Can three-dimensional patient-specific cutting guides be used to achieve optimal correction for high tibial osteotomy? Pilot study

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1. Introduction

In patients with moderate tibiofemoral osteoarthritis and leg misalignment [1], a high-tibial osteotomy (HTO) is an ideal conservative treatment [2]. However, the angular correction must be optimal in all three planes for the osteotomy to be effective. Radiology studies have revealed that an under-correction is common, and that it is more significant with opening-wedge than closing-wedge osteotomies [3,4].

Computer-assisted surgery can solve this problem, but it is not devoid of errors and complications [5]. The recent introduction of patient-specific cutting guides (PSCGs) has raised the possibility of making instrumentation specific to each patient, which could result in more accurate correction of the bone deformity.

The objectives of this study were:

• to evaluate the reliability of the method by comparing the achieved angular correction to the planned correction;
Table 1

Patient population.

<table>
<thead>
<tr>
<th>Patient series</th>
<th>Side</th>
<th>Preoperative HKA</th>
<th>Preoperative tibial slope</th>
<th>Preoperative mMPTA</th>
<th>Ahlback stage</th>
<th>Age</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>series</td>
<td>Right (2)/Left (8)</td>
<td>172.8 (167.1–179.5)</td>
<td>8.8 (1.8–22.4)</td>
<td>87.1 (86–88.8)</td>
<td>2 (1–2)</td>
<td>46 (31–59)</td>
<td>28.6 (24.2–39.4)</td>
</tr>
</tbody>
</table>

BMI: body mass index.

- to evaluate the intra- and postoperative complications specific to this method.

We hypothesized that performing a tibial osteotomy with PSCGs following three-dimensional (3D) planning is accurate (within 2 degrees) without increasing the intra- and postoperative complications.

2. Material and methods

All the patients undergoing medial opening wedge HTO with PSCGs between February 2014 and February 2015 were enrolled in this single-center, prospective, observational study. Inclusion criteria were: patient <60 years of age with medial knee osteoarthritis (Ahlback ≤ 2 [6,7]) with significant genu varum. Exclusion criteria: advanced osteoarthritis (Ahlback ≥ 3) and artefacts that would interfere with obtaining a high-quality CT scan (Table 1).

Preoperatively, the mean HKA angle was 171.9° (range 166–179°), the mean tibial slope was 7.5° (1.8–22.4°) and the mean mechanical medial proximal tibial angle (mMPTA) was 86.7° (86–88°).

The first 10 osteotomies performed by two different surgeons using this technique during the enrollment period were analyzed with a minimum follow-up of 1 year. Patient consent was collected preoperatively after they were informed of the procedure, in accordance with the principles of the Helsinki declaration.

2.1. Two-dimensional preoperative planning

Preoperatively, all patients had standard X-ray views taken (weight bearing long-leg radiographs, Schuss view, sky-line view, A/P and lateral, stress views) and underwent a CT scan according to a protocol developed collaboratively with the imaging department. The surgeon took measurements and filled out an order form for the engineer that specified the correction objectives in the frontal and sagittal planes through variations in the hip knee ankle (HKA) angle and the tibial slope (Fig. 1).

2.2. Virtual HTO

The CT scan protocol consisted of one acquisition centered on the femoral head, one on the knee that captured the distal femur and 15 cm of the proximal tibia, 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).

The position of the resection plane and the frontal and sagittal corrections were confirmed by the surgeon. The HTO model was used to virtually position the Activmotion plate (Newclip Technics©, Haute-Goulaine, France) on the tibia while following the manufacturer’s recommendations for ideal positioning on the anteromedial side of the tibia (Fig. 2). The design of the PSCGs took into account the resection plane and the position of the screw tunnels relative to the virtual positioning of the plate.

2.3. Surgical technique

The PSCGs were secured to the bone with two pins and then fluoroscopy done to confirm the orientation of the osteotomy cut (Fig. 3). The six holes needed for the plate were drilled before performing the osteotomy. The osteotomy was performed with the PSCGs in place. The saw blade was guided by a specific portion of the PSCG and then the proximal portion of the guide was removed to finish the osteotomy in the same plane or two planes, depending on the planned correction and the position of the patellar tendon.

The lateral cortex was weakened with a drill bit to preserve a lateral hinge and then the osteotomy cut was gradually opened with a lamina-spreader distractor until the pre-drilled screw holes

Fig. 1. Two-dimensional planning with measurements of the tibial slope, HKA angle and mechanical medial proximal tibial angle (mMPTA): a: the tibial slope is defined by the angle between the anterior tibial cortex and the axis of the medial tibial plateau on a lateral view of the knee; b: the HKA is measured on long-leg standing radiographs as the intersection of two femoral head diameters, the middle of the line joining the tibial intercondylar eminence and the middle of the articular surface of the distal tibia; c: the mMPTA is the angle between the line joining the center of the ankle with the center of the knee and the axis of the tibial plateau on long-leg standing radiographs.
were aligned with the holes in the plate (Activmotion™ and self-tapping-screws, Newclip Technics™, Haute-Goulaine, France). The plate was secured using six screws of the size chosen during the preoperative planning and then the bone defect filled with injectable calcium phosphate cement (Quickset, Graftys®, Aix-en-Provence, France).

### 2.4. Postoperative radiological and clinical follow-up

All patients were reviewed at 1 month postoperative to evaluate any early complications, then at 3 months for regular follow-up with radiographs (long-leg standing, A/P and lateral) and CT scan. With Centricity™ software (GE), the X-ray views were used to compare the resulting radiographic parameters (HKA, tibial slope, mMTPA) to those planned preoperatively (Fig. 4). The postoperative CT scan was used to perform a new 3D reconstruction of the tibia to calculate the mMTPA angle and tibial slope [8] and compare them to the preoperative model (Fig. 5).

To verify the reproducibility and accuracy of the measured angles, the analysis was repeated four times by a single observer and then again by a second independent observer to obtain the inter- and intra-observer intraclass correlation coefficient (ICC) (Table 2).
Fig. 4. Postoperative radiographic measurements (mMPTA, HKA and tibial slope).

Fig. 5. Preoperative (grey) and postoperative (white) 3D reconstructions providing a visual comparison of tibial slope and mMPTA.

Table 2
Inter- and intra-observer intraclass correlation coefficients (ICC).

<table>
<thead>
<tr>
<th></th>
<th>Intra-observer ICC</th>
<th>Inter-observer ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean HKA (min, max)</td>
<td>0.98 [0.95–0.99]</td>
<td>0.92 [0.85–0.97]</td>
</tr>
<tr>
<td>Mean tibial slope (min, max)</td>
<td>0.98 [0.94–0.99]</td>
<td>0.91 [0.83–0.95]</td>
</tr>
<tr>
<td>Mean mMPTA (min, max)</td>
<td>0.98 [0.94–0.99]</td>
<td>0.92 [0.86–0.96]</td>
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</tbody>
</table>

mMPTA: mechanical medial proximal tibial angle.

3. Results

Patients were reviewed at 1 year to ensure there were no delayed complications.

3.1. Two-dimensional analysis

Postoperatively, the mean HKA was 182.3° (180.3–185°), the tibial slope was 6.6° (1–13.2°) and the mMPTA was 94.3° (90.8–98.1) (Table 3). The differences from the target value requested by the surgeon were 0.98 [0.92–0.99] for the HKA and 0.96 [0.79–0.99] for the tibial slope.

In the coronal plane, none of the knees were more than 2° from the planned value. In the sagittal plane, one knee had more than 2° difference between the planned and measured tibial slope (Table 4).

3.2. Three-dimensional analysis

The difference with the target was measured using a 3D transformation between the preoperative planned value and the correction achieved. The results were comparable to those observed in 2D. In the coronal plane, the difference was always less than 2°. In the
The small sample size is the primary limitation of this study. However, this was a pilot study of reliability and safety, hence, the small number of patients enrolled. In addition, the study population is comparable to other published studies reporting on the use of this technology (Table 6). The other studies included cases of tibial and femoral osteotomy and did not have systematic CT scan follow-up measurements. Secondly, our study had no control group. This is related to the study objectives, which were to assess the reliability of this technique relative to its planned correction and to assess its safety, not to demonstrate that this system was better than the conventional method. A comparative study will be needed to determine whether this system is superior.

The primary objective of this study was to analyze the reliability of this technique by comparing the accuracy of the achieved correction relative to the planned correction. Since the intraoperative methods used to verify the correction can be inaccurate,
we chose to carry out another set of CT reconstructions and measurements [9]. There are only two published studies on the use of PSCGs for HTO. Victor et al. [10] reported accuracy of 1° in the frontal plane and 2° in the sagittal plane; however, the analysis was performed with radiographs only. Perez-Mananes et al. [11] had similar results in the frontal plane with an accuracy of 2°, but the tibial slope was not measured, nor was CT performed. Saragaglia et al. [12] reported 96% accuracy for a planned HKA angle of 184° ± 2° in their study with computer-assisted surgery. The results of our study compare favorably to those of Saragaglia; however, a comparative study would be needed to show that one method is superior to the other. Moreover, navigation is more costly and lengthens the operating time [12,13]. An opening wedge HTO is known to increase the tibial slope [3,14–16]. With the PSCGs, the tibial slope can be maintained close to the initial anatomical data. Published radiological results often point to under-correction after HTO. This problem is particularly apparent with an opening-wedge procedure as the under correction is about 2° more than with closing wedge [3,4]. Marti et al. reported a 50% accuracy between the correction achieved and the one planned after opening wedge HTO [17], which was vastly different from our study where use of PSCGs led to a reliable correction that was similar to the planned correction.

Our second objective was to evaluate the occurrence of intra- and postoperative complications. Intraoperative complications have rarely been reported in osteotomy studies [18–20]. Lobenhoffer [21] reported a relatively high rate of postoperative complications (6%), mainly due to soft tissue problems (infection, hematoma). In our study, there was one case of postoperative hematoma that spontaneously resolved without infection and that did not delay the functional recovery. According to Gomoll [22], the typical postoperative complications of opening-wedge HTO are delayed union and non-union, with resulting loss of correction. There were no instances of delayed union in our study; the follow-up was too short to detect any loss of correction.

5. Conclusion

The results of this study evaluating the reliability and safety of PSCGs during HTO showed that this technique achieves an optimal correction in a safe and reliable manner. A prospective study comparing use of PSCGs with the standard technique will be needed to confirm the advantages of this technology.

Disclosure of interest

Jean-Noël Argenson is an educational consultant for Zimmer. Sébastien Parratte is an educational consultant for Newclip, Zimmer and Arthrex.

Mathias Donnez received a scholarship grant from Newclip Technics.

The other authors declare that they have no competing interest.

References