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Patient-Specific Instrumentation in Total Knee Arthroplasty. Should we adopt it?

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Patient-Specific Instrumentation in Total Knee Arthroplasty. Should we adopt it?

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Patient-Specific Instrumentation in Total Knee Arthroplasty. Should we adopt it?

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Patient-Specific Instrumentation in Total Knee Arthroplasty. Should we adopt it?

Instrumentação Personalizada na Prótese Total do Joelho. Devemos adotar?

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Conflict of interest

The authors have no conflicts of interest to declare

Abstract

Total knee arthroplasty (TKA) represents a surgical procedure of paramount relevance that restores a substantial degree of function in arthritic knees. Increased consideration has been placed on the influence of limb alignment on longevity after TKA, as errors in component placement can be associated with inferior function and compromised long-term performance. Consequently, numerous studies comparing patient-specific instrumentation (PSI) to standard instruments (SI) have been published. Patient-specific approaches use preoperative imaging to manufacture specific material for each patient's anatomy and were designed to achieve a higher rate of success in TKA, causing the entire procedure to be more efficient and cost-effective. However, it is not clear to what degree these studies support the potential advantages of PSI. For that reason, the purpose of the present study is to perform a review of the current evidence comparing PSI to SI, concerning alignment, cost-effectiveness and postoperative functional evaluation.

Key words: total knee arthroplasty; patient-specific instrumentation; alignment; cost-effectiveness

Resumo

A prótese total do joelho (PTJ) é um procedimento cirúrgico de elevada relevância que restabelece um considerável nível de função ao joelho com artrose. Um grau de atenção cada vez maior tem sido dado à influência do alinhamento do membro inferior na longevidade da PTJ, uma vez que erros na colocação dos componentes poderão ser associados a um grau inferior de função, comprometendo o desempenho a longo prazo. Consequentemente, têm sido publicados vários estudos que comparam a instrumentação personalizada a cada doente com a técnica convencional. A instrumentação personalizada requer o uso de técnicas de imagem pré-operatórias, de modo a serem fabricados componentes específicos para a anatomia de cada doente, e foi desenvolvida para que se atingisse uma taxa de sucesso mais elevada, esperando-se um procedimento mais eficiente e benéfico em termos de custos. Contudo, a bibliografia ainda não sustenta, claramente, as vantagens das abordagens personalizadas. Assim sendo, o objetivo do presente estudo é conduzir uma revisão da informação atual comparativa dos dois procedimentos, relativamente ao alinhamento obtido, aos custos e à avaliação funcional pós-operatória.

Palavras chave: prótese total do joelho; instrumentação personalizada; alinhamento; custo-efetividade

Introduction

Total knee arthroplasty (TKA) is considered a successful orthopaedic procedure in the management of degenerative joint disease based on the rate of revision. It represents one of the most regularly performed musculoskeletal procedures, restoring, in most cases, a substantial degree of function in arthritic knees. One can anticipate an increase in TKA in the future, given estimated enlargement in population size and longevity. Therefore, perfecting surgical technique is of paramount relevance, as errors in component placement can be associated with inferior function and compromised long-term performance (1,2).

For the past few years, increased consideration has been placed on the influence of limb alignment and component position on longevity and outcomes after TKA, reviewing the survivorship and postoperative performance of the procedure (3–5). It has been established that neutral mechanical alignment is critical in the overall success of the surgical technique (2,6). Consequently, tibial and femoral component malalignment remains a significant concern, as deviations exceeding 3° of varus/valgus in the mechanical axis have been related with poor survivorship due to the accelerated wear resultant of abnormal stresses at the bearing surfaces. Accordingly, tibial and femoral components are needed to be placed as precisely as possible and preventing malalignment may prove to be cost-effective.

That being said, two technological advancements, aiming at improving the likelihood of achieving neutral TKA alignment, have emerged: computer-assisted navigation and patient-specific instrumentation (PSI) (7). Recently, numerous comparative studies and randomized controlled trials that compare patient-specific cutting blocks to conventional instruments have been published. However, it is not clear to what degree these studies support the potential advantages of PSI (8–10). For that reason, the purpose of the present study is to perform a review of the current evidence comparing PSI to SI, concerning alignment, cost-effectiveness and postoperative functional evaluation. Existing information concerning computer-assisted navigation will not be assessed in this review.

Patient-Specific Instrumentation

Aiming at enhancing the outcomes of the surgery, the manufacturing process for knee implants has improved over the years, involving, lately, patient-specific approaches. The purpose was to get the most accurate positioning for the tibial and femoral components (3,11). This technology employs the generation of a preoperative image of the knee, along with hip and ankle images for the evaluation of the overall alignment of the limb, most commonly computed tomography (CT) or magnetic resonance imaging (MRI). Computer software is used to generate an ideal three-dimensional (3D) model of the patient's lower limb anatomy, allowing the anatomical landmarks of the knee to be easily identified, and to create the 3D models of the femoral and tibial components with optimal size, position and alignment. A preoperative plan proposed with bony resections is generated and provided to the operating surgeon, who is then able to assess the 3D planning of the knee implant with the proposed bony resections and with the final implants in place. At this point, the surgeon is expected to approve or review the preoperative plan, adjusting as required bony resection. When approved, generally within 3 weeks, the manufacturer fabricates a corresponding set of custom cutting blocks individualized to the patient's native anatomy (1,3). These cutting jigs are expected to not only determine the proper coronal orientation, but also set the depth of femoral and tibial resection, anteroposterior position, rotation, and slope based on the preoperative prototype. Alterations in preoperative scheduling are inevitable with the implementation of PSI: first, the planning process has to be anticipated, since, as mentioned above, at least 3 weeks are necessary to fabricate the cutting blocks; second, the 3D imaging studies mandatory preoperatively

were not typically performed previously for conventional TKA. At last, manufacturer and surgeon must cooperate for the elaboration and approval of the preoperative plan, ensuring that the guides are available by the time of the procedure (7,12).

Patient-specific instrumentation was designed to achieve a higher rate of success in TKA, decreasing the odds of revision. The anticipated benefits of this technology are numerous, causing the entire procedure to be more efficient and cost-effective (7,13,14).

First, being the patient-matched technology potentially more precise and accurate, with a reduction in the number of outliers expected to be significant, neutral postoperative alignment would be more reproducible with the use of patient-specific jigs when compared to standard alignment techniques(12). Second, the surgeon has preoperative data regarding the size and location of the bony resections, along with implant sizing and rotation information. This way, it is possible to intraoperatively determine if the surgery is proceeding as expected. Third, as fewer instruments trays are required per procedure, the sterilization costs would be reduced (12,15). Fourth, a more efficient surgery is predicted with reduction of the time of the procedure, once different steps have already been performed, also minimizing intraoperative decision making (11,12,16). Finally, by not requiring the use of intramedullary rods to determine alignment, PSI avoids violation of the intramedullary canal, potentially enabling to the incidence of fat embolism and perioperative blood loss (14,17).

Despite several potential surgical benefits of using patient-specific cutting blocks, there are no long-term implant survival data to support its use. It remains controversial whether advantages overcome weaknesses (3,16,17). With the necessity of a preoperative CT scan, the radiation exposure increases. Additionally, it is unclear if the anticipated costs reduction offset those of the preoperative studies and manufacturing to fabricate the materials (15,17). Moreover, surgeries may need to be delayed due to the substantial amount of time required to obtain the suitable preoperative imaging, formulate the intraoperative plan, and to fabricate the cutting blocks. Lastly, the precision of anatomic landmarking has been found to be crucial to the final accuracy of the technique. Deformities that may misrepresent the exactness of the CT scan or MRI, possibly will lead to a compromised 3D model.

Methods

A literature review was conducted related to the use of PSI in TKA using Pubmed database, on September 25, 2015, using the query "total knee arthroplasty/instrumentation" AND ("patient specific" OR "patient matched"). The literature search identified 100 studies, which were then limited to 31 published based on the following inclusion criteria: (1) comparison of patients who underwent TKA with PSI to those who underwent TKA with conventional instrumentation; (2) performed *in vivo*; (3) assessment of postoperative coronal, sagittal or rotational component alignment, operative time, cost and/or function scores. Review articles, editorials and technique descriptions were excluded. Studies that did not meet the criteria or did not address the purpose of the present review were excluded, as were studies published in another language than English and before 2010. The bibliographies of the selected studies were not searched additionally.

Results

The main results are summarized in Table 1.

1. Alignment

Achieving the most possible accurate alignment at the completion of TKA has been the upmost surgical goal for the procedure, with numerous publications demonstrating improved survivorship with this result. At least theoretically, patient-specific cutting blocks are believed to improve the accuracy of limb alignment by guiding the critical bone cuts toward the hypothetically ideal position for each patient. Despite much debate on the usefulness of the instruments, there are studies comparing the value of the new mechanically aligned PSI system to that of standard procedure that validate the surgical accuracy of the technique to date.

Four randomized clinical trials (RTC) reported results supporting PSI. With respect to achieving mechanical alignment closer to neutral, Noble et al. (12) favored PSI over SI (1.7° vs 2.8°; *P*=0.03). Chareancholvanich et al. (11) and Vundelinckx et al. (3) reported no difference in mechanical alignment but the first one did note an improvement in frontal tibial component alignment with PSI being closer to neutral (89.8° versus 90.5°; *P*=0.03), while the second one found that PSI was more accurate in reproducing the desired tibia posterior slope (2.9° versus 5.0°; *P*=0.0008). Silva et al. (18) aimed at studying the rotational alignment and the authors assumed that there is a smaller chance of internal malrotation of the tibial component with PSI, having the traditional instrumentation higher dispersion and amplitude of the tibial component rotation around the neutral position. Numerous retrospective studies noted similar results, with significant improvement in extremity mechanical alignment after PSI (2,6,7,19). Also Renson et al. (20) prospectively reported more outliers with respect to mechanical axis with SI (*P*=0.043). Additionally, femoral component frontal plane position (19) and rotational alignment of the femoral component (7) were also reported to be enhanced with PSI.

Although proponents of patient-matched instrumentation contend that it improves alignment, other well-designed comparative trials have revealed no improvement in alignment. These authors were not able to show improvement with PSI, but the customized technique did not end up being worse than traditional instrumentation. The accuracy between TKAs performed with PSI and those done with SI was considered comparable. A randomized controlled trial conducted by Roh et al. (9) showed no significant difference neither in the mean alignment in all parameters evaluated (mechanical axis, sagittal and coronal alignment of each component and femoral component rotation) nor in the percentage of outliers. For Nunley et al. (16,21), in a retrospective study, both groups had the mean coronal alignment measurements falling within the accepted ranges and the mean HKA and equivalent the number of outliers. The same results are shared by other authors (5,10,17,22,23).

At last, some authors not only concluded that no improvement in alignment was achieved with the use of PSI, but also reported decreased alignment accuracy. In a recent randomized controlled trial, Victor el al. (1) compared conventional instrumentation with patient-specific guides from four different implant suppliers: Signature® (Biomet Inc, Warsaw, IN, USA), TruMatch® (DePuy Inc, Warsaw, IN, USA), Visionaire® (Smith & Nephew Inc, Memphis, TN, USA) and Patient-Specific Instruments® (Zimmer Inc, Warsaw, IN, USA). The use of PSI did not reduce the number of outliers. Actually, the authors found more outliers in the sagittal and coronal alignment of the tibial component (23% vs 17%; *P*=0.002 and 15% vs 3%; *P*=0.03, respectively) with the use of PSI. Deviations from target alignment among PSI subgroups were similar, except for sagittal alignment of the femoral component, which was significantly better for the PSI subgroup using Visionaire®

system (*P*=0.02) and had fewer outliers (*P*=0.001). Yet, the same system revealed more overall coronal alignment outliers (*P*=0.04). In another recent RCTs, both evaluating TruMatch® (DePuy Inc, Warsaw, IN, USA) system, Hamilton et al. (15) showed improved posterior tibial slope in SI cases (*P*=0.001), whereas Woolson et al. (8) reported a significant increase in the number of outliers for the same parameter in the PSI group. Additionally, Kotela et al. (24) found an increase in the number of outliers for coronal tibial component after with PSI having conducted a RCT. Similarly, Stronach et al. (25) retrospectively reviewed data that revealed decreased accuracy with the use of PSI for tibial slope (38% PSI vs. 61% SI, *P*=0.01). On the basis of these results, the authors did not endorse the use of this new technology for TKA.

2. Cost-effectiveness

Another source of conflict associated with the implementation of PSI is whether this technique will reveal itself cost-effective or not. Considering it was consensual that PSI is comparable to SI, equivalent outcomes with more expensive technology do not fit into the current cost-effectiveness paradigm. Multiple factors play a substantial role in the overall efficiency and economics of TKA. The advantages claimed by supporters of PSI in the surgery time, the number of instrument trays used and the need for applying changes may support a cumulative decrease in resource use. Currently, TKA represents a large expense in the health budget and any reduction in the expenses it carries is of particular interest in respect to the present health economic climate.

- **Operative time**

Decreased surgical time with PSI has been described, allowing increased overall procedure efficiency and cost-effectiveness of TKA. Still, it was not unanimously observed.

There are available data from RCTs supporting a reduction of the operating time using PSI system. Chareancholvanich et al. (11) randomized 80 patients to undergo TKA with PSI or SI and reported that this new technology reduced skin-to-skin operative time by a mean 5.1 minutes (*P*=0.019). Additionally, comparable results were reported by Boonen et al. (14), having the PSI surgery taken 5 minutes less than the procedure with SI (*P*<0.001) and Noble et al. (12) (PSI took 6.7 minutes less; *P*=0.048). Also Renson et al. (20), in a prospective study, showed the time of surgery would decrease with PSI.

Using an activity-based cost model, Tibesku et al. (13) found that PSI cutting blocks allowed a more efficient use of time in the operating room, leading to increased revenues for the hospital. The authors observed a decrease of 10 minutes in cutting time and 20 minutes in the preparation of the operating room, per procedure. The explanation is given by the use of the implant guide as a way to reduce time for determination of the size of the implant during a procedure. By allowing the surgeries to end earlier, the authors assume it would enable the hospital to carry out additional procedures. Moreover, the cost savings was matched with the additional cost associated with the new technology. The overall costs were almost identical, with PSI costing just 59€ more, indicating how the theoretical increased efficiency of the procedure conducted with PSI may offset its extra costs, especially after surgeons gain more experience.

On the contrary, after having performed a financial analysis incorporating the cost of preoperative imaging and the cutting guide, as well as spared operating room time and instrument processing, Barrack et al. (17) showed that PSI was actually more expensive than SI. As a result of diminished surgery time and sterilization costs, a total saving of $322 per case was reported with the use of PSI. Nonetheless, the custom cutting guide was estimated to cost $950 and preoperative MRI was

predicted to vary from $400 to $1250, based on insurance. It was concluded that any savings borne by operating room time gained and instrument processing were overwhelmed by the overhead costs demanded by PSI. Also three RCTs failed to show decreased operative time with PSI. The primary outcome measured by Hamilton el al. (15) was total surgical time calculated from initial skin incision to end of closure. 52 patients were randomized to either PSI or conventional TKA. While the PSI group took an average of 61:47 minutes, the mean time for SI group was 57:27 minutes (P=0.006), with the most of the time difference occurring during femoral preparation. Similarly, Roh et al. (9) counted 59.4 minutes for PSI compared to 46.6 minutes for SI (P<0.001). At last, Woolson et al. (8) also failed to show any difference between groups. Comparable results were also observed by other authors (22,25,26).

- **Number of instrument trays**

PSI is also expected to decrease the number of instrumentation trays used, given the abolition of steps such as IM alignment guide placement. The costs associated with maintenance, storage and sterilization could potentially decrease after fewer trays are needed to be opened. Noble et al. (12) recorded the number of instrument trays opened for each case and demonstrated a significant reduction in the number of instrument trays used (mean 4.3 vs mean 7.5; P<0.0001). Similarly, Hamilton et al. (15) reported a significantly higher number of surgical instrument trays used in the SI cases, compared with the trays required for the PSI (mean 7.3 vs mean 2.5; P<0.001). Additional authors analyzed this same variable and unanimously supported the claim that PSI does result in a decreased number of instrument trays (16,17,20). Tibesku et al. (13) in their activity-based costing analysis, observed that PSI led to utilization of 4 trays less, which was estimated to correspond to 1400 trays less annually, compared to SI. This decrease was anticipated to result in potential cost savings of 160€ per procedure.

- **Need for applying changes**

One of the theoretical advantages of PSI is decreased operative time through minimization of intraoperative decision making and instrument handling. Numerous preoperative steps must be completed meticulously for the resultant guides to be precise. The accuracy of the preoperative plan accompanying the PSI was also called into question by different authors.

Recently, Ivie et al. (19), in a retrospective study, reported all the surgeries to have proceeded without requiring additional surgeon intervention or a change from the preoperative surgical plan, not being necessary any conversion to conventional TKA. This is in contrast to other investigations that have shown frequent surgeon-directed changes during PSI TKA. According to Victor et al. (1), in a randomized study with the inclusion of four different PSI systems, the custom instruments procedure had to be modified in 28% of the patients and abandoned in more than 20%. The most common reason for modifying the use of the PSI was the necessity to change the size. Also Roh et al. (9) sought to evaluate the reliability of PSI by intraoperatively investigating whether the surgery could be completed with PSI alone. Actually, in 8 knees (16%), the procedure could not accurately be completed and the technique was abandoned and converted to SI. Finally, Stronach et al. (26) showed that only 23% of the femoral and 47% of the tibial implanted component size was properly predicted by PSI.

3. Postoperative functional evaluation

It is noticeable a lack of published studies on the functional results and gait parameters of patients that have undergone PSI TKA. Especially after the popularization of minimally invasive surgical

techniques, even though long-term survivorship is pertinent, early pain relief and improved functional outcomes have become increasingly important to patients and surgeons. It remains unknown whether PSI improves function and pain-related outcomes and gait. For that reason, some authors decided to appropriately measure these parameters, in order to determine whether they could potentially be improved with PSI.

Four of the selected studies addressed these questions, resulting in conclusions substantially consensual. Vundelinckx et al. (3) conducted a study with a mean follow-up of little more than 6 months, randomizing 62 patients, and reported that PSI do not confer any function gains compared to the traditional TKA. The PSI did not show itself of greater value with respect to postoperative pain (measured using the visual analog scale), patient satisfaction, functional outcome, based on Lysholm score and Knee injury and Osteoarthritis Outcome Score (KOOS), and gait parameters.

Similarly, Abdel et al. (4) performed a randomized clinical trial with 40 patients, evaluating subjective and objectively functional and gait outcomes, preoperatively and 3 months postoperatively, using patient-reported outcome scores (new Knee Society Score (KSS), KOOS and SF-12) and gait parameters. At 3 months postoperatively, almost all functional scores were increased in both groups compared with preoperatively. However, there were no statistical significant differences in postoperative functional scores between groups and the same occurred concerning the analyzed gait parameters. Hence, the authors agreed that no benefit in pain or early function and no comparative improvement in gait parameters were conferred by PSI when compared with conventional TKA, as assessed by the KSS, KOOS and SF-12 and comprehensive gait analysis.

Yaffe et al. (5) also failed to show a difference in KSS or pain score improvement between PSI and conventional jigs, after a 6 month follow-up of 122 patients. Still, PSI did show a significantly higher Knee Society function subscore improvement from the preoperative period to the 6-month postoperative period, when compared to conventional instrumentation. Enhanced component rotation and positioning and improved component size accuracy may be the explanation for the results. However, as this is a retrospective case-control study, there was not randomization of the patients, introducing potential bias. In fact, PSI group had higher preoperatively knee scores, function scores and pain scores than manual instrumentation group. Consequently, firm conclusions from this finding remain elusive due to the affected ability of the authors to draw definitive conclusions from the raw postoperatively scores, even though the groups are similar in body mass index, gender, age and preoperative diagnosis.

More recently, Woolson et al. (8), in a RCT, reported no significant difference with regard to Knee Society rating or function score.

Discussion

In order to gain acceptance into modern practice, new technology must demonstrate either (1) increased efficacy compared to existing technology or (2) equivalent outcomes with reduced cost.

On the basis of their data, some authors showed results that sustain of the value of customized cutting blocks (2,7,12,13,19,20). One can expect that this technology will assist in restoring the mechanical axis with accuracy potentially better than conventional instrumentation. In fact, all the selected studies showed no inferior mechanical and femoral component alignment with PSI. Only the tibial component revealed controversial results.

However, different examples have shown deficient guide fit intraoperatively in which conventional instrumentation was preferred rather than accepting the potential risk of an undesirable resection (1,9,26). This pre surgical process adds complexity, time, expense, and multiple steps to the TKA process. An error made in the initial steps of the process will lead to continued reproduction of that error. This raises a concern that the preoperatively proposed implant size and alignment from PSI may not be an accurate reflection of patient anatomy and, therefore, unreliable. Surgeons must be cautious against blind approval of PSI technology without supportive data. Additionally, some authors claim that more intraoperative decision-making was required by PSI, preventing it to reduce operative time (9,15). Accordingly, no difference in surgery time between the groups was established. This may result from additional time taken to evaluate each step, regularly repeated resections and rejected blind acceptance of the proposed cuts, preventing the authors from immediately make the cuts after placing the surgical guides, which could compromise the accuracy of the components size and position. Nonetheless several authors believe the PSI cutting jigs to achieve larger progresses in surgery time with more experience, as the studies were led during the early learning curve for high-volume surgeons who have performed several thousand TKAs using SI (1,2,16). Lack of expertise with the PSI may be enough to bias the results. Surgeons are expected to improve the technique and be able to make fewer adjustments, reducing the surgical time with PSI, as the volume of performances increases.

Conclusion

The value of any medical technology depends on whether or not it improves clinical outcomes and PSI offers numerous theoretical advantages that make it an attractive alternative for TKA. As this technology still remains a relatively new concept, it is not surprising that, despite its increase, the body of literature remains limited. Regardless of whether this technology is found to be acceptable in the future, the truth is that different studies assumed both techniques are able to restore limb alignment and place the components with equivalent accuracy. However, although there is decisive evidence to support this innovative technique, PSI has not consistently been shown to be cost-effective or to offer any clinical benefit with regard to functional scores assessed. The extensive number of angles that can be measured to evaluate the efficacy of PSI also makes the comparison between different studies difficult. Additionally, is possible that a six-month follow-up period may not be sensitive enough to detect PSI's effect on functional outcomes and component survivorship.

PSI may have a small and specific role in certain cases, such as when the use of an IM or extra-medullary rod with mounted cutting block is impossible, for example after severe post-traumatic sequels of distal femoral or proximal tibial fractures or for patients with IM hardware or extra-articular deformities, but additional justifying data is vital prior its routine use.

It is possible that more precise conclusions may emerge. That being said, additional RCTs should be conducted comparing the clinical outcomes of PSI to the traditional technique with a longer postoperative follow-up period and a larger sample before definitive conclusions are made, concerning functional efficacy of this technology and the potential applicability of PSI to special situations.

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Table 1 Summary of the data regarding the results of PSI studies.

Study	Study type	PSI system	Number of TKAs	Results	Outcomes
Abdel et al. (4)	RCT		20 PSI 20 SI	No difference in early functional, quality-of-olife or gait outcomes.	Functional evaluation
Barke et al. (22)	Retrospective	Visionaire® (Smith & Nephew)	39 PSI 50 SI	SI achieved a MA closer to neutral. OT was equivalent.	MA, OT
Barrack et al. (17)	Retrospective	Signature® (Biomet)	100 PSI 100 SI	Equivalent MA accuracy, decreased OT and reduced number of instrument trays with PSI.	MA, OT, number of instrument trays
Barret et al. (23)	Prospective non-RCT	TruMatch® (DePuy)	66 PSI 86 SI	Comparable MA and OT between groups.	MA, OT
Boonen et al. (14)	RCT	Signature® (Biomet)	90 PSI 90 SI	Equivalent MA, sagittal and coronal alignment of femur and tibia. PSI decreased OT by 5 minutes.	MA, CFC, CTC, SFC, STC, OT
Chareancholvanich et al. (11)	RCT	Patient-Specific Instruments® (Zimmer)	40 PSI 40 SI	No difference in MA. Improved accuracy in CTC (89.8±1.2 vs 90.5±1.9, P=0.030) and fewer outliers in SFC with PSI (P=0.012). PSI decreased OT by 5 minutes.	MA, CFC, CTC, SFC, OT
Daniilidis et al. (6)	Retrospective	Visionaire® (Smith & Nephew)	150 PSI 156 SI	MA equivalent, with fewer outliers with PSI (9.3% vs. 21.2%).	MA
Hamilton et al. (15)	RCT	TruMatch® (DePuy)	26 PSI 26 SI	No difference in MA, CFC, CTC and SFC with PSI. Increased posterior slope in SI (P<0.001). PSI required fewer instrument trays but it was 4 minutes longer.	MA, CFC, CTC, SFC, STC, OT, number of instrument trays
Heyse et al. (7)	Retrospective	Visionaire® (Smith & Nephew)	46 PSI 48 SI	Reduced rate of FCR outliers in PSI group compared to SI (2.2% vs 22.9%, P=0.003).	FCR
Ivie et al. (19)	Retrospective	iTotal® G2 (ConforMIS)	100 PSI 100 SI	MA and CFC more accurate with PSI, with fewer outliers (P=0.0016 and P=0.032, respectively). No difference in CTC and in sagittal alignment between the two groups. No changes were required.	MA, CFC, CTC, SFC, STC, need for applying changes
Kotela et al. (24)	RCT	Signature® (Biomet)	49 PSI 46 SI	CTC showed more outliers in PSI group (38.78% vs 19.57%, P= 0.0458).	MA, CFC CTC, SFC, STC
Marimuth et al. (10)	Retrospective	Visionaire® (Smith & Nephew)	115 PSI 185 SI	No differences in the evaluated parameters. Similar number of outliers.	MA, CFC, CTC, SFC, STC, FCR
Ng et al. (2)	Retrospective	Signature® (Biomet)	105 PSI 55 SI	Overall MA similar, but fewer outliers with PSI (9% vs 22%, P=0.018); CFC (90.7 vs 91.3, P<0.001) and CTC (89.9 vs 90.4, P=0.005) closer to neutral in PSI group compared to SI.	MA, CFC, CTC
Noble et al. (12)	RCT	Visionaire® (Smith & Nephew)	15 PSI 14 SI	MA closer to neutral with PSI (1.7 vs 2.8, P=0.03). PSI showed reduction in OT (7 minutes) and number of instrument trays needed.	MA, CFC, CTC, OT, number of instrument trays
Nunley et al. (16)	Retrospective	Signature® (Biomet)	57 PSI 57 SI	Equivalent numbers of outliers with respect to MA. Decreased OT by 12 minutes after PSI.	MA, OT
Nunley et al. (21)	Retrospective	Signature® (Biomet)	50 PSI 50 SI	Equivalent numbers of outliers with respect to MA.	MA

Renson et al. (20)	Prospective case series	Signature® (Biomet)	71 PSI 60 SI	Fewer outliers in MA with PSI compared to SI (13% vs 29%, *P*=0.043). Decreased OT time by 9 minutes and the number of instrument trays by six trays with PSI.	MA, CFC, CTC, SFC, STC, OT, number of instrument trays
Roh et al. (9)	RCT	Signature® (Biomet)	42 PSI 48 SI	No difference groups with respect to all evaluated parameters. Equivalent number of outliers. OT was 13 minutes longer with PSI and PSI had to be aborted in 16% of knees.	MA, CFC, CTC, SFC, STC, FCR, OT, need for applying changes
Silva et al. (18)	Prospective randomized	Signature® (Biomet)	23 PSI 22 SI	No significant difference in FCR and TCR between groups, but less dispersion and amplitude of TCR around the neutral position with PSI.	FCR, TCR
Stronach et al. (25)	Retrospective	Signature® (Biomet)	58 PSI 62 SI	No improvement in alignment with PSI. Worsening of accuracy of the tibial slope with PSI (38% vs 61%, *P*=0.01). Equivalent OT.	MA, CFC, CTC, SFC, STC, OT
Stronach et al. (26)	Retrospective	Signature® (Biomet)	66 PSI 62 SI	Equivalent OT but multiple changes required intraoperatively with PSI (2.4 changes/knee).	OT, need for applying changes
Tibesku et al. (13)	Activity-based costing model	Visionaire® (Smith & Nephew)		Increased efficacy in OT and utilization of instrument trays with PSI. PSI is economically effective.	OT, number of instrument trays
Victor et al. (1)	RCT	Signature® (Biomet) TruMatch® (DePuy) Visionaire® (Smith & Nephew) Patient-Specific Instruments® (Zimmer)	61 P SI 64 SI	No significant differences between PSI and SI with respect to component alignment. PSI had more outliers than SI in CTC (14.6% vs 3.1%, *P*=0.03) and STC (21.3% vs 3.1%, *P*= 0.002). Visionaire® subgroup had more overall coronal alignment outliers (*P*=0.04) but fewer SFC outliers (*P*=0.001). PSI was abandoned in 22% of patients and modified in 28% of patients.	MA, CFC, CTC, SFC, STC, FCR, need for applying changes
Vundelinckx et al. (3)	RCT	Visionaire® (Smith & Nephew)	31 PSI 31 SI	Equivalent MA. Improved STC with PSI (2.9±2.39 vs 5.0±2.14, *P*=0.0008). No difference in pain, patient satisfaction, or functional outcomes (KOOS, Lysholm score).	MA, STC, functional evaluation
Woolson et al. (8)	RCT	TruMatch® (DePuy)	22 PSI 26 SI	Increased number of outliers in PSI group with respect to tibial slope (32% vs 8%, *P*=0.032). No significant difference with regard to OT or Knee Society rating or function score.	MA, CFC, CTC, STC, FCR, OT, functional evaluation
Yaffe et al. (5)	Retrospective	Patient-Specific Instruments® (Zimmer)	44 PSI 40 SI	No difference in MA, SFC or STC. No difference in pain, motion, Knee Society knee scores; PSI had higher Knee Society function scores pre- and postoperatively	MA, SFC, STC, functional evaluation

MA: mechanical alignment; CFC: coronal femoral component; CTC: coronal tibial component; SFC: sagittal femoral component; STC: sagittal tibial component; FCR: femoral component rotation; OT: operative time

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Anexos

Publication Norms

INSTRUCTIONS FOR AUTHORS

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