Patient specific instrumentation in total knee arthroplasty: a state of the art

Lorenzo Mattei, Pietro Pellegrino, Michel Calò, Alessandro Bistolfi, Filippo Castoldi

CTO Hospital, Città della salute e della Scienza, Turin, Italy

Contributions: (I) Conception and design: L Mattei, P Pellegrino, M Calò; (II) Administrative support: A Bistolfi, F Castoldi; (III) Provision of study materials or patients: A Bistolfi, F Castoldi; (IV) Collection and assembly of data: L Mattei, P Pellegrino, M Calò; (V) Data analysis and interpretation: L Mattei, P Pellegrino, M Calò; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Calò Michel. via Zuretti, 29 Turin, Italy. Email: michelcalo@me.com.

Abstract: Patient specific instrumentation (PSI) is a modern technique in total knee arthroplasty (TKA) aiming to facilitate the implant of the prosthesis. The customized cutting blocks of the PSI are generated from pre-operative three-dimensional model, using computed tomography (CT) or magnetic resonance imaging (MRI). A correct surgical plan is mandatory for a good surgical implant. The PSI guide takes into account any slight deformities or osteophytes and applies preoperative planning for bone resection, using the pre-determined implant size, position, and rotation. The apparent benefits of this technology are that neutral postoperative alignment is more reproducible, surgical time is decreased, and the entire procedure results more efficient and cost-effective. The use of PSI is indicated when advanced osteoarthritis, severe pain, and limited function/walking ability are present, such as in a standard instrumentation TKA. In addition to that, PSI finds its indication when intra-medullary guides cannot be used. For example, when there is a post-traumatic femoral deformity. Large debates have taken place about this topic during the last years and, at the moment, there is no consensus in literature regarding the accuracy and reliability of PSI as many studies have shown controversial and inconsistent results. Literature does not suggest PSI techniques as a gold standard in TKA, and therefore it cannot be recommended as a standard technique in standard, not complicated primary TKA. Moreover, literature does not underline any improvement in components alignment, surgical time, blood loss or functional outcomes. Nevertheless, many patients who underwent TKA suffered a previous trauma. In case of deformities, like femoral or tibial fractures healed with a malalignment, preoperative planning may result difficult, and some intra-operative technical difficulties can occur, such as the use of intra-medullar rod. In these selected cases, PSIs may be very useful to avoid errors in alignment and planning.

Keywords: Patient; specific; instrumentation; total knee arthroplasty (TKA)

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Introduction

Patient specific instrumentation (PSI) is a modern technique in total knee arthroplasty (TKA) aiming to facilitate the implant of the prosthesis. The customized cutting blocks of the PSI is generated from pre-operative three-dimensional model, using computed tomography (CT) or magnetic resonance imaging (MRI) (1). A correct surgical plan is mandatory for a good surgical implant.

The success of a TKA depends on knee alignment, gap kinematics and soft tissue balancing, and all three depend on the proper position of the components.

The PSI guide takes into account any slight deformities or osteophytes and applies preoperative planning for bone resection, using the pre-determined implant size, position, and rotation. The apparent benefits of this technology are that neutral postoperative alignment is more reproducible, surgical time is decreased, and the entire procedure results more efficient and cost-effective. Many manufacturers

Table 1 Some patient specific instrumentations available in the market at the moment of publishing

Name of the system	Producer	Planning technology
VISIONAIRE Patient Match Technology	Smith & Nephew, Inc., Memphis, TN, USA	MRI and radiographs
TruMatch	DePuy Orthopaedics, Warsaw, IN, USA	CT scan
GMK MyKnee	Medacta International S.A., Castel San Pietro, Switzerland	CT scan/MRI
PSI	Zimmer, Warsaw, IN, USA	MRI
PROPHECY® Preoperative Navigation Guides	Microport Orthopaedics, Shanghai, China	CT scan/MRI

MRI, magnetic resonance imaging; CT, computed tomography; PSI, patient specific instrumentation.

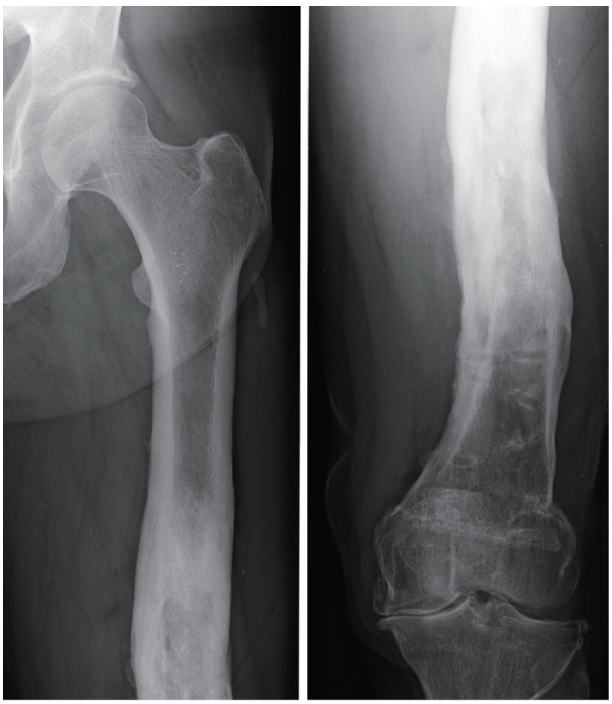

Figure 1 An example of post-traumatic femoral deformity that doesn't allow the use of intra-medullary femoral guides.

have invested in PSIs (*Table 1*). Large debates have taken place about this topic during the last years and, at the moment, there is no consensus in literature regarding the accuracy and reliability of PSI as many studies have shown controversial and inconsistent results.

Preoperative planning and surgical technique

The use of PSI is indicated when advanced osteoarthritis, severe pain, and limited function/walking ability are present, such as in a standard instrumentation TKA. In addition to that, PSI finds its indication when intra-medullary guides cannot be used. For example, when there is a post-traumatic femoral deformity (*Figure 1*) (2).

PSI facilitates cutting guides by creating a 3-dimensional (3D) model of the knee preoperatively, using CT or MRI and a full-leg antero-posterior radiograph. With a specific software program manufacturing engineers turn 2D CT or MRI images into 3D representations of the knee and lower limb. Using these 3D images, the anatomical landmarks of the knee are easily identified. A preoperative planning with bony resections is then created and presented to the operating surgeon. Using a specific software, the operator is then able to evaluate the 3D planning of the TKA with the bony resections. During this phase, the surgeon is able to approve or modify the pre-operative plan, adjusting as needed the tibial and femoral bone resections. In this phase, it is also possible to accurately plan the depth and the coronal orientation of the resection, as well as the rotation and the slope of the cuts. The rotation of the femoral implant is based on the transepicondylar axis (3). The tibial rotation is controlled and set-up according to the anterior tibial tuberosity. After the operator's authorization, custom cutting guides that fit on the patient's anatomy are manufactured and then sent to the surgeon (*Figures 2*,*3*). The PSI femoral guides are used to determine the valgus angle, level of resection, alignment, rotation, and size of the femoral component, whereas the patient-specific tibial guides are used to determine tibial alignment, level of resection, and tibial slope and rotation. Usually, 3 to 4 weeks are required to the final production of these cutting guides (4).

During surgery, the PSI guides are either used directly as slotted cutting guides or for an accurate pin positioning, using standard resection instrumentation for the bone cuts. The cutting guides are used for the primary distal femoral cut and proximal tibial cut. The subsequent bone cuts are achieved with standardized instrumentation. If the resections do not appear well aligned or orientated from

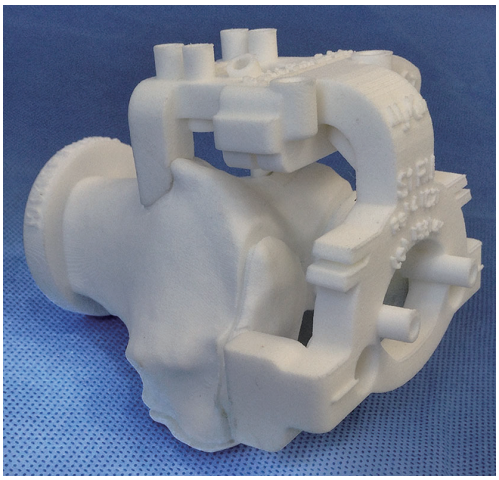

Figure 2 An example of a PSI distal femoral cutting guide and a 3D model of the patient's distal femur. PSI, patient specific instrumentation; 3D, 3-dimensional.

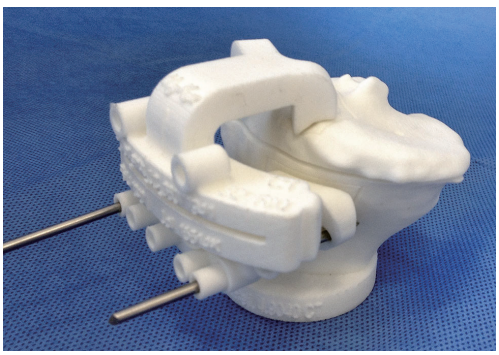

Figure 3 An example of a PSI proximal tibial cutting guide, and a 3D model of the patient's proximal tibia. PSI, patient specific instrumentation; 3D, 3-dimensional.

the operator's point of view, intraoperative modifications can be realized by using standard instrumentation for additional femoral and tibial cut. Using a MRI-based PSI, it is mandatory to leave cartilage, osteophytes and bone spurs as they act as a reference for cutting guide positioning. On the other hand, using a CT-based PSI, the cartilage and especially the soft tissues above the cutting blocks contact points must be accurately removed using electrocautery in order to properly expose the bone before pin fixation. These steps are compulsory, knowing that the CT-scan hardly detects cartilage or soft tissues during the planning. Without it, the CT-based PSI could be unstable and as a consequence, fail. The remaining procedure is then carried out as a usual TKA procedure.

Clinical results

Pre-operative planning and components alignment

In a comparison with navigation instrumentation, Conteduca *et al.* (5) demonstrated that PSIs are not fully able to achieve satisfactory alignment in both planes, especially evaluating the position of isolated tibial or femoral component. In a review by Sassoon *et al.* (6), the authors claim that there is a need to frequently change the cutting guides, modifying, as a result, the pre-operative planning. There is no complete consensus on the accuracy of the component alignment with a PSI. The importance of the coronal alignment in a TKA is well known. It should accurately match the mechanical axis and a higher complication rate has been reported if this result was not reached (7). Different authors showed how the coronal limb alignment as outliers in the frontal plane is an important factor in the implant survival, inducing an high risk of faster polyethylene wear (8,9).

With a traditional instrumentation, a series of cutting guides are used to provide bone resections in order to achieve correct alignment. With a PSI the final alignment results is checked after the preoperative planning using the appropriate software. But, as previously mentioned, the surgeon changes frequently, during surgery, the pre-operative planning in order to achieve better sizing and alignment. Rho *et al.* found no difference in alignment comparing PSI and traditional technique. But they reported a 16% rate of abandoned PSI guide due to not satisfactory alignment (10). They found an excessive femoral extra-rotation in 12% of cases. Similar results were observed by Stronach *et al.* (11), who reported an excessive femoral rotation in about 20% of cases. They also reported a decreased accuracy for tibial slope which results generally increased with the use of PSI instrumentation (38% PSI *vs.* 61% TI, P=0.01). Lustig *et al.* (12) comparing with the computer navigation, have evaluated the final alignment of the component, reporting that PSI do not improve accuracy. Also, Victor *et al.* (13) in 2014, have found more outliers in the sagittal and coronal alignment of the tibial component with the use of PSI in comparison to conventional instrumentation. Other authors, such as Barrett *et al.* (14) have tried to compare computer assisted surgery and PSI. A very small difference between the goup was found, with the computer assisted technique being slightly more accurate.

Boonen *et al*. (15) have reported a 29% outliers from the mechanical axis, defined as exceeding a threshold of 3° of the mechanical axis of the lower limb in the coronal plane, using PSI instrumentation. Nunley *et al*. (16) reported a much higher rate, with 37% of patients recorded with malalignment.

However, despite these findings, some Authors report a greater accuracy with the PSI system, justifying it with a more precise preoperative planning that must nevertheless be carefully evaluated and not blindly accepted.

Anderl *et al*. (17) present results that show significantly superior accuracy in mechanical alignment restoration and 3D-component positioning compared with conventional instrumentation in primary TKA. In their prospective study, they detected a mean value of less than 2° deviations from targeted component position in all planes as well as in the hip-knee-ankle angle. In recent studies (18,19), Heyse *et al*. compared rotational component alignment using an MRI study following TKA. They report that PSI was effective in significantly reducing outliers of optimal rotational tibial component alignment and that in both PSI and conventional TKA, almost all outliers were in excessive external rotation, which may have less negative impact on the function of the TKA than internal rotation. Furthermore, they affirm that PSI technique improves the rotation of the femoral component in comparison with standard techniques, although the same mean rotational values are found in both groups.

In conclusion we have not found in literature, a universal consensus on the precision of the PSI instrumentation on obtaining a correct alignment of the components. From our experience, we are not used to blindly accept the planning proposed by the software, and we carefully check intraoperatively the correct alignment. By doing this, we have reduced the rate of outliers and inaccuracy of the component's alignment.

Functional outcome

About the clinical and functional outcome, we have found in literature different results from the clinical studies. Yaffe *et al*. (20) report significantly greater improvement in functional score 6 months after surgery when compared to standard TKA. These results have to be carefully analyzed, considering that in this study, the Author have not performed a randomization of the patient's groups. In fact, in the PSI group, the patients have higher preoperative knee score compared with the standard TKA group. On the other hand, different authors demonstrated recently, with high quality studies, that no significant clinical benefits could be demonstrated with personalized techniques. This has been established for both total and unicompartmental knee replacement (21-23).

Blood loss

Thienpont *et al*. (24) have evaluated the impact of PSIs on blood loss, comparing it with a conventional TKA. By the most, rod entry hole has been considered a source of peri and postoperative oozing resulting in an increased blood loss. PSI do not violate intramedullary canal mainly because the use of intramedullary rod is not necessary to set the correct alignment. Controversial data was found in literature on the use of extramedullary guide or navigation and blood loss (5,25-27).

In this study, however, it is demonstrated that the use of PSIs does not reduce blood loss in TKA and that a well-performed conventional TKA with bone plugging of the femoral hole and extramedullary tibial alignment can be considered as a blood sparing surgery that reduces hidden blood loss. Voleti *et al*. have found similar results (28).

Surgical time

It is a common idea that PSIs could theoretically shorten operating time, especially for less experienced surgeons. In a randomized controlled trial, Hamilton *et al*. (29) demonstrated that PSIs do not shorten surgical time in comparison with traditional cutting blocks surgery. On the other hand, other authors showed different results. Nunley *et al*. (16) and Voleti *et al*. (28) found similar surgical times, Bali *et al*. (30) found shorter skin-to-skin time compared with traditional surgery. Certainly, to reduce surgical time, the surgeon has to spend time in the preoperative planning to achieve the desired alignment, and the learning curve for PSI technique has to be completed.

Economic costs and effectiveness

Some surgeons support PSI technique as a useful way to save surgical time, with consequent economical benefits. In our opinion, a real cost/benefits analysis should take into account the amount of surgical time saved that could really be used for other procedures. For example, saving five of surgical time of a procedure that normally lasts 1 hour, does not improve the work rate of a surgical theatre. The pre-

operative imaging and the cutting blocks custom-crafting costs should be considered, as well as the time spent by the surgeon during the pre-operative planning evaluation, as it has to be carefully analyzed in order to not jeopardize the final result.

In literature, to our knowledge, an accurate and complete analysis of the effective costs does not exists; for this reason, we cannot support the idea that PSIs have inferior nor superior costs than traditional instrumentation.

Conclusions

Literature does not suggest PSI techniques as a gold standard in TKA, and therefore it cannot be recommended as a standard technique in standard, not complicated primary TKA. Moreover, literature does not underline any improvement in components alignment, surgical time, blood loss or functional outcomes.

Further studies are needed to evaluate precisely the economic impact and effectiveness of PSIs.

Nevertheless, we think that in some particular situation, a patient specific cutting guide could improve results, especially for less experienced surgeons.

Furthermore, nowadays, many patients who underwent TKA suffered a previous trauma. In case of deformities, like femoral or tibial fractures healed with a malalignment, preoperative planning may result difficult, and some intra-operative technical difficulties can occur, such as the use of intra-medullar rod. In these selected cases, PSIs may be very useful to avoid errors in alignment and planning.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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