Design Strategies of a Personalized Surgical Instrument to Adjust the Distraction Angle and Posterior Slope for Open Wedge High Tibia Osteotomy Surgery

Kuo-Yao Hsu
Department of Orthopedic Surgery, Chang Gung Memorial Hospital, Linkou

Chun-Ming Chen
High Speed 3D Printing Research Center, National Taiwan University of Science and Technology

Yi-Sheng Chan
Department of Orthopedic Surgery, Chang Gung Memorial Hospital, Keelung

Chen-Te Wu
Department of Medical Imaging and Intervention Radiology, Chang Gung Memorial Hospital, Linkou

Chi-Pin Hsu
High Speed 3D Printing Research Center, National Taiwan University of Science and Technology

Su-Ching Chen
Department of Orthopedic Surgery, Chang Gung Memorial Hospital, Linkou

Shang-Chih Lin (Orthodont.cax@gmail.com)
Graduate Institute of Biomedical Engineering, National Taiwan University of Science and Technology

Research Article

Keywords: OWHTO, PSI, osteotomy, distraction, lateral hinge, tibia plateau, distraction angle, tibial slope

Posted Date: May 12th, 2023

DOI: https://doi.org/10.21203/rs.3.rs-2829887/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License
Abstract

The precise creation and control of osteotomy and distraction have been a problem in opening wedge high tibial osteotomy (OWHTO). This study aimed to investigate the impact of the cutting edge of a personalized surgical instrument (PSI) to control the distraction angle, tibial slope, and tibial twist of the distracted tibiae. This study correlated the PSI design with the results of biomechanical tests on wedge inclination (WI), saw progression (SP), and distraction site (DS) of the proximal tibiae, which were systematically varied and three-dimensionally (3D) printed as the specimens. The lateral hinge 3D orientation was determined by the WI and SP. Different DSs deviate from the hinged motion of the distracted tibiae to some extent. The coronal angle, which is the major OWHTO target, is more sensitive to the SP and DS. However, the concurrence of the sagittal and horizontal angles induces undesirable effects on knee biomechanics and potentially risks the lateral hinge. The cutting edge is a key design that serves as the cutting and sawing guide to control the initial cut on the medial tibia (i.e., WI) and the sawing path near the lateral cortex (i.e., SP). Intraoperative planning of manipulating the SP is the most effective method for adjusting the sagittal rotation. A higher WI angle is a determinant factor of the horizontal rotation that must be cautiously mitigated to reduce the risk of lateral hinge cracking and to adjust the patellofemoral contact.

Introduction

Opening wedge high tibial osteotomy (OWHTO) is an operation that transfers the knee load from the medial to the lateral articular surface using osteotomy and distraction [1]. This is often recommended for young and active patients whose knee replacement needs to be delayed or avoided as long as possible [2]. The preoperative osteotomy planning process evaluates the anatomical and mechanical axes of the lower limb and the angles between the femur and the tibia to define surgical parameters such as osteotomy wedges, lateral hinge, distraction site, and angle [3]. However, the operation of both osteotomy and distraction constitutes a demanding three-dimensional (3D) technique-related problem. In addition to preoperative planning, precise execution is also an important factor affecting surgical success. Efforts taken to overcome this problem led to the development of a computer-aided navigator and 3D-printed personalized surgical instrument (PSI) that preoperatively sets the principle OWHTO parameters in computer programs or instrument designs [4–13].

Generally, there are two types of OWHTO parameters that are preoperatively defined and intraoperatively executed. These include the biomechanical evaluation of the lower limb and surgical manipulation of the proximal tibia (Fig. 1). Preoperative and postoperative weight-bearing lines (WBLs) are planned based on the residual height of the medial cartilage [14]. During an osteotomy, the first and second osteotomy wedge cuts, the site and orientation of the lateral hinge, and the site and angle of the wedge distraction are meticulously planned and executed [3]. In addition to coronal rotation, undesired sagittal and horizontal rotations of the distracted tibia have been reported as factors affecting OWHTO and need to be well controlled during surgery [15–18]. Changes in the posterior tibial slope (i.e., sagittal rotation) and twist (i.e., horizontal rotation) have been identified as potential factors that affect the stability of the
cruciate ligaments and the patellofemoral contact force, thus necessitating the maintenance or adjustment of the sagittal and horizontal rotation before OWHTO [17, 18].

Prior literature states that certain PSIs have been designed and used in the OWHTO to serve as a targeting device for precise osteotomy and distraction [6–13]. These technologies, including the use of X-ray and computed tomography (CT) images, provide an anatomical fit and precise positioning of instruments onto the proximal tibia. However, the methods presented in prior literature to achieve a design that can maintain the distraction angle and avoid the other two undesired rotations are distinct, as each study is contextually different from the other. This study divides the PSI functions presented in prior literature into six categories: 1) osteotomy site, 2) wedge inclination, 3) saw depth, 4) distraction height, 5) saw progression, and 6) plate position (Table 1). However, these studies do not present details on the finer adjustments made to the PSI designs that affect the surgical outcomes (e.g., tibial slope and twist). This constitutes the major objective of this study.

From a biomechanical perspective, the 3D orientation of the lateral hinge determines the rotation axis of the distracted tibia along the sagittal, coronal, and horizontal planes. The 3D hinge orientation was surgically defined by two procedures: wedge inclination onto the proximal tibia (Fig. 2(A)) and saw progression near the lateral cortex (Fig. 2(B)). These procedures determine the lateral hinge inclination angle projected onto the sagittal and horizontal planes. The control of both wedge inclination and saw progression should be planned preoperatively and operated intraoperatively if the surgeon aims to control the hinge orientation. This study further describes how to control the wedge inclination and saw progression using an OWHTO PSI, with the use of specially designed and 3D-printed specimens.

Materials and methods

Surgical Planning using a two-dimensional (2D) X-ray Image

Using an anteroposterior (AP) X-ray image, a preoperative weight-bearing line (WBL) was defined by the reference points of the femoral head (Point H) and distal tibia (Point A) (Fig. 1(A)). The width \( w \) of the tibial plateau line and the width \( d \) between Point B and the most medial outline were used as the index \( d/w \) to evaluate the valgus knee severity (Fig. 1(B)). Before surgery, the surgeon should assume the desired WBL percentage \( x\% \) by relocating the postoperative WBL. The reported relationship between the presumed WBL percentage and remaining cartilage height can be used as a guideline to determine the WBL percentage \( x\% \) (Fig. 1(C)) [15, 16].

Subsequently, the three parameters of the wedge site, lateral hinge, and distraction angle were determined (Fig. 1(D)). For the first two parameters, the wedge site was a plate-related factor that ensured sufficient space to allow stable fixation of the screws above the wedge. The top of the plate was located at least 10 mm from the tibial plateau line, and the lateral hinge was located above the fibular head, approximately 10 mm from the tibial plateau line and lateral cortex [3, 19]. Both the osteotomy orientation and depth
along the AP direction can be determined and precisely controlled by the PSI based on the lateral hinge location (Point L) (Fig. 2(A)).

The third parameter was to calculate the angle (α) of wedge distraction after osteotomy (Fig. 1(D)). The postoperative distal tibial end location (Point A) was determined by intersecting the postoperative WBL and the circular arch, with the radius from Points L to A. The angle inclined by the lines LA and LA′ was practically defined as the distraction angle (i.e., coronal rotation), that guides the surgeon to precisely distract the first wedge using the distractor. The sawing depth was the distance between the wedge point and the lateral hinge (Fig. 1(D)). It was a crucial procedure to osteotomize the tibia using a bone saw with the known depth and a guide slot that was preoperatively designed and 3D-printed (Fig. 2(B)).

**PSI Design using 3D CT Images**

CT images below the tibial plateau of approximately 15 cm were used to reconstruct the tibial 3D model (Fig. 2(A)). The coronal plane of the reconstructed tibia was created and aligned with the preoperative X-ray images. The aforementioned parameters of the wedge site (O), lateral hinge (L), and sawing depth were rechecked during the 3D planning process. Using computer-aided design software, the PSI was designed to fit the medial tibial surface and was stabilized using four pins in the targeted region. The PSI was created with the first wedge cutting slot and the second wedge cutting plane to guide the osteotomy. Lines a and b constrain and stabilize the bone saw and guide the sawing direction. The cutting edge (Line c) defines the sawing depth along the lateral hinge and its 3D orientation. Line c is a dominant factor in defining the wedge inclination (Fig. 3(A)) and saw progression (Fig. 3(B)). The impact of wedge inclination and saw progression on the 3D rotation of the distracted tibiae was investigated in the biomechanical tests of this study.

The PSI is composed of upper and lower parts that are connected at the first wedge cutting slot before osteotomy (Fig. 2(A)). The upper and lower parts are separated, and the osteotomes continue to distract the wedges until the parallel lines (a and b) are expanded to make the aligning rod smoothly pass through the two post-osteotomy alignment holes. Initially, two non-coaxial alignment holes were designed. The coaxial alignment of the two holes can be designed using computer-aided simulation to control the sagittal, coronal, and horizontal rotations of the distracted tibiae. This can achieve precise wedge distraction, maintain or adjust the tibial slope, and reduce radiation exposure to enable the cautious osteotome insertions, which is a highly technical procedure.

**Biomechanical Test**

This study systematically varied the lateral hinge parameters of the tibial model and employed the 3D-printing method to manufacture osteotomized OWHTO specimens (Fig. 3). Three parameters were identified to create the lateral hinges and distract the osteotomized tibiae, namely, 1) wedge inclination (WI), 2) saw progression (SP), and 3) distraction site (DS). In total, six WI and SP variations were prearranged in this study: -10°, 0°, and +10° inclination angle in the sagittal plane, and −5°, 0°, and +5° orientation angles in the horizontal plane. A distracting block of height 10 mm was 3D-printed to distract the osteotomized wedges at the posterior, middle, and anterior sites. To conclusively define the tibial
plateaus, three rectangular blocks were designed in different regions to form a tibial plane. The tibial planes before and after distraction provided 3D rotation of the distracted plateaus [19].

Using a high-end 3D printer, the aforementioned OWHTO models were manufactured using a 3D HP Jet Fusion 4200 (Hewlett Packard, Barcelona, Spain). The material used to print the OWHTO specimens was polyamide 12 (PA12) with a flexural 1500 modulus of 1500 MPa [20]. The PA12 material elastic behavior is compatible with that of the cortical bone (17 to 21 GPa) [21]. Figure 4(A) shows the appearance of the 3D-printed OWHTO specimen.

Twenty-seven variations of the distracted tibial specimens were systematically investigated during biomechanical tests. All specimens were distracted with the 3D-printed osteotomes of 10-mm height. All non-distracted specimens were prearranged in an ordered matrix, and their bases were attached to a plastic tray (Fig. 4(A)). Subsequently, the distraction blocks were sequentially distracted by the osteotomized specimens at the three sites. After the distraction, nine distracted specimens were sent for CT scanning to reconstruct the 3D model of the distracted plateaus (Fig. 4(B)). Three orthopedic surgeons distracted each specimen thrice. In total, there were 81 tests (3 WIs × 3 SPs × 3 DS × 3 surgeons) in the test.

Spatial registration was used to measure the 3D rotation of the original and distracted specimens. The two-stage strategy of rough and fine registrations facilitates minimal error in the surface profiles between the original and distracted specimens (Fig. 4(C)) [22]. After registration, the tibial planes (TP and T'P') before and after distraction were defined in terms of the three corners of the original and distracted plateau blocks (Fig. 5). Two orthogonal lines were defined on each tibial plane and projected onto the coronal, sagittal, and horizontal planes to calculate the rotation angles (α, β, and γ). An independent ANOVA test was performed to determine whether the data between the guides were significantly different. Statistical significance was set at p < 0.05. Statistical analysis was performed using the SPSS software (Version 23, SPSS Inc., Chicago, IL, USA).

Results

The proposed PSI can be 3D printed at a very high resolution of ± 0.01 mm to serve as the target device (Fig. 5(B)). Furthermore, even the patient’s information and distraction angle value can be 3D printed directly on the PSI surface for labeling. Compared to the cadaveric specimen, the 3D reconstructed tibia and osteotome can systematically reduce the degree of variation in the test results. After two-stage registrations, the initial and reconstructed tibiae provided a standardized method to measure the 3D rotation of the distracted plateau (Fig. 5(C)). The testing results of 81 WI, SP, and DS variations were divided into coronal, sagittal, and horizontal angles (Fig. 6). Detailed information on the testing results is shown in Table 2. Coronal rotation is the primary purpose of OWHTO; therefore, its value is significantly higher than that of the others. The distraction angles of 27 variations were not equal, showing that the three parameters affected the coronal angle (Fig. 6(A)). This illustrates that any mathematical equation
used to predict the distraction angle or height should correlate these three parameters into the equation formulation.

The testing results show that the distraction procedure simultaneously causes the other two rotations (Figs. 6(B), (C)). The SP had a greater impact on sagittal rotation than WI and DS (p < 0.05). The SP (-5) and SP (+5) results, that represent the negative and positive sagittal angle values, respectively, can serve as an adjunctive parameter for the posterior tibial slope. Furthermore, WI only affected the sagittal angle value. In the SP (0) situations, the DS (ant) and DS (post) deviate from the tibial rotation and lead to positive and negative sagittal angle values, respectively. Horizontal rotation is the axial rotation of the distracted tibia. From a biomechanical viewpoint, this may affect the relative orientation of the proximal and distal tibiae, potentially affecting the periarticular ligaments and patellofemoral contact. The WI had the highest impact on the horizontal effect, followed by SP and DS (p < 0.05). Generally, inclined upward and downward wedges result in inward and outward rotation, respectively. The control in WI appears to be a good method for adjusting the axial rotation of the distally and proximally osteotomized tibiae.

**Discussion**

After the distraction, the biomechanical tests showed the concurrence of one intended (i.e., sagittal) and two undesired (i.e., coronal and horizontal) rotations (Fig. 6). The minimal change in the tibial slope and twist occurs in the WI (0), SP (0), and DS (mid) conditions. Without precise manipulation, this indicates the inherent effects of kinematic or kinetic changes in the cruciate knee ligaments and patellofemoral contact forces [23–25]. The reported change in the sagittal angle of the distracted plateau induces improper changes in the postoperative range of motion, tibial shear force, and anterior tibial translation of the knee. Based on the findings of this study, the optimal strategy for sawing procedures can be preoperatively planned to minimize or adjust the posterior tibial slope and patellofemoral contact force (Figs. 3(A), (B)). The focus of this study was to highlight the impact of two osteotomy procedures, WI and SP, on the knee biomechanics of the periarticular ligaments and joints.

The proposed PSI design comprises three characteristics: 1) anatomical fitness between the PSI and attached tibia, 2) precise control of the distraction angle and tibial slope, and 3) surgical indicator using an aligning rod. The first characteristic is the consequence of employing CT images to reconstruct the PSI configuration (Figs. 2(A), (B)). The inner PSI surfaces fit well with the patient’s targeted tibia region. The correlation of the cutting slot and the two sawing parameters can be illustrated in terms of the projected slot edge lines (**Line C**) onto the sagittal and horizontal planes (Fig. 7(A)). Before distraction, the WI can be defined by the slot edge and line normal to the coronal plane. The surgeon saws the medial tibia along the slot to achieve an accurate WI. Similarly, the slot edge can guide the sawing depth to precisely determine the SP. This constitutes the second characteristic of the ideal cutting guide for achieving a precise osteotomy.

The lateral hinge orientation can be finely controlled through the design of the first slot edge (Fig. 7(B)). The hinged motion of the proximal and distal tibiae deviated owing to non-middle distraction. At the DS
(post) and DS (ant), the testing results illustrate the significant effect of the non-middle distraction on inducing the sagittal and horizontal rotations (Fig. 6). From the authors’ experiences, the middle site can be 3D printed as a mark on the cutting slot surface for the surgeon’s reference. If the tibial slope adjustment and patellofemoral contact is desired, the method used to control the WI and SP is determined to be more effective than that of the DS (p < 0.05).

A detailed comparison of the PSI functions, as discussed in studies published from 2016 until the present, is provided in Table 1. One of the six comparative indices that are easier to achieve is the indication of the osteotomy site, followed by the saw depth, distraction height, and plate position, while edge inclination and SP comprise the most challenging indices. On comparing the studies conducted by Yang, Jacquet, Sandro, and Jud, it is noted that the cutting slots were designed but not finely used postoperatively as the adjusting or controlling tibial slope and twist references [6, 7, 10, 13]. Even with a precisely designed cutting slot, the bone saw with a stop to avoid overcutting and ensure that the saw was orthogonal to the slot edge was necessary to achieve precise control of the target outcome. Except for studies conducted by Yang, Jacquet, and Jud [6, 7, 13], there is no detailed discussion concerning the precise PSI positioning on the tibial surface pins prior to the utilization of guiding pins.

During distraction, surgeons often face difficulty in accurately confirming whether the presumed distraction height or angle has been reached. In clinical practice, gradual distraction and the final WBL can be monitored and confirmed using common fluoroscopy methods [3]. However, the surgical accuracy of these methods is prone to technical errors owing to manual and visitional methods. Consequently, computer-navigated techniques and novel instrumentation have been introduced to improve OWHTO accuracy [4–13]. This study provides a method to intraoperatively monitor the 3D rotation of the distracted tibia in real time (Fig. 8(A)). Furthermore, the aligning holes were not initially coaxial. Using computer-aided technology, PSI designers can simulate the angle change of the two PSI holes to be aligned when the distracted tibiae rotate. This allows surgeons to concentrate on the distraction procedure without having to excessively monitor the fluoroscopy system. Once the metal rod can smoothly pass through the two holes, it implies that the presumed distraction angle or WBL percentage has been reached (Fig. 8(B)). From the authors’ experiences, this requires sophisticated procedures to simulate the coronal, sagittal, and horizontal rotations of the distracted tibia, which is reconstructed using CT images.

It is worth noting that certain biomechanical and surgical limitations are inherent in this study. Improper WI and SP might induce hinge fractures. In the situation of excessive sawing depth—SP (5), the distraction potentially risks the fracture of the lateral cortex owing to the remaining deficient bone. Contrarily, the lack of sawing depth in the case of SP (-5) potentially exposes the proximal part of the osteotomized tibia to intercondylar fracture. Similarly, the inclined wedge of WI (-10) and WI (+ 10) should be cautiously created and distracted to avoid hinge fractures. Limited experiences concerning the higher inclination of WI and SP can be concluded as the PSI design guidance. The simulation of the aligning holes was based on the 3D model of the proximal tibia, excluding the distal tibia effect and the periarticular tissue constraints. These testing results do not support the mathematical formula for
predicting the spread angle in the literature [26–28]. The same distraction height leads to different
distraction angles, showing that WI, SP, and DS affect the distraction angle (Fig. 6(A)). The formulation to
correlate the PSI parameters and three tibial rotations is still ongoing in the current authors’ laboratory.

In conclusion, the orientation of the lateral hinge was determined by the WI and SP. By controlling the two
sawing parameters, the ideal PSI can be well-designed to serve as a target guide, thus precisely
maintaining or adjusting both the distraction angle and tibial slope. Preoperative planning of the sawing
procedure involves a trade-off between distraction efficiency and undesired effects (i.e., sagittal and
horizontal rotations) on the knee biomechanics and potential lateral hinge risk. The most critical design
area for OWHTO PSI is the cutting slot that guides the WI and SP.

Declarations

- **Ethics approval and Consent to participate:**

The local institutional review board of Linkou Chang Gung Memorial Hospital approved the use of patient
information (201801982A3). The subjects were informed of the “Consent To Be A Research Subject”
context related to their computed tomography (CT) scanning images. The subjects agreed to participate
in the project. All methods of the study were performed in accordance with relevant guidelines and
regulations.

- **Consent for publication:**

Not applicable.

- **Availability of data and materials:**

The datasets generated and/or analyzed during the current study are available from the corresponding
author and co-authors on reasonable request.

- **Competing interests:**

The authors declare that they have no conflict of interest.

- **Funding:**

This research is supported by the Chang Gung Medical Research Project (CMRP) of Linkou Chang Gung
Memorial Hospital, the total project number is CMRPG3K1621, and the sub-project number three is
CMRPG3K1591.

- **Authors' contributions:**

KY Hsu, SC Lin, and YS Chan designed the experimental study protocol and drafted the manuscript. CT
Wu acquired CT scanning data. SC Lin and CM Chen designed and manufactured OWHTO specimens,
and CP Hsu and SC Chen performed biomechanical tests. YS Chan performed the clinical use of the PSI. KY Hsu, and YS Chan critically revised the manuscript. SC Lin and KY Hsu supervised the study. All authors read and approved the final manuscript.

- **Acknowledgements:**

Thanks to Linkou Chang Gung Hospital, Keelung Chang Gung Hospital and National Taiwan University of Science and Technology for their support for this study.

**References**


Tables

Table 1 and 2 are available in the Supplementary Files section.

Figures

(A) Method to define and calculate the key OWHTO parameters. (A) Sites of the lateral hinge (Point L) and osteotomy (Point O). (B) Points B and C are the intersections of the plateau line and the preoperative and postoperative WBLs, respectively. Point T is the plateau line midpoint. The WBL percentage is defined as...
the width ratio of d/w. (C) Strategy of residual cartilage height is used to shift Point C to x% of the WBL percentage. (D) Preoperative radiograph. Points L and O denote the lateral hinge and osteotomy site, respectively. (D) 2D preoperative planning of distracting the osteotomized tibia to rotate around the lateral hinge.

Figure 2

(A) Cutting slot for the first wedge designed for precise operation of osteotomy wedge and saw progression. (B) 3D-printed PSI with biocompatible and sterilizable nylon.
Figure 3

Three surgical parameters of tibial specimens (A) Variations of wedge inclination. (B) Variations of saw progression. (C) Variations of distraction site.
Figure 4

(A) Nine 3D-printed specimens used as distractions at three distraction sites. (B) After the distraction, the specimens were sent to the CT-scanning machine to reconstruct the 3D models. (C) Reconstructed model. (C) Registered models.
Figure 5

Three rotation angles of the distracted plateau calculated from the registered models of the original and reconstructed tibiae: coronal (α), sagittal (β), and horizontal (γ) angles. These angles were measured from the projected lines of the original and distracted tibial planes and defined in the content.
Figure 6

Testing results of the three rotation angles for 27 variations. (A) Coronal angle. (B) Sagittal angle. (C) Horizontal angle.
Figure 7

(A) Slot edge can be used to preoperatively control definition of the inclined lateral hinge angles onto the horizontal (SP) and sagittal (WI) planes. (B) Osteotome-driven distraction along the different lateral hinge orientations.
Figure 8

(A) Application of distraction after osteotomy is gradually applied until the metal rod can smoothly pass through the two holes that were not initially aligned. (B) Application of PSI to OWHTO shows the PSI application to the OWHTO.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- BMCTable1.pdf
- BMCTable2.pdf