



Double level knee osteotomy using patient-specific cutting guides is accurate and provides satisfactory clinical results: a prospective analysis of a cohort of twenty-two continuous patients

Francesco Grasso, Pierre Martz, Grégoire Micicoi, Raghbir Khakha, Kristian Kley, Lukas Hanak, Matthieu Ollivier, Christophe Jacquet

► To cite this version:

Francesco Grasso, Pierre Martz, Grégoire Micicoi, Raghbir Khakha, Kristian Kley, et al.. Double level knee osteotomy using patient-specific cutting guides is accurate and provides satisfactory clinical results: a prospective analysis of a cohort of twenty-two continuous patients. *International Orthopaedics*, 2021, 46, pp.473-479. 10.1007/s00264-021-05194-z . hal-03553769

HAL Id: hal-03553769

<https://hal.science/hal-03553769>

Submitted on 8 May 2022

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

**Double level Knee osteotomy using patient-specific cutting guides
are accurate and provide satisfactory clinical results: a
prospective analysis of a cohort of twenty-two continuous patients**

Running Title : Accuracy of “Patient Specific” double level osteotomies cutting guides

**Francesco Grasso, M.D.[”]
Pierre Martz, MD. Ph.D.[#]
Grégoire Micicoi, M.D.^{*}
Raghibir Khakha, M.D.^{*}
Kristian Kley, M.D.^{*}
Lukas Hanak M.D.^{*}
Matthieu Ollivier, M.D. Ph.D.^{°*}
Christophe Jacquet, M.D.^{°*}**

- [°] Aix-Marseille Université, CNRS, ISM UMR 7287, 13288, Marseille cedex 09, France.
^{*} Institute of movement and locomotion, Department of Orthopedics and Traumatology
St. Marguerite Hospital 270 Boulevard Sainte Marguerite, BP 29 13274 Marseille,
[”] IRCCS-Istituto Ortopedico Galeazzi, University of Milan, Milan, Italy.
[#] Service de Chirurgie Orthopédique, Centre-Hospitalo-Universitaire de Dijon, Dijon,
France.

ABSTRACT

Purpose: Double level osteotomy (femoral and tibial) (DLO) is a technically demanding procedure for which pre-operative planning accuracy and intraoperative correction are key factors. The aim of this study was to assess the accuracy of the achieved correction using patient-specific cutting guides (PSCGs) compared to the planned correction, its ability to maintain joint line obliquity (JLO) and to evaluate clinical outcomes and level of patient satisfaction at a follow-up of 2 years.

Methods: A single-center, prospective observational study including 22 patients who underwent DLO by PSCGs between 2014 and 2018 was performed. Post-operative alignment was evaluated and compared with the target angular values to define the accuracy of the correction for the Hip-Knee-Ankle Angle (Δ HKA), Medial Proximal Tibial Angle (Δ MPTA), Lateral Distal Femoral Angle (Δ LDFA) and Proximal Posterior Tibial Angle (Δ PPTA). Pre- and post-operative JLO was also evaluated. At 2 years follow-up, changes in the KOOS sub-scores and patient satisfaction were recorded. The Mann-Whitney U test with 95% confidence interval (95% CI) was used to evaluate the differences between two variables, the paired Student t test was used to estimate evolution of functional outcomes.

Results: The mean Δ HKA was $1.3 \pm 0.5^\circ$, the mean Δ MPTA was $0.98 \pm 0.3^\circ$, the mean Δ LDFA was $0.94 \pm 0.2^\circ$; Δ PPTA was $0.45 \pm 0.4^\circ$. The orientation of the joint line was preserved with a mean difference in the JLO of 0.4 ± 0.2 . At last follow-up it was recorded a significant improvement in all KOOS scores and 19 patients were enthusiastic, 2 satisfied and one moderately satisfied.

Conclusion: Performing a DLO using PSCGs produces an accurate correction, without modification of the joint line orientation and with good functional outcomes at 2 years follow-up

Key Words: Double level osteotomy; Patient Specific Cutting Guide; Accuracy; Joint line obliquity; Clinical Outcomes

DECLARATIONS

Funding:

The authors did not receive support from any organization for the submitted work.

No funding was received to assist with the preparation of this manuscript.

No funding was received for conducting this study.

No funds, grants, or other support was received.

Conflicts of interest for all authors:

MO is educational consultant for New-Clip, Stryker and Arthrex

KK is educational consultant for New-Clip

CJ, RK, FG, PM, GM, LH have no relevant financial or non-financial interests to disclose.

Ethics approval and consent to participate and to publish

Patient consent was collected pre-operatively after they were informed of the procedure in accordance with the principles of the Declaration of Helsinki. Local Ethical Committee approval was obtained prior to study's initiation (Comité Informatique et Liberté (CIL) / Assistance Publique des Hopitaux de Marseille (AP-HM) / Registration Number 2019-127)).

Availability of data and material:

Copy of the initial spreadsheet kept available

Author Contributions Statement:

MO,LH, CJ designed the protocol

MO, LH, KK gathered patients data anonymously

FG, KK, RK performed database analysis

CJ, MO, FG wrote the initial draft

MO, CJ, FG, KK, RK, GM, PM edited the different version of the draft

MO, CJ, FG, KK, RK,LH, GM, PM approved of the submitted and final versions.

**Double level Knee osteotomy using patient-specific cutting
guides are accurate and provide satisfactory clinical
results: a prospective analysis of a cohort of twenty-two
continuous patients**

23

24 ABSTRACT

25 **Purpose:** Double level osteotomy (femoral and tibial) (DLO) is a technically demanding procedure
26 for which pre-operative planning accuracy and intraoperative correction are key factors. The aim of
27 this study was to assess the accuracy of the achieved correction using patient-specific cutting guides
28 (PSCGs) compared to the planned correction, its ability to maintain joint line obliquity (JLO) and to
29 evaluate clinical outcomes and level of patient satisfaction at a follow-up of 2 years.

30

31 **Methods:** A single-center, prospective observational study including 22 patients who underwent DLO
32 by PSCGs between 2014 and 2018 was performed. Post-operative alignment was evaluated and
33 compared with the target angular values to define the accuracy of the correction for the Hip-Knee-
34 Ankle Angle (Δ HKA), Medial Proximal Tibial Angle (Δ MPTA), Lateral Distal Femoral Angle
35 (Δ LDFA) and Proximal Posterior Tibial Angle (Δ PPPTA). Pre- and post-operative JLO was also
36 evaluated. At 2 years follow-up, changes in the KOOS sub-scores and patient satisfaction were
37 recorded. The Mann-Whitney U test with 95% confidence interval (95% CI) was used to evaluate the
38 differences between two variables, the paired Student t test was used to estimate evolution of
39 functional outcomes.

40

41 **Results:** The mean Δ HKA was $1.3 \pm 0.5^\circ$, the mean Δ MPTA was $0.98 \pm 0.3^\circ$, the mean Δ LDFA was
42 $0.94 \pm 0.2^\circ$; Δ PPPTA was $0.45 \pm 0.4^\circ$. The orientation of the joint line was preserved with a mean
43 difference in the JLO of 0.4 ± 0.2 . At last follow-up it was recorded a significant improvement in all
44 KOOS scores and 19 patients were enthusiastic, 2 satisfied and one moderately satisfied.

45

Conclusion: Performing a DLO using PSCGs produces an accurate correction, without modification of the joint line orientation and with good functional outcomes at 2 years follow-up

Key Words: Double level osteotomy; Patient Specific Cutting Guide; Accuracy; Joint line obliquity; Clinical Outcomes

65 INTRODUCTION.

66 Osteotomies around the knee represent an ideal joint preserving procedures for the treatment of early
67 tibiofemoral osteoarthritis [1, 2] with extra-articular deformities [3, 4]. When correcting large
68 deformities in a single bone (tibia or femur), surgeons exposed them to the risk of creating abnormal
69 joint line obliquity (JLO), which can compromise post-operative outcomes [5].

70 Double level osteotomy (femoral and tibial) (DLO) is a technically demanding procedure for which
71 pre-operative planning accuracy and intraoperative correction is a key factor for achieving a corrected
72 lower limb alignment [6, 7]. The accuracy has been improved by the introduction of three-dimensional
73 (3D) pre-operative assessment systems [8], assisted surgery techniques such as computer assisted
74 surgery [5] and 3D patient-specific cutting guides (PSCGs) [9, 10].

75 The recent introduction of PSCGs using pre-operative computed tomography (CT) scan templating has
76 raised the possibility of making instrumentation specific to each patient, which in turn could result in a
77 more accurate correction of the bony misalignment with a decrease in operative time compared with
78 conventional techniques during single level osteotomy procedure [11–13].

79 There are, however, potential difficulties when performing a DLO using PSCGs. One example is the
80 inability to adapt the planned correction intra-operatively. The accuracy may also be compromised
81 owing to the fact that the procedure requires a perfect match between the planned correction, the guide
82 for the femoral correction and the guide for the tibial correction [14, 15] compared to a single level
83 correction which simply requires a single accurate PSCG [16].

84 To date, little has been published on the results and accuracy of DLO procedure using PSCGs. The
85 aim of our study was to evaluate the accuracy of the achieved correction using PSCGs compared to the
86 planned correction and its ability to maintain JLO in patients who suffered from knee pain, who had
87 never undergone knee surgeries, in a context of important varus alignment with both tibial and femoral
88 deformity. The second objective was to evaluate clinical outcomes and level of patient satisfaction at a
89 follow-up of 2 years.

The hypothesis was that performing a DLO using PSCGs results in an accurate correction, similar to that seen in single level corrections, without adversely affecting the JLO (with an acceptable increase of JLO $< 2^\circ$) and achieve satisfactory patient reported functional outcomes at 2 years follow-up.

MATERIAL AND METHODS

Population

All patients undergoing a DLO using PSCGs between February 2014 and November 2018 were enrolled in this single-center, prospective continuous cohort, observational study. Indication for DLO included patients aged under 65 years old with important knee pain and isolated medial knee osteoarthritis (Ahlbäck ≤ 3), a preserved status of the patellofemoral and lateral tibiofemoral joints assessed using clinical and radiological examination, a stable knee in the sagittal and coronal planes, a significant varus alignment (Hip-Knee-Ankle angle (HKA) $\leq 170^\circ$) with concomitant tibial and femoral varus deformity (Medial Proximal Tibia Angle (MPTA) $< 85^\circ$ and Lateral Distal Femoral Angle (LDFA) $> 90^\circ$) and the failure of all non-surgical treatments. The exclusion criteria comprised of previous ipsilateral knee surgery and hardware or bony abnormalities that would interfere with obtaining a high-quality CT scan.

Twenty three patients met the inclusion and exclusion criteria, 1 patient was lost to follow-up and finally twenty two patients (19 men and 3 women) were included in this study. Minimum follow-up was 24 months

Patient consent was collected pre-operatively after they were informed of the procedure in accordance with the principles of the Declaration of Helsinki. Local Ethical Committee approval was obtained prior to study initiation.

114

115 *Pre-operative planning*

116 In the pre-operative planning stage, the planned correction was first calculated by the surgeon using
117 conventional radiographs (calibrated weight-bearing long-leg, A/P, and lateral views). Subsequently,
118 all patients underwent a CT scan. The CT scan protocol consisted of acquiring images centered on the
119 femoral head, the knee (allowing the distal femur and 15 cm of the proximal tibia to be captured), and
120 over the ankle. The slice thickness was 0.625 mm for the knee and 2 mm for the hip and ankle (GE
121 Light Speed VCT64). The surgeon took measurements and filled out an order form for the engineer
122 which specified the correction objectives in the frontal and sagittal planes through variations in the
123 HKA, MPTA, LDFA and Posterior Proximal Tibia Angle (PPTA). Pre-operative angles are
124 summarized in the table 1. Joint orientation was also evaluated by measuring the joint line obliquity
125 (JLO) and joint line convergence angle (JLCA) to assess soft tissue laxity. As there were no sagittal
126 femoral correction planned, the posterior distal femoral angle was not considered.

127 Tibial and femoral osteotomy models were used to virtually position PSCGs (*Figure 1*) and
128 Activmotion plates (Newclip Technics®, Haute-Goulaine, France) both on the tibia and the femur
129 using the protocol defined by the manufacturer. The PSCG design takes into account the resection
130 plane and the position of the screw tunnels relative to the virtual positioning of the plates. The
131 objective behind PSCGs is to define the optimal plate position after osteotomy correction, and then to
132 transfer this anatomical position to the pre-osteotomy guide position. When the final plate's position
133 fits the drill holes using the PSCG, the osteotomy is performed according to the pre-operative plan.

134

135 *Surgical technique*

136 All surgical procedures followed the same surgical steps, starting off with the distal femoral closing
137 wedge osteotomy [14]. The distal femoral lateral surface was exposed and the anatomical cutting

guide was positioned. When an optimal position was confirmed by fluoroscopy, the guide was secured to the bone by 4 to 7 pins. Additional pins (cutting and hinge pins) were positioned to secure the osteotomy cutting plane. The nine holes required for the plate were pre-drilled prior to performing the osteotomy. The valgus femoral osteotomy was then performed with the PSCG in place; the saw blade was guided utilizing a specific slotted capture. Next, the distal part of the PSCG was removed and a closing wedge (with a 4-5 mm lateral base) was removed to complete the osteotomy. The plate was secured using nine screws, the sizes of which were pre-determined during the pre-operative planning.

The second stage consisted of performing the opening wedge high tibia osteotomy following a previously published method [15, 17]. The medial aspect of proximal tibia was exposed. The eight holes needed for the plate were pre-drilled prior to performing the osteotomy. The osteotomy was then performed with the PSCG in place and the proximal portion of the modular cutting guide was removed to finish the osteotomy in a single plane or two planes. This step was dependent on the planned correction and the position of the patellar tendon. The osteotomy was then gradually opened/distracted with a laminar-spreader until the pre-drilled screw holes were aligned with the holes in the plate. The bone defect was left empty or filled with a femoral head wedge allograft.

Post-operative management

Weight-bearing was not allowed for the first 3 weeks. Then, progressive partial weight bearing with the aid of 2 crutches was commenced after 3 weeks to reach a full weight bearing after 6 weeks. Range of motion was not restricted during the rehabilitation phase. All patients received thromboprophylaxis with low molecular-weight heparin pre- and post-operatively for 45 days.

After surgery, patients were reviewed at 1, 3, 6, 12 and 24 months for regular follow-up with radiographs (long-leg standing (*Figure 2*), A/P, and lateral) and KOOS score evaluation. Femoral and tibial bone union were systematically assessed by radiological evaluation at 1, 3, 6, 12 and 24 months: the bone repair process was considered complete when there was continuity in 3 out of 4 cortices in

anterior and lateral projections (both femoral and tibial) after 5 months; delayed between 5 and 8 months and not completed (non-union) after 8 months [18]. Post-operative alignment was evaluated and compared with the target angular values, by two independent observers, to define the correction accuracy. We reported an Intraclass Correlation Coefficient (ICC) of 0.79, 0.81, 0.87 and 0.85 for the Δ values (Δ HKA, Δ MPTA, Δ PPTA, Δ LDFA respectively) and an ICC of 0.80 and 0.82 for JLO and JLCA measurements. For all angular values both in the sagittal and coronal planes, the goal was to obtain a perfect coincidence between the planned and the obtained angular values ($\Delta = 0$) with a degree of tolerance of 2° .

Changes in the KOOS sub-scores were recorded, comparing pre-operative to the 24 months assessment: Δ KOOS Pain, Δ KOOS Symptoms, Δ KOOS ADL, Δ KOOS Sport/Rec, and Δ KOOS QOL were defined this way. Ability to return to work and sport were also recorded. At 24 months follow-up, patient satisfaction was ranked upon 5 items questionnaires (disappointed, not-satisfied, moderately satisfied, satisfied, and enthusiastic).

Statistical analysis

Statistical analyses were performed with use of SSPS software (IBM; Armonk, New York). Means and standard deviations (SDs) were determined for each of the measured and desired anatomic parameters. Normal (Gaussian) distributions was verified to determine adequate statistical testing method (either parametric or non-parametric) to estimate difference between pre-operative, planned and post-operative parameters groups in an univariate analysis. The Mann-Whitney U test for two independent samples with 95% confidence interval (95% CI) was used to evaluate the differences between two variables, the paired Student t test was used to estimate evolution of functional outcomes during follow-up. Following the data collection, the statistical power was checked. Using the Δ angular corrections (planned corrections - obtained corrections) as a primary parameter with 80% of power, Alpha 0.05 and a value of $\Delta < 3.0^\circ$, it was estimated that the sample size should be 14. Therefore, the sample size of 22 in the present study is reasonable in terms of statistical power.

RESULTS

Correction accuracy and radiographic results

The mean Δ HKA was 1.3 ± 1.5 ($p = 0.12$), the mean Δ MPTA was 0.98 ± 1.3 ($p = 0.09$), the mean Δ LDFA was 0.94 ± 1.2 ($p = 0.09$); Δ PPTA was 1.05 ± 1.4 ($p = 0.2$). For all the radiographic parameters, there were no statistically significant differences between the target values and the post-operative values (Table 2). A mean pre-operative JLO of $1.4 \pm 1.2^\circ$ and a mean post-operative JLO of $0.9 \pm 1.2^\circ$ were observed, thus the orientation of the joint line was preserved with a mean difference in the JLO of 0.5 ± 0.90 .

Mean consolidation time at radiographic control was 4.4 ± 1.8 months for the femur and 5.1 ± 1.5 months for the tibia. No case of non-union was reported.

Functional outcomes

At final follow-up assessment, 24 months after surgery, an improvement of 37 ± 16 for the KOOS pain (5–75), 37 ± 25 for the KOOS Symptoms (2–82), 37 ± 32 for the KOOS ADL (4–92), 34 ± 37 for the KOOS Sport/Rec (2–87) and 36 ± 25 for the KOOS QOL (7–73) ($p < 0.0001$) (Table 3) were observed. The mean time to return to work and sports were 4.0 ± 1.6 (3–12) and 4.9 ± 1.2 (2–7) months, respectively. At 24 months follow-up 19 patients were enthusiastic, 2 satisfied and one moderately satisfied.

Complications

One minor complication (post-operative hematoma) and one major complications (deep wound infection) were observed in the cohort. No revisions to total knee arthroplasty or unicompartmental knee arthroplasty were observed at 24 months follow-up.

DISCUSSION

The main finding of this study was that performing a DLO with PSCG is an accurate procedure and preserves pre-operative joint line orientation. The results for achieving desired corrective accuracy are in keeping with those previously published for both single femoral and tibial osteotomies. Good functional outcomes at 2 years follow-up were observed in this cohort.

Conventional DLOs are highly demanding procedures and require a protracted learning curve. In 1969, Benjamin et al [19] was the first to report a series of 57 DLO with indications of rheumatoid osteoarthritis and osteoarthritis. In this series, he reported a good level of patient satisfaction despite some complications including limited range of motion and six patients without reduced pain. Analyses of the pre-operative deformity and the post-operative correction (HKA angle or JLO) were not mentioned. Babis et al. [20] reported on 24 patients (29 knees) operated on utilizing a conventional technique. A computer-aided analysis of the mechanical status of the knee was used for pre-operative planning. Their results showed a mean post-operative HKA angle of 176.9° (169.4–184.9°) with a residual varus in two cases (4.6–4.9°) and an over correction of more than 4° in ten cases and more than 6° in five. No information was available concerning the pre-operative and post-operative JLO.

Otherwise, a high level of post-operative alignment accuracy was reached in computer assisted procedures despite their cost and increased surgical time [21, 22]. Saragaglia [23] reported a case series of 38 patients in which the pre-operative target was reached in 92.7% of patients for HKA and 88.1% for MPTA with 2° of accuracy. No information was reported concerning the pre-operative and post-operative JLO. The results of the present study are comparable with those of Saragaglia. Our study demonstrates that pre-operative targets were reached in all the patients with a slight difference between the planned correction and the post-operative values, which were not statistically significant

and always within the gap of 2° of discrepancy. A lower accuracy in the correction was observed for the HKA angle compared to other parameters. This angle is influenced by both the bony and soft tissue status [24]. This is accounted for the joint line convergence angle (JLCA). HKA measurements include JLCA values; therefore, it is important to assess the accuracy of the system by evaluating only direct bone corrections (MPTA, mLDFA and PPTA).

Previous studies have analyzed the accuracy of the PSCG system, but have been restricted to single level knee osteotomy [25]. Nevertheless, a high level of precision has been demonstrated in single level osteotomies. Cerciello et al. in a systematic review analyzed 28 studies which focused on single level osteotomies performed by computer navigation and patient specific instrumentation. In their conclusions they stated that it had been observed a reduced rate of post-operative outliers for PSI instrumented osteotomies compared to conventional techniques [26, 27]. Specific accuracy correction results of open-wedge high tibial osteostomy procedures using PSCGs have been published by Chaouche et al [15]. They observed that the mean Δ HKA was $1 \pm 0.95^\circ$, the mean Δ MPTA was $0.54 \pm 0.63^\circ$, and the mean Δ PPTA was $0.43 \pm 0.8^\circ$. In all cases, the discrepancy between planned and achieved correction was less than or equal to 2°. Similar results were published in distal femoral osteotomies using PSCGs by Jacquet et al [14]. The HKA target was also reached in 100% of case with 2° of discrepancy. Finally, the correction accuracy observed in the present study was similar to those previously described for both femoral or tibial single level osteotomies using PSCGs.

Double level osteotomies have been introduced to avoid joint line obliquity [28, 29]. Nakayama et al. reported that a JLO >5° (medial proximal tibial angle of 95°) determines detrimental stress to the articular cartilage, so they proposed that DLO should be indicated for varus knees with a pre-operatively anticipated MPTA of >95 [30]. Our study highlights the benefits of this technique[31], with preservation of the joint line orientation in cases where there is extra-articular varus deformity arising from both the tibia and femur. An acceptable difference of 2°, as recommended by most studies, was found in this study [30, 32].

Finally, the second main outcome was to investigate clinical results at 24 months follow-up. A consistent improvement in all sub-categories of the KOOS score was observed and 86.6% of patients were enthusiastic regarding the results of their surgeries. Comparing these clinical results to previously published DLO results, they were comparable [23] or even superior [33].

The present retrospective study has several limitations. Firstly, this is a non-comparative study; even if data exist on the accuracy and recurrence of JLO in conventional techniques, a control group of conventional DLO would have been interesting for doing a direct comparison. Secondly, the surgeons who performed these procedures, were familiar with osteotomy surgeries and had already used PSCGs during femoral or tibial single level osteotomies. Their results may not be directly transferrable to other less experienced surgeons. Thirdly, follow-up time was limited to two years following surgery and so long-term data on functional outcomes, revision rates, total knee arthroplasty conversion rates were not available.

CONCLUSION

Performing a DLO using PSCGs produces an accurate correction, without modification of the joint line orientation and with good functional outcomes at 2 years follow-up. The use of PSCGs in the execution of DLOs guarantees very high levels of precision comparable to those obtained through the use of the same instrumentation for single level osteotomies. Therefore, it represents a useful tool in the hands of surgeons with less experience in this complex surgery, with the assumption of correct planning and adequate indications.

Figure Legends

Fig.1: Planification of ideal cutting guides positioning using a 3D-CT Based corrected femoral and tibial models. A: Femur frontal view/ B: Femur sagittal view/ C: Tibia frontal view/ D: Tibia sagittal view

Fig.2: Pre-operative and Post-operative full leg x-rays of a 51 years old patient who underwent double level osteotomy. The weight-bearing line (green line) cross the tibial plateau just outside the tibial spine after DLO

Tables

	Pre-op	Post-op	Δ : difference between planned and obtained correction.
HKA (°)	$165.7 \pm 4.4^\circ$	$179.7 \pm 1.2^\circ$	$1.3 \pm 1.5^\circ$
MPTA (°)	$81.1 \pm 1.2^\circ$	$86.9 \pm 2.8^\circ$	$0.98 \pm 1.3^\circ$
PPTA (°)	$80.8 \pm 4.3^\circ$	$81.5 \pm 3.7^\circ$	$1.05 \pm 1.4^\circ$
LDFA	$92,8 \pm 0.2^\circ$	$88.7 \pm 0.2^\circ$	$0.9 \pm 1.2^\circ$
JLO (°)	$1.4 \pm 1.2^\circ$	$0.9 \pm 1.2^\circ$	N/E
JLCA	$2.8 \pm 2.3^\circ$	$1.7 \pm 2.3^\circ$	N/E

Table 1 Radiological parameters

HKA hip-knee-ankle angle; MPTA medial proximal tibial angle; PPTA posterior plateau tibial angle; JLO joint line obliquity; JLCA joint line convergence angle; LDFA mechanical lateral distal femoral angle; Δ accuracy of the post-operative alignment correction was defined by the difference between the desired corrections defined pre-operatively and the correction obtained post-operatively measured on Ct scan; N/E: Not evaluated

	Pre-op	Post-op	Δ	<i>p</i>
KOOS pain	52 ± 17	89 ± 16	37±16	<i>p</i> <0.0001
KOOS symptoms	46 ± 21	83 ± 15	37±25	<i>p</i> <0.0001
KOOS ADL	42 ± 20	80 ± 23	37±32	<i>p</i> <0.0001
KOOS sport/rec	37 ± 21	71 ± 26	34±37	<i>p</i> <0.0001
KOOS QOL	44 ± 11	80 ± 24	36±25	<i>p</i> <0.0001

Table 2 Functional outcomes.

Δ KOOS pain, Δ KOOS symptoms, Δ KOOS ADL, Δ KOOS sport/rec, Δ KOOS QOL: difference between the value obtained in the pre-operative questionnaire and that obtained at 24 months follow-up

Conflicts of interest

MO is educational consultant for New-Clip, Stryker and Arthrex

KK is educational consultant for New-Clip

CJ, RK, FG, PM, GM, LH have no relevant financial or non-financial interests to disclose

REFERENCES

- 330 1. Coventry MB (2001) Osteotomy of the upper portion of the tibia for degenerative arthritis of
331 the knee. A preliminary report by Mark B. Coventry, MD. From the Section of Orthopedic
332 Surgery, Mayo Clinic and Mayo Foundation, Rochester, Minnesota. 1965. *J Bone Joint Surg Am*
333 83:1426
- 334 2. Ferner F, Lutter C, Dickschas J, Strecker W (2019) Medial open wedge vs. lateral closed wedge
335 high tibial osteotomy - Indications based on the findings of patellar height, leg length, torsional
336 correction and clinical outcome in one hundred cases. *Int Orthop* 43:1379–1386.
337 <https://doi.org/10.1007/s00264-018-4155-9>
- 338 3. Amendola A, Bonasia DE (2010) Results of high tibial osteotomy: review of the literature. *Int*
339 *Orthop* 34:155–160. <https://doi.org/10.1007/s00264-009-0889-8>
- 340 4. Seil R, van Heerwaarden R, Lobenhoffer P, Kohn D (2013) The rapid evolution of knee
341 osteotomies. *Knee Surg Sports Traumatol Arthrosc Off J ESSKA* 21:1–2.
342 <https://doi.org/10.1007/s00167-012-2175-3>
- 343 5. Saragaglia D, Chedal-Bornu B, Rouchy RC, et al (2016) Role of computer-assisted surgery in
344 osteotomies around the knee. *Knee Surg Sports Traumatol Arthrosc Off J ESSKA* 24:3387–3395.
345 <https://doi.org/10.1007/s00167-016-4302-z>
- 346 6. Sharma L, Song J, Felson DT, et al (2001) The role of knee alignment in disease progression and
347 functional decline in knee osteoarthritis. *JAMA* 286:188–195.
348 <https://doi.org/10.1001/jama.286.2.188>
- 349 7. Dugdale TW, Noyes FR, Styer D (1992) Preoperative planning for high tibial osteotomy. The effect
350 of lateral tibiofemoral separation and tibiofemoral length. *Clin Orthop* 248–264
- 351 8. Sailhan F, Jacob L, Hamadouche M (2017) Differences in limb alignment and femoral mechanical-
352 anatomical angles using two dimension versus three dimension radiographic imaging. *Int Orthop*
353 41:2009–2016. <https://doi.org/10.1007/s00264-017-3428-z>
- 354 9. Donnez M, Ollivier M, Munier M, et al (2018) Are three-dimensional patient-specific cutting
355 guides for open wedge high tibial osteotomy accurate? An in vitro study. *J Orthop Surg* 13:171.
356 <https://doi.org/10.1186/s13018-018-0872-4>
- 357 10. Ke S, Ran T, He Y, et al (2020) Does patient-specific instrumentation increase the risk of notching
358 in the anterior femoral cortex in total knee arthroplasty? A comparative prospective trial. *Int*
359 *Orthop* 44:2603–2611. <https://doi.org/10.1007/s00264-020-04779-4>
- 360 11. Thienpont E, Schwab PE, Fennema P (2014) A systematic review and meta-analysis of patient-
361 specific instrumentation for improving alignment of the components in total knee replacement.
362 *Bone Jt J* 96-B:1052–1061. <https://doi.org/10.1302/0301-620X.96B8.33747>
- 363 12. Haglin JM, Eltorai AEM, Gil JA, et al (2016) Patient-Specific Orthopaedic Implants. *Orthop Surg*
364 8:417–424. <https://doi.org/10.1111/os.12282>
- 365 13. Jacquet C, Sharma A, Fabre M, et al (2019) Patient-specific high-tibial osteotomy's "cutting-
366 guides" decrease operating time and the number of fluoroscopic images taken after a Brief
367 Learning Curve. *Knee Surg Sports Traumatol Arthrosc Off J ESSKA*.
368 <https://doi.org/10.1007/s00167-019-05637-6>

- 369 14. Jacquet C, Chan-Yu-Kin J, Sharma A, et al (2019) "More accurate correction using "patient-
370 specific" cutting guides in opening wedge distal femur varization osteotomies. *Int Orthop*
371 43:2285–2291. <https://doi.org/10.1007/s00264-018-4207-1>
- 372 15. Chaouche S, Jacquet C, Fabre-Aubrespy M, et al (2019) Patient-specific cutting guides for open-
373 wedge high tibial osteotomy: safety and accuracy analysis of a hundred patients continuous
374 cohort. *Int Orthop* 43:2757–2765. <https://doi.org/10.1007/s00264-019-04372-4>
- 375 16. Gómez-Palomo JM, Meschian-Coretti S, Esteban-Castillo JL, et al (2020) Double Level Osteotomy
376 Assisted by 3D Printing Technology in a Patient with Blount Disease: A Case Report. *JBJS Case*
377 *Connect* 10:e0477. <https://doi.org/10.2106/JBJS.CC.19.00477>
- 378 17. Munier M, Donnez M, Ollivier M, et al (2017) Can three-dimensional patient-specific cutting
379 guides be used to achieve optimal correction for high tibial osteotomy? Pilot study. *Orthop*
380 *Traumatol Surg Res OTSR* 103:245–250. <https://doi.org/10.1016/j.otsr.2016.11.020>
- 381 18. Dijkman BG, Sprague S, Schemitsch EH, Bhandari M (2010) When is a fracture healed?
382 Radiographic and clinical criteria revisited. *J Orthop Trauma* 24 Suppl 1:S76-80.
383 <https://doi.org/10.1097/BOT.0b013e3181ca3f97>
- 384 19. Benjamin A (1969) Double osteotomy for the painful knee in rheumatoid arthritis and
385 osteoarthritis. *J Bone Joint Surg Br* 51:694–699
- 386 20. Babis GC, An K-N, Chao EYS, et al (2002) Double level osteotomy of the knee: a method to retain
387 joint-line obliquity. Clinical results. *J Bone Joint Surg Am* 84:1380–1388.
388 <https://doi.org/10.2106/00004623-200208000-00013>
- 389 21. Saragaglia D, Roberts J (2005) Navigated osteotomies around the knee in 170 patients with
390 osteoarthritis secondary to genu varum. *Orthopedics* 28:s1269-1274
- 391 22. Maurer F, Wassmer G (2006) High tibial osteotomy: does navigation improve results?
392 *Orthopedics* 29:S130-132
- 393 23. Saragaglia D, Blaysat M, Mercier N, Grimaldi M (2012) Results of forty two computer-assisted
394 double level osteotomies for severe genu varum deformity. *Int Orthop* 36:999–1003.
395 <https://doi.org/10.1007/s00264-011-1363-y>
- 396 24. Lee D-H, Park S-C, Park H-J, Han S-B (2016) Effect of soft tissue laxity of the knee joint on limb
397 alignment correction in open-wedge high tibial osteotomy. *Knee Surg Sports Traumatol Arthrosc*
398 *Off J ESSKA* 24:3704–3712. <https://doi.org/10.1007/s00167-015-3682-9>
- 399 25. Predescu V, Grosu A-M, Gherman I, et al (2021) Early experience using patient-specific
400 instrumentation in opening wedge high tibial osteotomy. *Int Orthop*.
401 <https://doi.org/10.1007/s00264-021-04964-z>
- 402 26. Pérez-Mañanes R, Burró JA, Manaute JR, et al (2016) 3D Surgical Printing Cutting Guides for
403 Open-Wedge High Tibial Osteotomy: Do It Yourself. *J Knee Surg* 29:690–695.
404 <https://doi.org/10.1055/s-0036-1572412>
- 405 27. Cerciello S, Ollivier M, Corona K, et al (2020) CAS and PSI increase coronal alignment accuracy
406 and reduce outliers when compared to traditional technique of medial open wedge high tibial

osteotomy: a meta-analysis. *Knee Surg Sports Traumatol Arthrosc Off J ESSKA*.
<https://doi.org/10.1007/s00167-020-06253-5>

28. Schröter S, Nakayama H, Yoshiya S, et al (2019) Development of the double level osteotomy in severe varus osteoarthritis showed good outcome by preventing oblique joint line. *Arch Orthop Trauma Surg* 139:519–527. <https://doi.org/10.1007/s00402-018-3068-9>

29. Micicoi G, Grasso F, Kley K, et al (2021) Osteotomy around the knee is planned toward an anatomical bone correction in less than half of patients. *Orthop Traumatol Surg Res OTSR* 102897. <https://doi.org/10.1016/j.otsr.2021.102897>

30. Nakayama H, Schröter S, Yamamoto C, et al (2018) Large correction in opening wedge high tibial osteotomy with resultant joint-line obliquity induces excessive shear stress on the articular cartilage. *Knee Surg Sports Traumatol Arthrosc Off J ESSKA* 26:1873–1878.
<https://doi.org/10.1007/s00167-017-4680-x>

31. Akamatsu Y, Nejima S, Tsuji M, et al (2021) Joint line obliquity was maintained after double-level osteotomy, but was increased after open-wedge high tibial osteotomy. *Knee Surg Sports Traumatol Arthrosc Off J ESSKA*. <https://doi.org/10.1007/s00167-020-06430-6>

32. Song J-H, Bin S-I, Kim J-M, Lee B-S (2020) What Is An Acceptable Limit of Joint-Line Obliquity After Medial Open Wedge High Tibial Osteotomy? Analysis Based on Midterm Results. *Am J Sports Med* 48:3028–3035. <https://doi.org/10.1177/0363546520949552>

33. Nakayama H, Iseki T, Kanto R, et al (2020) Physiologic knee joint alignment and orientation can be restored by the minimally invasive double level osteotomy for osteoarthritic knees with severe varus deformity. *Knee Surg Sports Traumatol Arthrosc Off J ESSKA* 28:742–750.
<https://doi.org/10.1007/s00167-018-5103-3>





