

Three dimensional-printed patient-specific cutting guides for femoral varization osteotomy: Do it yourself

Juan Arnal-Burró*, Rubén Pérez-Mañanes, Eudaldo Gallo-del-Valle, Cristina Igualada-Blazquez, Manuel Cuervas-Mons, Javier Vaquero-Martín

Department of Orthopaedic and Trauma Surgery, General University Hospital Gregorio Marañón, Madrid, Spain

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ABSTRACT

Introduction: In valgus knees of young patients, opening-wedge distal femoral osteotomy is a valid treatment option for axial corrections. It allows the surgeon to achieve accurate correction, which is directly related to the functional outcome and survivorship of the osteotomy. This study presents a new technique based on three-dimensional (3D)-printed cutting guides for opening-wedge distal femoral osteotomies, in which pre-operative planning and intraoperative executional accuracy play a major role.

Material and methods: Pursuing axial correction accuracy, 3D-printed patient-specific positioning guides and wedge spacers were both created and used by the surgeon to implement the femoral osteotomy. The proposed technique was performed in 12 consecutive patients (cases). The results were compared with 20 patients (controls) in which opening-wedge distal femoral osteotomies were performed following the traditional technique. Accuracy of the axial correction, surgical time, fluoroscopic time and costs were measured.

Results: More accurate axial correction with reduced surgical time (32 min less), intraoperative fluoroscopic images (59 images less) and costs (estimated €412 less) were achieved with the use of the customized guides when compared with the traditional technique.

Discussion: Accurate correction of the axial alignment of the limb is a critical step in survivorship of the osteotomy. Improving the technique to enhance accuracy focused on this issue.

Conclusions: The use of patient-customized cutting guides minimised human error; therefore, surgical time was reduced and accurate axial correction was achieved. The surgeon mastered all steps in a do-it-yourself philosophy style.

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1. Introduction

Lateral compartment osteoarthritis (OA) of the knee represents a challenge for orthopaedic surgeons, especially when coupled with valgus malalignment in young patients [1]. In elderly patients, partial or total knee arthroplasty (TKA) achieves pain relief and long-term implant survival. However, less favourable results have been reported in younger, more active patients undergoing a knee replacement procedure [2]. A three- to five-fold higher risk of revision surgery has been found in patients aged <55 years [3].

Realignment varus osteotomy is a successful treatment option for lateral unicompartamental knee OA with associated valgus malalignment in young or middle-aged patients [4]. It results in a weight-bearing transfer to unload the damaged lateral compartment [5]. While valgus osteotomies are usually performed on the tibial side, varus osteotomies are most common in the femur [4,6]. However, high tibial osteotomy (HTO) may also be performed in a valgus knee when a small varus correction is required

* Corresponding author at: Avenida la Gavia 11, portal F, 4b, 28051 Madrid, Spain.

E-mail address: juanarnal@hotmail.com (J. Arnal-Burró).

[7]. In greater deformities (i.e. valgus malalignment $>10\text{--}12^\circ$) an osteotomy performed on the femoral side is preferred, as HTO may lead to joint instability due to iatrogenic joint line obliquity [8,9]. Although distal femur varus osteotomy (DFVO) is not a common procedure, even in major orthopaedic centres, recent literature reported it achieving good results with 10-year survival rates ranging 74–94% [4,10–12].

Traditionally, closing-wedge techniques have been most commonly used for DFVO, but the good results achieved in studies with opening-wedge high tibial osteotomy (HTO) performed for correcting varus deformities have led surgeons to pursue the advantages of opening-wedge procedures in the distal femur [13]. Opening-wedge DFVO allows for more accurate correction of alignment compared with closing-wedge techniques, with a narrower range of final tibiofemoral angles [1,14]. Achievement of optimal mechanical alignment is crucial in perigenicular osteotomies [1,15], and is directly related to the longevity of the native knee function [16]. Moreover, opening-wedge DFVO is considered technically easier than closing-wedge procedures, as the latter may lead to a less accurate axis correction because removal of a precise bone wedge is technically difficult and inaccurate [17].

Appropriate predictive surgical planning is essential to achieve the ideal correction angle that will ensure a good functional result, because selection of the osteotomy site and wedge position and size are the key points in performing an accurate correction that avoids joint line obliquity or creation of a new deformity [18]. In order to improve accuracy in axis correction, navigation techniques have recently been used with good results [19].

The purpose of this study was to describe a new surgical procedure based on patient-specific three-dimensional (3D)-printed cutting guides, with intraoperative positioning of an opening-wedge DFVO, in order to achieve the maximum accuracy and surgical time efficiency, and to analyse clinical experience with this procedure.

2. Material and methods

A case-control study was conducted on patients undergoing DFVO for lateral OA of the knee that was performed by orthopaedic surgeons at the present hospital from 01/01/2014 to 31/12/2015 using mainly open available software. The authors contributed to pre-operative planning (ABJ, PMR), data collection, outcome assessment, and figure preparation (GDVE, IBC, CMC, VMJ). Institutional review board approval was obtained for this study (IRB number CEIC 476/14).

2.1. Patient population

Patients were enrolled consecutively. Inclusion criteria were recent onset of pain (within one year), being aged <60 years, and low-grade lateral joint OA [20]. Exclusion criteria were range of motion $<90^\circ$ and radiographic Kellgren/Lawrence grade III or IV knee OA [15]. The group consisted of 12 patients consecutively recruited and operated on using the new procedure. The control group consisted of patients who received a standard DFVO procedure for lateral OA of the knee by surgeons experienced in DFVO between 01/01/12 and 31/12/15, and who had met the same inclusion and exclusion criteria. Twenty control patients were enrolled. Specific written informed consent for this study was obtained from all patients that were recruited.

2.2. Independent variables and outcomes

The primary outcome measure was accuracy of the osteotomy, defined as final axis-limb correction and execution accuracy. Final axis correction was defined as the deviation in degrees in the final mechanical axis of the operated limb (three degree slope as compared to that of the vertical axis) [21]. Execution accuracy was defined as the difference between the planned wedge (lateral opening gap) and the lateral cortex opening performed [17]. The difference was considered excellent if <1 mm, good if ranging from one to 1.5 mm, fair if ranging from 1.5 to two millimetres, and poor if >2 mm.

Differences in operating times, need for fluoroscopy, and estimated costs between both procedures were considered as secondary variables. They were measured as: (1) tourniquet time in minutes, (2) number of intraoperative fluoroscopic images, and (3) estimated costs. Cost analysis included the potential economic differences between both procedures during surgery planning and performance (pre-operative investment and operating time savings); a cost-effectiveness analysis was not conducted.

Data and variables were prospectively collected and evaluated by two independent assessors (GDVE, IBC); the new and classical procedures were compared. Demographic data were collected (age, sex, height, weight, etc.), and primary and secondary variables were recorded in all patients.

2.3. Intervention

The 3D-guided technique consisted of two phases: (1) a pre-operative planning phase where the opening gap was calculated and guides were designed by the surgeon himself; and (2) an intraoperative phase, which was simplified thanks to a 3D-printed patient-specific guide as a surgical aid.

2.3.1. Pre-operative planning

Calibration was performed in each case with the help of a 28-mm sphere radiolabel as a magnification marker for weight-bearing long-leg alignment radiographs. The calibrated long-leg alignment images were loaded to Orthoview® software (Materialise, Leuven, Belgium; free download at <http://www.orthoview.com/>) in DICOM (Digital Imaging and Communication in

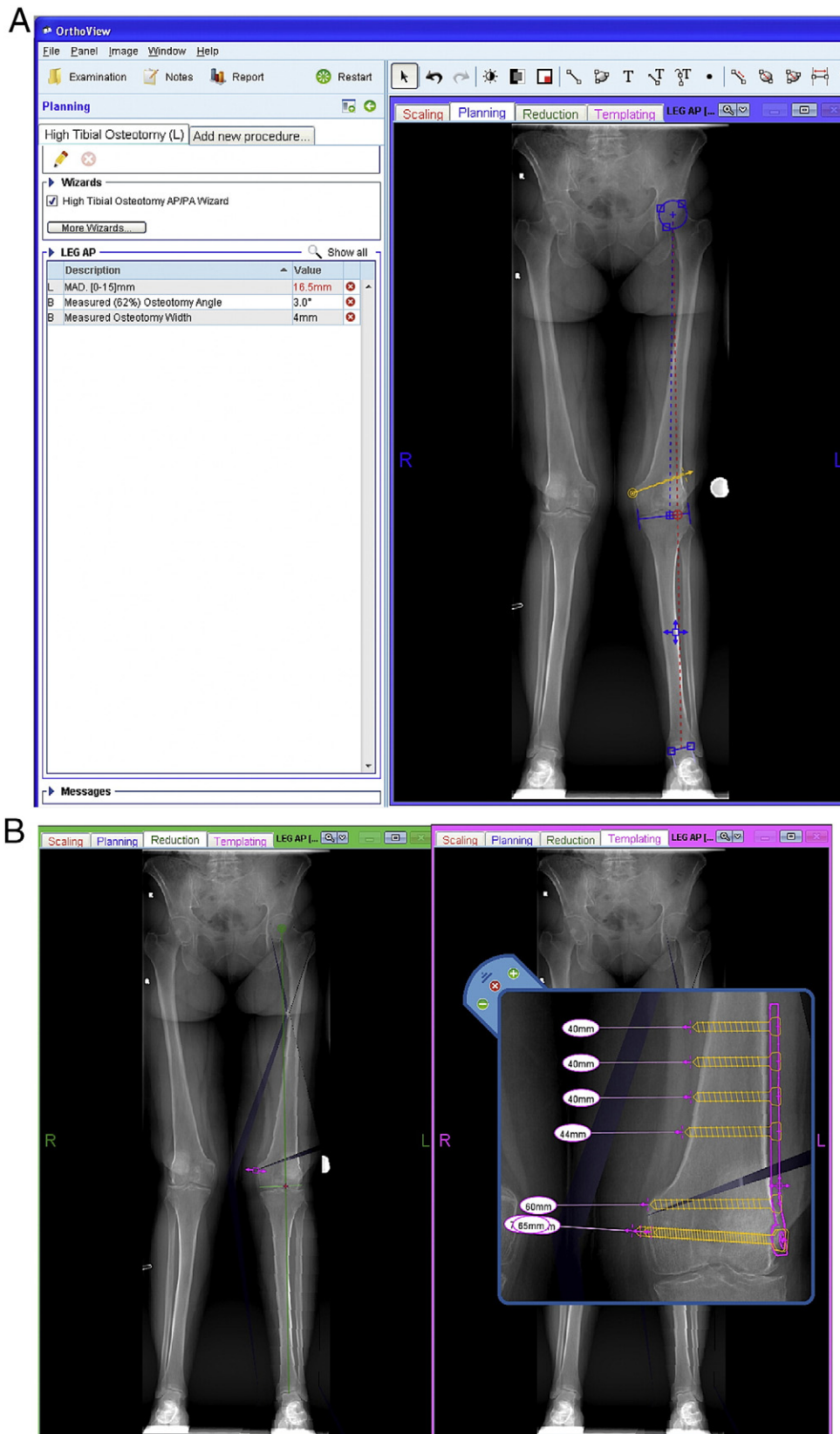


Figure 1. Digital templating using Orthoview®. a. Planning the osteotomy. b. Simulation of final correction and fixation.

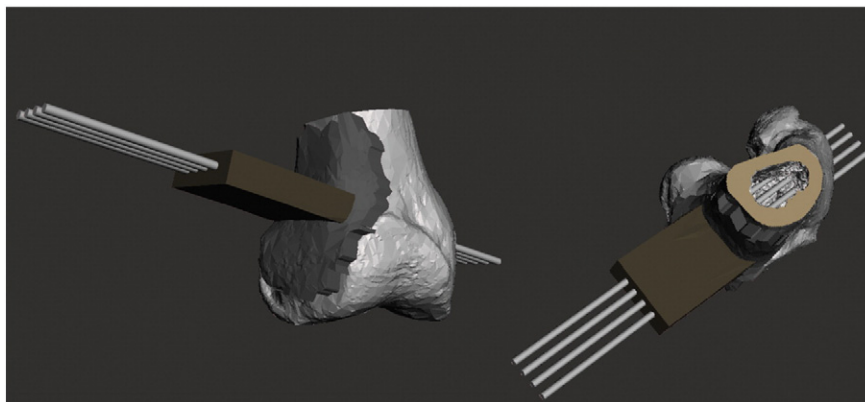


Figure 2. Design of the osteotomy positioning to guide four Kirschner wires immediately below the selected plane.

Medicine) format. Orthoview® modules allow for simulating limb correction by intersecting at the Fujisawa point (62% of cross length of the plateau); [22] the two lines originate in the centre of the femoral head and the centre of the talus. The desired location for the osteotomy in the distal femur was then established, and wedge dimensions on the coronal plane for corrective DFVO were calculated (Figure 1a and b).

Computed tomography (CT) scans (Siemens, Somatom Spirit, Munich, Germany) of the distal femur were requested for pre-operative planning. The CT DICOM images were then imported into radiographic postprocessing software (GNU open-source OsiriX/Horos <http://www.horosproject.org>) using a Macintosh personal computer (Apple Computers, Cupertino, CA). Images were processed for subtracting the patella and soft tissue (in a semi-automated segmentation process), applying 3D surface rendering and exporting the images as a stereolithography (STL) file format.

The STL files were uploaded to free Autodesk Meshmixer 2.4 software (<http://www.meshmixer.com/>) to design a 3D 1:1 scaled digital model of the distal femur. The cutting guide accurately reproduced the location and dimensions of the previously calculated wedge by using the distal femur joint line as a reference. In this step, a patient-specific template (lateral aspect of the femur) was created by a digital extrusion process to guide four Kirschner wires (K-wires), and to guide the osteotomy cut during the surgical procedure. Axial views were used to adjust the direction of K-wires to the posterior cortical, thus avoiding neurovascular damage (Figure 2). Cutting depth was also measured; 12 mm of medial cortex was preserved to open the gap by osteoclasis.

A desktop 3D printer (Witbox, BQ, Madrid, Spain) using fused deposition modelling (FDM) was then used to obtain three elements: (1) a patient-specific osteotomy guide; (2) three polyhedral wedges; and (3) the patient's distal femur. Thermoplastic filament of polylactic acid (PLA) 1.75 mm in diameter was used for 3D printing. The polyhedral wedges reproduced the lateral height and slope calculated by the Orthoview®, and served as spacers during the procedure. The 3D model of the patient's femur was used for confirming adequate adaptation of the positioning guide before surgery (Figure 3). The PLA components were sterilised for surgical purposes using ethylene oxide during a long cycle of 12–16 h at 37 °C.

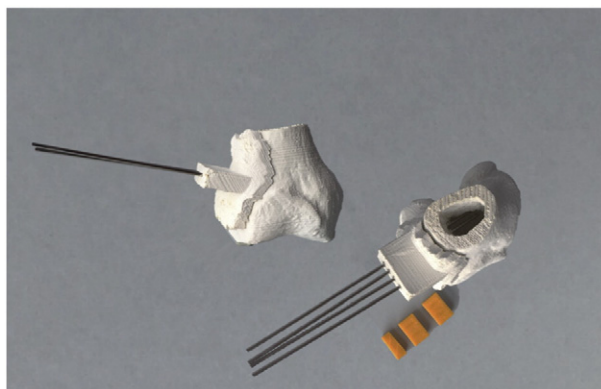


Figure 3. Checking correct implementation of the guide on the printed 3D model of the distal femur.

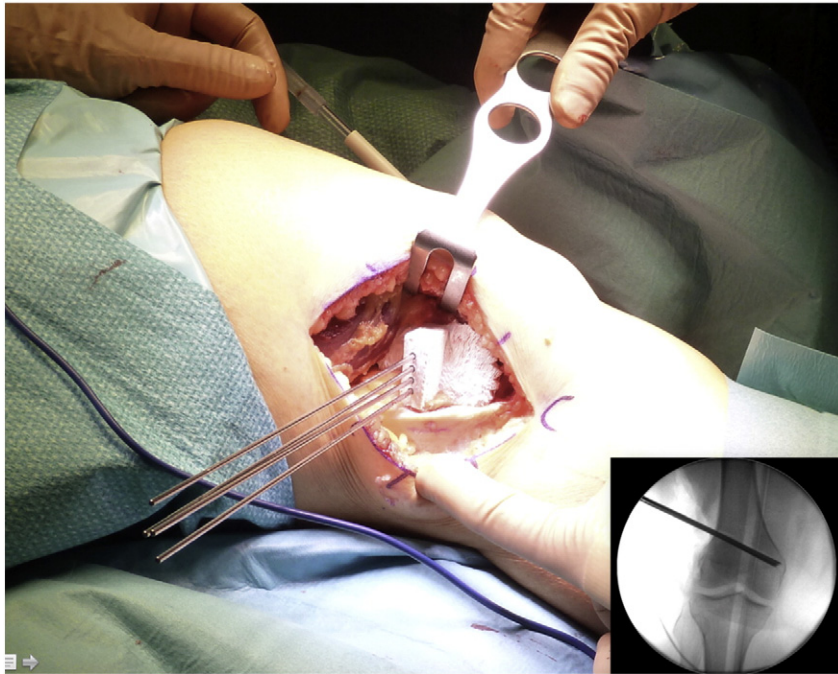


Figure 4. Intraoperative adjustment of the osteotomy-positioning guide on the femoral lateral cortex, with four Kirschner wires inserted through the guide. Depth and orientation checked under fluoroscopy.

2.3.2. Intraoperative phase

The patient was placed in a supine position, and a standard distal lateral approach to the femur was used. Once the periosteal femoral surface was exposed, the customized osteotomy-positioning guide was adapted by simple apposition. K-wires were then inserted through the cannulated rectangular prism into the medial cortex. Adequate orientation and positioning were assessed using fluoroscopy (Figure 4). The osteotomy-positioning guide was removed, keeping the K-wires in position. Osteotomy was performed by sliding an oscillating saw over the proximal aspect of the wires. The measured depth was previously marked on the saw to avoid breakage of the medial cortex. Progressive distraction of the osteotomy allowed for inserting two of the three

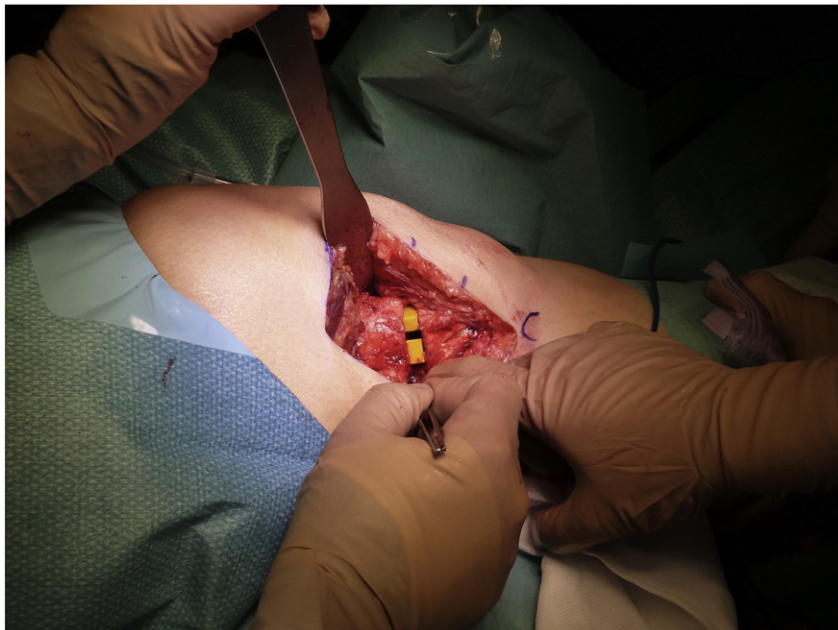


Figure 5. Progressive distraction of the osteotomy until insertion of two PLA spacer wedges.



Figure 6. Autologous bone graft carved according to wedge dimensions.

PLA spacer wedges, leaving a central space between them (Figure 5). Anterior and posterior symmetry was always checked. An iliac crest graft or a proximal tibial graft was then harvested. The third printed wedge was used as a model for carving the angulation and height of the wedged graft (Figure 6). Once a graft of adequate size was obtained, it was inserted into the space of the femoral osteotomy. Every osteotomy was fixed with a locking plate (TomoFix system, DePuy-Synthes, Umkirch, Germany).

2.4. Statistical plan

A statistical analysis was performed using IBM SPSS Statistics® version 20.0 (IBM®, Armonk, USA). Data were given as mean (range $\pm$ standard deviation (SD)) or median ($\pm$ interquartile range) for asymmetric variables. Hypothesis testing was performed using a Mann–Whitney test and a Wilcoxon signed-rank test. Values of $P \leq 0.05$ were considered statistically significant.

3. Results

A total of 32 patients – 12 cases (3D-guided DFVO) and 20 controls (standard DFVO) – were studied. No significant between-group differences were seen in age (mean 41 years $\pm$ 33–57 SD in the control group versus 44 years $\pm$ 34–60 SD in cases) or sex (75% females versus 65% females, respectively).

Mean final mechanical axis deviation was 0.28° ($0-1 \pm$ SD) in cases and 1.8° ($0-4 \pm$ SD) in controls, with a statistically significant between-group difference ($P = 0.002$) (Figure 7). Mean execution accuracy in the case group was 0.5 mm of lateral cortex opening ($0-1.5 \pm$ SD) compared with 2.5 mm ($0-4 \pm$ SD) in the control group, with a statistically significant difference ($P = 0.004$) (Figure 7).

In analysis of secondary variables, mean tourniquet time was 63 min ($52-81 \pm$ SD) in the cases and 95 min ($85-122 \pm$ SD) in the controls ($P < 0.001$). On average, six ($4-12 \pm$ SD) intraoperative fluoroscopic images were required in the cases compared with a mean of 65 images ($41-86 \pm$ SD) in the control group ($P < 0.001$). Cost analysis found that an average of 120 g ($110-190 \pm$ SD) PLA was required to print the models. As the cost of PLA filament was €0.02/g, the cost of printing each model was approximately €2.4. The estimated cost of a CT scan at the present hospital was €105, and the average cost of surgery was €981/h [23]. Shortening the operating time by 32 min (92 min in controls versus 63 min in cases) represented average cost savings of €522 per procedure. Therefore, the estimated average savings, considering the technical features of both procedures only (CT scan, operating time, plastic), were €415 per surgery.

4. Discussion

Osteotomy is best indicated in young, active patients who are usually aged $<60-65$ years and with a low arthritis grade (grade 0 to 2) in the Kellgren and Lawrence system, because of preserved bone stock and ligament structures [11,12,24]. The two most important features in knee osteotomies are adequate patient selection and maximum accuracy in limb axis correction [25]. However, limb axis correction in DFVO remains an important challenge for the surgeon due to imprecise and inaccurate surgical procedures, which may lead to suboptimal results [26]. Moreover, unicompartmental OA is approximately 10 times less common

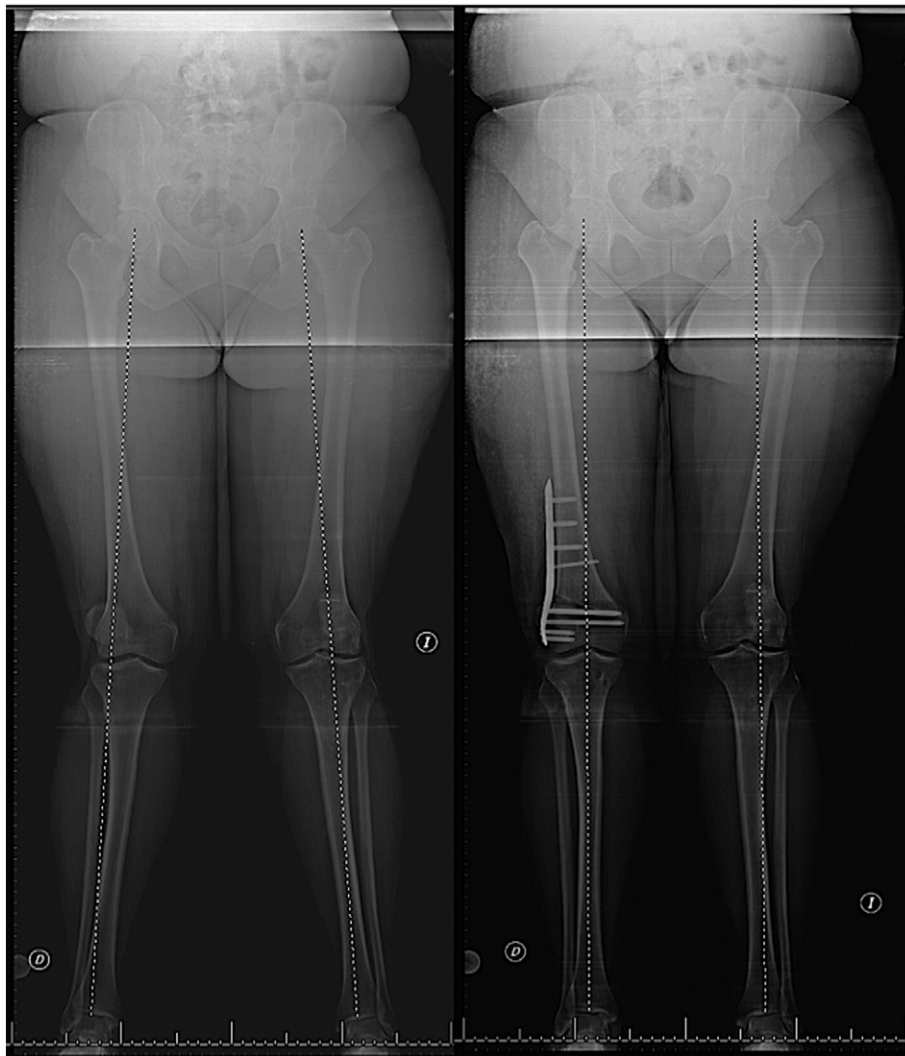


Figure 7. Pre-operative and postoperative weight-bearing, long-leg alignment X-rays of one of the cases where the new procedure was used.

in the lateral than the medial compartment, and it is therefore difficult to acquire experience with DFVO [27]. The new procedure is intended to focus effort on optimization of each surgical step, with two main goals: to minimise human errors and to increase surgical precision.

An opening-wedge osteotomy is preferred to a closing-wedge osteotomy because of its greater reproducibility and accuracy, according to studies by authors such as Duivenvoorden et al. [28]. Moreover, the modern locked plates may be used to achieve greater stability, allowing for immediate weight bearing and active rehabilitation program, and to help prevent secondary loss of correction [29]. In a review of the literature, more studies were found on the survival rate after the closing-wedge osteotomy procedure, which shows that this has been historically preferred to an opening-wedge osteotomy. A 10-year survival rate of 82% was reported by Backstein et al. in their study of closing-wedge DFVO in 40 knees [30], while Wang and Hsu reported a 10-year survival rate of 87% in their series of 30 patients [31]. No great differences are found in the survival series available between opening-wedge and closing-wedge procedures [12,32–34]. The survival rate of opening-wedge osteotomies was studied by Dewilde et al., who found a seven-year survival rate of 82% in their series of 19 opening-wedge DFVOs stabilized with Puddu plates [34]. By contrast, Zarrouk et al. reported a survival rate of 91% at eight years of follow-up in the 22 knees included in their series [12,33].

Since survival and functional results depend on precision of the correction [17], the classical surgical procedure has been modified to increase surgeon control on axis correction. Navigation-assisted techniques have been used to improve accuracy in limb axis correction with encouraging results, such as the 87% of satisfactory axial corrections reported in the series by Saragaglia and Chedal-Bornu [35]. The main disadvantages of navigation are the long learning curve and the increased operating time [36]. Navigation is based on real-time intraoperative positioning, whereas positioning guide systems, such as the method

proposed in the present study, are based on investing that time in the pre-operative planning period. The procedure described here, including rigorous predictive surgical planning and precise intraoperative execution, is meant to be an easy and reproducible surgical technique that allows for decreasing risk of human errors. The proposed modifications of the classical procedure include use of a calibration system to achieve accurate measurement of the required corrections on radiographs. Absence of radiographic calibration would convert the planning efforts into a simple estimate [37].

The role of pre-operative planning in the lower limb has experienced greater change in modern digital planning than techniques described by Dugdale et al. [38]. While both procedures are based on the same mechanical principle, digital planning has been shown to be a more reproducible method. Moreover, use of digital formatting for measurements has been shown to have a greater precision than standard manual methods [39]. Use of software such as Orthoview® decreases variability in pre-operative calculations between surgeons. However, the critical time occurs intraoperatively, when the surgeon selects the osteotomy location and orientation. The fact that a single bone cut is needed makes the opening-wedge DFVO technically more feasible than closing-wedge procedures [5,15], in which very precise resection of the wedge is required, which may be technically very demanding.

With the present method, the desired size and position of the osteotomy are transferred to a 3D-printed custom guide to achieve limb correction, so that even inexperienced surgeons will safely be able to perform the osteotomy. It should be noted that HTO is performed in metaphyseal bone, while femoral osteotomy is located in the metadiaphyseal junction, closer to diaphyseal bone, which is known to have a slower bone healing capacity than metaphyseal bone. Too proximal osteotomies will increase the non-union rate, while involuntary orientation changes will yield unexpected mechanical changes. Cameron et al. reported a three percent non-union rate, finding complete radiographic union six months after surgery [10]. In their study, valgus deformity correction was less accurate than expected. They used the surgical procedure described by Paley and Pfeil [20] and achieved the goal of restoring mechanical alignment to neutral in 10 of their 21 patients who had follow-up X-rays of the mechanical axis. The present authors believe that this lack of accuracy was related to their pre-operative analysis, which was based on the assumption that one millimetre of linear correction at the osteotomy site corresponds to one degree of axial alignment correction. This underlines the importance of the pre-operative planning phase, which is one of the main points that must be emphasised, as it is directly related to the final clinical and radiographic outcome. Cameron points out that “an improved method of preoperative planning and refinement of the intraoperative technique may improve this” [10]. Use of custom guides does not only help locate the osteotomy plane, but has a particular advantage in replicating the height of the measured osteotomy by using a specific patient wedge spacer. While execution precision (lateral cortex opening) guarantees the transfer of planning into surgery, both planning and execution are involved in final limb correction. In both measurements, significant differences favouring the 3D technique were found. The precision in lateral cortex opening provided by the customized wedge is an independent predictor with a strong correlation with final limb alignment and lower intra-observer variability [17].

Use of 3D-printed patient-specific guides also significantly decreased the need for fluoroscopy and operating time compared with the classical technique. Potential clinical advantages of this time reduction include reduced blood loss and lower infection rates [40]. The spacer was also used to carve the graft for the osteotomy. The decision as to whether the graft was taken from the iliac crest or the proximal tibia metaphysis was made during surgery and based on the size of the opening, as no differences in union rate have recently been shown [41].

Predictive surgical planning decreases the chance of making mistakes and increases the surgeon's understanding of the patient's problem. It is believed that the surgeon should do all pre-operative planning, from the post-processed radiographic images to the 3D-printed medical models, which implies a learning process of the digital tools involved. However, this increased pre-operative complexity results in a simpler and faster surgical procedure that may be performed by less experienced surgeons, thanks to the availability of the osteotomy positioning guide and spacers. An attempt was made to objectively assess the difficulty perceived by the surgeon during the procedure, but in the absence of validated scales, it is believed that the decrease in operating time and the increased precision are good indicators of how the 3D guides reduce potential human error. Moreover, as this is a procedure entirely developed by surgeons with no dependence on commercial companies, cost savings were achieved. This new technique initially increases costs derived from acquisition of the selected 3D printer (price range, €500–2000) and consumables (one kilogramme of PLA filament costs approximately €20), and the need for a CT scan of all patients. Cost of scans was calculated based on purchase price of the equipment and costs of maintenance and human resources and the number of scans performed every year (€105 per scan at the present hospital). Shortening of operating time represents a difference in costs of €415 per procedure; [23] thus, the costs of the 3D printer are quickly recouped.

The main disadvantage of this technique is exposure to the radiation associated with a pre-operative CT scan of the distal femur. This should be weighed against the decreased intraoperative radiation and the potential clinical benefits of a shorter operating time.

One limitation of this study was that patients were not randomised to undergo one or the other procedure. The decision to perform either the classical or the 3D-guided procedure was based on patient preference and on the temporary ability to perform CT scan, 3D printing, and sterilisation process during the waiting time for this elective procedure.

5. Conclusion

Accurate axial correction should be sought when performing distal femoral varus osteotomy for lateral compartment knee OA. Modern software tools and the new applications of 3D printing techniques can help surgeons to design and create cutting guides and wedge spacers; this leads to precise osteotomy, which translates into optimal functional results. As the surgeon develops

rigorous pre-operative planning that will allow for a straightforward execution phase using 3D printed guides, less intraoperative time is needed, thus decreasing fluoroscopic time and costs. The result is an easy procedure that may be performed by less experienced surgeons.

Competing interests

The authors declare that they have no competing interests.

Author's contributions

All authors have made substantial contributions to all of the following: [1] the conception and design of the study, or data acquisition, or analysis and interpretation of data, [2] drafting the article or revising it critically for important intellectual content, and [3] final approval of the version to be submitted. No writing assistance was used.

The manuscript, including related data, figures and tables, has not been previously published and is not under consideration elsewhere.

Ethical guidelines

The Institutional Review Board of Hospital General Universitario Gregorio Marañón (CEIC Comité Ético de Investigación Clínica) approved the paper.

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