Review article
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Contemporary Use of 3D Printed Jigs and Guides for Osteotomies Around the Knee: A Systematic Review

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Abstract

Background. With improved accessibility of imaging and additive manufacturing, custom targeting guides and jigs are now widely accepted across many areas of orthopaedics. During orthopedic surgery, patient-specific guides assist in the accurate drilling and cutting of bone in conjunction with meticulous pre-operative planning. Given their increased uptake, it is important to define the lessons learned from recent clinical experience, and to document the reported benefits when using this technology intra-operatively.

The aim of this review is to evaluate the potential benefits of patient-specific guides for osteotomies about the knee, and to clarify what evidence currently exists to support their use.

Methods. A systematic review of PubMed, Embase, and Web of Science was performed for studies investigating the use of intra-operative patient-specific guides for realignment osteotomies about the knee. Randomised controlled trials, non-randomised studies, observational studies, case series, and case reports, as well as *in vitro* studies, were included. Screening was conducted with the Covidence software, and risk of bias was assessed with the Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) tool.

Results. A total of 38 studies satisfied the inclusion criteria: 21 of these included patient-specific instrumentation (PSI) for high tibial osteotomy, 6 with distal femoral osteotomy, 4 — for combined tibial/femoral rotational corrective osteotomies, 4 — in double-level osteotomies, and 6 — for intra-articular osteotomies. The main outcomes reported were accuracy of surgical correction, typically with reference to pre-operative plans, and execution accuracy based on radiographic measurements. Other common outcomes were operative time, intra-operative fluoroscopy, and operative costs. Many studies were observational in nature, with no control groups available for suitable comparison.

Conclusions. For corrective osteotomies about the knee, the literature suggests PSI has very strong potential to improve accuracy in achieving pre-operative targets. This was reported for both opening and closing wedge osteotomies of the femur, and for high tibial osteotomy. Some contradictory results have been reported for high tibial osteotomy, based on limited evidence from small studies that in many instances lacked controls for comparative analysis. Additional controlled trials are necessary to confirm the benefits of PSI for osteotomies about the knee, considering it has not yet been conclusively validated. The literature currently available indicates PSI can improve the accuracy of corrective osteotomies about the knee.

Keywords: patient-specific instrumentation, patient-specific guide, orthopedics, patient-specific jig, osteotomy, 3D printed, knee.

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Применение индивидуальных направителей для проведения остеотомий около коленного сустава: систематический обзор литературы

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Реферат

Введение. Использование индивидуально изготовленных направителей в комбинации с тщательным предоперационным планированием способствует выполнению более точных опилов во время остеотомии и позиционированию сверла при формировании отверстий. Учитывая повсеместное использование подобных устройств, важно проанализировать накопленный клинический опыт и определить преимущества интраоперационного использования технологий 3D-печати.

Цель обзора — оценить потенциальные преимущества индивидуально изготовленных направителей для остеотомии в области коленного сустава и целесообразность их использования.

Материал и методы. Для поиска использовались базы данных PubMed, Embase и Web of Science. В обзор вошли исследования, посвященные интраоперационному использованию индивидуально изготовленных направителей для корригирующих остеотомий в области коленного сустава. Были включены рандомизированные контролируемые исследования, нерандомизированные исследования, обсервационные исследования, серии клинических случаев, а также исследования *in vitro*. Скрининг проводился с помощью программного обеспечения Covidence. Риск системной ошибки оценивался с помощью инструмента Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I).

Результаты. В анализ вошло 38 исследований: 21 из них было посвящено использованию индивидуально изготовленных инструментов (ИИИ) для проксимальной остеотомии большеберцовой кости, 6 — для дистальной остеотомии бедренной кости, 4 — для комбинированных ротационных корригирующих остеотомий большеберцовой и бедренной костей, 4 — для двухуровневых остеотомий и 6 — для внутрисуставных остеотомий. Основными выявленными преимуществами применения данных устройств были точность хирургической коррекции в соответствии с предоперационным планом, а также рентгенологически подтвержденная точность ее реализации. Среди других часто отмечавшихся преимуществ были время операции, возможность интраоперационного рентгеноконтроля и стоимость операционного вмешательства. Многие исследования носили обсервационный характер и не имели контрольных групп для корректного сравнения.

Заключение. Согласно литературным данным, ИИИ позволяют значительно повысить вероятность достижения поставленных предоперационных целей при выполнении корригирующих остеотомий в области коленного сустава. Это было подтверждено как при открыто-, так и при закрытоугольной клиновидной остеотомии бедренной кости, а также при проксимальной остеотомии большеберцовой кости. В исследованиях, посвященных проксимальной остеотомии большеберцовой кости, результаты были противоречивы ввиду ограниченного числа публикаций, в большинстве которых отсутствовали контрольные группы для сравнительного анализа. В связи с этим необходимо проведение дополнительных контролируемых исследований для подтверждения преимуществ использования ИИИ при остеотомии в области коленного сустава. Современные источники литературы указывают на то, что использование технологий 3D-печати может повысить точность выполнения данных хирургических вмешательств.

Ключевые слова: индивидуально изготовленные инструменты, индивидуально изготовленный хирургический направитель, ортопедия, остеотомия, коленный сустав, технологии 3D-печати.

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INTRODUCTION

Deformity correction via osteotomy is conceptually quite simple; fracture the bone, straighten the limb, stabilize, and allow to heal in the chosen position. However, at the standard expected in contemporary orthopedic practice, corrective osteotomies are in fact highly demanding. The expectation is that even the simplest lower limb realignment procedure should be completed within a tolerance of less than 2°. An isolated coronal plane deformity still requires three-dimensional control of the osteotomy site, with at least 4° of freedom. Moreover, higher complexity corrections require high magnitude, multi-apical realignment, sometimes requiring multiple osteotomy sites. It is likely the combination of these factors that has led to the increasing implementation of patient-specific instrumentation (PSI) for these procedures. The added confidence provided by PSI has been proposed to assist in reducing the technical difficulty of complex osteotomies, and PSI guides may reduce the inconsistency of less experienced surgeons.

The use of additive manufacturing to create PSI has several potential benefits. The ability to plan pre-operatively, first performing a virtual procedure, and then executing the planned procedure under such guidance is believed to provide more accuracy with respect to the correction. Having pre-fabricated guides specific to the patient anatomy and based on a pre-operative plan should enhance the accuracy of any osteotomy, and therefore influence the quality of the achieved correction. Theoretically, this would affect the clinical biomechanics and perhaps improve post-operative outcomes.

By using unique patient-specific templates designed for each case, the use of a custom guide can potentially expedite procedures. With knowledge gained through meticulous pre-operative planning, the location, orientation, and magnitude of the required corrective osteotomy is already pre-determined, for the surgeon to perform without needing extensive fluoroscopy during the procedure. While any reduction in intra-operative radiation is at least in part offset by the need for pre-operative CT scans, less fluoroscopy during the procedure has the more significant impact of decreased operative time. Less time in theatre under anaesthetic leads to a lower potential for infection, blood loss, and anaesthetic risk. All these aspects would be expected to benefit outcomes, and, while difficult to determine accurately, would also be expected to reduce the overall cost to the healthcare system.

Considering the potential benefits of PSI and their rapidly increasing uptake in many areas of orthopedic surgery, it was *the aim of this review* to establish whether or not the currently available literature supports the use of PSI for realignment osteotomies about the knee. The main outcome of interest was accuracy of surgical correction. Other outcomes of interest included operative time, intra-operative fluoroscopy use, and operative costs.

METHODS

The methods described in the Cochrane handbook were used to perform this systematic review [1]. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline statements were used to report the results [2]. The search strategy was developed to include all studies within the orthopedic literature utilising any type of PSI for osteotomies or surgical guidance. Given the heterogeneity of terms in use, a variety of different synonyms were selected to ensure sufficient coverage of the chosen databases. The search terms are belaw*. These search parameters were applied to PubMed, Embase, and the Web of Science on 29 March 2024.

The following types of studies utilising 3-dimensional (3D) printed patient-specific guides intra-operatively for orthopedic procedures were included: randomised controlled trials, non-randomised controlled trials, observational studies, case reports, and *in vitro* studies. The following exclusion criteria were applied for screening and full text review: non-medical 3D printing applications; 3D printing applications in a non-medical setting; full text unavailable, conference abstract only; dental, spinal surgery, general surgery, thoracic surgery, maxillofacial surgery, or veterinary applications; 3D printed implants only; 3D printed surgical models only; and 3D bioprinting. The following exclusion criteria were applied for full text review: orthopedic applications outside the knee; total knee arthroplasty; or unicompartmental knee arthroplasty. The Covidence software (Melbourne, Victoria, Australia) was utilized for screening of studies. Two independent reviewers screened titles and abstracts based on the criteria described. Studies were assessed as eligible by voting “yes”, “maybe”, or “not eligible”. All voting was blinded and all references deemed eligible were carried forward for full text review. Discrepancies between the reviewers were resolved by discussion and consensus; indeterminate studies were carried forward into full text screening stages.

* (Orthopaedics) AND (3D print OR 3D printed OR 3D printing OR additive manufacturing OR additive fabrication OR additive layer manufacturing OR layer manufacturing OR fused deposition modelling OR freeform fabrication OR Patient Specific) AND (Targeting OR Osteotomy OR Cutting) AND (Guide OR Guides OR Guiding Jig OR Jigs OR Instrumentation OR Template).

Risk of bias was assessed using the Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) tool [3]. Narrative synthesis of included studies was performed with consideration to the study design and quality of evidence identified in the quality assessment.

RESULTS

The search parameters were applied to PubMed, Embase, and Web of Science on 29 March 2024, identifying 854, 619, and 128 candidates, respectively. Following screening and full text review, 38 studies were ultimately included, with further details in the PRISMA flow diagram (Figure 1). Of the 38 selected studies, 21 included PSI use for high tibial osteotomy (HTO) [4-24], 6 — with distal femoral osteotomy (DFO) [7, 10, 25-28], 4 — in combined tibial/femoral osteotomies for rotational corrections [29, 30-32], 4 — during double-level osteotomies (DLO) [7, 33-35], and 6 — with intra-articular osteotomies of the knee [36-41]. The main outcomes reported were accuracy of surgical correction, typically with reference to pre-operative plans, and execution accuracy based on radiographic measurements (see Tables 1-5). Other common outcomes were operative time, intra-operative fluoroscopy, and operative costs. The majority of these articles were observational studies without control groups for comparison.

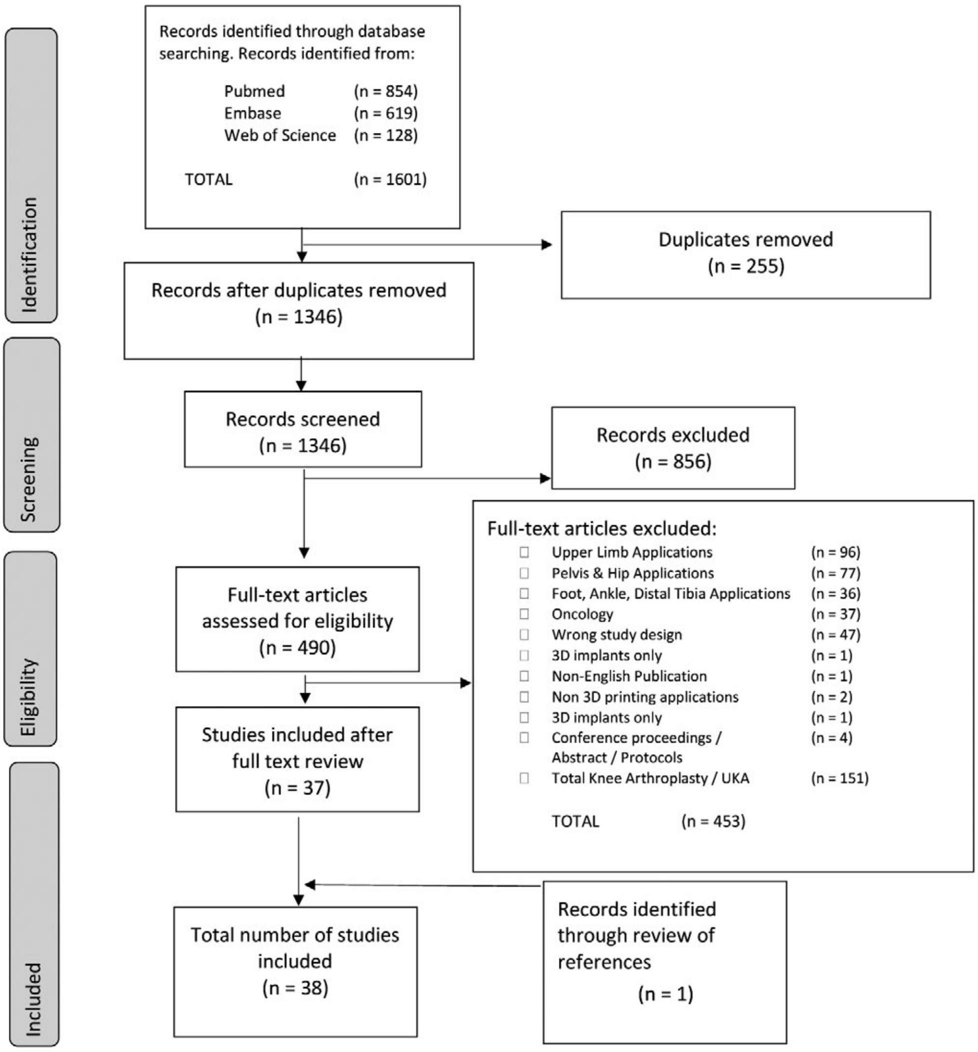


Figure 1. PRISMA flow diagram [2]

Table 1

High Tibial Osteotomy

Reference	Study type	Procedure	Participants	Measurement target	PSI accuracy (mean)	Control accuracy	P-value
Pérez-Mañanes R. et al. [4]	Observational Case-Control	Medial opening wedge osteotomy	PSI = 8 Controls = 20	Executional accuracy Coronal Final Valgus	0.5° (range, 0-1.2°) 7±2°	1.1° (range, 0-2.8°) 7±2°	"Non-significant"
Kim H.J. et al. [5]	Observational Case-Control	Medial opening wedge osteotomy	PSI = 20 Controls = 20	Absolute differences between the target point of 50% WBL	2.3±2.5%	6.2±5.1%	p = 0.005
Tardy N. et al. [6]	Observational Case-Control	Opening wedge osteotomy & Closing wedge osteotomy	PSI = 39 Controls = 61	HKA	0.3±3.1°	1.1±3 °	"Non-significant"
Abdelhameed M.A. et al. [7]	Observational Case-Control	Opening wedge osteotomy & Closing wedge osteotomy	PSI=55	HKA **NB!** Pooled results with HTO, DFO & DLO	1.3±0.7°	1.5±0.9°	"Non-significant"
Fayard J.M. et al. [8]	Observational Case-Control	Medial opening wedge osteotomy	PSI = 49 Controls = 38	HKA % (n) within ±2° of target	0.8±1.6° 90%	1.4±3.1° 65%	– p = 0.006
Predescu V. et al. [9]	Observational	Medial opening wedge osteotomy	PSI = 25	Coronal plane accuracy Sagittal plane accuracy	<2° <2°	–	–
Savov P. et al. [10]	Observational	Medial opening wedge osteotomy	PSI = 13	MPTA	0.86±0.6°	–	–
Chaouche S. et al. [11]	Observational	Medial opening wedge osteotomy	PSI = 100	HKA MPTA PPTA	1±0.95° 0.54±0.63° 0.43±0.8°		
Yang J.C. et al. [12]	Observational	Medial opening wedge osteotomy	PSI = 10	WBL percentage error Tibial slope percentage error	4.9% 4.1%		
Munier M. et al. [13]	Observational	Medial opening wedge osteotomy	PSI = 10	HKA Sagittal plane accuracy	0.84° 0.98°	–	–
Jacquet C. et al. [14]	Observational	Medial opening wedge osteotomy	PSI = 71	Coronal plane accuracy (HKA) Sagittal plane accuracy (PPTA)	1.0±1.0° 0.4±0.8°	–	–
Fucentese S.F. et al. [15]	Observational	Medial opening wedge osteotomy	PSI = 23	HKA PTS	0.8±1.5° 1.7±2.2°	–	-
Van Genechten W. et al. [16]	Observational	Medial opening wedge osteotomy	PSI = 30	MPTA	1.1±0.7°	–	–
Zaffagnini S. et al. [17]	Observational	Medial opening wedge osteotomy	PSI = 25	HKA PTS	2.1±2.9° 0.2±0.4°	–	–
Zhu X. et al. [18]	Observational	Medial opening wedge osteotomy	PSI = 48 Controls = 48	HKA	0.6±1.0°	2.6±2.0°	(p<0.001)
Jeong S.H. et al. [19]	Case Report	Medial opening wedge osteotomy	PSI = 1	HKA PTS	0.7° 0.3°	–	–
Lau C.K. et al. [20]	Case Report	Complex post traumatic malunion correction	PSI = 1	Valgus correction Flexion correction	14° 18° "As per pre-op plan"	–	–
Donnez M. et al. [21]	*In vitro* cadaveric	Medial opening wedge osteotomy	PSI = 10	mMPTA PTS	0.2±0.3° 0.1±0.5°	–	–
Miao Z. et al. [22]	*In vitro* cadaveric	Medial opening wedge osteotomy	PSI = 10	MPTA	0.72° (-3…2°)	–	–
MacLeod A.R. et al. [23]	*In vitro* cadaveric	Medial opening wedge osteotomy	PSI = 8	Gap opening angle	0.0±0.2°	–	–
Rosso F. et al. [24]	*In vitro* cadaveric	Medial opening wedge osteotomy	PSI = 12	MPTA PTS	1.2±0.6° 1.2±1°	–	–

Table 2

Distal Femoral Osteotomy

Reference	Study type	Procedure	Participants	Measurement target	PSI accuracy	Control accuracy	P-value
Arnal-Burró J. et al. [25]	Observational Case-Control	Lateral opening wedge osteotomy	PSI = 12 Controls = 20	Deviation from planned mechanical axis	0.28±1°	1.8°±4°	p = 0.002
Jacquet C. et al. [26]	Observational Case-Control	Lateral opening wedge osteotomy	PSI = 21 Controls = 21	Planned Coronal Correction Planned sagittal correction	0.43±0.50° 0.52±0.60°	3.95±1.64° 3.10±1.83°	p<0.001 p<0.001
Shi J. et al. [27]	Observational Case-Control	Medial closing wedge osteotomy	PSI = 33 Controls = 21	Planned WBL coordinates	4.9% (range 2-11%)	7.6% (range 2-13%)	p = 0.024
Abdelhameed M.A. et al. [7]	Observational Case-Control	Medial closing wedge osteotomy & lateral closing wedge osteotomy	PSI = 17	HKA **NB!** Pooled results with HTO, DFO & DLO	1.3±0.7°	1.5±0.9°	“Non-significant”
Savov P. et al. [10]	Observational	Medial closing wedge osteotomy & medial opening wedge osteotomy	PSI = 8	LDFA	1.98±1.33°	–	–
Huang Y.C. et al. [28]	Observational	Medial closing wedge osteotomy Double chevron cut technique	PSI = 25	Target point of 50% WBL	2.3±2.9%	–	–

Table 3

Double-Level Osteotomies

Reference	Study type	Procedure	Participants	Measurement target	PSI accuracy	Control accuracy	P-value
Abdelhameed M.A. et al. [7]	Observational Case-Control	Tibia and femur medial closing wedge osteotomy & lateral distal femoral closing wedge with medial high tibial opening wedge	PSI = 19	HKA **NB!** Pooled results with HTO, DFO & DLO	1.3±0.7°	1.5±0.9°	“Non-significant”
Grasso F. et al. [33]	Observational	Lateral distal femoral closing wedge with medial high tibial opening wedge	PSI = 22	HKA MPTA LDFA PPTA	1.3±1.5° 1.0±1.3° 0.9±1.2° 1.1±1.4°	–	–
Pioger C. et al. [34]	Observational	Medial closing wedge tibial and femoral osteotomy	PSI = 26	HKA mMPTA mLDFA	0.9±0.9° 0.7±0.7° 0.7°±0.8°	–	–
Gomez-Palomo J.M. et al. [35]	Case Report	Medial closing wedge osteotomy of the distal femur & medial opening wedge osteotomy of the tibia	PSI = 1	Coronal, sagittal & axial planes	<2°	–	–

Table 4

Rotational Osteotomy Tibia/Femur

Reference	Study type	Procedure	Participants	Measurement target	PSI accuracy
Jud L. et al. [29]	Observational	Femoral derotational osteotomy Tibial derotational osteotomy	PSI = 12 PSI = 7	Target torsional correction	4.8±3.1° 7.9±3.7°
Micicoi G. et al. [30]	Observational	Femoral derotational osteotomy Tibial derotational osteotomy	PSI = 7 PSI = 30	Target torsional correction	1.5±1.4° 1.3±1.1°
Sabatini L. et al. [31]	Case Report	Femoral & tibial derotational osteotomy	PSI = 1	Target of 16° for femoral anteversion and 25° for external tibial rotation	"Targets achieved"
Imhoff F.B. et al. [32]	*In vitro* cadaveric	Distal femoral rotational and varization osteotomy	PSI = 10	mLDFA	0.14±0.56°

Table 5

Intra-Articular Osteotomies

Reference	Study type	Procedure	Participants	Measurement target	PSI accuracy	Control accuracy	P-value
Fürnstahl P. et al. [36]	Observational	Intra-articular osteotomy for malunited tibial plateau fracture	PSI = 3	Reduction Accuracy (mm) Reduction Accuracy (deg.)	<1 mm <1.8°	–	–
Wang H. et al. [37]	Observational	Intra-articular osteotomy for malunited tibial plateau fracture	PSI = 6	–	–	–	–
Yang P. et al. [38]	Observational	Intra-articular osteotomy for malunited tibial plateau fracture	PSI = 7	Plateau collapse height (mm) **NB!** Pre-operative 4-12 mm	≤1 mm	–	–
Pagkalos J. et al. [39]	Case Report	Intra-articular osteotomy following malunited tibial plateau fracture	PSI = 1	Coronal plane accuracy (mMPTA)	0.2°	–	–
Zaleski M. et al. [40]	Case Report	Intra-articular osteotomy for traumatic defect reconstruction	PSI = 1	Clinical evaluation only			
Hsu C.P. et al. [41]	In vitro	Intra-articular osteotomy for malunited tibial plateau fracture	PSI = 7	Drilling accuracy error (mm)	0.5±0.19 mm	1.58±0.67 mm	p<0.05

Risk of bias assessment

Risk of bias was assessed using the ROBINS-I tool [3], and has been summarised in Appendix to the article. It can be found on the journal website — https://doi.org/10.17816/2311-2905-17524-151096. Nine non-randomised studies with case-controls were evaluated, with all 9 categorised as having an overall "moderate" risk of bias. Another 22 observational studies with no comparison group were also evaluated; 20 of these were classified as "moderate" risk, and 2 was classified as "serious" risk.

DISCUSSION

Orthopadic surgery can be considered inherently complicated, yet is still governed by basic principles of physics that have been well known for centuries. It is therefore bound by the same fundamental laws of mechanics that determine how modern buildings are designed, bridges are constructed, and towers are raised. Although routinely taken for granted, the sophisticated biomechanics of normal stance and gait demands quite literally a delicate balance of large loads in almost constant motion on complex surfaces through limbs with multiple articulations. Corrective osteotomies about the knee to restore normal lower limb alignment have been widely practiced for over 60 years, but have become increasingly more reliant on jigs, guides, and navigation in the past decade.

The term *PSI* encompasses a wide range of custom jigs, guides, and other devices used to assist surgeons to complete surgical procedures with the greatest accuracy and precision possible. These are generally designed and manufactured after meticulous pre-operative planning that has been completed based on 3D reconstructions of CT scans or other advanced imaging modalities. This is often implemented using a mirror image of the contralateral limb (when normal) as a virtual template. Custom patient-specific guides are similar in many features to conventional surgical jigs and guides, although further characterised by several distinguishing features. Typical PSI designs include openings to drill holes and insert osteotomes or saws at carefully planned locations and in specific orientations. These are based on pre-operative plans and are positioned so that subsequent screw placement and bony correction aligns with the definitive selected implants and planned correction. In this way, the subsequent plate can act as a reduction device, finalising bony position in the planned orientation.

High tibial osteotomy

Most included studies examining high tibial osteotomy (HTO) were observational cohort studies with no control group for comparison. However, several single group observational studies without comparison included considerable cohort sizes. V. Predescu et al. [9] reported coronal and sagittal plane accuracies of <2° in 25 patients. S. Chaouche et al. [11] similarly observed small differences in the accuracy of correction for the hip-knee-ankle angle (HKA), medial proximal tibial angle (MPTA), and posterior proximal tibial angle (PPTA), with a mean variation of less than 1° across a 100 patient cohort. Standard deviation, and therefore precision with respect to the HKA, MPTA, and PPTA was also very narrow in this group, with a range of ±1° [11]. This contrasts markedly with the accuracy and precision typically reported for HTO using standard instrumentation. In the systematic review of HTO using conventional techniques by M. Van den Bempt et al. [42], reported levels of accuracy were ±5.6°, with a range of 4-8° [42].

The studies including formal comparison groups were, for the most part, non-statistically significant. Studies by R. Pérez-Mañanes et al., [4] N. Tardy et al. [6], and M.A. Abdelhameed et al. [7] all reported improvements in post-operative accuracy for PSI compared to conventional instrumentation, although none were statistically significant. A meta-analysis from S. Cerciello et al. aggregating results from two of the included comparison studies demonstrated PSI use reduced the rate of correction outliers with a small trend towards superior accuracy [43]. In a recent systematic review by Aman et al. [44], low rates of correction outliers were also observed in comparison with conventional techniques. Similar to the techniques described in the included studies, at our institution PSI are designed and manufactured to contour to a patient's unique bony anatomy, allowing the guide to be precisely positioned in a predetermined location. Case 1 described below illustrates the application of HTO (Figure 2).

Case 1

A 42-year-old male patient with constitutional genu varum deformity of the right lower extremity who underwent a proximal tibial valgizing osteotomy (HTO) to unload the medial compartment and achieve mild valgus alignment. Instead of neutral, alignment is taken to a point 0.625 of the distance across the width of the tibial plateau towards the lateral side (Fujisawa point).

Long-standing X-rays or weight-bearing EOS scans of both lower extremities are necessary to complete the initial radiographic assessment and determine the nature of the deformity, and the magnitude of the correction necessary to create alignment through the Fujisawa point. The medial proximal tibial angle (MPTA) measures 84°, resulting in 2.1° of overall varus. A correction of 5° of valgization is necessary to achieve an MPTA of 89°, in order to achieve a mechanical axis of 2.9° valgus and place the mechanical axis through the Fujisawa point. The pre-operative plan must also maintain a neutral proximal tibial slope, and not introduce an iatrogenic flexion deformity (Figure 2 a).

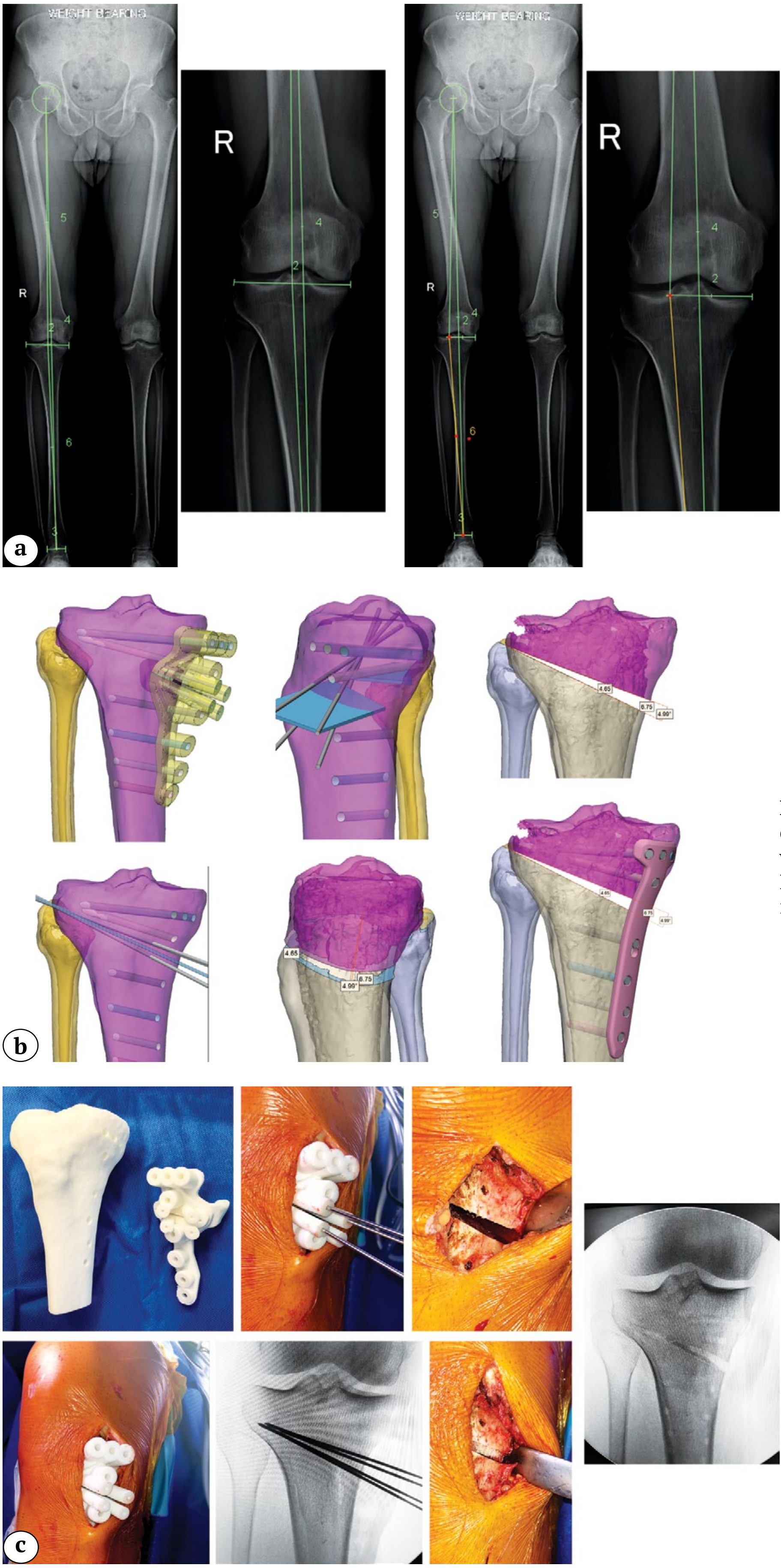
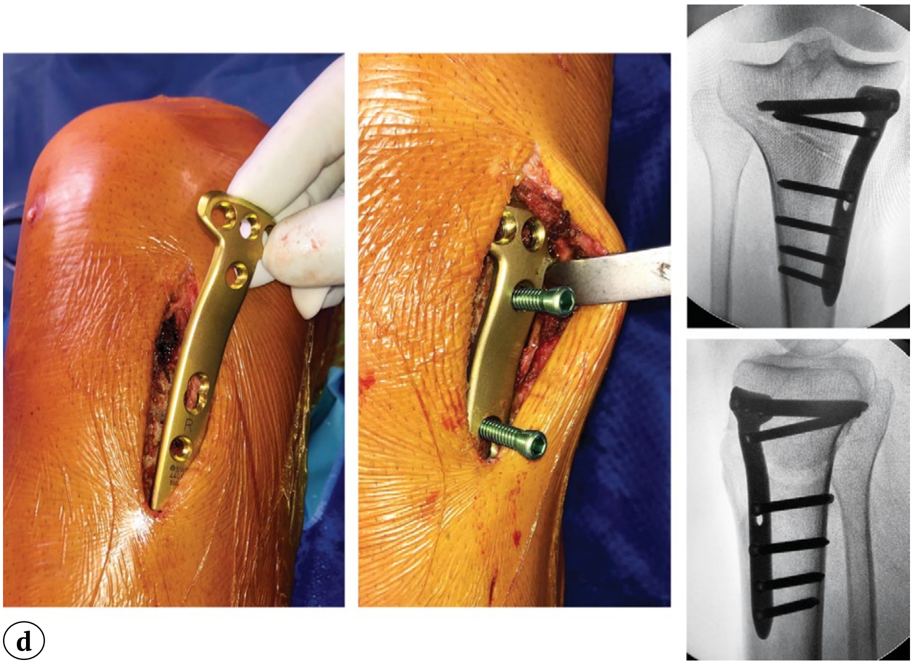


Figure 2 (a, b, c). High tibial osteotomy (unilateral opening wedge/valgizing).
Read the Case 1 description in the article text above



d

Figure 2 (d). High tibial osteotomy (unilateral opening wedge/valgizing HTO). Read the Case 1 description in the article text above

The PSI jig for the right HTO, as designed and visualized in both the coronal and sagittal planes, when mounted on the virtual realization of the intact right proximal tibia (marked in purple). Virtual realization of the 5° valgizing corrective osteotomy, depicting the size of the opening wedge as well as the position of the plate planned to stabilize the osteotomy and maintain the correction until solid union is achieved 6-8 weeks post-operatively. (**NB!** The opening wedge is always intended to be trapezoidal in appearance, slightly wider posterior, to limit the potential to introduce iatrogenic flexion) (Figure 2 b).

Intra-operative images demonstrating sequential stages of the actual surgical procedure. The PSI jig is inserted through the medial incision, and secured with 4 K-wires. The wires converge laterally and act as a "capture" to limit the progress of the saw blade and prevent inadvertent disruption of the lateral cortex. After confirming satisfactory placement and orientation of the PSI jig, precision drill holes are made through the jig that correspond with the orientation they will later occupy in the corrected position. At this point, the opening wedge (incomplete laterally) osteotomy is performed, again using the PSI jig to orient the saw blade at the planned level. The opening wedge is created and provisionally held in place with a small allograft bone wedge, and X-rays obtained to confirm (Figure 2 c).

The definitive fixation plate is inserted and the pre-drilled holes are aligned with the plate both proximally and distally. Initially 2 screws are incompletely inserted to maintain orientation of the plate while still allowing the pre-drilled holes to achieve the planned correction. To avoid potential under-correction and residual varus deformity, slight over-correction to the Fujisawa point of 2.9° valgus was introduced. This mechanically unloads the previously overloaded medial compartment, which is the most important clinical consideration. In this instance, 5° of valgization was planned and 5.1° of valgization was achieved, resulting in a final overall alignment of 3° valgus. The inherent inaccuracy and limited precision of repeated measurements, as well as minor ligamentous laxity, are perhaps responsible for the inability to perfectly reproduce the virtual correction during any actual procedure (Figure 2 d).

Distal femoral osteotomy

Compared to HTO, there are relatively few studies examining the benefits of PSI for distal femoral osteotomy (DFO). Among lateral open wedge varizing DFO, J. Arnal-Burró et al. demonstrated a significant difference in terms of accuracy relative to their planned correction [25]. The mean final mechanical axis deviation was 0.3° (±1°) with custom jigs, compared to 1.8° (±4°) without ($p = 0.002$). They also demonstrated further benefits of using patient-specific guides, with corresponding reductions in operative time, total cost, and intraoperative fluoroscopy time. In 21 lateral opening wedge DFO, C. Jacquet et al. evaluated PSI against age-matched controls [26]. The PSI group demonstrated significantly greater accuracy in both coronal and sagittal plane corrections. The mean residual coronal plane angular deviation was 0.4° (±0.5°), compared to 3.9° (±1.6°) with conventional instrumentation ($p<0.001$). The mean sagital plane axial deviation measured 0.5° (±0.6°), compared to 3.1° (±1.6°) with conventional intrumentation

[26]. While selection bias against matched controls may be a consideration across these results, their reported accuracy with standard instrumentation is very similar to previosuly published results of 4° to 4.5° [45, 46].

Opening wedge osteotomies about the knee are generally preferred, due to their greater reproducibility and accuracy compared to closing wedge techniques [47, 48]. The technical difficulty of the closing wedge method can in part be attributed to the demand for two independent but very closely matched osteotomies that must be completed to allow a precise segment of bone to be removed, and this alone may lead to less accurate correction when using a closing wedge compared to an opening wedge [49]. The use of PSI to assist accurate resection is therefore of particular interest with a closing wedge correction, as the precision demand is particularly high. Y.C. Huang et al. describes a PSI assisted double chevron technique in closing wedge DFO, which further emphasises the demand on precise, matched osteotomies [28]. In their opinion, the inherent stability and native bone-bone contact achieved from this double chevron technique can be performed accurately only with the application of PSI. The ratio of the distance from the medial tibial spine relative to the width of the tibial plateau (weight-bearing line ratio — WBL) was corrected with a mean accuracy of 2.3±2.9% relative to pre-operative targets. Again, similar to the techniques described in the included studies, at our institution PSI are designed and manufactured to very closely contour to a patient's unique bony anatomy, allowing the guide to be precisely positioned in a predetermined location. Case 2 described below illustrates the application of DFO (Figure 3).

Case 2

A 34-year-old male patient with constitutional bilateral genu valgum who underwent sequential (not simultaneous) bilateral DFO to restore normal (neutral) alignment. This case demonstrates the pre-operative status and planning, the PSI osteotomy jigs as designed, and the postoperative X-rays confirming satisfactory correction was achieved.

Long-standing X-rays or weight-bearing EOS scans of both lower extremities are necessary to complete the initial radiographic assessment and determine the nature of the deformity, and the magnitude of the correction necessary to restore normal alignment. On the right side, the lateral distal femoral angle (LDFA) measures 79°, and 7°

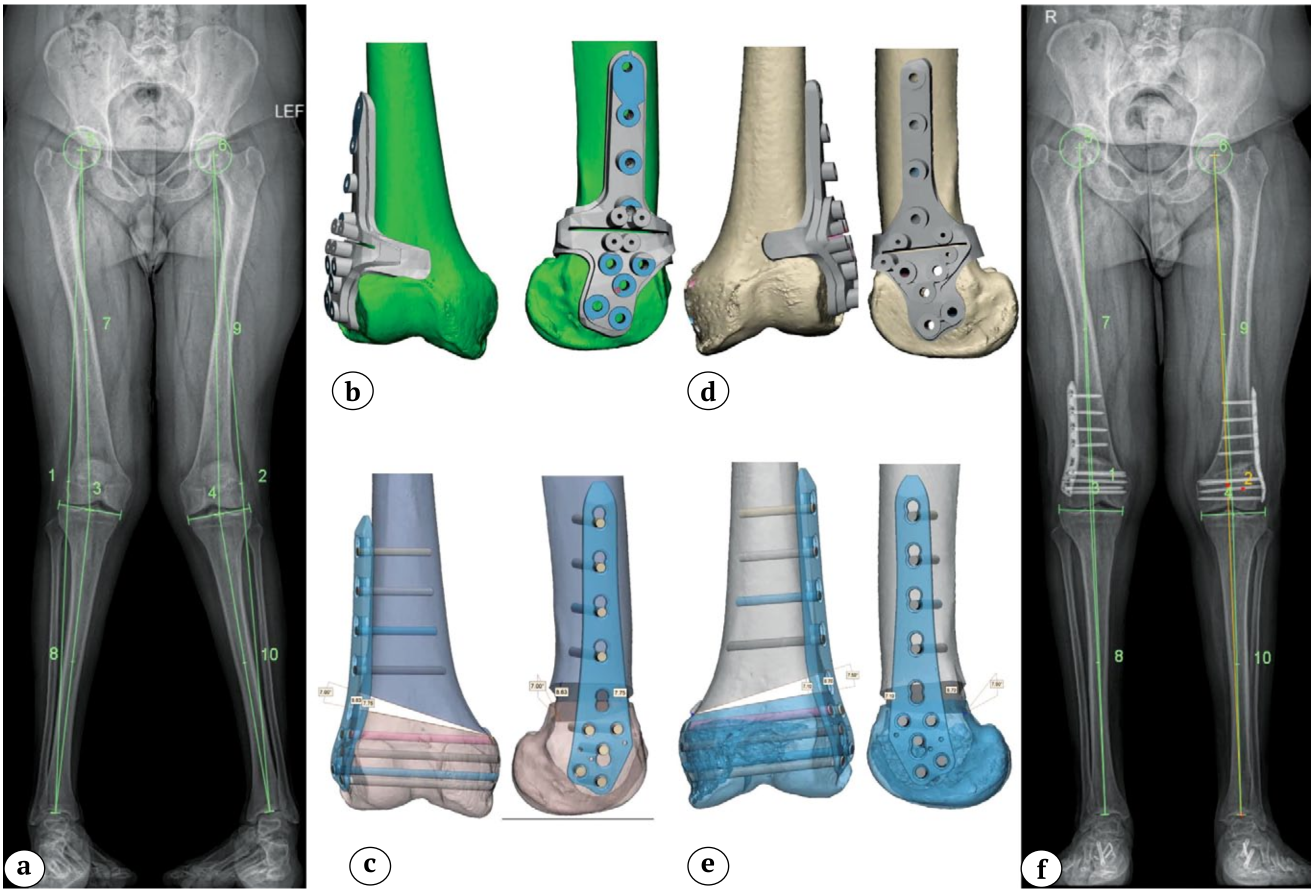


Figure 3. Bilateral opening wedge/varizing DFO. Read the Case 2 description in the article text above

of varization is necessary to achieve an LDFA of 86°, in order to achieve a mechanical axis of 0°. On the left side, the LDFA measures 80.5°, and 7.5° of varization is necessary to achieve an LDFA of 88°, in order to achieve a mechanical axis of 0° (Figure 3 a).

The PSI jig for the right DFO, as designed and visualized in both the coronal and sagittal planes, when mounted on the virtual realization of the intact and deformed right distal femur (marked in green) (Figure 3 b).

Virtual realization of the 7° corrective osteotomy, depicting the size of the opening wedge as well as the position of the plate planned to stabilize the osteotomy and maintain the correction until solid union is achieved 6-8 weeks post-operatively. (**NB!** The opening wedge is always intended to be trapezoidal in appearance, slightly wider posterior, to limit the potential to introduce iatrogenic flexion.) (Figure 3 c).

The PSI jig for the left DFO, again as designed and visualized in both the coronal and sagittal planes, when mounted on the virtual realization of the intact and deformed right distal femur (marked in beige) (Figure 3 d).

Virtual realization of the 7.5° corrective osteotomy, again depicting the size of the opening wedge as well as the position of the plate planned to stabilize the osteotomy and maintain the correction until solid union is achieved (Figure 3 e).

Final weight-bearing images of both lower extremities, 6 months following the second procedure and confirming satisfactory union of both osteotomies was achieved. To avoid potential under-correction and residual valgus deformity, in each instance slight over-correction to a final very minor varus alignment of less than 2° was introduced bilaterally. This mechanically unloads the previously overloaded lateral compartment in both instances, which is the most important clinical consideration. On the right side, 7° of varization was planned and 7.3° of varization was achieved, resulting in slight over-correction and a final overall alignment of 0.9° varus. On the left side, 7.5° of varization was planned and 8.5° of varization was achieved, resulting in slight over-correction and a final overall alignment of 1.4° varus. Again, the inherent inaccuracy and limited precision of repeated measurements, as well as minor ligamentous laxity, are most likely responsible for the inability to perfectly reproduce the virtual correction during the actual procedure (Figure 3 f).

Rotational osteotomy

For rotational osteotomies involving the tibia and/or femur, there were no comparative studies identified in the literature. L. Jud et al. [29] reported differences between the planned and achieved rotation of 4.8° (± 3.1°) for the femur, and 7.9° (± 3.7°) for the tibia. More accurate corrections were reported by G. Micicoi et al., where the planned axial rotation was achieved within 1.5° (±1.4°) and 1.3° (±1.1°) for the femur and tibia, respectively [30]. In their series, the coronal and sagittal operative targets were essentially always matching the pre-operative values (either identical to or within <2°). Across the radiographic criteria of MPTA, lateral distal femoral angle (LDFA), PPTA, and posterior distal femoral angle (PDFA), targeted values were noted to be highly accurate to less than 1° (±0.9°). The targeted axial correction is another valuable endpoint; however, given that the surgeon actively requires adequate three-dimensional control of the osteotomy site in all directions, these are still valuable secondary endpoints. Accurately controlled coronal and sagittal alignment throughout rotational osteotomies is demonstrated here, an added level of security provided by PSI in this setting.

Intra-articular osteotomy

Within the literature examining intra-articular osteotomies of the knee, all pertained to complex intra-articular osteotomies following tibial plateau fracture malunion. P. Fürnstahl et al. described 3 cases of tibial plateau malunion corrected with PSI [36]. Using their technique, PSI permitted accurate multiplanar correction of deformities with an accuracy of within 1 mm and 1.8° relative to pre-operative targets. H. Yang et al. reported an improvement in the height of the collapsed lateral plateau from 4-12 mm pre-operatively to ≤1 mm in all cases [38]. H. Wang et al. [37] noted considerably reduced articular step-off following surgery using PSI in 6 tibial plateau malunion cases. In the correction of a malunited Schatzker V fracture using PSI, J. Pagkalos et al. reported very close reproduction of their pre-operative plan of 88.8° MPTA, achieving 89° post-operatively [39]. C.P. Hsu et al. provided *in vitro* results where PSI improved accuracy of screw placement compared to conventional techniques during simulated tibial plateau malunion correction [41].

Deformity following intra-articular fracture is often multiplanar and can require complex correction to achieve an anatomical reduction. Theoretically, this would be an ideal setting for PSI. These small observational studies suggest the potential benefit of PSI for intra-articular corrections; however, the small cohorts and lack of comparison groups limits their generalizability and significance.

Reduction in operative time

Use of PSI significantly reduces operative time when compared with traditional techniques for osteotomies about the knee [4, 9, 25, 26, 27].

Operative time reduction averaged 31 minutes for HTO, a time reduction of 34% [4]. For DFO, operative time was reduced on average 32 minutes [25], 7 minutes [26], and 19 minutes [27] across various studies. These equated to a reduction of 15%, 34%, and 20%, respectively. Although the magnitude of the reduction varies, these studies all consistently demonstrate operative time is reduced with PSI. The potential clinical benefits of reduced operative time include decreased blood loss and lower infection rates, while limiting aneasthetic risk. This reduction in time may not be directly appreciated by the surgeon, as there is an additional time investment required pre-operatively for virtual planning and jig design. The assessment and meticulous planning for the correction is carried out formally well in advance of surgery, rather than informally during the procedure itself.

Reduction in radiation exposure

Utilising PSI can also significantly reduce the use of fluoroscopy and surgeon radiation exposure intra-operatively. The number of fluroscopic images taken during surgery was reduced from 65 to 6 [25], 55 to 8 [4], 12 to 5 [26], and 35 to 6 [27] across the studies that have investigated this aspect. J. Arnal-Burró et al. make a valid point regarding these benefits, arguing any reduction in intra-operative fluoroscopy needs to be weighed against the patient's additional pre-operative radiation exposure from CT scans [25]. Although CT scans are becoming more routinely used in orthopedic practice, it could be considered disingenuous to claim possible radiation reduction using jigs, given the pre-requisite for a pre-operative CT. Nevertheless, most likely the decreased need for intra-operative fluoroscopy actively contributes to the considerable time reduction associated with the use of guides.

Reduction in costs and other benefits

J. Arnal-Burró et al. calculated the cost savings that result from the use of guides and PSI [25]. In their example, this was principally due to the reduction in surgical time, offset by the additional expenses associated with 3D printing materials and CT scanning. They did not consider the cost of design or of the necessary specialist salaries in their analysis. In our opinion, it is likely that considerable cost-savings still occur with PSI when based on more advanced machines, even with the added expense of an engineer and a medical modeller or technical support. It has been estimated that operating room running costs can range between $40 to $100 a minute, when accounting for all costs of staff and equipment [50]. Using a modest time reduction figure from the included studies, a reduction of 19 minutes operating time results in a gross savings of $1330 [27]. Based on our own experience in this field, the current cost for print material is approximately $0.50/ml, with the upper threshold for the volume of a typical guide approaching 180 ml [4]. As such, the necessary guide materials would equal approximately $90.00 USD. Currently, CT scanning of a knee without contrast costs approximately $225 USD. Engineers in our facility generally require 2-4 hours to design a guide, and technicians can require 1-2 hours per guide produced, resulting in a total of $320 USD in personnel costs. Based on these estimated costs, the net savings equal nearly $700 USD per operation.

Other purported benefits include reducing surgeon stress, and the ability for low-volume surgeons to successfully perform these demanding procedures with greater confidence [14]. The PSI guides reduce the surgeon's stress level intraoperatively, especially for those least experienced [14]. In complex cases that may normally be limited to select senior surgeons, there is the potential to further enhance their technical abilities [14]. In areas with limited sub-specialty access, the guides may enable broader interventions to be carried out where they would not otherwise be available.

In the context of corrective osteotomies, biomechanical correction is reliant upon a very high degree of accuracy. Many publications have explicitly identified specific correction targets for osteotomies around the knee, and deformity correction planning has become much more sophisticated over the past 30 years. Ultimately, the ability to perform corrections accurately and reliably enables pre-operative plans to be more consistently realised post-operatively. With greater consistency in the accuracy of correction, it may become possible to further optimize the correction parameters. Combining rigorous biomechanical analysis, sophisticated pre-operative planning, and enhanced intra-operative accuracy may ultimately define the correction parameters that result in the greatest clinical benefit.

CONCLUSIONS

For corrective osteotomies about the knee, PSI shows strong potential in achieving improved accuracy relative to pre-operative targets. This included both opening and closing wedge techniques for the distal femur, as well as HTO, despite some contradictory reports for the latter. It should be noted that this is largely based on the limited evidence provided by small observational studies, which in many cases lack adequate controls for comparison. As such, larger controlled trials will be necessary to confirm the benefits of PSI for osteotomies about the knee, particularly multi-planar and intra-articular corrections. The available literature currently suggests PSI improves both the accuracy and precision of corrective osteotomies about the knee. However, large, multi-planar corrections are where the proposed benefits of PSI theoretically provide the greatest benefit, and this remains an important area for further investigation.

DISCLAIMERS

Author contribution

All authors made equal contributions to the study and the publication.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

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Consent for publication. Written consent was obtained from the patients for publication of relevant medical information and all of accompanying images within the manuscript.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Заявленный вклад авторов

Все авторы сделали эквивалентный вклад в подготовку публикации.

Все авторы прочли и одобрили финальную версию рукописи статьи. Все авторы согласны нести ответственность за все аспекты работы, чтобы обеспечить надлежащее рассмотрение и решение всех возможных вопросов, связанных с корректностью и надежностью любой части работы.

Источник финансирования. Авторы заявляют об отсутствии внешнего финансирования при проведении исследования.

Возможный конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

Этическая экспертиза. Не применима.

Информированное согласие на публикацию. Авторы получили письменное согласие пациентов на публикацию медицинских данных и изображений.

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