Fixation stability of opening- versus closing-wedge high tibial osteotomy

A RANDOMISED CLINICAL TRIAL USING RADIOSTEREOMETRY

Valgus high tibial osteotomy (HTO) is a well-established technique for the treatment of osteoarthritis of the medial compartment of the knee. The aim is to change the load distribution across the knee from the diseased medial part to the healthy lateral part in order to reduce pain, slow the degenerative process and to delay the requirements for total knee replacement. The stability of the initial fixation in HTO has been evaluated in biomechanical and clinical studies. There have been few which have been specifically aimed at testing and comparing fixation stability after medial opening-wedge (OW) and lateral closing-wedge (CW) HTO. These studies used fixation techniques which did not offer the best initial stability from a biomechanical perspective. Furthermore, the type of fixation used medially and laterally were not comparable, such as staple fixation placed laterally compared with plate fixation medially. Radiostereometric analysis (RSA) is an accurate technique for evaluating the movement of implants and bones. It has been used in vitro as well as in clinical studies to measure the initial stability of fixation and the post-operative stability at specific intervals after HTO.

Protocols for rehabilitation after HTO differ according to the osteotomy technique and the method of fixation. Full weight-bearing is allowed according to the stability of the fixation and bone healing as found on follow-up radiographs. In OW-HTO weight-bearing may be delayed for up to six weeks post-operatively, depending on the fixation technique, with full weight-bearing deferred for up to ten weeks. In CW-HTO full weight-bearing is allowed usually after partial weight-bearing for six weeks at 15 kg.

Many studies have shown good short- and mid-term follow-up results for both OW- and CW-HTO. Newer fixation techniques for HTO using so-called angle-stable implants have not yet been tested in a randomised, clinical trial involving RSA with comparison of medial and lateral techniques while following similar rehabilitation protocols.

We therefore set out to test and compare the initial fixation stability of angle-stable implants in OW- and CW-HTO using RSA in a randomised, controlled study. Our primary aim was to determine if there was any difference in the primary stability and ability to retain the correction between opening and closing-wedge techniques. We hypothesised that there was no difference between the two.
The secondary aim was to identify if there is a difference in functional outcome at follow-up.

**Patients and Methods**

With the approval of the medical Ethics Committee, patients aged between 18 years and 70 years who were scheduled for their first osteotomy were prospectively recruited between December 2001 and August 2004 into a randomised, clinical trial comparing OW- and CW-HTO. Randomisation was done before the start of the trial, using a computer-generated random allocation to both groups, in blocks of four per participating surgeon (Block Stratified Randomisation version 4.4; S. Piantadosi, Baltimore, Maryland). The patients were not told about the allocation and the participating surgeons were informed just before surgery.

The inclusion criteria were unilateral osteoarthritis of the medial compartment of the knee with a varus mechanical axis deformity of less than 12° and a body mass index (BMI) < 30 kg/m². Patients with rheumatoid arthritis were excluded, as were those with insufficiency of the medial collateral ligament, patellofemoral symptoms or previous surgery on the same knee. The mean age at the time of surgery of the 42 patients (27 men and 15 women) was 53 years (40 to 68). A total of 23 underwent OW-HTO (group 1) and 19 CW-HTO (group 2), with all included patients being analysed. In all knees the aim was an overcorrection to a mechanical axis of 3° of valgus. Standard planning techniques for HTO were used to determine the amount of correction needed in each patient on standing whole-leg radiographs. Figure 1 is a flow chart detailing the patient groups and treatment.

Two experienced surgeons (ABW, RJvH) performed all the osteotomies in a similar fashion according to standard techniques. Angle-stable fixation was obtained using lateral or medial TomoFix plates and screws (Synthes GmbH, Oberdorf, Switzerland) (Fig. 2). In group 1 a ChronOS-β-Tri-Calcium Phosphate wedge (Mathys Ltd, Bettlach, Switzerland) was inserted in order to facilitate bone growth but this conferred no additional advantage to fixation stability. In both groups the patients were mobilised using two crutches post-operatively and were allowed 15 kg of weight-bearing for six weeks. Thereafter all patients started full weight-bearing.
For the RSA measurements, five to nine tantalum beads (1.6 mm) were implanted during surgery in the proximal and distal part of the osteotomy with a special insertion instrument (Mathys Ltd). At one to three days post-operatively, after mobilisation had started, baseline RSA radiographs were taken. RSA follow-up images were taken at six weeks and at three, six, 12 and 24 months post-operatively. A digital radiology system (Agfa-Gevaert AG, Rijswijk, The Netherlands) and direct digital RSA radiographs with 165 dpi and 11-bit grey scale resolution were used. The radiographs were analysed using the RSA-CMS software, version 4.0 Beta (Medis Medical Imaging Systems BV, Leiden, The Netherlands) to calculate migration. This was defined as micromovement of the centre of gravity of the proximal tibial part relative to the distal tibial part in terms of translation and rotation around the three cardinal axes (Fig. 3). The mean migration in all directions was calculated at six weeks and at 12 and 24 months post-operatively in both groups, as was the increase in migration during three time intervals, namely, from zero to six weeks, six weeks to 12 months and 12 to 24 months.

In order to assess the detection limit, double examinations were made in 40 patients at the six-week follow-up evaluation. These radiographs, 40 for translations and 38 for rotations, were used to calculate the upper limits of the 99% confidence interval (CI). This resulted in a detection limit of 0.3 mm, 0.2 mm and 0.4 mm for the translations along the x, y and z axes. The detection limit for the rotations was 0.9°, 0.7° and 0.6° around the x, y and z axes. Using an a priori calculation with \( \alpha = 0.05 \), power = 90\%, and SD = 0.9, 17 patients per group were needed to detect a significant difference of 1 mm or 1°.

The measured migration was categorised into two groups, \(< 1 \text{ mm} \) and \(< 2° \) in any direction or \( > 1 \text{ mm} \) and \( > 2° \) in any direction. The osteotomies in the first group were considered to be stable. The movement in the latter group was considered to be of possible clinical significance. Furthermore, these possible clinical values (1 mm and/or 2°) were defined to represent a significant difference between the groups.

The clinical outcome was measured using the Lysholm score pre-operatively and post-operatively at six weeks and at 12 and 24 months. Pain was scored on a visual analogue scale (VAS) with 0 as ‘no pain’ and 10 as ‘worst imaginable pain’. Regular anteroposterior and lateral radiographs were taken within seven days post-operatively and after 12 and 24 months as part of the clinical routine. Whole-leg standing radiographs were taken pre- and post-operatively to calculate the correction of the alignment.

**Statistical analysis.** This was performed using SPSS version 12.0.1 for Windows (SPSS Inc, Chicago, Illinois). Student’s \( t \)-test was used to compare the Lysholm and pain scores. The RSA data were not normally distributed, because of some outliers, and therefore non-parametric methods were used. The Mann-Whitney \( U \) test was used to compare the migration at the three follow-up examinations between the two groups. The non-parametric Wilcoxon signed-rank sum test was used to detect a substantial increase in migration between two consecutive follow-up evaluations within each group. Besides identifying any statistical significance it was recognised that any increase in migration should exceed the detection limit to be considered relevant. Tests were two-sided and p-values < 0.05 were considered to be statistically significant.
Results

Clinical findings. No intra-operative or early post-operative complications occurred. However, in nine patients an intra-operative fracture of the opposite tibial cortex was diagnosed on post-operative radiographs, one in group 1 and eight in group 2. There were no differences between the groups in the time to regain knee function and full weight-bearing. At three months 61% of the patients in group 1 and 63% in group 2 were able to walk full weight-bearing without any walking aid. At six months only one patient (group 1) used a walking stick. On average the clinical outcome was between satisfactory and good (Table I). The mean Lysholm scores pre-operatively and at the different post-operative evaluations were similar in both groups. Function improved post-operatively, and at the 24-month follow-up. The mean Lysholm score pre-operatively increased from 63 (SD 16) to 86 (SD 14) in group 1 (p = 0.0001) and from 58 (SD 13) to 80 (SD 18) in group 2 (p = 0.001) (p = 0.164).

The mean pre-operative VAS scores were similar in the two groups, 56 (SD 22) and 59 (SD 16) respectively. At 24 months the mean VAS for pain was 15 (SD 25) in group 1 (p = 0.005) and 23 (SD 32) in group 2 (p = 0.002). This difference was not statistically significant (p = 0.222).

The mean varus angle pre-operatively was 5.0° (SD 2.6) in group 1 and 6.8° (SD 3.1) in group 2, with a planned mean correction angle of 8.1° (SD 3.1) and 9.7° (SD 2.9) respectively. The mean angle of correction post-operatively was 3.4° (SD 3.0) and 0.9° (SD 2) respectively. The undercorrection, from the aim of 3° of valgus, in group 2 was statistically significant (p = 0.001). There was an absolute undercorrection with the alignment of the leg still in varus post-operatively in one patient in group 1 and five patients in group 2. The clinical outcome ranged from fair to good and excellent. There was no relationship between the post-operative alignment of the leg and the clinical outcome. All the osteotomies had united at follow-up at 12 months.

RSA. The mean translation at 24 months was < 0.4 mm and the mean axial rotation (Ry) was < 0.2° in both groups (Table II). The mean varus rotation (Rz) was < 1° with the largest rotational movement being seen around the x-axis (Rx), tilting in the dorsal direction (Fig. 3). The mean dorsal tilting of the proximal tibial part at six weeks in group 1 was larger than that in the group 2 (Table II), but the difference was not statistically significant (p = 0.346). In both groups the dorsal tilt increased significantly between six weeks and 12 months, resulting in a similar amount of dorsal tilting in both groups after one year (Table III) with minimal change occurring at follow-up at 24 months (group 1, p = 0.012, group 2, p = 0.01; difference between groups, p = 0.879). The rotation in the varus direction showed different patterns in both groups. In group 1 the greatest rotation was found at between six weeks and 12 months whereas in group 2 it was seen at six weeks post-operatively. In both groups varus rotation stabilised in the second year. The final results showed a slightly larger, but not significant, overall migration in group 2 compared with group 1 (p = 0.152). The number of osteotomies with micromovement during the first year was not significantly different between the groups (p = 0.726). In the second year of follow-up all the osteotomies had stabilised (Table IV). Except for one patient, all movement after the first year was within the detection limit of the RSA measurement.

In the patient in group 1 who sustained a fractured lateral cortex, the proximal aspect of the tibia tilted 6.1° in the dorsal direction during the first three months. In the rest of the first year, it tilted 1.5° in the opposite direction. At 12 months, varus rotation of 2° and dorsal translation of 2 mm were also observed. In the patient’s opinion the overall clinical result was satisfactory. In the second year of follow-up the osteotomy became stable.

In the eight patients in group 2 with fractured cortices, two showed migration of the proximal aspect of the tibia greater than our threshold of clinical relevance (Table IV). In one patient, translation as well as rotation increased during the first 12 months, with 8.4° of dorsal tilt being the largest movement. In the second year the proximal tibia tilted slightly (1.8°) in the opposite direction, which might have been due to an error in the RSA measurement, since the osteotomy had united on a radiograph at 12 months. Clinically, the outcome slightly improved in the second year, but the patient’s outcome was ‘poor’. Knee alignment at one year was 3° of varus. The micro-movements in the other patient were smaller and over a shorter period, 1.8° of dorsal tilt and 3.9° of varus rotation during the first three months, after which the osteotomy stabilised. Alignment of the knee at 12 months was 2° of varus and the patient was asymptomatic. In two other patients in group 2 with intact cortices marked migration occurred. In one patient rotations in all axes were recorded during the first three months, 5.2° of dorsal tilt, 2.1° of internal rotation and 1.6° of varus rotation, after which the osteotomy stabilised. At 12 months, alignment of the knee was 1° of varus, pain had increased and function was reduced. These scores stabilised in the second year and resulted in a fair overall score. The other patient showed an increasing varus rotation of up to 4.1°.
during the first year, which stabilised in the second year. Alignment of the knee was 1° of varus and the patient was asymptomatic with improved function. The overall score at 24 months was excellent.

Although the mean dorsal tilting (1.1°, Rx = 0.64) and the mean varus rotation (0.7°, Rz = 0.70) were slightly larger in the ‘fractured’ group (Rx = 0.171, Rz = 1.35, respectively) there was no significant difference (Rx, p = 0.260; Rz, p = 0.269) in the mean migration between those in group 2 with fractured cortices, and those with intact cortices. The number of osteotomies, which showed micromovement of clinical relevance (> 1 mm and/or > 2°) during the first year of follow-up, did not differ significantly between the groups (p = 1.000, Table IV).

### Discussion

The direction of the largest amount of displacement in both groups was dorsal tilting which increased significantly after six weeks. This might have been due to the introduction of full weight-bearing at this stage causing increased pressure on the tibial plateau and a posteriorly directed force. Displacement in this direction increases the tibial slope (Fig. 3). However, in both groups generally the increase in the slope was small. The mean dorsal tilt in group 1 was 1.2° and in group 2 was 1.1° at 24 months.

Lateral closing-wedge osteotomies supposedly offer greater initial stability because of the larger cortical contact area.1 Medial opening-wedge techniques are preferred nowadays because they are safer and easier to perform.1,21 Post-
operative stability, however, greatly depends on the ability of the fixation method to withstand the forces which act upon the proximal tibia. Biomechanical studies have shown great differences between the various available fixation methods in HTO.\textsuperscript{7} According to Agneskirchner et al\textsuperscript{7} rigid plates with locking bolts offer superior stability. Flamme et al\textsuperscript{9} tested several lateral implants in closing-wedge HTO in a cadaver model and found that staples and an external fixator offered the greatest initial stability compared with a blade plate and a semitubular plate. Angle-stable implants were not tested.

RSA was used by Gaasbeek et al\textsuperscript{16} to compare medial with lateral techniques using a rigid plate and locking bolts in both as fixation. They tested the initial stability in a cadaver model using a materials testing system and found no difference in the initial stability between opening- and closing-wedge techniques. Magyar et al\textsuperscript{13} and Pape et al\textsuperscript{17} used RSA clinically to measure stability in HTO. The latter compared stability in patients who had an accidental fracture of the opposite medial cortex with those with an intact cortex in lateral closing-wedge osteotomy, but did not compare the medial and lateral techniques. Fracture of the opposite cortex caused increased instability. A comparison of lateral staple fixation to hemicallotasis medially showed that there was less displacement in the hemicallotasis group.\textsuperscript{13} In our series, opening- and closing-wedge osteotomies were compared using the same fixation method, allowing a direct comparison. According to our RSA data and our criteria for stability all the osteotomies became stable after 12 months in both groups.

There are few randomised trials which compare opening- to closing-wedge techniques. Brouwer et al\textsuperscript{12} compared the use of staples for lateral fixation with that of a Puddu plate (Arthrex Inc, Naples, Florida) for medial fixation in a series of 92 patients undergoing HTO. They concluded that closing-wedge osteotomy achieved a more accurate correction with less morbidity, but found no difference in the clinical outcome. Magyar et al\textsuperscript{28} compared the use of lateral staples with hemicallotasis and found that the latter gave more precise and predictable results, and less loss of correction, but again there was no difference in the clinical results. In a prospective cohort study, comparison of a lateral AO/ASIF L-plate (AO, Davos Platz, Switzerland) with a medial Puddu plate showed a higher rate of nonunion, loss of correction and failure of the implant in the opening-wedge group.\textsuperscript{18} Patients were less satisfied in this group. However, in all three studies different techniques of fixation were compared. Any difference can be attributed in part to the nature of the osteotomy technique and the method of fixation. In our series no difference was found in the rate of complications, the rate of bone healing, the clinical outcome and improvement in pain at short-term follow-up. Pain and knee function improved significantly at the short-term follow-up.

In a study using a tibial model the influence of the integrity of the opposite lateral cortex in medial opening-wedge HTO showed disruption of the opposite cortex which led to increased micromovement.\textsuperscript{29} Repair using staples restored stability. In clinical studies fracture of the opposite cortex occurred more frequently in closing-wedge than in opening-wedge HTO, but without major consequence and without malalignment.\textsuperscript{18,30} In the opening-wedge HTO a fracture of the lateral cortex led to a tendency to recurrent varus malalignment. Our findings were similar, but all osteotomies became stable at 12 months. In spite of the fractured cortex no difference in the outcome was found in these patients. Fracture of the opposite cortex causes either a varus (medial fracture) or a valgus directed force on the construct but in our series the fixation technique was strong enough to withstand these increased forces. The effect of the amount of correction on the clinical outcome in HTO has been well documented\textsuperscript{6,18,22,31} and Brouwer et al\textsuperscript{12} and Gaasbeek et al\textsuperscript{16} both reported undercorrection in their opening-wedge groups. By contrast, in our series there was undercorrection in the closing-wedge group and a more exact correction was achieved in the opening-wedge group. No significant differences in migration were seen at the different intervals of the 24-month follow-up. From this we inferred a difference in the mode of fixation was not the cause of the loss of correction but rather that the undercorrection in the closing-wedge group occurred at the time of operation. In spite of the undercorrection in this group

<table>
<thead>
<tr>
<th>Group</th>
<th>0 to 6 wks</th>
<th>6 wks to 12 mths</th>
<th>12 to 24 mths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable</td>
<td>ØW</td>
<td>CW-i</td>
<td>CW-f</td>
</tr>
<tr>
<td>&lt; 1 mm and/or &lt; 2°</td>
<td>21</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Micromovement</td>
<td>&gt; 1 mm and/or &gt; 2°</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

1464 J. W. H. LUITES, J.-M. BRINKMAN, A. B. WYMENGA, R. J. VAN HEERWAARDEN

THE JOURNAL OF BONE AND JOINT SURGERY
and the small difference in posterior tilt there were no differences in clinical outcome between the groups.

The weight-bearing programme was the same in both groups. Whereas closing-wedge osteotomies are supposed to have higher initial stability because of a larger bone contact area and more rapid post-operative stability because of faster healing, the opening-wedge technique secured by the TomoFix implant was equally stable affording sufficient initial stability to withstand the force exerted on the tibial plateau. A faster return to full weight-bearing may be possible. Takeuchi et al32 reported that simultaneous opening-wedge HTO patients were mobilised with immediate full weight-bearing without any reported loss of correction.

In conclusion, our RSA measurements showed no differences in the stability of opening- and closing-wedge HTO, secured by TomoFix plates at two years. Both methods resulted in significantly reduced pain and improved function in patients with osteoarthritis of the medial compartment of the knee. Although not of clinical significance in this series, the closing-wedge HTO tended to provide an under-correction. We recommend that HTO is performed using a medial opening-wedge technique secured by a TomoFix plate.

We thank E. R. Valstar, H. G. de Gouw and the Department of Radiology for their contributions to the study. This study was supported by the AO Foundation grant number 01-W305. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References