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**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

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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

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

KK is educational consultant for New-Clip

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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)).

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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.

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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.

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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.

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

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65 **INTRODUCTION.**

66 Osteotomies around the knee rep 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.

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

93

94

95 **MATERIAL AND METHODS**

96

97 *Population*

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

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

111 Patient consent was collected pre-operatively after they were informed of the procedure in accordance
112 with the principles of the Declaration of Helsinki. Local Ethical Committee approval was obtained
113 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

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

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

153

154 *Post-operative management*

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

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

163 anterior and lateral projections (both femoral and tibial) after 5 months; delayed between 5 and 8
164 months and not completed (non-union) after 8 months [18]. Post-operative alignment was evaluated
165 and compared with the target angular values, by two independent observers, to define the correction
166 accuracy. We reported an Intraclass Correlation Coefficient (ICC) of 0.79, 0.81, 0.87 and 0.85 for the
167 Δ values (Δ HKA, Δ MPTA, Δ PPTA, Δ LDFA respectively) and an ICC of 0,80 and 0.82 for JLO and
168 JLCA measurements. For all angular values both in the sagittal and coronal planes, the goal was to
169 obtain a perfect coincidence between the planned and the obtained angular values ($\Delta = 0$) with a
170 degree of tolerance of 2° .
171 Changes in the KOOS sub-scores were recorded, comparing pre-operative to the 24 months
172 assessment: Δ KOOS Pain, Δ KOOS Symptoms, Δ KOOS ADL, Δ KOOS Sport/Rec, and Δ KOOS QOL
173 were defined this way. Ability to return to work and sport were also recorded. At 24 months follow-
174 up, patient satisfaction was ranked upon 5 items questionnaires (disappointed, not-satisfied,
175 moderately satisfied, satisfied, and enthusiastic).

176

177 *Statistical analysis*

178
179 Statistical analyses were performed with use of SSPS software (IBM; Armonk, New York). Means
180 and standard deviations (SDs) were determined for each of the measured and desired anatomic
181 parameters. Normal (Gaussian) distributions was verified to determine adequate statistical testing
182 method (either parametric or non-parametric) to estimate difference between pre-operative, planned
183 and post-operative parameters groups in an univariate analysis. The Mann-Whitney U test for two
184 independent samples with 95% confidence interval (95% CI) was used to evaluate the differences
185 between two variables, the paired Student t test was used to estimate evolution of functional outcomes
186 during follow-up. Following the data collection, the statistical power was checked. Using the Δ
187 angular corrections (planned corrections - obtained corrections) as a primary parameter with 80% of
188 power, Alpha 0.05 and a value of $\Delta < 3.0^\circ$, it was estimated that the sample size should be 14.
189 Therefore, the sample size of 22 in the present study is reasonable in terms of statistical power.

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193 **RESULTS**

194

195 *Correction accuracy and radiographic results*

196 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
197 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,
198 there were no statistically significant differences between the target values and the post-operative
199 values (Table 2). A mean pre-operative JLO of $1.4\pm 1.2^\circ$ and a mean post-operative JLO of $0.9\pm 1.2^\circ$
200 were observed, thus the orientation of the joint line was preserved with a mean difference in the JLO
201 of 0.5 ± 0.90 .

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

204 *Functional outcomes*

205 At final follow-up assessment, 24 months after surgery, an improvement of 37 ± 16 for the KOOS pain
206 ($5-75$), 37 ± 25 for the KOOS Symptoms ($2-82$), 37 ± 32 for the KOOS ADL ($4-92$), 34 ± 37 for the
207 KOOS Sport/Rec ($2-87$) and 36 ± 25 for the KOOS QOL ($7-73$) ($p < 0.0001$) (Table 3) were observed.
208 The mean time to return to work and sports were 4.0 ± 1.6 ($3-12$) and 4.9 ± 1.2 ($2-7$) months,
209 respectively. At 24 months follow-up 19 patients were enthusiastic, 2 satisfied and one moderately
210 satisfied.

211

212 *Complications*

213

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

217

218 **DISCUSSION**

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

223 Conventional DLOs are highly demanding procedures and require a protracted learning curve. In
224 1969, Benjamin et al [19] was the first to report a series of 57 DLO with indications of rheumatoid
225 osteoarthritis and osteoarthritis. In this series, he reported a good level of patient satisfaction despite
226 some complications including limited range of motion and six patients without reduced pain. Analyses
227 of the pre-operative deformity and the post-operative correction (HKA angle or JLO) were not
228 mentioned. Babis et al. [20] reported on 24 patients (29 knees) operated on utilizing a conventional
229 technique. A computer-aided analysis of the mechanical status of the knee was used for pre-operative
230 planning. Their results showed a mean post-operative HKA angle of 176.9° (169.4–184.9°) with a
231 residual varus in two cases (4.6–4.9°) and an over correction of more than 4° in ten cases and more
232 than 6° in five. No information was available concerning the pre-operative and post-operative JLO.

233 Otherwise, a high level of post-operative alignment accuracy was reached in computer assisted
234 procedures despite their cost and increased surgical time [21, 22]. Saragaglia [23] reported a case
235 series of 38 patients in which the pre-operative target was reached in 92.7% of patients for HKA and
236 88.1% for MPTA with 2° of accuracy. No information was reported concerning the pre-operative and
237 post-operative JLO. The results of the present study are comparable with those of Saragaglia. Our
238 study demonstrates that pre-operative targets were reached in all the patients with a slight difference
239 between the planned correction and the post-operative values, which were not statistically
significant

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

245 Previous studies have analyzed the accuracy of the PSCG system, but have been restricted to single
246 level knee osteotomy [25]. Nevertheless, a high level of precision has been demonstrated in single
247 level osteotomies. Cerciello et al. in a systematic review analyzed 28 studies which focused on single
248 level osteotomies performed by computer navigation and patient specific instrumentation. In their
249 conclusions they stated that it had been observed a reduced rate of post-operative outliers for PSI
250 instrumented osteotomies compared to conventional techniques [26, 27]. Specific accuracy correction
251 results of open-wedge high tibial osteostomy procedures using PSCGs have been published by
252 Chaouche et al [15]. They observed that the mean Δ HKA was $1 \pm 0.95^\circ$, the mean Δ MPTA was $0.54 \pm$
253 0.63° , and the mean Δ PPTA was $0.43 \pm 0.8^\circ$. In all cases, the discrepancy between planned and
254 achieved correction was less than or equal to 2°. Similar results were published in distal femoral
255 osteotomies using PSCGs by Jacquet et al [14]. The HKA target was also reached in 100% of case
256 with 2° of discrepancy. Finally, the correction accuracy observed in the present study was similar to
257 those previously described for both femoral or tibial single level osteotomies using PSCGs.

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

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

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

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281 **CONCLUSION**

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

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293 **Figure Legends**

294

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

298

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

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303

304 **Tables**

305

306

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

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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

316

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

321

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

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