



Original Research

Accurate correction with a novel patient-specific instrument for medial opening wedge high tibial osteotomy



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ARTICLE INFO

Keywords:

Medial opening wedge
High tibial osteotomy
Patient-specific instruments
Osteotomy
Accuracy

ABSTRACT

Introduction: Patient-specific instruments (PSIs) have been introduced to enhance the accuracy of medial opening wedge high tibial osteotomy (MOWHTO). This study aimed to evaluate the accuracy of a newly developed PSI and its impact on postoperative clinical outcomes.

Methods: Forty patients with varus alignment who underwent MOWHTO using the newly developed PSI were retrospectively analyzed for accuracy of correction. Radiographic evaluations, including hip-knee-ankle angle (HKA) and medial proximal tibial angle (MPTA) were performed using long-leg standing radiographs preoperatively and at 6 months postoperatively. Overall error was defined as the difference between the planned and achieved HKA (Δ HKA), while surgical error was defined as the difference between the planned and achieved MPTA (Δ MPTA). Planning error was defined as the difference between overall error and surgical error. For each type of error, positive values indicated over-correction, while negative values indicated under-correction. Knee Injury and Osteoarthritis Outcome Score (KOOS) data were collected and compared between preoperative and 12-month postoperative assessments.

Results: The mean planned HKA was $182.4^\circ \pm 0.3^\circ$, and the achieved HKA was $182.6^\circ \pm 1.5^\circ$ ($p = 0.382$). The mean planned MPTA was $93.1^\circ \pm 1.9^\circ$, and the achieved MPTA was $92.8^\circ \pm 1.9^\circ$ ($p = 0.358$). The overall error was $0.2^\circ \pm 1.5^\circ$ (38% under-correction and 62% over-correction). Surgical error (Δ MPTA) averaged $-0.3^\circ \pm 1.1^\circ$ (55% under-correction and 45% over-correction), while planning error averaged $0.6^\circ \pm 1.1^\circ$ (30% under-correction and 70% over-correction). All KOOS subscales showed a statistically significant improvement at 12 months postoperatively compared to preoperative scores ($p < 0.001$).

Conclusion: The newly developed PSI workflow proved to be an accurate method for planning and performing MOWHTO. While overall error was low, the observed tendencies for surgical under-correction and planning over-correction highlight the need for careful consideration of these factors to optimize outcomes in the future.

Level of evidence: Level IV, Retrospective Case Series.

What are the new findings?

- A newly developed patient-specific instrument workflow for medial opening wedge high tibial osteotomy was introduced.
- The workflow demonstrated high accuracy, achieving a low overall error ($0.2^\circ \pm 1.5^\circ$) between planned and achieved alignment.
- This study is the first to separately evaluate surgical and planning errors, revealing a tendency for surgical under-correction and planning over-correction.
- While overall error was low, tendencies for surgical under-correction and planning over-correction require careful consideration to optimize alignment correction.

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<https://doi.org/10.1016/j.jisako.2025.100859>

Received 1 February 2025; Received in revised form 6 March 2025; Accepted 30 March 2025

Available online 5 April 2025

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INTRODUCTION

Medial opening wedge high tibial osteotomy (MOWHTO) is a well-established surgical procedure for treating early-stage medial compartment osteoarthritis with varus deformity in active patients, typically aged 40 to 60 years [1,2]. Clinical outcomes rely heavily on accurate postoperative lower limb alignment. Under-correction may lead to deformity recurrence, inadequate symptom relief, or early failure, requiring revision osteotomy or arthroplasty. Over-correction can result in lateral compartment overloading, excessive shear stress, cosmetic deformity, lateral pain, and poor postoperative outcomes [3–6]. While various techniques for preoperative planning have been described to achieve precise alignment, unexpected correction errors continue to occur [7,8].

To optimize alignment correction and aid surgical workflow, patient-specific instruments (PSIs) have been introduced. PSIs are designed using 3D imaging and virtual surgery planning, allowing for precise positioning of the cutting guide and optimized wedge opening. This approach aims to reduce postoperative alignment variability by reducing surgical error relative to the preoperative surgical plan [9,10]. Previous studies have shown the use of PSI in MOWHTO ensures accurate alignment correction and improves patient-reported outcome measures (PROMs) [11,12]. However, despite the implementation of PSIs, correction errors still occur [13]. These overall correction errors may stem either from surgical error, such as imprecision in achieving the planned wedge angle, or from planning errors such as flaws in the preoperative planning process. Previous research has not adequately investigated the sources of overall error, underscoring the need to separately evaluate surgical error and planning error.

In this study, we introduce a novel PSI designed to improve surgical accuracy. With the introduction of any new technology, a comprehensive evaluation of its clinical efficacy and safety is necessary. To our knowledge, no studies have directly compared the accuracy between different PSI systems for MOWHTO. This lack of comparative studies highlights the importance of validating each PSI system individually to ensure clinical reliability. The objectives of this study are: (1) to assess the overall error of our MOWHTO workflow using the PSI system, (2) to evaluate the source of this error while distinguishing between surgical error and planning error, and (3) to report postoperative clinical outcomes and complications.

METHODS

Participants

The study was approved by the Human Research Ethics Committee of Northern Sydney Local Health District, reference: HREC/17/HAWKE/140. Due consent was obtained for the use of data from all patients of this study. A retrospective analysis of prospectively collected data for patients with medial compartment osteoarthritis who underwent MOWHTO from September 2020 to March 2023 was performed. Consecutive patients with medial compartment knee osteoarthritis aged <60 years old who failed to respond to conservative management were included. Patients who had any previous knee surgery or who had insufficient radiographic and clinical data or who did not proceed with surgery were excluded.

Image acquisition

Coronal and sagittal weight-bearing long-leg radiographic images were obtained simultaneously using the EOS imaging system (EOS imaging Inc., Paris, France). Full-leg thin slice (0.6 mm) computed tomography (CT) scans were acquired for 3D planning and PSI design (Aquilion Prime SP, Canon Medical Systems, Otawara, Japan). High-resolution magnetic resonance imaging (MRI) scans were acquired to confirm patient suitability for MOWHTO surgery.

Preoperative planning

Image data were uploaded to the Personalised Surgery app (PS CaseNote) for quality control and preoperative planning. 3D models of the femur, tibia, and fibula were created from CT DICOM images using a combination of standard thresholding and manual segmentation techniques in Mimics (Materialise NV, Leuven, Belgium). The 3D models were overlaid on, and aligned to the EOS images to simulate a 3D weight-bearing stance. Measurements of radiographic parameters, including the hip-knee-ankle (HKA) angle, weight-bearing line (WBL) ratio, medial proximal tibial angle (MPTA), mechanical lateral distal femoral angle, the joint line convergence angle (JLCA), and posterior tibial slope angle (PTSA) were made. The HKA angle was defined as the medial angle between the mechanical femoral and tibial axes. The WBL ratio was measured as the percentage position where the mechanical axis of the lower extremity crosses the proximal tibial plateau. The MPTA was defined as the angle between the mechanical axis of the tibia and the proximal tibial articular surface. The JLCA was determined as the angle formed between the tangential lines of the distal femoral and proximal tibial articular surfaces. The PTSA was measured as the angle between the anatomical tibial axis, defined by a line connecting the center of the proximal tibia at 20% of the total tibial length and the midpoint of the tibial plafond, and the medial tibial plateau. These parameters were uploaded into PS CaseNote to calibrate the patient-specific alignment algorithm, enabling the surgeon to perform real-time surgical planning and precisely prescribe the desired surgical correction angle (Fig. 1). The target surgical correction angle for each patient was determined by one of three fellowship-trained consultant orthopedic surgeons, and in most cases set to achieve a 55%–62.5% WBL.

PSI design & manufacture

The 3D bone models were imported into 3-Matic (Materialise NV, Leuven, Belgium) where the MOWHTO procedure was virtually simulated based on the surgical correction prescribed by the surgeon. Digital models of the Personalised Surgery SMART HTO plate and screws were positioned on the simulated bone models. The screw positions were marked on the model before repositioning them back into the preoperative position. The guide was designed referencing the preoperative screw locations and osteotomy plane. The guide and models were manufactured in Nylon 12 using selective laser sintering with the Formlabs Fuse 1 system (Formlabs Inc., Somerville, Massachusetts). Prior to surgery, the parts were cleaned and sterilized using a standard steam pressure autoclave method.

Surgical technique

All patients underwent surgery performed by one of three experienced fellowship-trained knee surgeons affiliated with our research institute. Knee arthroscopy was initially performed to systematically assess the knee, ensuring that the lateral and patellofemoral compartments were well-preserved.

A 10-cm longitudinal incision was made midway between the tibial tubercle and the posteromedial tibial cortex, beginning 1 cm distal to the joint line and extending distally. The proximal part of the sartorius fascia was released, but pes anserinus tendons were left intact. A subperiosteal exposure at the osteotomy site was achieved by elevation of the medial collateral ligament and associated periosteum. The patellar tendon and infrapatellar bursa were exposed anteriorly and protected, creating the plane under the tendon and bursa to fit the PSI guide and create the osteotomy.

The first PSI was positioned on the tibia with one positioning arm resting on the proximal edge of the tibial tubercle underneath the patella tendon, and a second positioning arm fitted around the posterior cortex of the tibia. The detensioning wire was inserted through a distal PSI cylinder (Fig. 2A). The first PSI was then removed, and a second was positioned over the in-situ detensioning wire, and a second pin then

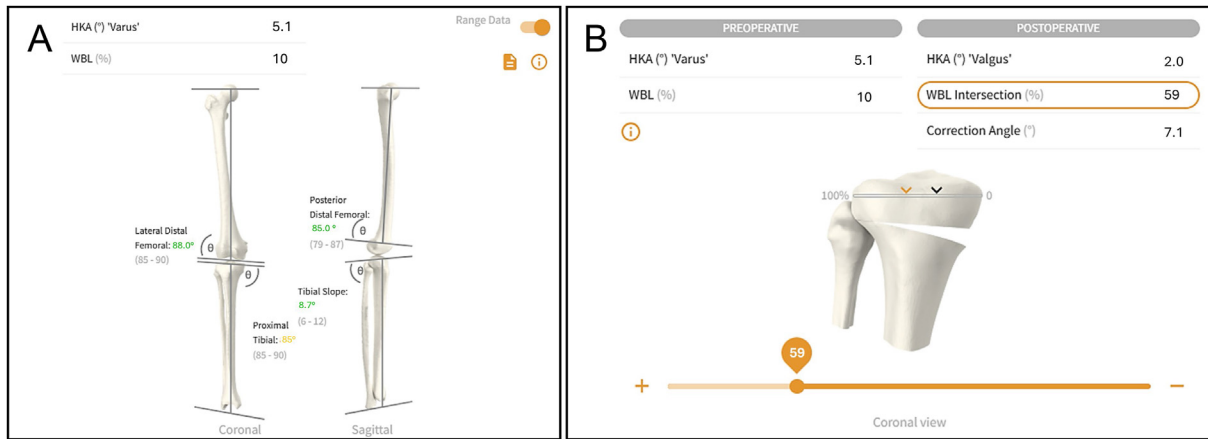


Fig. 1. Planning using the Personalised Surgery app (PS CaseNote). (A) Preoperative alignment: Preoperative parameters, including the HKA angle, WBL intersection, mechanical lateral distal femoral angle, medial proximal tibial angle, and posterior tibial slope angle were assessed. (B) Planning: Planning targeted optimal alignment with real-time correction simulation. Users can visualize alignment changes and interactively adjust the correction angle using a slider, allowing flexibility to tailor the surgical plan to patient-specific needs. HKA = hip-knee-ankle angle; WBL = weight-bearing line.

inserted through a proximal PSI cylinder above and parallel to the predetermined cutting plane (Fig. 2B). The positions of the two pins were compared to the preoperative plan using intraoperative fluoroscopy (Fig. 2C and D) to confirm the accuracy of the PSI position.

Predrilling of three proximal and two distal screw holes was performed to depths prescribed by the pre-operative plan. Metal lugs were sequentially inserted through the guide into each of the screw holes to secure the guide. An initial medial cortical cut was made using a bone saw through the PSI cutting slot. Removal of the proximal lugs and the proximal component of the PSI provided better access, while the depth of the cut was monitored and referenced to the plan via calibrations on the

saw (Fig. 3A). In this study, both monoplanar and biplanar osteotomies were performed and chosen based on the surgeon's preference and intraoperative considerations.

Upon completion of the saw cut, the distal lugs and PSI were removed, leaving the detensioning wire in place. The osteotomy was finalized using an osteotome, ensuring complete cuts of the anterior and posterior cortices with minimal risk of soft tissue injury. The osteotomy gap was carefully opened using an osteotomy jack and laminar spreader, taking care to avoid lateral hinge fracture by allowing time for plastic deformation in the hinge site (Fig. 3B). It was held open with a 3D-printed customized temporary retaining wedge.

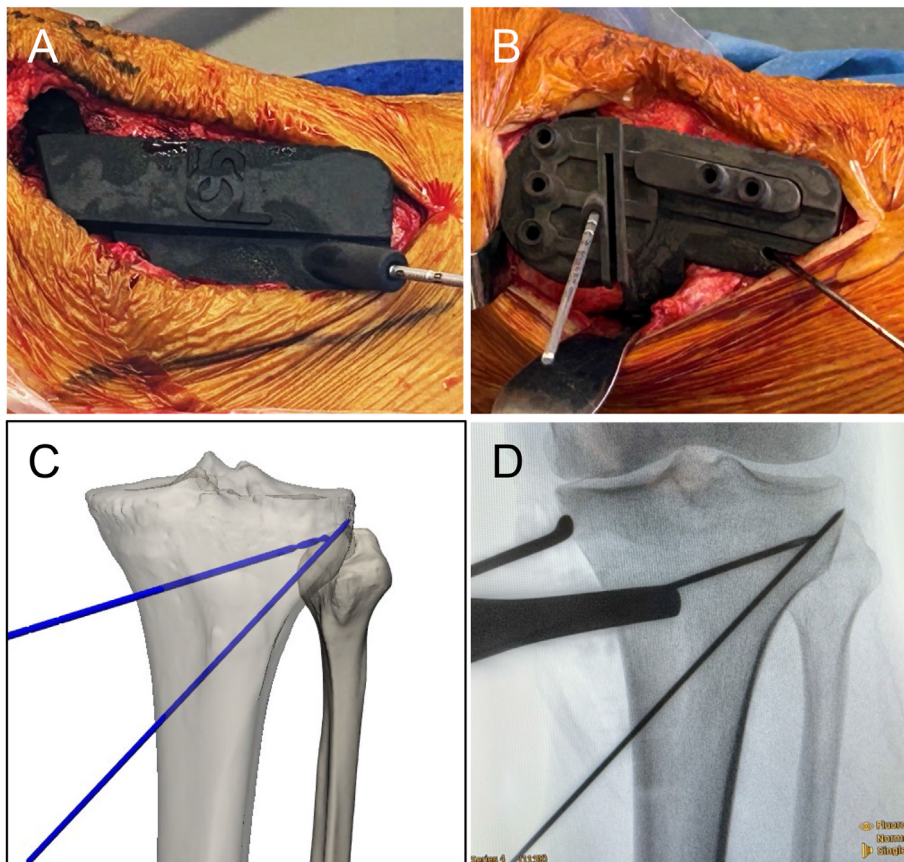


Fig. 2. Surgical exposure and PSI verification in MOWHTO. (A) A separate hinge wire guide used for precise initial detensioning wire insertion before applying the cutting guide. (B) The PSI was secured with the first pin inserted above the cutting plane and a detensioning wire placed through the distal hole. (C) 3D planning showing the positions of both pins was used as a reference. (D) Intraoperative fluoroscopy was used to compare the positions of both pins to the preoperative plan, ensuring accurate placement. PSI = patient-specific instrument; MOWHTO = medial opening wedge high tibial osteotomy.

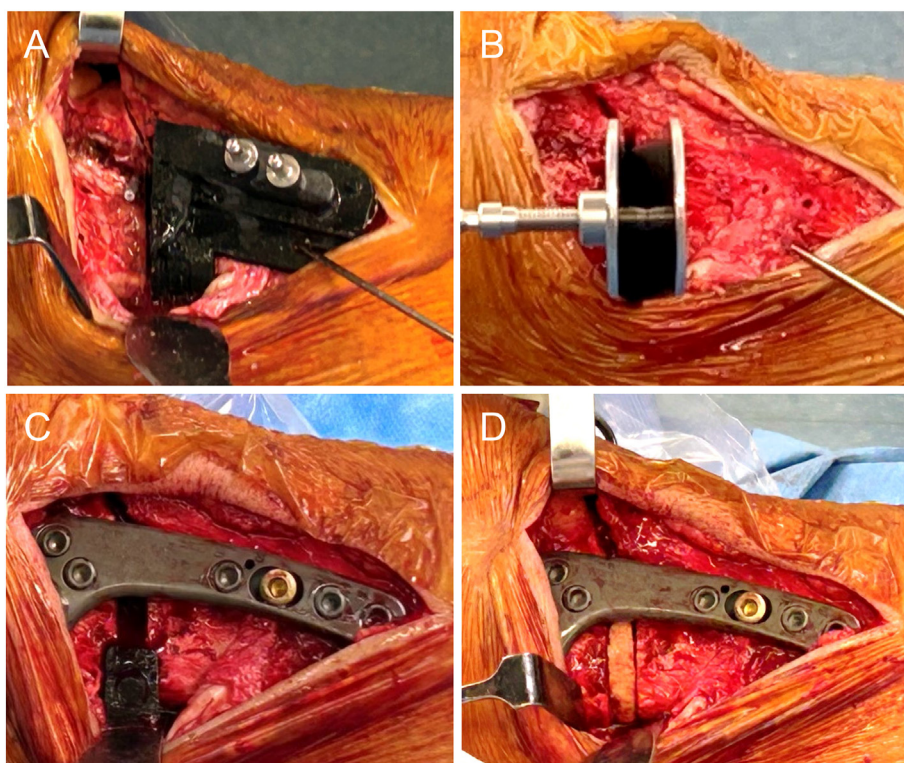


Fig. 3. Osteotomy, plate fixation, and bone grafting in MOWHTO. (A) After predrilling the screw holes and removing the proximal PSI component, the anterior osteotomy cut was completed to the planned depth. (B) the osteotomy gap was expanded using an osteotomy jack and laminar spreader. (C) The locking plate was fixed to the tibia using predrilled screw holes, securing the osteotomy gap while retaining the temporary wedge. (D) An allograft bone wedge, pre-cut to match the planned posterior tibial slope and osteotomy dimensions, was inserted into the osteotomy gap to ensure stability and facilitate healing. PSI = patient-specific instrument; MOWHTO = medial opening wedge high tibial osteotomy.

The Personalised Surgery SMART HTO plate was secured with two lugs in the predrilled holes on either side of the osteotomy, followed by definitive fixation using one cortical nonlocking screw and seven dual threaded locking screws (Fig. 3C). The temporary retaining wedge was then removed, and an allograft bone wedge (Australian Biotechnologies, New South Wales, Australia) was inserted into the osteotomy gap (Fig. 3D). The allograft bone wedge was pre-cut to match the osteotomy gap, particularly the planned PTSA and the anterior and posterior gaps of the osteotomy.

The postoperative rehabilitation protocol included four weeks of touch weight-bearing with a knee brace set to allow 0° to 90° of flexion, followed by gradual progression to full weight-bearing over the subsequent four weeks with the brace removed.

Postoperative radiographic evaluation

An EOS radiographic assessment was performed at 6 months postoperatively to measure the HKA, MPTA, and JLCA, and used to calculate correction accuracy. Overall error was defined as the difference between the planned and achieved HKA angle at the 6-month follow-up. Surgical error was calculated as the difference between the planned and achieved MPTA at the same follow-up. Planning error was defined as all other nonsurgical error and calculated as the difference between the overall error and the surgical error.

Overall error = Surgical error + Planning error

$$(\text{HKA}_{\text{postop}} - \text{HKA}_{\text{plan}}) = (\text{MPTA}_{\text{postop}} - \text{MPTA}_{\text{plan}}) + \text{Planning error}$$

For all error types, positive values indicated over-correction, while negative values indicated under-correction.

Patient reported outcome measures

Clinical evaluations were performed at the primary surgery and at 12 months postoperatively using the Knee Injury and Osteoarthritis Outcome Score (KOOS). The KOOS consists of five subscales: pain, symptoms,

activities of daily living (ADL), sport and recreation function (Sport/Rec), and knee-related quality of life (QOL) with higher scores indicating better knee function and fewer symptoms as perceived by the patient [14].

Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA). A paired t-test was used to compare PROMs between preoperative and postoperative measurements with statistical significance set at $p < 0.05$. Interobserver and intraobserver reliability were assessed using the intraclass correlation coefficient (ICC). To evaluate interobserver reproducibility, two experienced orthopedic surgeons independently reviewed postoperative HKA and MPTA measurements. Intraobserver repeatability was assessed by having one researcher review the radiographs twice at two separate time points. No formal sample size calculation was performed as this study aimed to evaluate the accuracy of PSI-assisted MOWHTO without predefined statistical comparisons.

RESULTS

A total of 40 patients were included in this study, with a mean age of 47.3 ± 7.3 years (32 males, 8 females) and a mean body mass index (BMI) of 29.3 ± 6.8 . Preoperative radiographic measurements showed a mean HKA of $174.5 \pm 2.5^\circ$ and a mean MPTA of $85.6 \pm 1.8^\circ$. The mean planned correction angle was $8.0 \pm 2.5^\circ$. The mean planned HKA was $182.4^\circ \pm 0.3^\circ$, and the mean achieved HKA was $182.6^\circ \pm 1.5^\circ$ ($p = 0.382$). The mean planned MPTA was $93.1^\circ \pm 1.9^\circ$, and the mean achieved MPTA was $92.8^\circ \pm 1.9^\circ$ ($p = 0.358$). The mean overall error was $0.2^\circ \pm 1.5^\circ$ (range 3.0° to -4.9°), with 38% of cases ($n = 15$) exhibiting under-correction and 62% ($n = 25$) showing over-correction. The mean surgical error was $-0.3^\circ \pm 1.1^\circ$ (range 1.6° to -3.8°), with 55% of cases ($n = 22$) exhibiting under-correction and 45% ($n = 18$) showing over-correction. The mean planning error was $0.6^\circ \pm 1.1^\circ$ (range 3.2° to -1.5°), with 30% of cases ($n = 12$) exhibiting under-correction and 70% ($n = 28$) showing over-correction (Fig. 4). The mean preoperative JLCA was $2.8^\circ \pm$

1.6°, and the mean postoperative JLCA was $2.2^\circ \pm 1.5^\circ$ ($p < 0.001$). All KOOS subscales (Table 1) demonstrated a statistically significant improvement at 12 months postoperatively compared to preoperative scores ($p < 0.001$), with the observed changes exceeding the previously reported minimum clinically important difference thresholds [15].

Complications included superficial infections requiring irrigation and debridement ($n = 2$), distal deep vein thrombosis ($n = 1$), and delayed union of the osteotomy ($n = 2$). The delayed unions resolved without the need for additional surgical intervention. Hardware removal was performed in 7 knees during the final follow-up. No hinge fractures occurred either intraoperatively or postoperatively.

Both interobserver reproducibility and intraobserver repeatability demonstrated excellent agreement for radiographic alignment measurements. The mean ICC values for interobserver reliability were 0.98 for HKA and 0.97 for MPTA, while the mean ICC values for intraobserver reliability were 0.99 for HKA and 0.97 for MPTA.

DISCUSSION

This study's major finding was that the novel PSI MOWHTO workflow demonstrated high overall accuracy, high surgical accuracy ($0.2^\circ \pm 1.5^\circ$ mean overall error), and resulted in favorable functional outcomes with a low risk of complications. While earlier studies have demonstrated the accuracy of PSIs, most have solely reported the difference between planned and postoperative HKA [10,16]. Chaouche et al. reported $0.1^\circ \pm 1.5^\circ$ [9], Zaffagnini et al. observed $2.1^\circ \pm 2.0^\circ$ [17], and Tardy et al. showed $0.3^\circ \pm 3.1^\circ$ [18]. Our study's overall error of $0.2^\circ \pm 1.5^\circ$ is comparable to or better than these findings, underscoring the efficacy of this PSI. Achieving precise alignment is crucial, as alignment deviations can alter joint loading patterns; under-correction may overload the medial compartment, while over-correction increases lateral stress, accelerating cartilage degeneration [3,19].

This study is the first to evaluate the overall error of a PSI-based HTO workflow explicitly as a sum of surgical and planning errors by introducing a new formula: "Overall error (postoperative HKA – planned HKA) = Surgical error (postoperative MPTA – planned MPTA) + Planning error." Since changes in MPTA directly correspond to changes in the HKA (Fig. 5), it is valid to treat both measurements, and their errors, as directly proportional. This formula is based on the principle that the overall mechanical outcome of MOWHTO depends on the quality of the surgical plan as well as the surgeon's ability to achieve this plan.

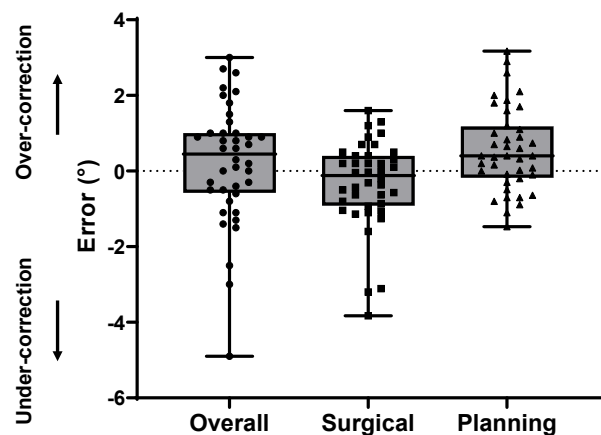


Fig. 4. Overall, surgical, and planning error. The overall error was $0.2^\circ \pm 1.5^\circ$ (38% under-correction, 62% over-correction), the surgical error $-0.3^\circ \pm 1.1^\circ$ (55% under-correction, 45% over-correction), and the planning error $0.6^\circ \pm 1.1^\circ$ (30% under-correction, 70% over-correction). Box-and-whisker plots show the median (horizontal line), interquartile range (box), and minimum-to-maximum values (whiskers), with all individual data points displayed as dots.

Table 1
Comparison of clinical scores between pre- and post-operative.

	Preoperative	Postoperative	P value	Cohen's d
KOOS-pain	53.0 ± 15.5	82.7 ± 14.0	<0.001*	1.09
KOOS-symptoms	55.2 ± 17.1	75.5 ± 12.8	<0.001*	0.96
KOOS-ADL	65.6 ± 20.4	87.8 ± 11.3	<0.001*	1.11
KOOS-Sport/Rec	33.2 ± 20.2	59.7 ± 14.7	<0.001*	1.40
KOOS-QOL	24.5 ± 15.9	52.5 ± 18.0	<0.001*	1.34

Values are presented as mean ± standard deviation. KOOS = Knee Injury and Osteoarthritis Outcome Score; ADL = activities of daily living; Sport/Rec = sports and recreation; QOL = quality of life. Cohen's d represents the standardized effect size, indicating the magnitude of change. * $p < 0.05$.

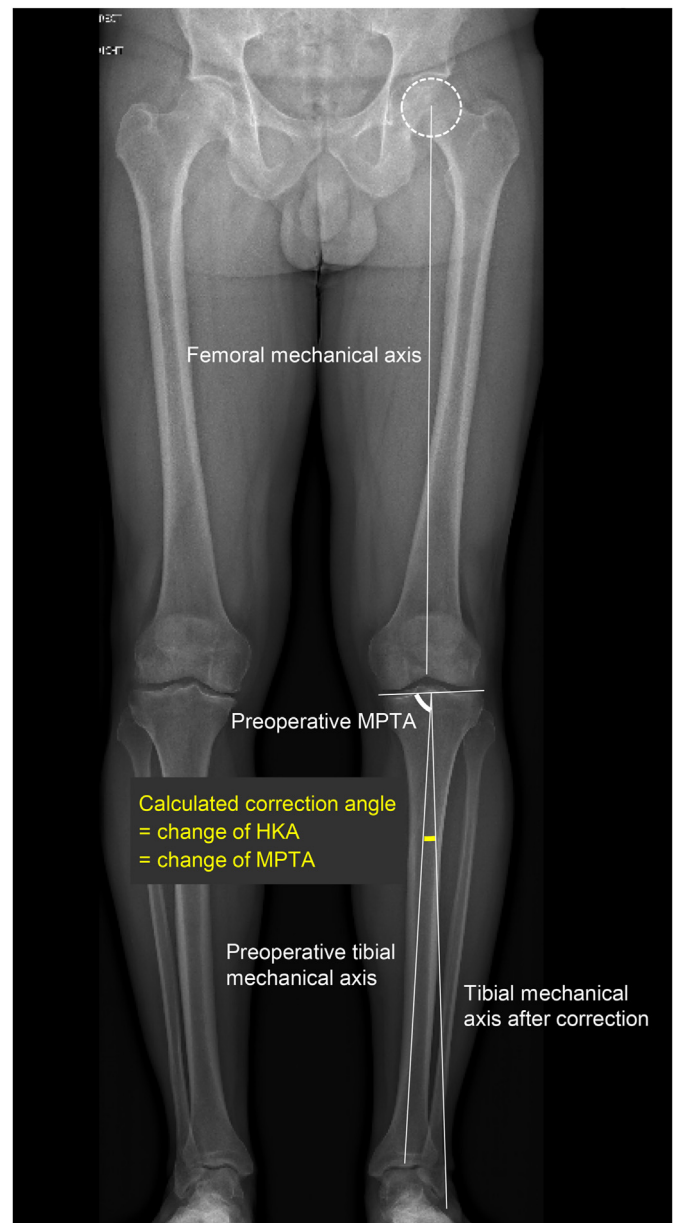


Fig. 5. Preoperative planning. The correction angle is calculated as the angle between the preoperative tibial mechanical axis and the tibial mechanical axis after correction. This calculated correction angle corresponds to the change in both the HKA and MPTA, as the femoral mechanical axis remains unchanged. HKA = hip-knee-ankle angle; MPTA = medial proximal tibial angle.

Similarly, Ogawa et al. proposed that: “Global correction (postoperative HKA – preoperative HKA) = Bony correction (postoperative MPTA – preoperative MPTA) + Soft tissue correction.” They emphasized the importance of accounting for soft tissue correction during preoperative planning to prevent over-correction and found that preoperative varus laxity correlated with soft tissue change [20].

Surgical error, measured as Δ MPTA, offers a consistent and objective evaluation of bone correction in the absence of soft tissue influences. Genechten et al. emphasized the utility of MPTA, noting its minimal influence from weight-bearing conditions compared to HKA [21]. A recent study evaluating PSI in 100 patients undergoing MOWHTO reported a mean Δ HKA of $1^\circ \pm 0.9^\circ$ and a mean Δ MPTA of $0.5^\circ \pm 0.6^\circ$ [9]. Another study using a different PSI found a Δ MPTA of $0.3^\circ \pm 2.2^\circ$ [21]. Consistent with these findings, our study observed a surgical error of $-0.3^\circ \pm 1.1^\circ$, further supporting the effectiveness of PSI in achieving precise bone correction. However, most studies have reported an overall correction error without specifically addressing Δ MPTA and have instead focused on radiographic parameters such as HKA and PTSA [10,16]. This highlights a critical gap in the current literature, as Δ MPTA provides a more direct and specific measure of surgical error compared to overall error in HKA. The novel 3-part PSI design enhanced the accuracy of the positioning of the detensioning wire and proximal cutting reference pin. Biomechanical studies have suggested that the detensioning wire enhances lateral hinge resistance to fracture, an effect supported by the absence of hinge fractures in our study [22–24]. Additionally, intraoperative comparison of fluoroscopic images with the preoperative plan, as shown in Fig. 2C and D enabled real-time confirmation of precise PSI placement, further ensuring surgical accuracy.

Planning error, calculated as the difference between overall error and surgical error, reflects discrepancies in preoperative planning and in vivo limb behavior. By our definition, planning error is present when surgical error does not fully account for the overall error. This study is unique in that we have separated all error associated with planning alone. The planning performed in this study was demonstrated to be biased toward over-correction and considered only bony corrections, excluding any potential effects of soft tissue influence on overall outcome. We believe soft tissue tension and intraarticular deformities, approximated by the JLCA, are primary factors impacting planning error. Previous studies have reported discrepancies between preoperative planning and postoperative alignment, which may be attributed to alterations in soft tissue balance under weight-bearing conditions and the resolution of pseudolaxity caused by cartilage and subchondral bone loss in the medial compartment [25,26]. While various methods exist to adjust correction for soft tissue effects, no consensus has been reached [20,25,27,28]. In our subanalysis, the cohort was divided into an outlier group (correction error $> 2^\circ$ or $< -2^\circ$) and an acceptable range group ($-2^\circ \leq$ correction error $\leq 2^\circ$). The median preoperative JLCA was higher in the outlier group (3.2°) than in the acceptable range group (2.4°), but the difference was not statistically significant ($p = 0.072$). Further investigation with a larger sample size is required to identify prognostic factors affecting planning error and to develop effective strategies for incorporating soft tissue correction.

This study had several limitations. First, its retrospective design and relatively small sample size may limit generalizability. Second, evaluations were limited to the coronal plane, as sagittal alignment was not assessed due to lack of postoperative sagittal full-length imaging for all patients. Third, other factors that may influence overall error, such as measurement precision and variability in imaging techniques, were not fully accounted for. Finally, the relationship between correction accuracy and long-term clinical outcomes was not evaluated. Future studies with larger sample sizes and a prospective design are warranted to address these limitations and build on the findings of this study.

CONCLUSION

The newly developed PSI workflow proved to be an accurate method for planning and performing MOWHTO. While overall error was low, the

observed tendencies for surgical under-correction and planning over-correction highlight the need for careful consideration of these factors to optimize outcomes in the future.

Authorship contributions

David Parker and Takaaki Hiranaka designed the study. Takaaki Hiranaka, Christopher Davey, and Samuel Grasso analyzed and interpreted the data. All authors contributed to data collection and interpretation, and critically reviewed the manuscript. All authors have read and approved the final version of the manuscript.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: We acknowledge that Samuel Grasso and Christopher Davey have affiliations with Personalised Surgery, which developed the PSI system used in this study. Additionally, Brett Fritsch and David Parker use PS products in their clinical practice, and they have a financial affiliation with the company. The remaining authors declare no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

We would like to thank Editage (<http://www.editage.jp>) for English language editing.

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