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ORIGINAL PAPER

“More accurate correction using “patient-specific” cutting guides in opening wedge distal femur varization osteotomies

Christophe Jacquet[1,2] · Johanna Chan-Yu-Kin[1,2] · Akash Sharma[1,2] · Jean-Noël Argenson[1,2] · Sébastien Parratte[1,2] · Matthieu Ollivier[1,2]

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Abstract

Purpose The distal femoral varization osteotomy (DFVO) by a lateral opening wedge osteotomy is an established intervention for patients suffering from lateral femoro-tibial osteoarthritis on a genu valgum deformity. In order to improve the accuracy of this correction, the use of a customized cutting guide (PSI) has been proposed as an alternative to conventional technique. The objective of our study was to compare the accuracy of post-operative alignment following DFVO in the coronal and sagittal plane using either a conventional abacus technique or PSI guide.

Method Twenty-one patients that underwent lateral opening wedge osteotomy from a technique using PSI based on 3D CT-scans were matched 1:1 to 21 patients operated on using a conventional technique (pre-operative planning performed on standard radiographs). The accuracy of the correction was analyzed, comparing coronal and sagittal mechanical post-operative angles with pre-operative planning.

Results With regard to alignment in the coronal plane (HKA correction), our study demonstrated a significant improvement in the accuracy of the correction obtained in the PSI group compared to the conventional group (0.43 ± 0.50 vs 3.95 ± 1.64 $p < 0.001$). In the sagittal plane (PDFA correction), we also found a significant improvement in correction accuracy in the PSI group (0.52 ± 0.60 vs 3.10 ± 1.83 $p < 0.001$).

There was a significant decrease in operating time (delta 7.7 ± 3.07 (1.5–13.9) ($p = 0.0.161$) and fluoroscopic images taken (6.9 ± 0.54 (5.8–8) $p < 0.001$).

Conclusion Our results suggest that the use of PSI in DFVO improves the accuracy of correction in both the coronal and sagittal planes compared to conventional techniques.

Keywords Femoral · Osteotomy · External-opening · Accuracy · Customized · Cutting-guide

Abbreviations

DFVO	Distal femoral varization osteotomy
PSI	Personal-specific implant
HTO	High tibial osteotomy
HKA	Hip knee angle (coronal alignment of the limb)
PDFA	Posterior distal femoral angle (sagittal alignment of the femur)
IKS	International Knee Society Score with a Global evaluation (IKSG) and Function evaluation (IKSF)

✉ Matthieu Ollivier
ollivier.matthieu@yahoo.fr

1 Aix-Marseille Université, CNRS, ISM UMR 7287, 13288, Marseille cedex 09, France

2 Department of Orthopedics and Traumatology, Institute of Movement and Locomotion, St. Marguerite Hospital, 270 Boulevard Sainte Marguerite BP 29, 13274 Marseille, France

Introduction

For young patients suffering from primary or post-traumatic valgus malalignment, a varus osteotomy has been advocated to transfer the mechanical axis and unload the failing lateral compartment [1, 2]. A small varus correction can be performed using a high tibial osteotomy (HTO) but deformities greater than 10° often require a distal femoral varization osteotomy (DFVO) as a HTO might lead to iatrogenic joint line obliquity [3–5]. Achieving optimal mechanical alignment is mandatory in peri-articular osteotomies to restore and ensure native knee function [6, 7]. Traditionally, closing-wedge techniques have been most commonly used for DFVO. Recent studies have shown that DFVO using an opening-wedge allows for more accurate correction of alignment compared with closing-wedge techniques, with a narrower range of post-operative tibio-femoral angles [8, 9]. Moreover, opening-wedge DFVO is considered technically easier than closing-wedge procedures,

Table 1 Pre-operative population's characteristics

	PSI group	Conventional group	*P* value
Number of patients	21	21	NC
Mean age at surgery	44.6 (40–49)	43.5 (35–52)	0.348
Gender ratio M: F	8: 13	8: 13	NC
Mean BMI	23.979 (19.59–31.5)	25.932 (19.84–32.89)	0.07
Mean IKSF (/100)	51 (10–80)	44 (10–70)	0.17
Mean IKSG (/100)	58.45 (7–87)	54.45 (7–82)	0.42
Mean active flexion (°)	123.5 (120–130)	124 (115–130)	0.75
Mean recurvatum (°)	0.75 (0–5)	0.32 (−4–5)	0.49
Mean HKA (°)	187.95 (182–192)	18.15 (181–193)	0.79
Mean LDFA (°)	84.1 (79–88)	83.6 (79–88)	0.59
Mean PDFA (°)	83 (76–90)	82.5 (77–88)	0.65
Mean HKA Target (°)	176.75 (175–180)	177.5 (175–180)	0.29

BMI body mass index, IKSF score International Knee Society Function, IKSG score International Knee Society Gain, HKA hip knee ankle angle in the frontal plane, LDFA lateral distal femoral angle, PDFA posterior distal femoral angle

as removal of a precise bone wedge is technically difficult and inaccurate [8]. Appropriate predictive surgical planning is essential to achieve the ideal correction angle and thus, different techniques have been proposed to optimize surgical steps such as computer-assisted or patient-specific ancillaries as an alternative to conventional abacus techniques [2, 10, 11]. Patients-specific cutting and drilling guides (PSI) are obtained by 3D printing based on pre-operative CT-Scan bone modeling [2, 11]. PSI allows for planning of correction as well as optimal plate positioning in contrast to basic cutting guides. In recent studies investigating the accuracy of coronal plane correction of those devices used in DVFO [2, 10], there is a lack of evidence demonstrating their ability to correct lower-limb deformity without unwanted sagittal plane modifications. The main objective of our study was to compare the accuracy of the pre and post-operative alignment of femoral varization osteotomies by lateral opening wedge in the coronal and sagittal plane using either our PSI custom cutting guide or a conventional abacus technique. The secondary objective was to compare their functional results using a validated scoring system. We hypothesized that there will be no difference between the two groups regarding radiological or clinical outcomes.

Method

Following local ethical committee approval, a cross-sectional analysis of a prospectively collected database identified every patient undergoing a DFVO between February 2012 and February 2016. The inclusion criteria consisted of patients < 60 years of age with painful lateral compartmental knee osteoarthritis (Ahlbäck ≤ 2 [12]) on a background of a significant valgus knee (hip knee angle > 185°). We excluded patients with advanced osteoarthritis (Ahlbäck ≥ 3) and/or artifacts that would interfere with pre-operative templating. Within the study, 21 patients operated-on using a patient specific cutting-guide (PSI group) were matched 1:1 on gender and age ± five years to 21 patients operated on using a conventional technique (pre-operative planning performed on standard radiographs: conventional group). The characteristics of the population studied are summarized in Table 1. There were no significant differences in demographic, radiographic, or operative parameters between the two groups. Pre-operatively in the whole series, the mean HKA angle was 185.5 ± 1.84° (183°–189°) (Fig. 2) and the mean sagittal angle (PDFA) was 82.75 ± 2.87° (80–90°) (Fig. 1).

Pre-operatively, all patients underwent complete radiographic evaluation including weight bearing long-leg radiographs, with standard A/P and lateral views. Pre-operative templating was performed to determine the mechanical axis and anatomical axis of the affected lower extremity (Figs. 1 and 2).

Paley's [12] method was used to determinate the mechanical axis (frontal: HKA, sagittal: PDFA) deviation and the required correction. Pre-operatively, the amount of correction was estimated using a simplified calculation of 1 mm of linear correction at the osteotomy site to 1° of correction of axial alignment. This estimation was adjusted intra-operatively based on both clinical findings and fluoroscopic analysis. All patients received either general anaesthesia or loco-regional anesthesia. They were placed supine with a tourniquet placed proximally on the limb. The Puddu's approach [13] was used: an 8- to 10-cm incision was made on the lateral distal femur extending from the lateral epicondyle proximally. The iliotibial band was incised and the vastus lateralis was elevated and dissected off the lateral intermuscular septum to expose the femoral shaft. Under fluoroscopic control, the starting point for the osteotomy was

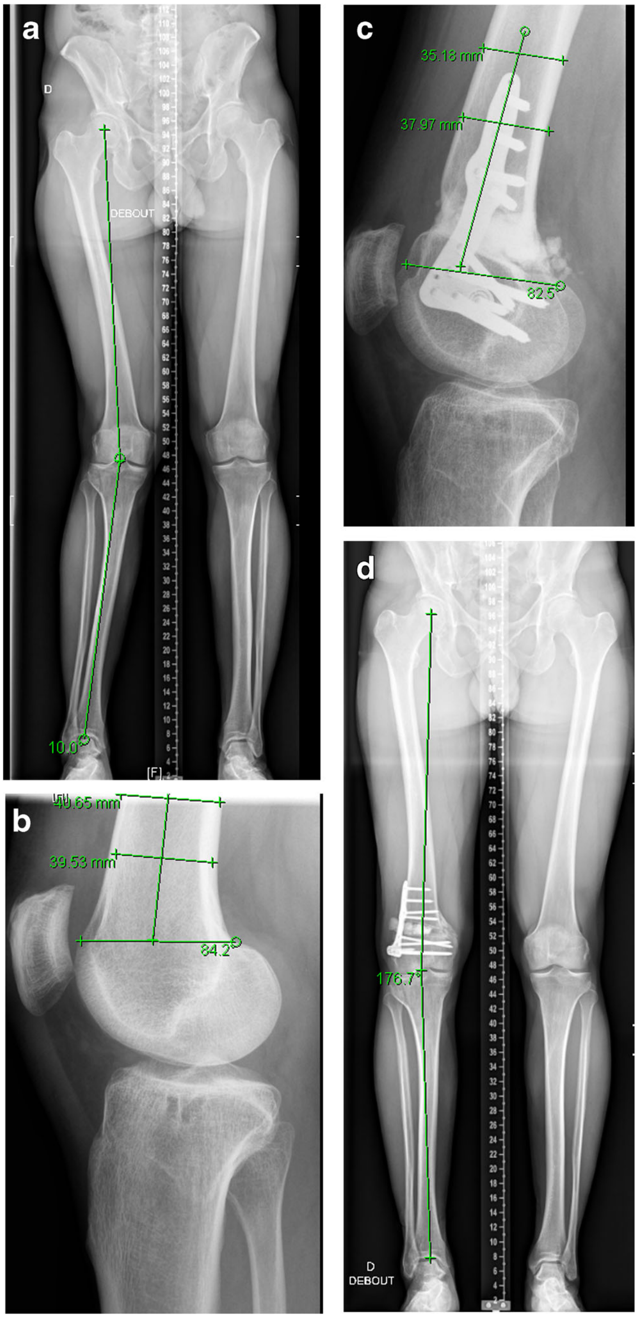

Fig. 1 **a**–**d** Illustrating, through the clinical case of a 41-year-old male, angulation measurement performed pre- and post-operatively: **a** hip knee ankle angle (HKA), **b** lateral distal femoral angle (LDFA)

located approximately 3 cm above the lateral femoral epicondyle and a guide pin was angled medially and distally toward the base of the metaphyseal flare of the medial femoral condyle just above the level of the medial epicondyle. After fluoroscopic confirmation of correct guide pin placement, an osteotomy was performed using an oscillating saw, while taking care to maintain 1 cm of medial bone bridge for osteotomy stability. Once the osteotomy was mobile, a Mehari distractor was placed inside of the osteotomy. The correction was

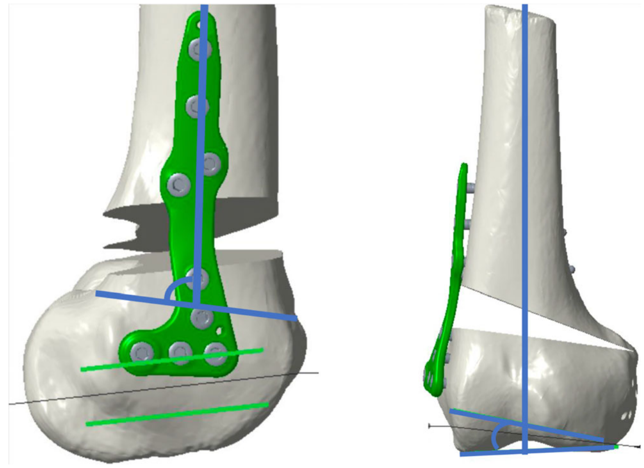

Fig. 2 Showing planification of ideal plate positioning using a 3D-CT Based corrected femoral models

progressively incremented until the intended opening was achieved from the pre-operative plan. Limb alignment was checked fluoroscopically and clinically. The opening-wedge plate was then placed in situ. We used a distal femoral Activmotion DFO Plate (Newclip Technics®, Haute-Goulaine, France) with eight locking screws (4 epiphyseal below and 4 diaphyseal above the osteotomy). The bone defect was filled using either allograft or calcium phosphate cement (Quickset, Graftys®, Aix-en-Provence, France).

The surgical time and the number of fluoroscopic images was evaluated for each intervention.

PSI group specificities

Pre-operatively, all patients had standard X-ray views taken (weight bearing long-leg radiographs, A/P and lateral views) and underwent a CT scan. Correction planning was performed by the surgeon assisted by a trained engineer.

The CT scan protocol consisted of acquiring images centered on the femoral head, the knee (allowing the distal femur and 15 cm of the proximal tibia to be captured), and one centered over the ankle. The slice thickness was 0.625 mm for the knee and 2 mm for the hip and ankle (GE Light Speed VCT64). An LFO model was used to virtually position the Activmotion DFO plate (Newclip Technics®, Haute-Goulaine, France) on the femur while following the manufacturer's recommendations for ideal positioning on the lateral side of the femur. The PSI design takes into account the resection plane and the position of the screw tunnels relative to the virtual positioning of the plate (Fig. 3). The objective behind the PSI is to define the optimal plate position after distal femur osteotomy and correction and then to report this anatomical position to the pre-osteotomy guide position. When the plates' position fits the drill holes using the PSI method, proceeding to an opening wedge of the lateral femur provides optimal HKA and LDFA correction.

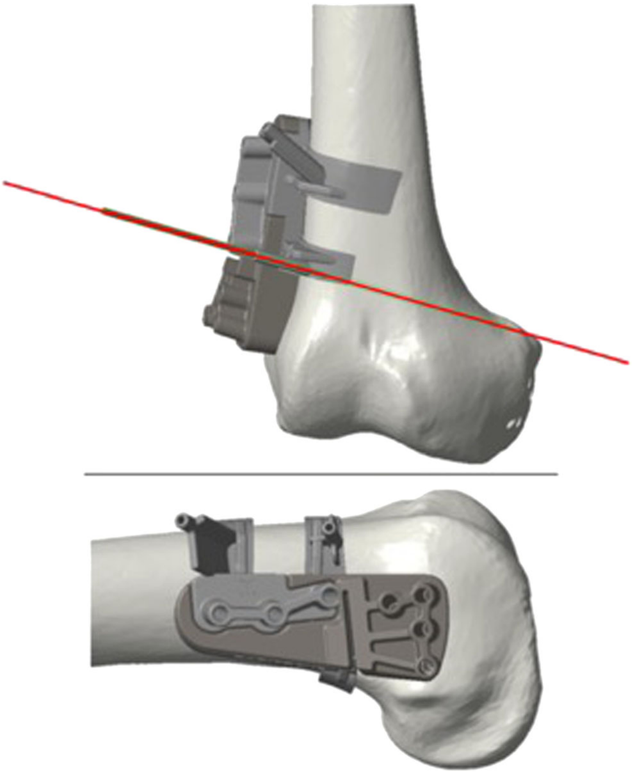

Fig. 3 Demonstrating PSI cutting guide position on the lateral femur

The same method and approach was used as for the conventional group. The PSI was secured to the bone using two pins and then fluoroscopy was utilized to confirm the orientation of the osteotomy cut (Fig. 3). The eight holes required for the plate were drilled prior to performing the osteotomy. The osteotomy was then carried out with the PSI in place. The saw blade was guided by a capture slot within the PSI and then the proximal portion of the guide was removed to complete the osteotomy in the same plane or two planes, depending on the planned correction. The osteotomy was then gradually opened with laminar-spreaders until the pre-drilled screw holes were aligned with the holes in the plate. The plate was held in position using eight screws, the correct length was chosen during the pre-operative planning stage. The osteotomy was filled with either allograft or phosphocalcic cement (Quickset, Graftys®, Aix-en-Provence, France). The surgical time and the number of fluoroscopic images were also evaluated for each intervention.

For the two groups, post-operative management included toe touch weight bearing for six weeks aided with the use of crutches. Full weight-bearing was allowed at six weeks and patients were allowed to return to professional and recreational activities at six months.

All patients were reviewed at one month post-operatively to evaluate potential early complications, then every three months for regular follow-up with radiographs (long-leg standing, A/P and lateral). Bone union and hinge stability were systematically assessed. Post-operative flexion was recorded post-operatively at one year.

CentricityTM software (GE Healthcare, USA) was used to compare the resulting radiographic parameters (HKA, PDFA, and LDFA) to those planned pre-operatively. To ensure the reproducibility and accuracy of the measured angles, the analysis was repeated four times by a single observer and then followed by a second independent observer to obtain the inter- and intra-observer intraclass correlation coefficient (ICC) (Table 2). The accuracy of the post-operative alignment was defined by the difference between the desired correction defined pre-operatively and the correction obtained post-operatively.

In order to evaluate the functional outcome, we used the IKSF and IKSG scores of the knee society that patients completed at one year [14].

Statistics

Based on previous research, investigating DFVO correction's precision, we designed our study to be able to detect difference between groups > 2° regarding delta between planed and measured correction of hip-knee-angle (expected difference between planed and post-operative HKA in the control group 2± 2°) with a statistical power of 80%. Both calculations are for a two-sided test with alpha of 0.05 and 1-Beta of 0.8.

Statistical comparison of pre- and post-operative variables was made using a two-tailed paired t test and $p < 0.05$ was taken to be statistically significant. Statistical comparison between groups was done using either parametric or non-parametric testing based on parameteric distribution.

Results

With regard to alignment in the Coronal plane (HKA correction), our study demonstrated a significant improvement in the accuracy of the correction obtained in the PSI group compared to the conventional group (0.43 ± 0.50 vs 3.95 ± 1.64 $p < 0.001$). In the sagittal plane (PDFA correction), we also found a significant improvement in correction accuracy in the PSI group compared to the conventional group (0.52 ± 0.60 vs 3.10 ± 1.83 $p < 0.001$) (Tables 3 and 4).

Table 2 Intraclass correlation coefficient (ICC)

	Intra-observer	Inter-observer
HKA (°)	0.87 IC95% (0.83–0.91)	0.83 IC95% (0.75–0.91)
LDFA (°)	0.79 IC95% (0.7–0.86)	0.73 IC95% (0.62–0.81)
PDFA (°)	0.91 IC95% (0.82–0.97)	0.88 IC95% (0.83–0.92)

Table 3 Post-operative results

	PSI group	Conventional group	Δ IC 95%	*P* value
Surgery time (min)	39.52 ± 8.57	47.25 ± 10.82	7.72 [1.51;13.94]	0.0161
Intra-operative fluoroscopic images (n)	5.33 ± 1.38	12.25 ± 2,39	6.92 [5.82;8.02]	< 0.0001
Mean IKSF (/100)	87.85 ± 5.20	86 ± 7.54	1.86 [− 2.26;5.98]	0.3676
Mean IKSG (/100)	62.76 ± 13.19	61.55 ± 13.00	1.21 [− 7.34;9.76]	0.7758
Mean active flexion (°)	127.61 ± 5.26	126.5 ± 5.87	1.12 [− 2.37; 4.60]	0.5198
Mean recurvatum (°)	0.71 ± 1.83	0.20 ± 2.95	0.51 [− 1.02;2.05]	0.5014
Mean HKA (°)	176.91 ± 2.26	174.45 ± 2.48	2.45 [0.97;3.94]	0.0018
Mean LDFA (°)	92.14 ± 2.38	94.30 ± 3.39	2.16 [0.33;3.99]	0.0220
Mean PDFA (°)	82.90 ± 1.52	85.60 ± 2.04	2.70 [1.56; 3.83]	< 0.001

BMI body mass index, IKSF score International Knee Society Function, IKSG score International Knee Society Gain, HKA hip knee ankle angle in the frontal plane, LDFA lateral distal femoral angle, FDFA frontal distal femoral angle

At mean follow-up at 12 months, no difference in functional outcome was observed either by considering the IKSF score (87.85 ± 5.20 vs 86 ± 7.54 $p = 0.3676$) or the IKSG score (62.76 ± 13.19 vs 61.55 ± 13.00 $p = 0.7758$).

No significant difference was found in terms post-operative active flexion (127.61 ± 5.26 vs 126.5 ± 5.87 $p = 0.5198$) and recurvatum (0.71 ± 1.83 vs 0.20 ± 2.95 $p = 0.5014$) between the PSI and conventional groups respectively. No hinge-related issues or osteotomy non-unions were observed in the present study.

We observed a significant reduction in operative time (39.52 ± 8.57 vs 47.25 ± 10.82 $p = 0.0161$) and the use of fluoroscopic images (5.33 ± 1.38 vs 12.25 ± 2.39 $p < 0.001$) favouring the PSI group.

Discussion

The main result of our study is that the accuracy of the post-operative alignment in both the coronal plane and the sagittal plane is significantly better when using custom-made patient specific cutting guides as compared to conventional techniques. We reject our hypothesis that there will be no difference between the PSI group and the conventional group: the use of our custom-made cutting guide allows a more precise coronal plane correction while avoiding inadvertent changes in the sagittal axis.

No study to date has investigated the impact of DFVO on distal femur sagittal position regardless of the surgical technique applied. However, these modifications might have a substantial clinical impact in knee biomechanics, creating iatrogenic fixed flexion deformity or a recurvatum [6].

It is important to note that the PSI-guide was aimed to obtain a post-operative LDFA to be accurately reproducible to that of the pre-operative plan. We believe this has the least effect on uncoupling knee kinematics. However, if we found significant differences between the groups in term of LDFA correction, they did not seem to be associated to potential modification of post-operative range of motion.

There is no consensus with regard to the degree of correction needed to obtain long-lasting results: Some authors suggest under-correcting the joint (0 to 6° for Zarrouk et al. [15]), while others suggest neutral correction [9] or slight over-correction [3]. Furthermore, the pre-planned correction is rarely obtained with the conventional technique and in reality is often is associated with widespread range of corrections around the selected target [13, 15–17]. In the study by Zarrouk et al. [15], the HKA's target was 2 to 3° varus. The mean post-operative correction of their 23 patients was − 1.5 ° with an important dispersion (standard deviation ± 4.5°) of post-operative measurment. Dewilde et Al [16] selected an

Table 4 Accuracy of post-operative alignment

	PSI group	Conventional group	Δ IC 95%	*P* value
HKA target gap (°)	0.43 ± 0.50	3.95 ± 1.64	3.52 [2.76;4.28]	< 0.001
LDFA target gap (°)	0.43 ± 0.50	3.95 ± 1.64	3.52 [2.76;4.28]	< 0.001
PDFA target gap (°)	0.52 ± 0.60	3.10 ± 1.83	2.57 [1.72;3.43]	< 0.001

The HKA target gap is the difference between the HKA target and the post-operative HKA

HKA's target was of 2° varus. The mean post-operative correction of their 19 patients was − 1.3 ° with a standard deviation ± 4°. In our study, the standard deviation obtained with the PSI was ± 0.50° and ± 0.60 within the HKA and PDFA's target value respectively.

Saragaglia et Al [10] has also shown to improve the accuracy of osteotomies around the knee using computer assisted surgery (CAS). Their technique allowed them to obtain a target HKA (179 ± 2°) in 86.2% of the cases. In our study, if we considered our correction values to lie within ± 2°, we would have obtained a target HKA in 100% of the cases with the PSI guide (21/21) and 40% with the conventional technique (8/20). The study by Saragaglia [10] et al. is not comparative and neither do the authors provide information on surgical time that appears to be a CAS related issue [18, 19]. This technique also requires expensive surgical equipment not available in all surgical centres, which therefore limits its accessibility.

The second technique proposed is the use of custom cutting guides. Juan Arnal-Burró et Al [2] studied the impact of using a custom cutting guide in comparison to conventional techniques. They demonstrated that this technique allowed a significantly more precise correction, a significant decrease in surgical time (63 minutes vs 95 minutes) and reduced cost per intervention (412 euros). However, the custom cutting guide used in their study, does not allow the positioning of the fix plate. The results obtained with the PSI in our study are similar in terms of correction accuracy in the frontal plane to those obtained by Arnal-burro and Al [2] with their cutting guide (target gap 0.28 °vs 0.43°).

Another method using custom cutting guides has been described by Shi et Al [11]. A medial closing was this time used as an osteotomy technique. It was described in the literature that this procedure of medial closing is associated with a higher rate of complication (13.3% for medial closing versus 5% for lateral opening) including malposition, loss of correction, infection, and hematoma but also associated with a higher recovery rate for arthroplasty at the long term (22% for medial closing versus 12% for lateral opening at 10 years) [8]. The cutting guides used in this study [11], such as those described by Juan Arnal-Burró et Al [2], did not allow the positioning of the fix plate. Their results show an improvement in accuracy of the final correction in frontal plane compared to conventional techniques, but without analysis of the sagittal plane modification. They also observed a decrease in surgical time from 96.5 min on average with conventional techniques to 77.7 min with custom cutting guides. This surgical time seems greater than those observed in our study using a distal opening osteotomy and patients' specific cutting + Drilling guides (39.52 min on average).

Our secondary objective was to compare the functional results of the 2 groups using the IKSF and IKSG score [14]. We did not observe any significant difference between our two groups. A possible explanation for the lack of difference might be related to our short study follow-up. We believe the consequences of unsatisfactory mechanical axis correction, which in our series are the group of patients within the conventional instrumentation vs PSI group, will negatively influence arthritic evolution and thus patient's perception of symptoms after a number of years.

This study has several limitations, including its retrospective design and low number of patients in the sample size. However, our study does represent inclusion of young patients with lateral femoro-tibial arthritis in a high-volume centre over a five year period. We were able to design a case-control study and compare our PSI patients to a control group operated with a gold standard procedure. Another limitation of our paper is the lack of long-term follow-up to demonstrate the radiographic and clinical implications of optimal or unsatisfactory mechanical axis correction. We do think that improved mechanical axis correction will decrease the rate of knee arthroplasty in our PSI group we will continue to monitor our patients to assess whether this mid to long-terms hypothesis is accurate.

Conclusion

We rejected our hypothesis that there will be no difference between the PSI group and the Conventional group. The accuracy of the post-operative alignment in both the frontal plane and the sagittal plane is significantly better when using custom-made cutting guide type PSI compared to conventional techniques.

Author contributions statement MO and SP designed the protocol.
MO and CJ performed database analysis.
CJ, MO, and AS wrote the initial draft.
MO, SP, and JNA edited the different version of the draft.
CJ, MO, SP, AS, and JNA approved of the submitted and final versions.

Compliance with ethical standards

Conflict of interest MO is educational consultant for New-Clip, Stryker and Arthrex.
SP is educational consultant for New-Clip, Zimmer and Arthrex.
JNA receives royalties from Zimmer.
CJ and AS have nothing to disclose.

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