoral component alignment but did note a difference in tibial component alignment with PSI being closer to neutral than standard instrumentation (89.8° versus 90.5°); however, this was deemed clinically insignificant by the authors [7]. The final Level I study favored PSI with respect to achieving a neutral alignment (1.7° versus 2.8°) [20], but again the likelihood that such a small angular difference translates to a clinical discrepancy remains in doubt.

The Level II studies identified also generated mixed results. Three of five Level II studies demonstrated no benefit with PSI [2, 3, 25] and one study demonstrated improved tibial component rotation [30]. The final Level II study demonstrated a greater number of alignment outliers when PSI was used [8].

The Level III studies also failed to show a strong trend in favor of PSI. Only two of the eight studies demonstrated improvement of component alignment in the PSI group. One study concluded that improved femoral component rotation was achieved with PSI [14] and another noted improved posterior slope accuracy [32]. An additional three studies demonstrated no overall improvement of alignment, but a decrease in the number of outliers was observed when PSI was used [5, 11, 19]. The remaining three studies concluded that no improvement was observed with PSI [1, 22, 33].

Does PSI Provide Financial Benefit Through Improved Surgical Efficiency?

The studies differed with respect to how they measured surgical cost and efficiency with three main outcome measures emerging: operative time, number of surgical trays required for processing, and the accuracy of the surgical plan as dictated by the PSI with respect to the component sizing, component position, and bony cuts required to perform the surgery.

There were mixed findings on several of the financial endpoints; however, most studies did not find substantial operative time benefits to use of PSI. Additionally, although the studies consistently showed a reduction in the number of surgical trays used, the potential benefits of this added efficiency seemed to be offset by the frequency with which PSI-generated surgical plans needed to be altered intraoperatively. All three Level I studies addressed operative time with mixed results. The first demonstrated no benefit with PSI [13]. The second study noted decreased operative time by 5 minutes; however, this improvement was marginalized and deemed not clinically or financially significant by the authors [7]. The final Level I study noted a decrease in operative times with the use of PSI by 7 minutes [20]. Among the studies providing a lower level of evidence, the results were again split. A Level II study [3] and two Level III studies [5, 21] demonstrated faster operative times with PSI, whereas another Level II [8] and a Level III study failed to demonstrate quicker surgery with PSI [1].

PSI does reliably lead to a decrease in the number of surgical instrument trays required to perform TKA. Two Level I studies investigated this question and unanimously supported this finding [13, 20].

The accuracy of the preoperative plan as generated by the PSI manufacturing process is another factor that plays a role in the overall surgical efficiency of the procedure. Secondary checks on cut thickness, component sizing, and component position all add time to the procedure and disrupt the ebb and flow of the operation. One Level II study concluded that the bony cuts achieved using the patient-specific cutting blocks did not always match the preoperative plan generated [29]. An additional Level II study [31] and a Level III study [27] noted a high frequency of intraoperative changes to the preoperative plan and component sizing required to achieve an optimal surgical result. Finally, another Level II study demonstrated that cuts achieved with PSI did not correspond to the preoperative plan when checked intraoperatively with computer-assisted navigation tools [10]. Only a single Level II study concluded that minimal changes were required to the preoperative plan laid out by the PSI manufacturer [15].

Does the Use of Patient-specific Cutting Blocks Translate to Improved Clinical Results After TKA When Compared With Conventional Instrumentation?

The consensus of the two studies that addressed this question was that the use of patient-specific cutting blocks did not confer any functional gains when compared with traditional instrumentation. One study demonstrated no difference with respect to postoperative pain (visual analog scale), patient satisfaction, or functional outcomes, based on Knee Injury and Osteoarthritis Outcome Score and Lysholm scores with a mean followup of a little more than 6 months [32]. The second study also failed to show a difference in Knee Society knee scores, ROM, or pain score improvement between PSI and conventional jigs [33]. This study did note greater improvement in Knee Society function scores in the PSI group at 6 months' followup; however, firm conclusions from this finding remained elusive, because the preoperative function scores in the PSI group were higher as well [33]. No identified studies addressed survivorship of components placed with PSI compared with those placed with standard instrumentation.

Discussion

Patient-specific cutting blocks have been touted as a more efficient and reliable means of achieving neutral mechanical alignment during TKA than conventional cutting blocks with the proposed downstream effect of improved clinical outcomes. However, because it was not clear to what degree published studies support these assumptions, we performed a systematic literature review to determine the validity of these claims.

This literature review was limited in that a selection bias was incurred by using papers only written in the English language. Other articles pertaining to our study questions may exist in other languages and would have been omitted. We would be unable to accurately interpret these articles if they existed; thus, the decision was made for exclusion. Another limitation is that each individual article included in the systematic review is also subject to its own biases. These inherent biases have the potential to create a downstream effect in the synthesis of the conclusions drawn from their inclusion in this review. This fact was mitigated in our review process by weighting the conclusions of each individual article based on the strength of the evidence that it supplied. Thus, articles with less inherent bias were relied on more heavily when forming our conclusions. Despite these limitations, we believe that valid conclusions can be drawn from our analysis of the available literature. A final limitation of this review is that most

of the included studies were authored by high-volume arthroplasty surgeons; thus, when variables such as post-operative limb alignment and operative times are compared between PSI and conventional instrumentation, the difference may not be as readily apparent as they would be in the hands of low-volume surgeons. In addition, there may exist some learning curve bias when comparing the newer technology of patient-specific cutting blocks with traditional instrumentation, which may have potentially impeded the potential advantages of this technique once more experience is gained.

The determination of whether PSI offers an advantage over standard instrumentation with regard to postoperative alignment can be based on two different observations. The first observation is the average alignment achieved by each method and the second is the number of outliers $\pm 3^\circ$ from a neutral axis created by either technique. When the former was investigated in the 16 articles identified addressing this study question, only one concluded that the mechanical alignment was improved with PSI [20]. That study did provide Level I evidence in 29 patients, citing an overall difference of 1.1° ; however, two other Level I studies with greater power did not corroborate this finding [7, 13]. Furthermore, a difference of 1.1° is unlikely to be clinically significant and is likely within the error of measurement when analyzing plain radiographs. Three Level III articles [5, 11, 19] demonstrated an increase of radiographic outliers when standard instrumentation was used; however, the majority demonstrated no difference. Additionally, one study noted fewer outliers with standard instrumentation [8]. None of the Level I studies noted an increase in radiographic outliers with regard to mechanical limb alignment. Based on these observations, it seems unlikely that PSI offers any advantage over standard instrumentation with regard to reliably achieving a neutral mechanical axis.

Multiple factors play a role in the overall efficiency and economics of TKA. Proponents of PSI claim that the decreased number of surgical trays, ease of use, and pre-operative assessment of component sizing and resection depths all result in decreased surgical time and cost. The results of this literature review support the claim that PSI does result in a decreased number of instrument trays being supported unanimously by all studies that analyzed that variable, including two Level I studies [13, 20], one Level II study [2], and one Level III study [21]. The fewer number of instrument trays result in decreased cost directly, in the form of processing fees, and indirectly, by decreasing time spent in the operating room setting up. The proposed ease of use translating to procedural speed and efficiency was not supported in our review of the literature. Decreased surgical time was not unanimously observed. Two Level I studies demonstrated decreased surgical time

with PSI [7, 20], whereas another noted the opposite [13]. Mixed results were also noted in the lower evidence studies. When decreases in time were noted, they ranged from 5 to 12 minutes. Thus, at best, five PSI TKAs would need to be performed to save an hour of time in the operating room. One Level II study performed a financial analysis incorporating the cost of saved operating room time, instrument processing, preoperative imaging, and the cutting guide and concluded that PSI increased the cost of a TKA by USD 1475 [2]. The accuracy of the preoperative plan accompanying the PSI was also called into question by our literature review. This represents a significant aspect in procedural efficiency, because four studies demonstrated inaccuracies in anticipated alignment or a need to change the preoperative plan with respect to the planned resections or component sizes [10, 27, 29, 31]. This apparent need for secondary checks would seem to diminish the value of PSI considerably as it relates to operative efficiency.

The proponents of PSI have hypothesized that shorter operative times and improved alignment translate downstream to improved functional results when compared with standard instrumentation. This review, however, shows that PSI does not reliably offer advantages in either limb alignment or operative time. Despite this break in reasoning, the literature was still probed with respect to the question of whether PSI leads to less pain, improved knee function, or greater ROM when compared with conventional cutting blocks. The first major observation is that data pertaining to these questions are extremely limited. Only two Level III studies [32, 33] were identified that addressed clinical outcomes of PSI relative to their standard counterparts. Neither demonstrated any improvement in pain or motion. Other equivalent clinical outcomes between PSI and standard instrumentation noted in these studies included Lysholm score, Knee Injury and Osteoarthritis Outcome Score, and Knee Society knee score. Only Knee Society functional scores were increased in the PSI group of a single study [33]; however, the preoperative scores were also higher, making conclusions difficult to reach regarding this observation. Finally, no data in any study commented on survivorship. This is likely the result of the more recent advent and promulgation of this technology.

In summary, patient-specific cutting blocks have failed to demonstrate advantages over traditional instrumentation with respect to alignment, efficiency, or functional outcomes. Further data regarding the clinical performance and survivorship of PSI TKAs at mid- or long-term followup are required to show an advantage over traditional instrumentation.

In conclusion, based on this systematic review of the current literature, PSI does not appear to offer an advantage with respect to achieving neutral mechanical alignment

more reliably than standard instrumentation. PSI does offer a benefit of decreased surgical processing of instrument trays; however, this did not translate to significant financial gains when the cost of the preoperative scan and custom jigs were factored in a cost analysis. Operative time is not reliably shortened in the hands of high-volume surgeons, and PSI-generated surgical plans are often flawed or not readily achieved by the PSI cutting blocks requiring secondary checks. Finally, PSI did not offer any clinical benefit with regard to patient satisfaction, pain, ROM, and the majority of outcome scores assessed. Given these findings, we contend that PSI offers no advantage when compared with standard instrumentation in the hands of a well-trained surgeon.

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