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Contribution of patient-specific cutting guides to lower limb alignment for total knee arthroplasty

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ABSTRACT

Patient-specific cutting guides (PSCG) are an extension of preoperative planning for total knee arthroplasty (TKA). We wanted to evaluate their contribution to postoperative lower limb alignment. This study involved primary TKA cases being performed with PSCG between 10/05/2010 and 05/03/2013 and then followed prospectively. The analysis involved the PSCG usage and postoperative measurement of the patient’s HKA, medial distal femoral joint angle (MDFA) and medial proximal tibia joint angle (MPTA). Of the 104 eligible cases, 68 were included; 11 of these cases were not performed completely with the PSCG as initially planned. Thus we compared these 11 cases with the 57 where PSCG were used. The preoperative HKA in the included cases was 175.8$° \pm 7.8$; the postoperative angles on average were 179.2$° \pm 2.9$ for the HKA, 89.9$° \pm 1.6$ for the MDFA and 89.0$° \pm 2.3$ for the MPTA. The average postoperative deviation from the target values was 2.22$° \pm 2.14$ for the HKA angle, 1.07$° \pm 1.15$ for the MDFA and 1.66$° \pm 1.90$ for the MPTA. There were no significant differences between the two groups in any of the measurements. The lower limb alignment goal was achieved in 50 cases (73%), with 41 of these achieved with PSCG (82%). Of the 18 cases where the target was not achieved, PSCG were used 16 times (88%). In this study cohort, lower limb alignment was not significantly closer to an HKA of 180$°$ or achieved more often with the use of PSCG versus standard instrumentation. Since the results of the two groups can be superimposed, we found no evidence that use of PSCG improves postoperative lower limb alignment.

Level of evidence: IV.
Study type: Cohort.

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1. Introduction

Total knee arthroplasty (TKA) is a procedure with demonstrated clinical and financial benefits for patients suffering from advanced knee osteoarthritis [1,2]. The 10-year survival of these implants is typically more than 90% [3–5]. However, a more detailed analysis of failed cases reveals that mechanical failures occur early in more than half the cases, with 40% occurring before 5 years according to Fehring et al. [6] and 50% at 3.7 years according to Sharkey et al. [7]. A multicentre study in France reported in 2011 that loosening occurred at 4.43 years on average [8]. This raises questions about the reproducibility of this treatment method when a 100% increase in demand for TKA is expected in the upcoming years [9].

Although recently brought into question [10], restoring neutral mechanical alignment in the frontal plane is a proven factor for implant survival [11–14]. Computer navigation was introduced in the 1990s to reproducibly achieve this neutral alignment. Its efficacy has been demonstrated since then, to the point where it is now the gold standard technique for lower limb alignment [15,16]. However, the cost, increased surgery time, learning curve and complications have hindered widespread acceptance of this technique [17,18]. Patient-specific cutting guides (PSCG) were designed with similar goals in mind to those of computer navigation (limb alignment, absence of morbidity related to intramedullary instrumentation) but also to simplify the procedure. The intent was to move the navigation step from the intra-operative period to the preoperative period, while keeping the precision associated with computer assisted surgery. Here we report on our experience with patient-specific cutting guides during TKA and evaluate if PSCG can help restore the mechanical axis of the leg.

2. Material and methods

This was a prospective, observational, single-centre, multi-surgeon study. The study involved patients undergoing primary
TKA with PSCG at our facility, no matter the indication. The posterior stabilized GENESIS II and LEGIONARY PRIMARY Total Knee Systems were used (Smith & Nephew Orthopedics, Memphis, USA). The only difference between these two models is that the GENESIS II has asymmetric posterior condyles. The design and size of the implants are identical in all other respects, thus do not affect the frontal plane lower limb alignment.

Patients were included from 10/05/2010 to 05/03/2013. This period encompassed our first cases; none of our learning curve patients were excluded. The following inclusion criteria were used: completed pre-surgical planning with PSCG delivered to our facility’s central pharmacy, preoperative long-leg standing radiographs, surgical report describing the use of PSCG, long-leg standing radiographs at more than three months post-surgery. The following exclusion criteria were used: pre-surgical planning that did not result in PSCG delivery due to technical problems, a change in the surgery date or the procedure being cancelled due to intervening events; incomplete patient records, especially lack of long-leg standing radiographs at the last follow-up. Of the 104 eligible cases, 68 were included. Of these 68 patients, 57 were performed with the PSCG and 11 were not as initially planned.

The VISIONAIRE technology (Smith & Nephew Orthopedics, Memphis, USA) was used for pre-surgical planning and to prepare the patient-specific cutting guides. The surgeon prepares an online preoperative form that includes the following information: patient’s name, operated side, type of implant chosen and general features of implant positioning in the frontal, sagittal and axial planes, along with the method for choosing the implant size. The goal was to achieve neutral mechanical axis of the leg, thus hip-knee-ankle (HKA) angle of 180°, with the implants perpendicular to the mechanical axes of the various bones. The surgery date and as well as the date of the image upload were recorded. The required images consisted of weight-bearing long-leg standing radiographs with metal markers placed at the knee to provide soft tissues referencing. MRI of the knee was also performed on a MRT machine that had been previously calibrated to correct image spatial distortion. Since MRI was required, any patients with existing hardware were excluded. Once the image quality was validated by the radiologist or surgeon, the images were sent to Smith & Nephew through a secure link. Engineers at Smith & Nephew also evaluated the image quality and conformity; if acceptable, the planning process was set in motion.

The planning process consisted of quantifying the bone and articular surface contours, segmenting the bones on the MRI slices and constructing a three-dimensional model aligned with the long-leg standing radiographs via virtual centering intramedullary rods, identifying the bone landmarks (transepicondylar axis, Whiteside line [19], tangent to posterior condyles, femoral sulcus, supra-trochlear anterior cortex, footprint of the anterior cruciate ligament on the tibia, tibial slope, medial third of the anterior tibial tuberosity), along with measuring the thickness of the bone cuts to be performed on the femur and tibia to meet the objectives set out by the surgeon.

This plan and its measurements were then sent electronically to the surgeon, along with the proposed orientation value and bone cut thickness for the implant size that best matches the patient’s knee anatomy and surgeon preferences. The plan was accompanied by dynamic three-dimensional reconstructions in an interactive PDF file that provide views of the proximal tibia and distal femur from multiple angles: before the bone cuts, after the bone cuts and with the implants in place. This proposed plan could either be approved as is or after being modified by the surgeon. The nylon PSCG guides were produced, labelled with the patient’s name and delivered sterile within three to six weeks. The VISIONAIRE cutting blocks were placed on the bone and then secured with threaded K-wires. These blocks have slots through which the distal femoral and proximal tibial cuts are made. The PSCG were visually aligned using alignment marks placed in the cutting slots through which an extra-medullary alignment rod had been introduced. The remainder of the procedure was performed with standard instrumentation and navigation. The fixation pegs on the PSCG provided axial orientation, tibial centring and implant sizing.

The following parameters were evaluated: whether the supplied PSCG were used and reasons for not using them; lower limb alignment via the HKA angle on the pre- and postoperative long-leg standing radiographs, along with implant alignment in the frontal plane, which was quantified on postoperative long-leg standing views through the medial distal femoral and medial proximal tibial joint angles [20]. Angles were measured on digital X-rays of long-leg standing radiographs as described by Ramadier et al. [21] using computerized tools (OrthoView®, Jacksonville, USA) integrated into our facility’s digital archiving system.

The goal was to achieve a neutral mechanical leg axis, defined as an HKA angle of 180° ± 3°. So as to not alter the comparison of averages due to bias of leg deformity distribution around 180°, we also evaluated the deviation from 180° calculated as the absolute value of the difference between the postoperative HKA angle and 180°. A similar analysis was performed with the medial distal femoral joint angle (MDFA) and medial proximal tibia joint angle (MPTA) relative to the 90° target value. We defined a well-aligned knee as one where the postoperative HKA angle was between 177° and 183°, inclusively. In bilateral TKA cases, the two knees were analysed as independent samples. Non-parametric statistical tests were used because of the low number of patients in which the PSCG were not used. Statistical tests were performed using StatView 4.47 software (Abacus Concepts, Inc., Piscataway, NJ, USA). The Mann-Whitney U test was used to compare group averages. Two-tailed tests were performed and the null hypothesis (H0) was defined as no difference or correlation between the two groups. The type I risk was set at 0.05.

3. Results

The 3 surgeons included 68 cases in 62 patients (6 bilateral), thus an inclusion rate of 65.4%. Of these 68 patients, 57 were performed with the PSCG and 11 (16%) were not performed fully with the PSCG as initially planned. We compared the results of these 11 cases (performed fully or partially with standard instrumentation) to the 57 cases performed with PSCG.

In the 11 cases performed without PSCG: 5 because of the tibial cut and 6 because of the femoral cut. In 5 cases, the PSCG were not used because the distal femur had to be recut due to a flexion deformity. Standard instrumentation was used to reduce the size of the femoral component. In the six other cases, the surgeon indicated that the resection that would have been performed with the PSCG in place was grossly abnormal. There was no information about any problems in PSCG positioning related to the surgeon, chondral defect or a cut being deemed irregular even though perfect PSCG fit had been achieved. In two cases, the PSCG could not be put into place because an anterolateral approach had been used due to valgus knee deformity in petite female patients (size 2 tibial component).

In all of the analysed cases, the average preoperative HKA angle was 175.8° ± 7.8. The postoperative angles on average were 179.2° ± 2.9 for the HKA angle, 89.9° ± 1.6 for the MDFA and 89.0° ± 2.3 for the MPTA. The average postoperative deviation from the target values was 2.22° ± 2.14 for the HKA angle, 1.07° ± 1.15 for the MDFA and 1.66° ± 1.90 for the MPTA.

In the group where the PSCG were used, the average preoperative HKA angle was 174.9° ± 6.68. The average postoperative deviation from the target values was 2.17° ± 2.13 for the HKA angle.
Table 1

<table>
<thead>
<tr>
<th>Group</th>
<th>HKA preop</th>
<th>HKA at FU</th>
<th>Difference from 180° HKA</th>
<th>Difference from 90° MDFA</th>
<th>Difference from 90° MPTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSCG (n = 57)</td>
<td>174.9 ± 6.68</td>
<td>178.8 ± 2.82</td>
<td>2.17 ± 2.13</td>
<td>0.96 ± 1.02</td>
<td>1.79 ± 2.03</td>
</tr>
<tr>
<td>Standard instrumentation (n = 11)</td>
<td>180.2 ± 11.4</td>
<td>181.0 ± 3.26</td>
<td>2.45 ± 2.25</td>
<td>1.64 ± 1.63</td>
<td>1.00 ± 0.63</td>
</tr>
<tr>
<td>Total</td>
<td>175.8 ± 7.8</td>
<td>179.2 ± 2.9</td>
<td>2.22 ± 2.14</td>
<td>1.07 ± 1.15</td>
<td>1.66 ± 1.90</td>
</tr>
</tbody>
</table>


Only a few studies have reported on the lower limb alignment after TKA performed with patient specific cutting guides [24–28]. One of these studies was a prospective, randomized study evaluating four different types of PSCG (Signature®, Biomet Inc.; TruMatch®, DePuy Inc.; Visionaire®, Smith & Nephew Inc. and Patient-Specific Instruments®, Zimmer Inc.) [29]. These studies found no benefit in terms of improving the lower limb alignment or quality of implant positioning, with a strong trend toward postoperative varus of the tibial component. Conversely, Ng et al. [30] reported a 10% improvement (88% vs 78%) in postoperative alignment when using PSCG in a significant number of patients (569 TKA with PSCG vs. 155 TKA with standard instrumentation). Ball et al. reported similar findings in a smaller number of cases [31].

This brings up questions about the lack of precision. Is it intrinsic to the technique or is it related to the user who does not place the PSCG properly? Two studies have attempted to answer this question by evaluating the alignment of bone cuts proposed by the Visionaire PSCG system with computer navigation [22,23]. The main error rate was intrinsic to the technique and mostly occurred in the sagittal plane; however there were a significant number of errors in the frontal plane, mostly affecting the tibia. This leads us to hypothesize that using long-leg standing radiographs to plan the bone cuts does not take into account bone rotation. This mainly impacts the tibia; it induces varus because it is externally rotated relative to the femur on the posterior medial tibial plateau, which is secondary to chronic ACL rupture.

The limitations of the current study revolve mainly around the small number of patients, heterogeneity, lack of control group. The latter would have allowed us to have adequate statistical power to compare TKA patients operated with PSCG with TKA patients operated with standard instrumentation. The prospective nature of the study was tempered by the fact that the inclusion rate was only 65.4%. In addition, this study included all the TKA that had been planned to be performed with PSCG at our facility by three different surgeons, without excluding any patients operated on during our initial learning curve with the VISIONAIRE technology (MRI quality, long-leg standing film quality, availability of patients and time needed to make the PSCG in conflict with the surgery date). Nevertheless, it accurately reproduced our experience with the technique and rigorously challenged the expectations that we had relative to improving post-TKA lower limb alignment.

It would be incorrect to limit the potential contribution of PSCG to TKA implant positioning. Benefits in terms of less bleeding, shorter surgical time and lower instrumentation sterilization costs can also be expected, although such evaluations were beyond the scope of our study [31,32].

4. Discussion

The primary finding of this study was that in 16% of cases where the surgeon expects to use PSCG, a standard instrumentation set must also be available. The second finding is that using PSCG did not optimise the postoperative lower limb alignment in the patients evaluated. In this cohort study, lower limb alignment was not significantly closer to an HKA angle of 180° or achieved more often with the use of PSCG compared to standard instrumentation. This result must be interpreted with caution because of the two groups had an unequal number of patients. Based on our findings, we found no evidence that use of PSCG improves postoperative lower limb alignment. As a consequence, we cannot recommend that PSCG be used to primarily optimize the postoperative alignment of TKA patients [22,23].

5. Conclusion

In this study cohort, lower limb alignment was not significantly closer to an HKA of 180° or achieved more often with the use of PSCG versus standard instrumentation. Since the results of the two groups can be superimposed, we found no evidence that use of PSCG improves postoperative lower limb alignment. As a consequence, we cannot recommend that PSCG be used to primarily optimize the postoperative alignment of TKA patients.

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Disclosure of interest

J. Brillhaut discloses the following conflicts of interest:

- clinical trials: co-investigator, associate researcher collaborator in studies sponsored by Smith & Nephew other than the one reported here;
- ad-hoc work: expert reports for Smith & Nephew;
- symposiums: invited as contributor by Smith & Nephew.

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