

3D Surgical Printing Cutting Guides for Open-Wedge High Tibial Osteotomy: Do It Yourself

Rubén Pérez-Mañanes, MD, PhD^{1,3} **Juan Arnal Burró, MD^{1,3}** Jose Rojo Manaute, MD, PhD²
 Francisco Chana Rodriguez, MD, PhD^{1,3} Javier Vaquero Martín, MD, PhD^{1,3}

¹ Department of Traumatology and Orthopaedic Surgery, Hospital General Universitario Gregorio Marañón, Madrid, Spain

² Department of Traumatology and Orthopaedic Surgery, Orthopaedics and Spine Hospital, Dubai, United Arab Emirates

³ Complutense University of Madrid, Madrid, Spain

Address for correspondence Juan Arnal Burró, MD, Department of Traumatology and Orthopaedic Surgery, Hospital General Universitario Gregorio Marañón, Calle doctor Esquerdo 46. 28007 Madrid, Spain (e-mail: juanarnal@hotmail.com).

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Abstract

Opening wedge osteotomy has recently gained popularity, thanks to the recent implementation of locking plates, which have shown equivalent stability with greater reproducibility, accuracy, and longevity than the closing wedge techniques and a lower prosthetic conversion rate. We present a new “do-it-yourself” cutting guides system for tibial opening osteotomy. Using a conventional computed tomography digital image, a positioning guide and wedge spacers were printed in three dimensions (3D) for implementing the osteotomy and obtaining the planned correction. The surgeon makes the whole process in a do-it-yourself style. This new technique was used in eight cases. Previous opening osteotomies with the standard technique were used as control (20 cases). Surgical time, fluoroscopic time, and accuracy of the axial correction were measured. The use of a custom positioning guide reduced the surgical (31 minutes less) and fluoroscopic times (6.9 times less) while achieving a high-axis correction accuracy compared with the standard technique. Digitally planned and executed osteotomies under 3D printed osteotomy positioning guides help the surgeon to minimize human error while reducing surgical time. The reproducibility of this technique is very robust, allowing a transfer of the steps planned in a virtual environment to the operating table.

Keywords

- HTO
- opening wedge osteotomy
- 3D printing
- custom positioning guide

High tibial osteotomy (HTO) is a procedure performed in most orthopedic departments worldwide with two major variants: opening wedge osteotomy and closing wedge osteotomy.¹

HTO and partial knee replacement are indicated for middle-aged patients (50–60 years old) with medial joint osteoarthritis and good range of motion.^{2,3} However, HTO may offer some advantages to these patients: (1) it preserves bone stock and (2) it allows for implementing an active postoperative life style without associating the risk for requiring increasingly complex reoperations derived from progressive wear of the implants.⁴

HTO's key biomechanical element is based on the modification of the mechanical axis for unloading the medial compartment.⁵

Traditionally, closing wedge osteotomy was the most widely used HTO due to its lower technical difficulty and higher primary stability. However, modern planning techniques are popularizing the use of the opening wedge HTO because of its greater reproducibility and accuracy.⁶ The long-term outcomes for opening HTO published in most series are good or excellent, with up to 98% survival rates at 5 years follow-up.⁷ Moreover, the development of wedge plate fixation and locked compression plates have shown an equivalent stability between closing and opening osteotomies.^{8,9}

The two most important factors for success in opening HTO success are proper patient selection and correction accuracy of the mechanical axis.¹⁰ This accuracy depends on two basic steps: proper preoperative planning and precise surgical reproducibility.¹¹

Proper preoperative planning for dimensioning a wedge for a desired correction is performed based on weight-bearing full-extension radiographs, where an approximately 3 to 4 degrees valgus are sought for the mechanical axis.¹² Despite the existing recommendations for calculating the dimensions of the required wedge (based on the deformity's angulation and on the tibial width),¹² classic methods do not take into account physiognomic differences among patients.

An accurate intraoperative reproduction of the desired wedge dimensions using anatomical landmarks and intraoperative fluoroscopy, without inadvertently altering other parameters such as the tibial slope or the extensor apparatus, is still a challenge for the surgeon.^{13,14}

For overcoming these accuracy limitations of the classic methods,¹² recently, specific software has been developed for simulating the corrections and synthesis with different plate models. Moreover, several authors have described superior intraoperative accuracy using navigation systems for HTO.^{15,16} In this feasibility study, we describe a new intraoperative three-dimensional (3D) positioning technique for calculating the location and dimensions of an opening wedge HTO and for surgically reproducing the planned osteotomy with safety and efficacy in a reduced surgical time.

Materials and Methods

This was a one-center case-control study performed in Madrid, Spain, at a third level referral university hospital. Patients were consecutively recruited and operated between November 2014 and April 2015 with the new technique. Twenty cases performed by the standard technique were used as controls. Accuracy between the planned wedge angle and the executed opening wedge, surgical time and fluoroscopy need between both techniques was compared.

Eligible participants for an opening wedge HTO had pain, age younger than 60 years old, and medial joint osteoarthritis. Exclusion criteria were range of motion < 90 degrees, flexion contracture > 10 degrees, and/or > 10 degrees varus.³

Preoperative Planning

Computed tomography (CT) scans (Siemens, Somatom Spirit, Siemens, Munich, Germany) of the patient's proximal tibia were requested for preoperative planning. Every case was calibrated with the aid of a 28-mm sphere radiolabel as a magnification marker for weight-bearing long-leg alignment radiographs. The sphere was attached to a device that allowed its 3D spatial positioning against bony prominences in the sagittal and coronal planes of the lower limb. The calibrated long-leg alignment images were then loaded into Orthoview software (Materialise, Leuven, Belgium; free download at <http://www.orthoview.com/>). Two lines were drawn (mechanical axis) for intersecting the lateral tibial plateau at the point of Fujisawa (62% of the cross length of the plateau¹⁷) with their origins located at the center of the femoral head and at the center of the talus. We then established the location and calculated the dimensions of the wedge on the sagittal and coronal planes for our corrective osteotomy (►Fig. 1a, b).

The CT scan DICOM images were then imported into the radiological postprocessing software (GNU open-source OsiriX, <http://www.horosproject.org/>), using a Macintosh personal computer (Apple Computers, Cupertino, CA). The images were processed for subtracting the patella and femur (segmentation process), applying 3D surface rendering and exporting the images as a stereolithography (STL) file. The STL files were uploaded into the open-source Autodesk Meshmixer 2.4 (<http://www.meshmixer.com/>) for creating a 3D-scaled digital model of the tibias for accurately reproducing the location and dimensions of the previously calculated wedge.

The tibial joint line acted as a reference for merging both calculations. Axial views were then used for simulating the safest position and direction of the two 2.2 mm Kirschner wires (K-wires) required for guiding the osteotomy cut during the surgical procedure (►Fig. 2).

We then proceeded with the 3D printing (da Vinci 1.0; XYZ Printing, New Kinpo Group, Taiwan) under fused deposition modeling technology of three elements: (1) an osteotomy positioning guide; (2) three polyhedral wedges; and (3) the patient's proximal tibia. Thermoplastic 1.75 mm diameter acrylonitrile butadiene styrene (ABS) was used for printing. The positioning guide consisted of two 35 × 3.5 mm cannulated cylinders attached to a template of the medial-proximal aspect of the tibia of the patient which were oriented for guiding two 2.2 mm K-wires that would follow in parallel the distal cut of the osteotomy. The polyhedral wedges reproduced the medial height and slope calculated by the Orthoview and would serve as spacers during the operation. The 3D model of the patient's tibia was used for preoperatively confirming the adequate adaptation of the positioning guide.

White thermoplastic 1.75 mm diameter ABS was used. The standard configuration (0.3 mm, 10% normal speed) was applied. The Meshmixer software was used for achieving an optimal positioning of the model on the printing tray and for designing supports that increased stability during printing. The sizes of the templates were made in each case made slightly larger than the standard surgical approach to the medial tibial plateau because ABS can easily be trimmed intraoperatively with a wire cutter. The osteotomy positioning guide showed an exact matching to every tibial model. All ABS components were sterilized using ethylene oxide for surgical use.

Surgical Technique

We used a standard positioning and a medial approach. We then exposed the periosteum of the tibia for adapting the osteotomy positioning guide, which spontaneously locked into the surface by simple apposition, as in our previous test on the tibial 3D printed model (►Fig. 3a, b). The K-wires were subsequently inserted through the cannulated cylinders to the lateral cortex. Correct orientation and positioning was assessed with fluoroscopy.

We then removed the osteotomy positioning guide, keeping the K-wires in their position, and performed the osteotomy by sliding an oscillating saw over the proximal aspect of the wires. More than a centimeter of the lateral metaphysis was preserved for opening the gap by osteoclasia, preserving



Fig. 1 Digital templating by Orthoview in one of the cases. (a) Planning the addition osteotomy. (b) Simulation of the final correction.

the lateral cortical bone. Progressive distraction of the osteotomy allowed the insertion of two of our three ABS spacer wedges (► Fig. 4a, b). Anterior and posterior symmetry was always checked. An iliac crest graft was then harvested. The third printed wedge was used as a model for carving the angulation and height of the wedged graft (► Fig. 5). Once the

graft was appropriately sized, it was inserted into the space of the tibial osteotomy. Clinical and fluoroscopic examination confirmed a correct graft adaptation and maintenance of the space after removing the plastic wedges. Every osteotomy was fixed with a locked conformed plate (Tomofix system, DePuy-Synthes, Umkirch, Germany) (► Fig. 6).

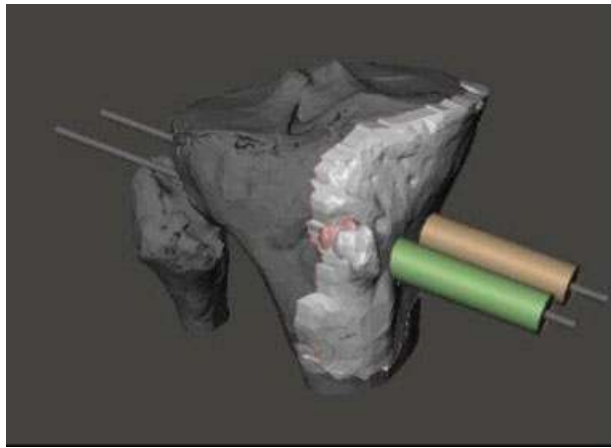


Fig. 2 Design of the osteotomy positioning guide and positioning immediately below the chosen plane.

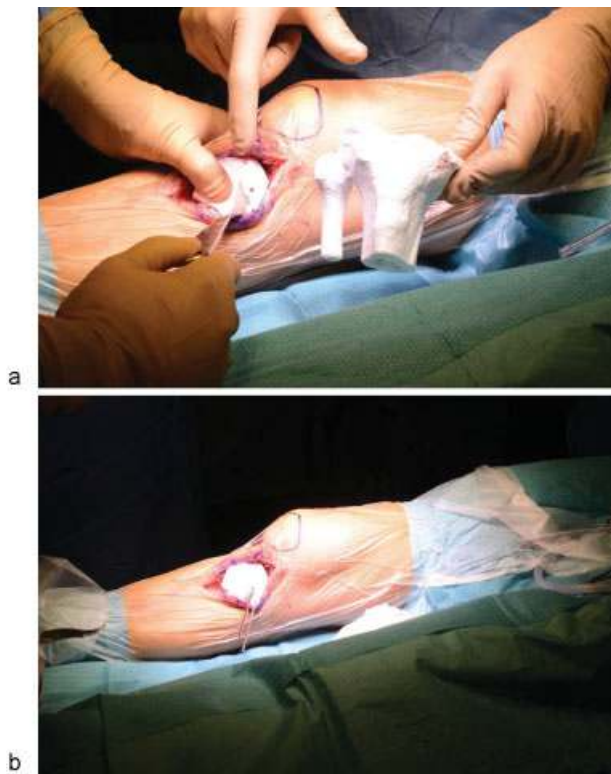


Fig. 3 Intraoperative use of the template. (a) Adjustment of the osteotomy positioning guide on the tibial metaphysis patient. (b) Kirschner-wire insertion through the guide and checking of the depth reached under intraoperative fluoroscopy.

Variables and Outcomes

Two independent assessors did the preoperative calculations and measured the variables for this study, which included executional accuracy (primary variable), final valgus, tourniquet time, number of intraoperative fluoroscopic images, preoperative time used in the planning phase, grams of ABS required, and economic costs. For the time used in the planning phase, we distinguished between the time used by an operator, the time taken for printing the 3D model and the total time. The operators used their preoperative time for software editing, slicing and calculations of the G-code, giving instructions per layer

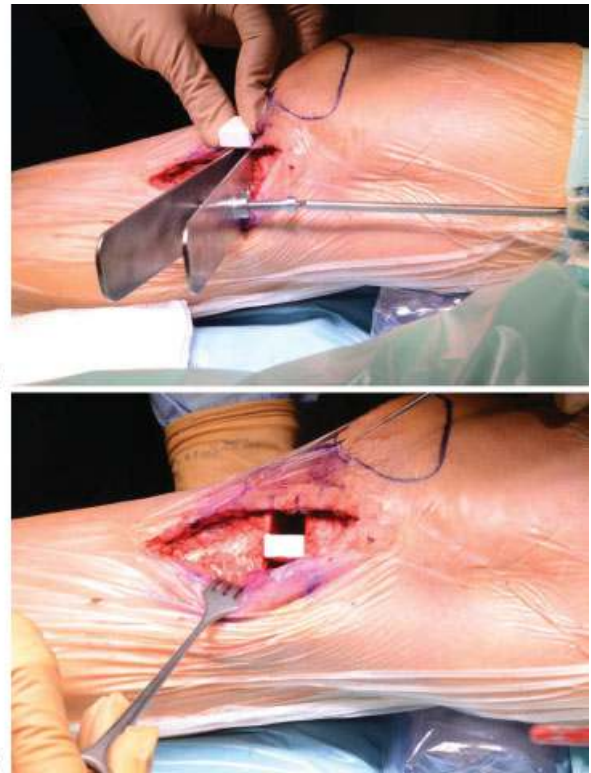


Fig. 4 Osteotomy opening. (a) Distraction of the osteotomy site using the 3D printed wedge-shaped spacer as a reference. (b) Same gap opening as previously calculated. 3D, three-dimensional.



Fig. 5 The autologous iliac crest graft is sculpted using one of the plastic wedges as a model.

(e.g., where, when, and how fast the plastic would be deposited), positioning, inspecting, and repairing the virtual model.

Mean and range were recorded (SPSS 19.0, IBM corporation, Armonk, NY). Mann–Whitney *U* and Wilcoxon test was considered significant at $p < 0.05$. Institutional Review Board approval and written informed consent were obtained for this study.

Results

We included 8 cases for using the new technique and 20 control cases (28 cases in total), which, respectively, showed



Fig. 6 Fluoroscopic control after fixation with a locked TomoFix plate.

no significant differences in average age: 44 years (range, 35–52 years) versus 45 years (range, 33–58 years).

The mean executional accuracy was 0.5 degrees (range, 0–1.2 degrees) versus 1.1 degrees (range, 0–2.8 degrees) for the new and control techniques; however, differences were not significant. There were no significant differences in final valgus; in both techniques, a final valgus of 7 ± 2 degrees was achieved.

The mean tourniquet time was 61 minutes (range, 49–84 minutes) compared with 92 minutes (range, 84–118 minutes) in the new versus control techniques, respectively ($p < 0.001$). An average of 8 (range, 6–14) intraoperative fluoroscopic images were required in the new technique, compared with 55 (range, 41–73) in the standard technique ($p < 0.001$).

The average preoperative time taken by the operators was 60 minutes (range, 75–32 minutes). The average time for printing the models was 225 minutes on average. Thus, on average, a total time of 285 minutes were used preoperatively. The plastic consumption for printing the models were on average 120 g (range, 87–184 g) of ABS. The price of ABS is €0.04 per gram; therefore, we printed our models for less than €5.

Discussion

The emergence of modern planning methods for opening wedge HTO have popularized this technique in the past years, showing a higher correcting accuracy and lower rates of conversion to total knee replacement than closing wedge HTO.^{18,19} The long-term results of these osteotomies are directly related to the surgical correction achieved.^{10,11} The use of modern locked plates (e.g., TomoFix) allows for having immediate postoperative stability that allows for immediate loading.²⁰ Our efforts in this work were focused on efficiently optimizing each of the surgical steps required for an open-wedge HTO (from preoperative planning to intraoperative execution) for reducing the risks of a human error in each step.

Choosing the appropriate plane is essential for achieving a successful HTO. If the osteotomy cut is too low, it may decrease the blood supply and increase the risk of nonunion, whereas if it is too high, we may increase the risk for articular overloading and for modifying the extensor apparatus.^{14,19} Traditionally, the surgeon chose the HTO's dimensions and position based on Dugdale method¹² and/or readjustments during the intraoperative period (at the cost of increasing surgical time). Dugdale method, which represents a correction to the standardized average population, has a high incidence of erroneous corrections.²¹

In the last decade, several techniques based on intraoperative navigation have shown an increased surgical accuracy in HTO for modifying axial alignment and for controlling tibial slope on the sagittal plane, with respect to classic techniques based on anatomic landmarks and intraoperative fluoroscopy.^{22,23} The main disadvantage of navigation techniques is the long learning curve, coupled with increased surgical time.¹⁵ Navigation is based on real-time intraoperative positioning, whereas positioning guide systems, such as the method that we propose, are not initially depending on intraoperative positioning, which reduces surgical time.

Our cutting-guide system depends on 3D imaging, which is based on CT scan. At present, we are not able to obtain weight-bearing images under CT scan, which forces us to take a previous weight-bearing full-extension teleoroentgenogram. For accurately measuring the required corrections on the X-rays, we require a calibration system. The absence of radiologic calibration would convert our planning efforts into a simple estimation.²⁴ Moreover, the use of digital formatting allows for selectively amplifying our reference regions (femoral head, tibial plateau, and talus) for measurements, which has shown greater precision than classic manual methods.²⁵ Orthoview also allows for easily calibrating a study by using any radiopaque marker and it also includes digital templates of the implants, to estimate their size and position to simulate the expected result. In our method, the desired size and position of our correction are then transferred to a 3D model. Preoperatively, the information in 3D allows the surgeon for (1) accurately planning the size of the osteotomy required for correcting the abnormal axial deviations in the coronal and sagittal planes and (2) detecting any space compromise in knee flexoextension that could be present after the osteotomy.²⁶

For decreasing the risks for committing errors and for increasing the surgeon's understanding of the patient's problem, we believe that all planning should be done directly by the surgeon: from the postprocessed radiological images to the 3D model printing, which implies a learning process of the digital tools involved. However, this increased preoperative complexity results into a much simpler and faster surgical technique that can be performed by less experienced surgeons, thanks to the availability of the osteotomy positioning guide and the spacers.

In our study, our preoperative time for planning decreased while we advance through out the cases, ranging from 75 minutes in the first case to 32 minutes in the eighth. In all cases, the printed guides could be fitted against the bone through a standard exposure.

The final axial correction achieved in our new technique was slightly better than the one in the standard control technique, not achieving a significant difference. Besides the executional accuracy, reduction in surgical times (33% lower tourniquet time compared with the standard method) and lower exposure to radiation (6.9 times less), other potential clinical advantages of our new technique include a reduced blood loss and lower infection rates.²⁷ Furthermore, the costs for investing in the costs of our 3D printer were €490. At our institution, the reduction in surgical time represents a difference in costs of €507 per operation²⁸; thus, the costs of the printer are recouped after a single clinical procedure. The need for performing a preoperative CT scan of the proximal tibia is a disadvantage that must be weighed against the reduced use of fluoroscopic time in the operating room.

Conclusion

Digitally planned and executed osteotomies under 3D printed osteotomy positioning guides help the surgeon to reduce surgical time by performing the tibial opening wedge osteotomy while minimizing human error. It is a potential efficient alternative to intraoperative navigation because it decreases surgical time by investing it in the preoperative phase. It is inexpensive being its main disadvantage the need for performing a CT scan of the proximal tibia, which must be weighted against the reduced use of fluoroscopic time in the operating room, improved reproducibility, surgical time savings, and the potential reduction of comorbidities.

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