Virtual 3D planning and patient specific surgical guides for osteotomies around the knee

A FEASIBILITY AND PROOF-OF-CONCEPT STUDY

We have investigated the benefits of patient specific instrument guides, applied to osteotomies around the knee. Single, dual and triple planar osteotomies were performed on tibias or femurs in 14 subjects. In all patients, a detailed pre-operative plan was prepared based upon full leg standing radiographic and CT scan information. The planned level of the osteotomy and open wedge resection was relayed to the surgery by virtue of a patient specific guide developed from the images. The mean deviation between the planned wedge angle and the executed wedge angle was 0° (-1 to 1, SD 0.71) in the coronal plane and 0.3° (-0.9 to 3, SD 1.14) in the sagittal plane. The mean deviation between the planned hip, knee, ankle angle (HKA) on full leg standing radiograph and the post-operative HKA was 0.3° (-1 to 2, SD 0.75). It is concluded that this is a feasible and valuable concept from the standpoint of pre-operative software based planning, surgical application and geometrical accuracy of outcome.

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Osteotomies around the knee have been used to correct lower limb mal-alignment for over 50 years. The procedure is technically demanding and carries risks of neurovascular injury and inadequate fixation. In recent years, with the advent of locking plates, fixation techniques have improved significantly but the correct planning and execution of the operation remains difficult.1 Despite the availability of computer tomography (CT) and magnetic resonance imaging (MRI) which can generate virtual three-dimensional images (3D), surgical planning is still commonly performed on two dimensional (2D) conventional radiographs.2 This in part may be because of the difficulty in appreciating the 3D information during a surgical procedure. Now, especially in case of multi-planar deformities, the old 2D technique is obsolete and prone to error.3 In addition, it can be argued that the traditional intra-operative tools such as rulers and protractors for checking the achieved geometrical correction are relatively crude and inaccurate.

Recently, patient specific guides which originated in dental surgery4,5 have been applied to orthopaedics.6-9 The manufacturers of knee implants currently heavily promote these tools for total knee replacement (TKR). However, patient specific guides for osteotomies have received little attention, which is paradoxical given their potential to add value particularly in multi-planar deformities. In these situations, complexity increases to such a degree that external spatial frames and fixators are often used to facilitate post-operative adjustments. The lack of consistency in performing osteotomies is probably one of the reasons for their fading popularity in the orthopaedic community. Consequently, the authors wanted to explore the feasibility of virtual pre-operative three-dimensional planning, and the subsequent effects on execution of osteotomies around the knee using individually crafted patient specific surgical guides and locking plates. This pilot study aims to answer the following questions:

1. Can CT scan data be used for planning the correction of angular deformity around the knee?
2. Is it possible to fit patient specific guides to the femur and tibia using a conventional surgical exposure?
3. What is the accuracy of a performed osteotomy in relation to the pre-operative plan?

Patients and Methods

Patients were recruited between May 2010 and November 2012. All were fully informed about the nature of the procedure, the imaging and the technology involved. Patients who agreed were consecutively included in the study. All underwent standard antero-posterior (AP), lateral and axial radiographs, in addition to full leg standing radiographs as...
union, two with ligament and meniscus injury, two with dysplasia, four with post-traumatic deformity due to malcauses of deformity included three with lateral condylar mean age at the time of surgery was 44 years (33-55), and 14 patients in the study, six of whom were female. The factors in the decision to proceed with surgery. We included increasing deformity and diminishing function were key been our patients for many years. Deteriorating symptoms, malalignment in the outpatient clinic. Several of them had abnormal morphology or alignment, the osteotomy had abnormality. The correction in this patient was performed at the level of the femur. The correction was limited to the coronal plane in nine patients. Four patients underwent biplanar correction and one patient underwent a corrective osteotomy of the distal femur in the coronal, sagittal and axial planes. Corrective angles ranged from 6 to 15° for biplanar and 23° for axial (Table I).

All patients underwent opening wedge osteotomies in the bone that contributed most to the deformity. In seven patients, the deformity was limited to one single bone. In one patient (no. 1) the deformity was largely due to femoral abnormality and to a lesser extent to tibial abnormality. The correction in this patient was performed at the level of the femur. The correction was limited to the coronal plane in nine patients. Four patients underwent biplanar correction and one patient underwent a corrective osteotomy of the distal femur in the coronal, sagittal and axial planes. Corrective angles ranged from 6 to 15° for biplanar and 23° for axial (Table I).

CT scans of both legs were taken including 1.25 mm slices from hip to ankle using a standard protocol. The CT images were segmented (Fig. 1) in Mimics® (Materialise N.V. Leuven, Belgium) and virtual 3D femur and tibia models were created for both the deformed and the contralateral leg. These three-dimensional computer models allow post-scan processing, three-dimensional annotation and measurements as well as visualisation from different angles. If the contralateral leg had a normal morphology and alignment, it served as the template to be matched by the operated limb after the osteotomy. Where the contralateral leg had abnormal morphology or alignment, the osteotomy was planned according to the mechanical axes in the coronal and sagittal planes. These axes were defined using the conventional anatomical landmarks previously described. The centre of the hip, knee and ankle could be located with high precision and low inter- and intra-observer variability on the CT model of the limb.10 The coordinate system for the femur and the tibia was built around these clinically relevant landmarks.11
In one case, a significant rotational deformity was present. An axis was created from the centre of the femoral head through the centre of the femoral neck to define the femoral neck axis. The projection of this line on the horizontal plane served as the reference to match rotation with the contralateral limb. Where the deformity on the femur was unilateral, the normal contralateral limb served as the reference. The healthy contralateral leg was mirrored and the tibias were aligned in 3-matic® (Materialise N.V. Leuven, Belgium) (Fig. 2). By superimposing the tibias with each other, a comparison of the two legs in 3D space is visualised and the difference in relative alignment of the femurs can be fully appreciated. In the next step the femur was virtually osteotomised in order to align the deformed femur to the desired alignment (Fig. 3).

The hinge axis was defined in the cut plane along the direction of correction at a specified distance, typically 5 mm to 7 mm from the far bony cortex. In case of a uniplanar correction in the coronal plane, the hinge axis was located in the sagittal plane. For biplanar corrections, the hinge axis did not fall within one of the three coordinate planes. The virtually selected fixation plate (Synthes® Tomofix™) was aligned to the planned surgical position. The plate’s screw positions and lengths were calculated based on the plate’s position and bi-cortical distance. Relevant angles and distances were noted on the operative plan for later use as a reference during surgery.

In the next step the virtual osteotomy was ‘undone’ and the bone was restored to its original, deformed morphology yet retaining the virtual screw holes and osteotomy plane. A surgical guide was now designed and constructed to match the pre-operative bone geometry and provide guidance for the osteotomy and the computed drill-hole locations. The guide was engineered to provide sufficient surface contact in order to create a unique fit on the bone. Drill cylinders were manufactured to match the pre-operative screw positions and orientations. The diameter of the cylinders was such that they accommodated the appropriate surgical drill sleeve. A cut slot with a surface parallel to the hinge axis served as a guide for performing the osteotomy. Small openings for K-wires are added in order for the position of the guide on the bone to be fixed. (Fig. 4)

The surgery is performed in supine position, under general anaesthesia. For the femoral osteotomies, a lateral approach is used, elevating the vastus lateralis from the inter-muscular septum. Hohman retractors facilitate exposure of the femur, allowing a direct fit of the guide onto the bone. The mechanical fit was excellent in all cases, with virtually no toggle. The guide is fixed with K-wires and the screw holes drilled through the cylinders on the guide. In one instance, the hinge axis was defined by drilling a 2.7 mm pin along the desired hinge path. A fluoroscopy check of the position of the guide was made. The osteotomy is performed via the captured cut slot, and is initiated with the oscillating saw, using a 1.27 mm blade. The guide is then removed and the osteotomy completed with double-edged osteotomes. For the uniplanar and biplanar corrections, the osteotome stops at a planned distance from the opposite cortex to retain a physical hinge of residual bone. The osteotomy is carefully and slowly wedged open, using limited force with two laminar spreaders until the drill holes match the screw holes in the plate (Fig. 5). Finally, the plate is inserted and fixed with locking screws. A final check of the osteotomy and plate positions are obtained with fluoroscopy and the wound is closed in layers. For tibial osteotomies, a standard medial approach is used for the
patients that underwent a valgus correction (n = 3). One patient underwent a lateral approach varus correction on the tibia. No drains are used and a compressive dressing applied. The patients are instructed to mobilise their knee and ankle, but non-weight bearing is advised for three weeks followed by progressive weight bearing.

Post-operative AP and lateral radiographs were taken for all patients, to be repeated at three and six weeks and three months post-operatively. The correction angle of the open wedge was measured on the AP and lateral radiographs (Fig. 6). A full leg standing radiograph was taken at six weeks for measurement of the HKA angle. The patient with the tri-planar correction was evaluated using a post-operative CT scan, to facilitate the measurement of the axial correction.

Results
All osteotomies could be planned based on the information provided on the full leg standing radiograph and the CT scan (Table I). No patients were lost to follow-up or excluded from the study after initial enrolment. In all cases, the guides could be fitted to the bone through a standard exposure. The mean length of the incision was 13 cm (10 to 15) for the femoral osteotomies and 12 cm (9 to 14) for the tibial osteotomies. In the first three femoral cases and the first two tibial cases, small parts at the periphery of the guide were removed to allow its introduction without extending the wound.

All patients healed well without complications, except the triple plane correction (MM). This correction was carried out on a previously injured limb and the patient was
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The authors acknowledge several weaknesses. Firstly, there was a potential bias towards patients interested in the new technology and who had complex deformities as they were more motivated to participate in the study protocol for the alleged advantage in the use of the guides. This explains the relative bias towards femoral osteotomies. However, three patients with constitutional varus of the tibia were included, (which is the most common deformity encountered in clinical practice) and there were five patients with just a single plane deformity of the femur. Therefore a good case mix was obtained, demonstrating a spectrum of deformities. Secondly, the technique investigated was limited to opening wedge osteotomies. The authors adhered to this technique for reasons of reproducibility and it is important to understand that the presented results cannot simply be extrapolated to the technique of closing wedge osteotomy without additional study.

Our first research question was whether CT scan data can be used for planning of correction of angular deformity around the knee. Although most published literature features 3D pre-operative planning for lower limb osteotomies using CT free methods, several studies have used CT images to calculate angular deformities and to plan osteotomies around the knee. In some cases, the use of CT free navigation systems is validated with CT data as a gold standard.

The authors found that 3D pre-operative planning is crucial in defining the necessary correction, especially in cases where bi and tri planar corrections are required. Use of the normal contra-lateral side has been described for long bone deformities where manual methods and mathematical models are discussed. In addition to determining the required angular correction, it is also useful to identify the apex of the deformity, and hence, the level of osteotomy. The hypothesis was that lack of weight bearing information may show a discrepancy in the angular values calculated from CT and radiographic data. Our results show that the coronal weight bearing radiograph HKA angle was generally higher than the coronal CT HKA angle. Hence, in the cases where the patients had abnormal contra-lateral limbs, the planned HKA was determined using information from both CT and radiograph to mitigate this effect. The results suggest that the mean difference was more pronounced in valgus than in varus deformity (-2.1° and -0.8°, respectively), however this effect was not statistically significant (p = 0.145).

The concern of radiation dosage arising from a full leg CT scan was not addressed in this study. Hankemeier et al postulate that the total fluoroscopy radiation time was significantly reduced with the use of a navigation system. As confidence grew in the use of the guides, fluoroscopic control during the last cases performed was limited to one image confirming the position of the guide, one image on the position of the osteotome close to the hinge, and one image confirming final osteosynthesis with plate and screws. The imperial knee protocol, developed by Henckel et al at Imperial College London, which is used for computer aided planning in knee replacement surgery, generates a radiation dosage equivalent to that of one long leg standing radiograph. While the required scan region for an osteotomy will be larger than that for knee replacement, the authors believe that with further work, similar results can be achieved with a CT protocol and reduced intra-operative radiation time that will justify the use of the system.

The second research question dealt with the feasibility of fitting the guide on the bone using a conventional surgical exposure. In the first cases, the dimensions of the guide...
were slightly reduced with bone nibblers to accommodate the available space with standard exposure. This was not necessary as surgeons and engineers gained experience, and the fit of the guide was snug and stable in all cases. The large cortical surface contact of the guide, the absence of slippery cartilage and the overall volume may explain its superiority over similar TKR guides.\(^2\)

The third research question was about the accuracy of projected osteotomy in relation to the pre-operative plan. While there are many methods advocated for pre-operative planning,\(^2\)\(^3\)\(^4\) it is clear that translating the plan to the actual surgical procedure is a crucial and difficult step.\(^2\)

The HKA angle is often used as a measure of surgical outcome with lower limb osteotomies.\(^3\)\(^1\)\(^3\)\(^2\)\(^5\)\(^2\)\(^6\) The results show that planned and post-operative HKA angle deviation had a mean of 0.3° (-1 to 2, SD 0.75). The difference in wedge angles in coronal, sagittal and in one occasion, axial planes are all within a range of -1° to -2°. In conclusion, these results are very promising and prove that this concept is feasible from the standpoint of pre-operative software based planning, surgical application and boasts accuracy of outcomes in terms of measurement. As such there is a sound basis for setting up a randomised controlled trial against standard techniques.

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References