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ORIGINAL PAPER

Three dimensional patient-specific printed cutting guides for closing-wedge distal femoral osteotomy

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Abstract

Purpose Medial closing-wedge distal femoral osteotomy (MCWDFO) was used to treat valgus knee malalignment combined with lateral compartment disease. The clinical outcome of the osteotomy depends on the accurate correction of valgus malalignment. The aim of this study was to evaluate the accuracy of a MCWDFO assisted by three-dimensional (3D)-printed cutting guides and locking guides.

Patients and methods Thirty-three consecutive patients (33 knees) were operated on using the same MCWDFO. 3D-printed cutting guides and locking guides were used to locate the osteotomy cut plane and to facilitate closing the wedge in 12 patients (3D-guide group). Another 21 patients (conventional group) underwent MCWDFO following the conventional technique. The desired correction was defined as a weight-bearing line (WBL) coordinate 50% of the width of the tibial plateau from the medial tibial margin. The deviation between the planned and executed WBL coordinate, surgical time and fluoroscopic time were compared.

Results The mean deviation between the planned and executed WBL coordinate was 4.9% in the 3D-guide group and 7.6% in the conventional group ($P = 0.024$). Shorter surgical time was found in the 3D-guide group (mean, 77.7 minutes vs. mean, 96.5 minutes; $P < 0.001$), while the mean number of intra-operative fluoroscopic images was 6.1, compared with 34.7 in the conventional group ($P < 0.001$).

Conclusion The use of 3D-printed cutting guides and locking guides can increase the precision of the MCWDFO in patients with lateral compartment disease and valgus deformity, making our surgery more efficiency and occupying less fluoroscopic time.

Keywords Lateral compartment knee osteoarthritis · Valgus knee · Medial closing-wedge distal femoral osteotomy · Patient-specific surgical guides · 3D printing

Introduction

Osteotomy around the knee has been reported as a treatment for unicompartmental knee osteoarthritis (OA) with frontal plane misalignment since the 1960s. Over the past two decades, the use of osteotomies has decreased because of the favourable outcome of unicondylar knee arthroplasty (UKA) or total knee arthroplasty (TKA) in elderly patients. However, Julin J et al. reported a higher risk of revision surgery in younger, more active patients undergoing knee arthroplasty [1]. On the other hand, osteotomy achieved pain relief and long-term survival in patients aged < 55 years [2]. In young patients who suffer from moderate lateral compartment OA and want to live an active post-operative life style, varus osteotomy is a reliable treatment option.

Varus osteotomy primarily refers to medial closing-wedge distal femoral osteotomy (MCWDFO), lateral opening-wedge distal femoral osteotomy (LOWDFO) or medial closing-wedge proximal tibial osteotomy. Because of the unreliable clinical outcomes with proximal tibial varus osteotomy that always causes joint line obliquity, the correction should be performed through the distal femur [3, 4]. As a result of the lower stability for early rehabilitation, the slow healing of the osteotomy and the frequent irritation due to the plate, LOWDFO has been abandoned by the authors, and MCWDFO has become the alternative treatment.

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The purpose of varus osteotomy is to delay the progression of OA and to increase the longevity of the native knee joint by transferring the mechanical axis medially. The most important factors to achieve this purpose are patient selection and the accuracy of the osteotomy [5, 6]. In recent years, there have been many methods used to improve the accuracy of the osteotomy, including use of wedge angle determined by the pre-operative long-leg alignment image, use of intra-operative fluoroscopy and the application of a navigation system; however, these methods have drawbacks [7, 8].

In the 1980s, a three-dimensional (3D) technique that accurately reconstructs physical objects was developed. At the beginning, most medical applications were in the field of reconstruction of maxillofacial and dental surgery [9]. However, the application of this technique in osteotomy around the knee has recently begun [10, 11].

In this study, we performed MCWDFO with a new surgical technique based on 3D-printed cutting guides and locking guides to achieve the maximum accuracy and greater time efficiency.

Patients and methods

Thirty-three knees in 33 patients who underwent the MCWDFO due to valgus malalignment and lateral compartment OA from January 2014 to December 2017 were prospectively evaluated. Patients were enrolled consecutively. Inclusion criteria and exclusion criteria are outlined in Table 1. The 3D-guide group consisted of 12 patients who underwent a MCWDFO procedure facilitated by a 3D-printed guide. The conventional group consisted of 21 patients who underwent the MCWDFO following the conventional technique. All patients were operated on by the same surgeon. Two independent assessors collected and calculated demographic data and statistical variables for all patients. The variables included executional accuracy, surgical time and number of intra-operative fluoroscopic images. Patient demographic and pre-operative data are listed in Table 2. There were significant differences in terms of age and BMI. The planned WBL coordinate was 50% [13]. The deviation between the planned and executed WBL coordinate was applied to describe the executional accuracy.

Pre-operative planning

All patients routinely underwent radiographs (anteroposterior and lateral views, a schuss view and a patella skyline view) and had computed tomographic (CT) scans (Siemens, Somatom Spirit, Munich, Germany) including the femoral head, 15 cm of the distal femur, the proximal tibia and the ankle. The slice thickness was 0.625 mm. The CT DICOM images were imported into Mimics® 16.0 (Materialise N. V. Leuven, Belgium) using a personal computer, and then virtual 3D models were created by a segmentation process that transformed the 2D slices into 3D surface mesh objects.

These virtual 3D models could be used to measure the WBL coordinate and the wedge angle. The distance from the intersection of the WBL (the line from the centre of the femoral head to the centre of the ankle) and the tibial plateau to the medial margin of tibial plateau was measured, and the WBL coordinate was scaled by the proportion of this distance to the tibial width (Fig. 1(a)). To measure post-operative WBL coordinates, all patients underwent CT scan of the femoral head, the tibial plateau and the distal tibia after the operation. All patients' wedge angles were calculated, because the angle was an important parameter to design the cutting guide in the 3D-guide group, and the angle was essential for accurate osteotomy in the conventional group. First, the desired post-operative WBL was drawn from the centre of the ankle through the centre of the tibial plateau. Second, the hinge point of the osteotomy (A) was determined, located on the upper margin of the lateral condyle and 5 mm within the lateral cortex. Third, point C (the planned location of the centre of the femoral head) was located on the desired post-operative WBL to make sure that line A-B was the same length as line A-C. Finally, the wedge angle (α) was the angle between line A-B and line A-C (Fig. 1(b)).

A cutting guide that had two cut slots to guide the cut planes and had four holes to fix to the femur with 3.0-mm K-wires was designed to meet the following conditions (Fig. 2(a)): (1) the guide had sufficient surface contact to produce a unique position on the bone; (2) the two bone cuts converged at the hinge point; (3) the angle between the two bone cuts was taken with the angle of the wedge (α); and (4) the distal bone cut was designed to be oblique so that the length of the two bone cuts was equal [14]. In the next step,

Table 1 Inclusion criteria and exclusion criteria

Inclusion criteria	Exclusion criteria
Age < 60 years	Medial and/or patellofemoral OA
Valgus deformity	Knee range of motion < 90°
Isolated lateral compartment OA	Flexion contracture > 10°
The modified Ahlbäck stage [12] ≤ 2	The modified Ahlbäck stage ≥ 3
	Laxity of medial collateral ligament

Table 2 Patient demographic and pre-operative data[a]

	3D-guide	Conventional	*P* value
Demographics			
Female[b]	8 (67%)	13 (62%)	0.784
Age (years)	44.4 (5.0)	49.0 (5.7)	0.024
Height (cm)	161 (6.6)	164 (6.5)	0.216
Weight (Kg)	62.8 (3.8)	60 (6.1)	0.191
BMI (Kg/m^2)	24.2 (2.8)	22.3 (1.4)	0.027
Pre-operative data			
WBL coordinate (%)[c]	89.8 (75–115)	89.1 (76–116)	0.869

BMI body mass index, *WBL* weight-bearing line

[a] Results presented as mean (standard deviation)

[b] Results presented as number of patients (%)

[c] Results presented as mean (range)

the virtual femur osteotomy was completed to obtain the desired alignment (Fig. 2(b)). A locking guide was engineered to ensure the accuracy of the reduction (Fig. 2(c)).

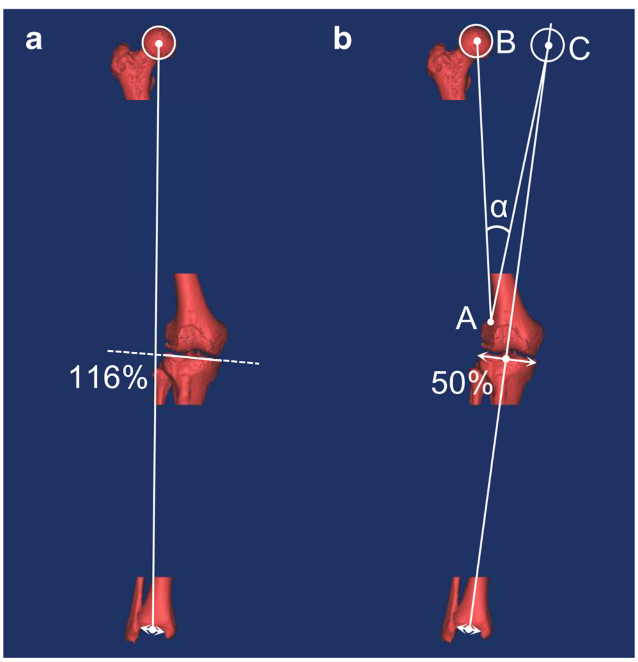

Fig. 1 Measurement of WBL coordinates and wedge angle. a The distance from the intersection of the WBL (the line from the centre of the femoral head to the centre of the ankle) and the tibial plateau to the medial margin of tibial plateau was measured and the WBL coordinate was scaled by the proportion of this distance to the tibial width. b First, the desired post-operative WBL was drawn from the centre of the ankle through the centre of the tibial plateau. Second, the hinge point of the osteotomy (A) was determined, located on the upper margin of the lateral condyle and 5 mm within the lateral cortex. Third, point C (the planned location of the centre of the femoral head) was located on the desired post-operative WBL to make sure that line A-B was the same length as line A-C. Finally, the wedge angle (α) was the angle between line A-B and line A-C

The data of the 3D model was exported in a stereolithography (STL) file format. A 3D printer (EOS FORMIGA P110, Electro Optical Systems Corporation, Munich, Germany) using a selective laser sintering (SLS) technique was used to print the cutting guide, the locking guide and the distal femoral model of the pre-operative and post-operative osteotomy (Fig. 2(d, e)). PA 2200, a type of nylon that is a special moulding material developed by German EOS for their SLS rapid prototyping equipment, was used for 3D printing. These components were sterilised using ethylene oxide for surgical purposes.

Intra-operative phase

The patients were placed in supine position, under general anaesthesia. A sterile tourniquet was applied. The medial side of the distal femur was exposed by a median incision, within which the vastus medialis was stripped from the septum. After the femoral surface was exposed, the cutting guide was placed on the unique position of the femur with complete fit and was fixed with 3.0-mm K-wires (Fig. 3(a)). The osteotomy was performed by an oscillating saw through the cut slot. A physical hinge of lateral cortex was retained. The cutting guide was removed, and the K-wires were kept in position. After the wedge was removed, the gap was closed by applying gentle pressure to prevent the lateral cortex fracture. Only after the malalignment was corrected accurately was the locking guide fixed on the femur with the remaining K-wires (Fig. 3(b, c)). In the conventional group, the position and direction of the bone cuts were marked with K-wires using fluoroscopy. After closing the gap, the alignment was controlled with fluoroscopy using a metal rod. All the osteotomies were fixed with locked conformed plates (Best®, Beijing, China) (Fig. 4(a, b)). The surgical time and number of images were recorded.

Statistical analysis

SPSS for windows software (Version 20, IBM®, Chicago, IL, USA) was used for statistical analysis. Statistical significance was set at $P \leq 0.05$. The deviation between the planned and executed WBL coordinates, surgical time and number of fluoroscopic images between the two groups were compared using the Mann-Whitney *U* test.

Results

All 3D-guides were excellent fits for the medial distal femur in the 3D-guide group. All patients' pre-operative and post-operative WBL coordinates were measured. The mean WBL coordinate was 48.6% (range, 39–56%) in the 3D guide group

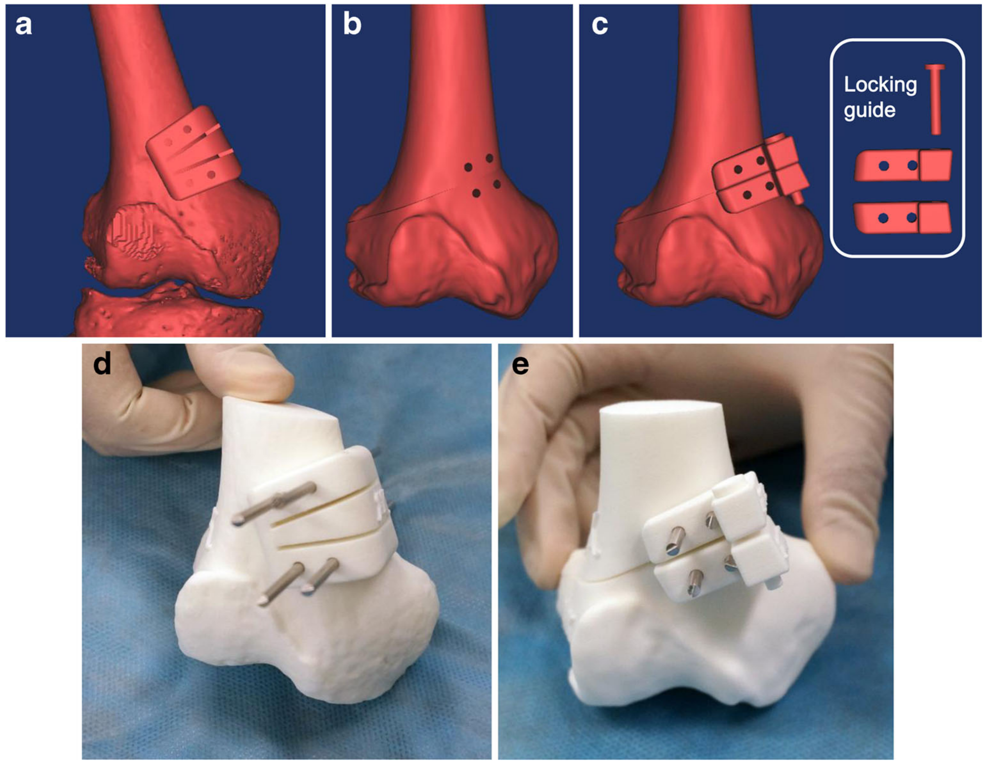

Fig. 2 The cutting guide and the locking guide were designed and printed. a A cutting guide that had two cut slots to guide the cut planes and four holes to fix to the femur by 3.0-mm K-wires was designed. b Screenshot of the virtual femur post-osteotomy. c Screenshot of the locking guide. d The cutting guide was fixed to the model of distal femur with 3.0-mm K-wires. e The locking guide was used to ensure the accuracy of the reduction

and 49.8% (range, 37–62%) in the conventional group, without a significant between-group difference ($P = 0.518$). The deviation between the planned and executed WBL coordinates had significant difference between the 3D-guide group and the conventional group (mean, 4.9%, range, 2–11%, vs. mean, 7.6%, range, 2–13%; $P = 0.024$). The mean surgical time was 77.7 minutes (range, 63–89 min) in the 3D-guide group and was 96.5 minutes (range, 81–115 minutes) in the conventional group ($P < 0.001$). There was a mean of 34.7 (range, 16–47) fluoroscopic images in the conventional group and a mean of 6.1 (range, 4–9) in the 3D-guide group ($P < 0.001$) (Table 3).

Discussion

A varus-producing distal femoral osteotomy can be a good option to relieve pain and improve function in young patients with lateral compartment OA and valgus alignment. In this procedure, achieving the desired alignment is an important factor to produce long-term satisfactory outcomes. In prior studies, several authors have used navigation to improve the accuracy of leg alignment correction [8, 15, 16]. Moreover, 3D printing technique has been used for corrective osteotomies and has achieved some promising results in the last decade [10, 11, 17–19]. Meanwhile, Murat Çalbıyık used

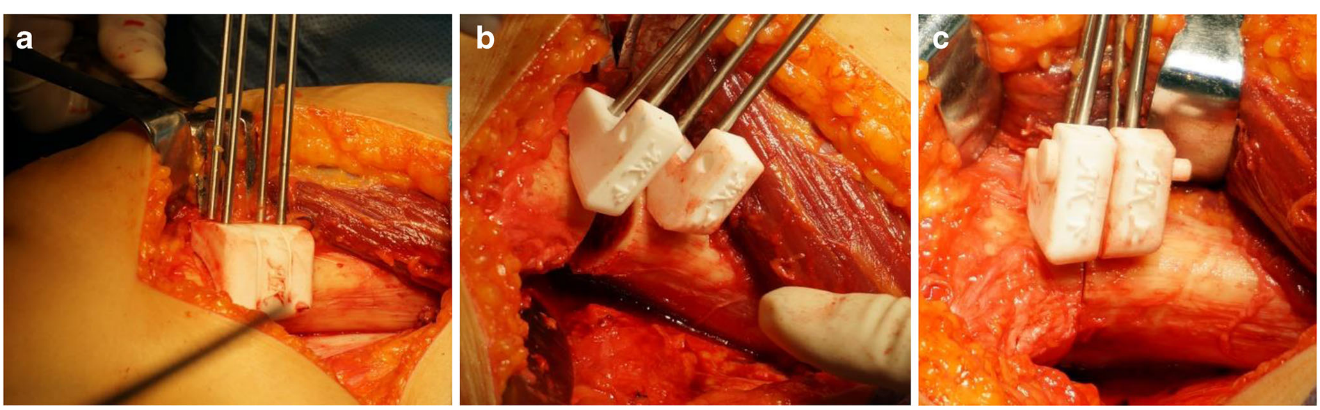

Fig. 3 The cutting guide and the locking guide were used in operation. a The cutting guide was placed on the unique position of the femur with complete fit and fixed with 3.0-mm K-wires. b After the wedge was removed, the locking guide was fixed on the femur with the remaining K-wires. c After the wedge was closed accurately, the bolt was inserted

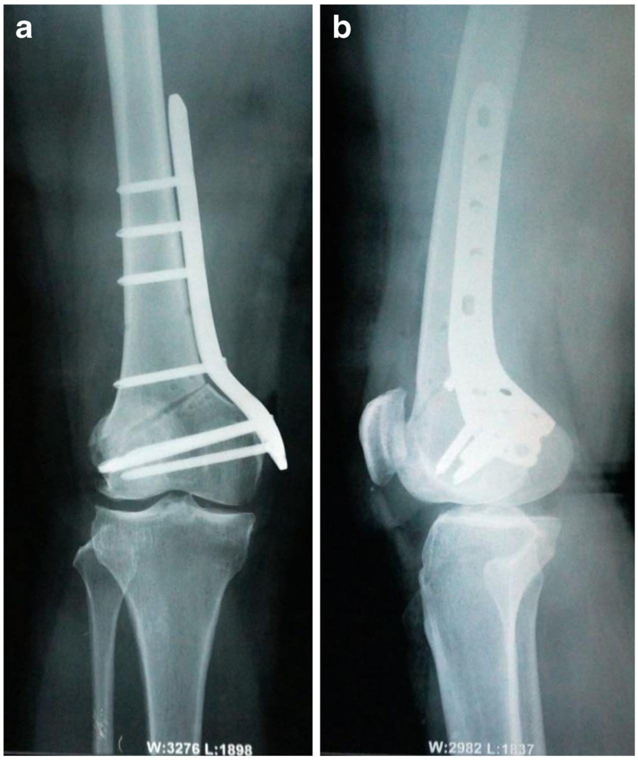

Fig. 4 The post-operative anteroposterior (a) and lateral (b) radiograph of the knee

patient-specific cutting guides to provide intra-operative guidance for better placement of the implant in total knee arthroplasty (TKA) and to increase the accuracy of osteotomy and post-operative alignment [20]. In the present study, 3D-printed cutting guides and locking guides were used to locate the osteotomy cut plane and to facilitate closing the wedge respectively for MCWDFO. To our knowledge, this is the first study to investigate the accuracy of MCWDFO assisted by a 3D printing technique.

The primary aim of this study was to evaluate the reliability of this technique by comparing the WBL coordinate deviation between the two groups. Compared to studies of valgus-producing osteotomy, there are not many studies describing the results of accuracy of varus-producing distal femoral osteotomy. Arnal-Burro J et al. used a 3D-printed custom guide to improve the accuracy of the opening-wedge distal femoral varus osteotomy [10]. In this study, the deviation between the planned and executed WBL coordinate was significantly different between the 3D-guide group and the conventional group (mean, 4.9%, range, 2–11%, vs. mean, 7.6%, range, 2–13%; $P = 0.024$). These results extend those of Arnal-Burro J, confirming that the use of the 3D printing technique can improve the accuracy of corrective osteotomies.

In our experience, 3D pre-operative planning is important in performing accurate osteotomies. In the virtual 3D model, we found that if the HKA angle was changed 1°, the WBL coordinate would change 4–5%. Therefore, we believe that using WBL coordinates to measure wedge angle of osteotomy is more sensitive than using HKA angle. In this study, CT data rather than coronal weight-bearing radiographs were used to scale the WBL coordinate, since coronal weight-bearing radiograph assessment of leg alignment may be influenced by the patient's position [21, 22], and some studies have used CT data to measure the angle of deformities [23, 24]. However, the CT scan is conducted in the supine position and weight-bearing radiographs may provide information regarding the condition of ligaments. Patients with laxity of the medial collateral ligament were excluded from this study, and as a result, this information may have been less valuable for corrective osteotomies.

In this study, the virtual 3D model was used to calculate the position and direction of the wedge on a computer. This parameter of the osteotomy was then transferred to a 3D-printed cutting guide. Then, the distal femur was osteotomized virtually and a 3D-printed locking guide was designed to ensure accuracy of the alignment correction. Using these guides, the surgeon does not need to determine the position and direction of the osteotomy during the operation. As a result, the procedure described in this study not only ensures the accuracy of osteotomy but also makes the operation easier. Even inexperienced surgeons can perform the osteotomy. Meanwhile, the surgical time is theoretically shortened.

In the present study, the surgical time and fluoroscopic time were significantly lower using the 3D-printed guide. These findings agree with those of previous studies [10, 11]. On the other hand, the navigation technique can improve the accuracy of the osteotomy and decrease fluoroscopic time [16], but it has the disadvantages of long learning curves and long surgical time [8] arising from the complexity of the navigation technique. Considering the advantages of the 3D-printed guide, it should be a reliable alternative to navigation.

Table 3 Comparison of variables in 3D-guide and conventional group[a]

	3D-guide	conventional	P value
Deviation of WBL coordinate (%) [b]	4.9 (2–11)	7.6 (2–13)	$P = 0.024$
Surgical time (minutes)	77.7 (63–89)	96.5 (81–117)	$P < 0.001$
Fluoroscopic images	6.1 (4–9)	34.7 (16–47)	$P < 0.001$

The deviation between the planned and executed WBL coordinate

[a] Results presented as mean (range)

However, some limitations are worth noting. First, there is the concern for exposure to unnecessary radiation arising from the CT scanner. The increased radiation exposure could be offset by the decreased fluoroscopic time. As we increased our experience in this technique, only four fluoroscopic images were performed in the last case. This was very similar to the results of Victor J et al., who reported using only one image to confirm the guide position, one image to ensure the osteotomy was close to the hinge (we performed two bone cuts) and one image to confirm the position of plate and screws. Second, there were significant differences in demographic characteristics between the two groups in the present study, because the patients were not randomly allocated to each group. However, we compared the accuracy of the osteotomy, surgical time and fluoroscopic time, none of which can be affected by demographic characteristics. Future work should therefore include an RCT to evaluate functional outcomes and survival of the osteotomy assisted by 3D-printed guides.

Conclusion

The use of 3D-printed cutting guides and locking guides can increase the accuracy of the MCWDFO in patients with lateral compartment disease and valgus deformity, making our surgery more efficient and consuming less fluoroscopic time. The procedure of osteotomy assisted by 3D-printed guide is easy to learn, can shorten the surgical time and may be a reliable alternative to navigation.

Compliance with ethical standards

Ethical approval This retrospective comparative study was approved by our Institutional Review Board.

Conflict of interest The authors declare that they have no conflicts of interest.

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