Fixation stability and new surgical concepts of osteotomies around the knee

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Fixation stability and new surgical concepts of osteotomies around the knee

Fixatie stabiliteit en nieuwe chirurgische concepten van osteotomieën rond de knie

(With a summary in English)

Proefschrift

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Chapter 1

Introduction

Osteotomy around the knee, in order to re-align the mechanical leg axis, thereby unloading certain degenerated and painful regions of the joint, was once a well-established technique in the treatment of uni-compartmental osteoarthritis of the knee. To a large extent this was because of a lack of other treatment options [1]. In more recent years, osteotomy around the knee has increasingly been replaced by total knee arthroplasty (TKA), which has proven to be a very successful and reliable procedure [2]. Compared to joint replacement, osteotomy is considered a technically more demanding procedure with a less predictable outcome, and associated with significant complications [3, 4].

Nevertheless, joint replacement has its own drawbacks. Especially in the young and active population, results are less satisfactory with early failure due to mechanical loosening [5]. Also, the importance and impact of acute and chronic prosthetic infection has become more apparent, and has led to a re-appraisal of corrective techniques which are able to preserve the joint [6-10]. Additionally, in the 1990s, due to questions raised in sports medicine, the role of correction of varus malalignment in the treatment of ligamentous injuries and imbalance of the knee also led to a re-appreciation of osteotomy [11]. In 2003 "The principles of Deformity Correction" by Dror Paley was published, redefining knowledge on the planning and correction of complex deformities [12]. Better guidelines have since been formulated for the selection of candidates for osteotomy by The International Society of Arthroscopy, Knee Surgery and Orthopedic Sports Medicine (ISAKOS) [13].

In the past, the surgical techniques for osteotomies were either dependent on fairly unstable methods of fixation, e.g. staples or just a plaster cast, or on difficult to use implants, i.e. the AO angled blade plate, making the surgical procedure more complex. As a result of new fixation techniques that were initially developed in fracture surgery, new options became available for the fixation of osteotomies [14, 15]. Specifically designed fixation plates based on the locking-compression-plate (LCP) concept, using so-called angle stable locking bolts developed in fracture surgery, hypothetically providing superior initial stability, have been adapted for use in osteotomy surgery [16, 17]. New opening-wedge tibia and femur osteotomy techniques have since been introduced, further decreasing the surgical difficulty of these procedures and increasing its predictability [18]. All these factors have led to a renewed interest in osteotomy around the knee. Depending on the anatomical location of the deformity to be corrected, osteotomies around the knee can be divided in ones below the joint line: High Tibial Osteotomy (HTO), and osteotomies above the joint line: Supracondylar Osteotomy (SCO) of the distal femur.

High tibial osteotomy

High tibial osteotomy (HTO), in order to correct a varus mal-alignment, is a well-established technique in the treatment of medial compartment osteoarthritis (OA) of the knee [18,19]. Most commonly used are medial opening-wedge (OW) and lateral closing-wedge (CW) techniques. Many studies have shown good short and mid-term follow-up results of both OW and CW HTO [20-26].

The goal in either is to change the load distribution across the knee joint from the diseased medial part to the relatively healthy lateral part to reduce pain, slow the degenerative process and postpone the placement of an artificial joint [27-30]. Medial OW techniques are preferred because of the ease of the procedure; only one saw cut is needed, the approach is less extensive, minimizing soft tissue damage, no fibula osteotomy is needed and the peroneal nerve is avoided. Furthermore OW HTO does not cause a change in shape of the proximal tibia which could complicate later placement of a TKA [31]. Concerns however exist regarding the ability of the fixation technique to withstand the forces that act on the proximal tibia; loss of correction leads to poorer results [23, 28, 32].

Ideally the fixation technique used should be strong enough to allow for early joint motion and early full weight bearing postoperatively. Early motion and weight bearing reduces the risk of venous thrombosis, joint stiffness, and muscle atrophy. Rehabilitation protocols after HTO differ according to osteotomy technique and fixation method used. Full weight bearing is allowed depending on the assumed primary fixation stability and bone healing as found on follow-up radiographs. In CW HTO usually after 6 weeks of partial weight bearing (15 kilograms), full weight bearing is allowed, similar to lower extremity fracture treatment. In OW HTO weight bearing may be delayed up to 6 weeks postoperatively, or longer, depending on the fixation technique used [33, 34].

Angle stable fixation plates with locking bolts (LCP) have been designed for use in OW HTO [16]. In biomechanical experiments, osteotomies stabilized with these plates clearly provide superior initial stability compared to other medial fixation devices, and equal stability compared to similar plates used for CW HTO [35, 36]. With these implants, immediate full weight bearing appears to be possible [37, 38].

Clinical studies have been performed, specifically aimed at testing and comparing fixation stability and ability to retain the correction after medial OW and lateral CW HTO [39-44]. In most of the studies that are available however, fixation techniques that do not offer the best initial stability from a biomechanical standpoint were used, unfortunately. Furthermore, types of fixation used medially and laterally were not always comparable, e.g. staple fixation lateral compared to plate fixation medial.

Radiostereometry (RSA) is an accurate measurement technique to evaluate motion of implants and bones [45-47]. RSA has been used in vitro as well as in clinical studies to measure initial fixation stability and postoperative stability at specific intervals after HTO, but not in a randomized controlled trial (RCT) [36, 41, 48].

Thus, whereas biomechanical experiments have clearly shown the benefit of LCP over conventional plates in OW HTO, it is still largely unclear which technique (OW or CW), and which rehabilitation protocol (partial or full weight bearing) should be used to achieve the fastest recovery after HTO. Therefore research questions were: *1) Which HTO technique, CW or OW, is more stable initially?* and *2) Is immediate full weight bearing safe?*

Ad 1. A RCT was designed to test and compare the initial fixation stability of angle-stable LCP concept based implants in Opening-wedge HTO and Closing-wedge HTO using RSA. Primary research questions were if there is a difference in primary stability and ability to retain the correction between OW and CW techniques; the hypothesis was that there is no difference between the two. Secondary outcome measure was if there is a difference in functional outcome at follow-up.

Ad 2. To document the safety of early full weight bearing, migration at the osteotomy was measured again using RSA in patients after OW HTO rehabilitated with an early full weight bearing protocol. The primary research question was if there is a difference in motion at the osteotomy because of the early full weight bearing as measured by RSA, compared to a historical cohort of patients rehabilitated using a standard protocol. Secondary research questions were if there was a difference in time to walking without aid, improvement in pain, and knee function.

Supracondylar osteotomy

Whereas valgus HTO is an often used and successful technique; varus supracondylar osteotomy (SCO), indicated for lateral compartment osteoarthritis (OA) of the knee, has not had the same success or widespread use [49-54]. The goal in SCO is similar to HTO, to shift the load from the diseased towards the healthy compartment of the knee, in order to reduce pain, improve function and delay knee replacement surgery [55]. Lateral compartment (valgus) OA however occurs much less frequently than medial (varus) OA and varus SCO is a technically more demanding procedure, making it a lot less popular treatment option [51, 52, 56, 57]. Complication rates related to the failure of fixation up to 16% have been reported [58]. Similar to HTO the osteotomy may be performed using a (lateral) OW, or a (medial) CW technique [53, 55, 59, 60]. In most available literature, a medial single-plane closing-wedge technique stabilized with a conventional angled blade plate, based on the principles of rigid compression of the osteotomy, is used.

No comparative studies, let alone RCT's, are available comparing the various options. Generally, medial CW SCO is considered a technically demanding procedure; especially the correct insertion of the blade plate is difficult; an error in the angle of its insertion can cause undue changes in correction in all planes, there is little room for re-inserting it without decreasing its hold. Furthermore, fracture of the opposite intact cortical hinge may be caused by the surgical procedure itself as large forces are transmitted over the hinge during preparation and insertion of the blade. In addition to that, the conventional procedure requires a large incision and an extensive subvastus approach to the femur. Finally, in this procedure the soft tissue gliding mechanism on the anterior side of the femur is disrupted. Lateral OW techniques appear to be technically easier, mainly because only one saw cut is needed, but have been associated with bone healing problems and soft tissue irritation by the implant [55, 61]. They can however be performed through a less invasive approach. Plates for fixation, based on the LCP concept are available for both OW and CW SCO. As with tibial osteotomy, stability of the plate and osteotomy construct after SCO is crucial in order to retain the achieved correction during functional postoperative rehabilitation. Whereas there is biomechanical data on the stability and stiffness of plates and techniques used for HTO, it is lacking in SCO. There is no sound scientific basis on which to decide between OW and CW, and LCP and conventional plating techniques. Therefore the research question related to this topic was: *3) Which SCO technique has the highest initial stability?*

Ad 3. In order to provide baseline data on the stability and stiffness of the various techniques and implants for SCO, a biomechanical study was designed, much like the work done in the tibia on HTO by Agneskirchner et al [35]. A composite biomechanical femur model with axial and torsional cyclical loading was used as a basis for comparison. Simulated physiological loading and subsequent loading to failure were applied using a material testing machine (MTS), and movement at the osteotomy was measured using a three-dimensional (3D) motion-analysis system. The specific research goals were to compare the stability and stiffness of OW and CW techniques, LCP and conventional plates and the influence of the saw cut direction on stability and stiffness.

An important disadvantage of the standard single-plane medial closing-wedge technique is the position of the osteotomy hinge point and saw cuts relative to the patello-femoral joint and the soft-tissues gliding surface on the anterior side of the femur. The saw cuts of the osteotomy need to be positioned proximally in the meta-diaphyseal area of the distal femur, proximal of the trochlea in order to avoid the patello-femoral joint. This area is known for its lesser tendency for bone healing as compared to the metaphyseal bone, and even a correctly placed osteotomy may disrupt the soft-tissue gliding mechanism of the quadriceps system, which causes a hematoma, and subsequent pain and swelling, potentially slowing rehabilitation.

To address this problem, a modification of the oblique medial closing-wedge technique has been developed, adapted from the bi-plane tuberosity cut that can be used in HTO. Compared to the single-plane technique, in the bi-plane technique the two saw cuts for the closing-wedge are made only in the posterior 3/4 of the femur after which an ascending saw cut is performed in the anterior part of the femur, completing the osteotomy. The ascending saw cut enables a more distal positioning of the closing-wedge saw cuts in the metaphyseal bone of the distal femur, which has better bone healing potential. Additionally the soft tissue gliding mechanism is not disrupted as the anterior ascending bone cut ends more proximal on the anterior cortex, avoiding the patello-femoral compartment. Furthermore, the ascending saw cut increases the cortical contact area, which should in theory further enhance stability, especially under torsion loads, and promote bone healing. But again the exact consequences for stability of the construct are unknown. Therefore the related research question was: *4) Which effect does this newly developed bi-plane technique have on stability of the osteotomy?*

Ad 4. A second biomechanical study was designed to measure the stability and stiffness of this newly developed bi-plane technique, using the same test setup as in the first biomechanical study, and to compare the results. Research question was if the new bi-plane medial closing-wedge technique showed improved stability and stiffness under axial and torsional loading, compared to the standard single-plane medial closing-wedge technique.

In an effort to improve the fit of the plate to the femur, to optimize screw-hole direction and minimize the potential for soft tissue irritation of an existing LCP based implant, the Tomofix Medial Distal Femur (MDF) plate (Synthes GmbH, Oberdorf, Switzerland), a newer design was developed and tested by its manufacturer. In their tests, however, the implant provided less stability and failed earlier as compared to the previous version. The methodology used in their tests led to questions on the validity and the clinical relevance of the so-called open gap model [17, 62-66] in the testing of closing-wedge osteotomy fixation techniques. Our next research question therefore was: *5) What is the influence of the test model used on the outcome of the tests; does using simulated physiological loading change the outcome in biomechanical testing of plates for SCO?*

Ad 5. For this (third) biomechanical study, both the current and the new design of the Tomofix MDF were tested again, but this time using a simulated physiologic postoperative test model for comparison. The test model was the same as used in the two previous biomechanical studies in this Thesis. The study hypothesis was that, in contrast to the open gap model test results, in our more physiological model there will be no difference in stability and stiffness between the two designs.

LCP concept based plates not only provide stability for fractures and osteotomies but the use of these plates also enables less invasive surgical approaches. For lateral OW osteotomies an approach may be chosen similar to the minimally invasive technique used in fracture surgery [67]. In fracture surgery a lateral Minimally Invasive Percutaneous Plate Osteosynthesis (MIPPO) technique has shown to disrupt femoral blood supply less than the traditional open lateral approach, subsequently soft tissue damage is minimized and bone healing potential optimized [68, 69]. For medial closing-wedge osteotomies, traditionally a medial subvastus approach is used. Vastus medialis atrophy caused by denervation and disrupted vascularisation resulting from the traditional approach may be prevented by a less invasive approach. The feasibility of a less-invasive approach to the distal medial aspect of the femur in SCO has not been documented previously. The anatomy of the medial side of the distal femur has been studied previously, but not with respect to osteotomy approaches. Our next research question therefore was: *6) Is a less invasive approach to the femur feasible, safe, and can it be used for SCO?*

Ad 6. To potentially minimize soft tissue damage and vascular disruption in the medial approach to the distal femur, a cadaver dissection study was designed to investigate the safety and feasibility of a less invasive medial approach to the distal femur.

This thesis thus aims to answer the following research questions in a number of clinical, anatomical, biomechanical and imaging studies that will be described in the subsequent chapters:

1) Which High Tibial Osteotomy technique, Closing-wedge or Opening-Wedge, is more stable initially?
2) Is immediate full weight bearing after Opening-wedge High Tibial Osteotomy safe, without undue risk of loss of correction?
3) Which Supracondylar Osteotomy technique, closing-wedge or opening-wedge, which method of fixation and which saw-cut direction has the highest initial stability?
4) Which effect does the newly developed bi-planar osteotomy technique for the distal femur have on initial stability?
5) What is the influence of the test model used on the outcome of the tests; does using simulated physiological loading change the outcome in biomechanical testing of plates for Supracondylar Osteotomy as compared to more traditional test models?
6) Is a less invasive approach to the medial side of the distal femur feasible, safe and can it be used for Supracondylar Osteotomy?

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Chapter 2

Fixation stability of opening- versus closing-wedge high tibial osteotomy: a randomized clinical trial using radiostereometry

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Abstract

Valgus high tibial osteotomy for medial compartment osteoarthritis of the knee can be performed using medial opening- and lateral closing-wedge techniques. Lateral closing-wedge techniques supposedly offer greater initial stability. Stability after opening- and closing-wedge osteotomies fixed with angle-stable implants was measured and compared using radiostereometry (RSA) in a series of 42 patients, in a prospective randomized clinical trial.

There were no differences between the opening-wedge and closing-wedge patients in time to regain knee function and full weight bearing. Pain and knee function improved significantly in both groups without differences between both; all osteotomies healed within one year. RSA measurements showed no clinically relevant bone movements and no differences between both osteotomy groups.

Medial opening-wedge high tibial osteotomy wedge fixated with an angle-stable implant offers equal stability to a lateral closing-wedge technique. Both offer excellent initial stability and provide significantly improved knee function and pain reduction.

Introduction

Valgus high tibial osteotomy (HTO) is a well-established technique in the treatment of medial compartment osteoarthritis of the knee [1]. The goal is to change the load distribution across the knee joint from the diseased medial part to the healthy lateral part to reduce pain, slow the degenerative process and delay placement of an arthroplasty [2-6].

The initial fixation stability in HTO has been evaluated in biomechanical and clinical studies [7-11]. Few studies have been performed specifically aimed at testing and comparing fixation stability after medial opening- (OW) and lateral closing-wedge (CW) HTO [12, 13]. In these studies fixation techniques that do not offer the best initial stability from a biomechanical standpoint were used. Furthermore, type of fixation used medial and lateral were not comparable, e.g. staple fixation lateral compared to plate fixation medial.

Radiostereometry (RSA) is an accurate measurement technique to evaluate motion of implants and bones [14, 15]. RSA has been used in vitro as well as in clinical studies to measure initial fixation stability and postoperative stability at specific intervals after HTO [13, 16, 17].

Rehabilitation protocols after HTO differ according to osteotomy technique and fixation method. Full weight bearing is allowed depending on fixation stability and bone healing as found on follow-up radiographs. In CW HTO usually after 6 weeks of partial weight bearing, 15 kilograms (kg), full weight bearing is allowed, similar to fracture treatment. In opening-wedge HTO weight bearing may be delayed up till 6 weeks postoperatively, depending on fixation technique [1, 18]. Time until the patient is fully weight bearing however can take up to 10 weeks [19].

Many studies have shown good short and mid-term follow-up results of both OW and CW HTO [20-26]. Newer fixation techniques for HTO using so called angle-stable implants have not yet been tested in a randomized clinical trial using RSA; comparing medial and lateral techniques and using similar rehabilitation protocols.

Therefore we set out to test and compare the initial fixation stability of angle-stable implants in OW HTO and CW HTO using RSA in a randomized controlled trail. Our primary research question was if there is a difference in primary stability and ability to retain the correction between OW and CW techniques; we hypothesized that there is no difference between the two. Secondary outcome was if there is a difference in functional outcome at follow-up.

Patients and methods

After approval by the medical ethics committee, patients, between the ages 18 to 70 with a Body Mass Index (BMI) < 30, scheduled for their first osteotomy were prospectively recruited from December 2001 till august 2004 for a randomized controlled trial comparing OW HTO and CW HTO. Randomization was done prior to the start of the trial, through a computer-generated random allocation to OW HTO and CW HTO, in blocks of 4, per participating surgeon (Block Stratified Randomization version 4.4, 1997, S. Piantadosi, Baltimore, Maryland). The patients were not informed about the allocation; the participating surgeons were informed just prior to surgery. Inclusion criterion was unilateral osteoarthritis of the medial knee compartment due to a mechanical axis varus deformity, less than 12°; the flow chart is presented in Figure 1. Patients with rheumatoid arthritis were excluded, as were patients with insufficiency of the medial collateral ligament, patella-femoral complaints or previous surgery on the same knee. The mean age at the time of surgery of the 27 men and 15 women was 53 years (40–68 years). Twenty-three patients underwent an OW HTO and 19 patients a CW HTO. In all knees the aim was an overcorrection to a mechanical axis of 3° valgus; standard planning techniques for HTO were used to determine the amount of correction needed in each patient on standing whole leg radiographs.

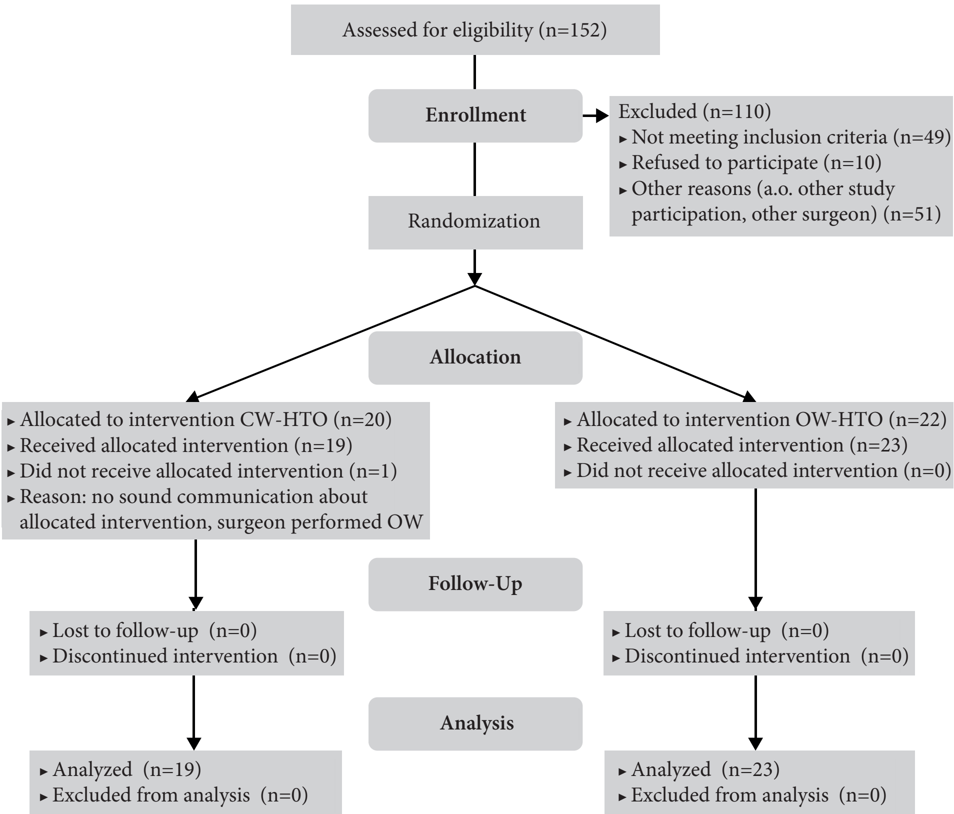

Figure 1. Flow chart according to consolidated standards of reporting trials (CONSORT) statement with the numbers of approached and excluded patients, as well as allocation of the randomized treatment and the analyzed patients (CW, closing-wedge; OW, opening-wedge; HTO, high tibial osteotomy).

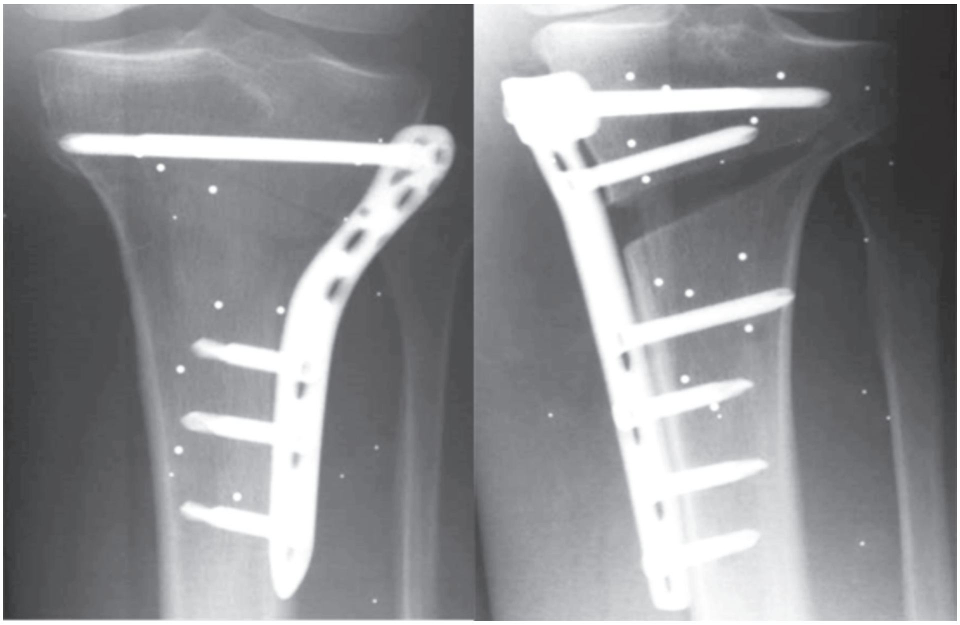

Figure 2. Radiographs that show the tantalum Radiostereometric analysis beads in (right) an opening-wedge high tibial osteotomy (HTO) with a medial TomoFix plate and (left) a closing-wedge HTO with a lateral TomoFix plate.

Two experienced surgeons performed all osteotomies in a similar fashion according to standard techniques. Lateral and medial TomoFix plates (Fig. 2) and screws (Synthes GmbH, Oberdorf, Switzerland) were used for fixation. In the opening-wedge group a ChronOS-β-Tri-Calcium Phosphate (TCP) wedge (Mathys ltd., Bettlach, Switzerland) was inserted in order to facilitate bone growth. This porous bone substitute has no additional value in fixation stability. In both groups the patients were mobilized between two crutches postoperatively and were allowed 15 kilograms (kg) of weight bearing for 6 weeks; thereafter all patients started full weight bearing.

For RSA measurements, 5 to 9 tantalum beads (1.6 mm) were distributed during surgery in the proximal and distal part of the osteotomy with a special insertion instrument (Mathys ltd., Bettlach, Switzerland). One to three days postoperatively, after mobilization of the patient, baseline RSA radiographs were taken. RSA analysis follow-up images were taken 6 weeks and 3, 6, 12, and 24 months postoperatively. 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 analyzed using the RSA-CMS software (version 4.0 Beta, Medis, Leiden, The Netherlands) to calculate migration [14]. Migration was defined as micro-motion of the center of gravity of the proximal tibial part relative to the distal tibial part, in three translation and three rotation directions (Fig. 3) [15].

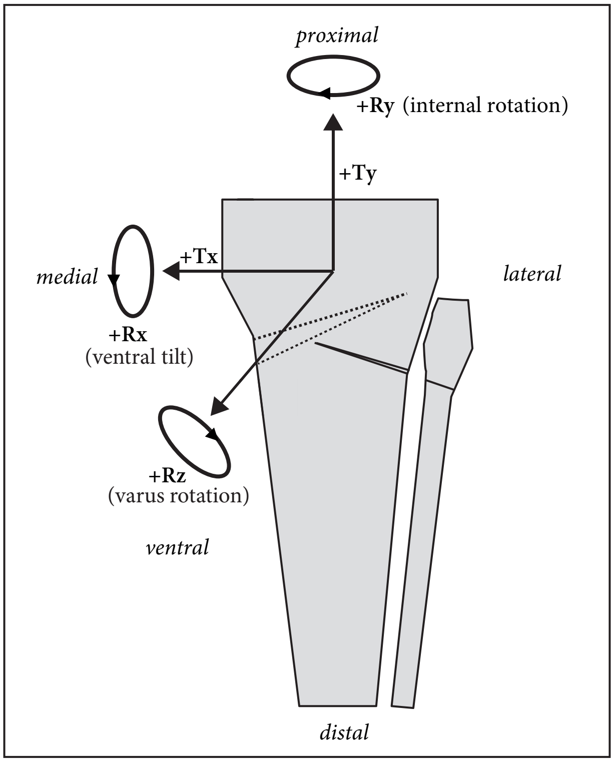

Figure 3. The six directions in which the migration of the center of gravity of the proximal aspect of the left tibia relative to the distal end was calculated. Rotation around the x-axis (Rx), ventral/dorsal tilt, influenced the tibial slope and rotation around the z-axis (Rz), varus/valgus tilt influences leg alignment (T, translation in mm; R, rotation in °; x, transverse axis; y, longitudinal axis; z, sagittal axis).

The mean migration in all directions was calculated at 6 weeks, 12 and 24 months postoperatively in both groups, as was the migration increase during three time intervals: from 0 to 6 weeks, 6 weeks to 12 months, and 12 to 24 months.

To assess the detection limit, double examinations were made in 40 patients at the 6-week follow-up evaluation. These radiographs, 40 for translational directions and 38 for rotational directions, were used to calculate the upper limits of the 99% confidence interval (CI) (Table I). This resulted in a detection limit of 0.3 mm, 0.2 mm and 0.4 mm for the translations in x, y and z directions. The detection limit for the rotations was 0.9°, 0.7° and 0.6° about the x, y and z axes. Using an a priori calculation with $\alpha=0.05$ and Power=90%, and SD=1.2, 18 persons per group were needed to detect a significant difference of 1 mm and/or 2 degrees.

The measured migration was categorized as; < 1mm and < 2° in any direction, and > 1mm or > 2° in any direction. The osteotomies in the first group were considered to be stable. The motion in the latter group was considered to be of possible clinical significance.

The clinical outcome was measured using the Lysholm score [27]; preoperatively and postoperatively at 6 weeks, 12 and 24 months. Pain was scored on a visual analogue scale (VAS). Regular AP and lateral radiographs were taken within 7 days postoperatively and after 12 and 24 months as part of the clinical routine. Whole leg standing radiographs were taken preoperative and postoperative to calculate the correction of the alignment.

Statistical analysis was performed using SPSS® (version 12.0.1 for Windows, SPSS Inc., Chicago, IL). Because the data were not normally distributed due to outliers, nonparametric methods were used. The Mann/Whitney U test was used to compare the Lysholm scores, pain, and migration at the three follow-up examinations between the OW HTO and CW HTO groups. The nonparametric Wilcoxon signed rank sum test was used to detect a substantial migration increase between two consecutive follow-up evaluations within each group. Besides statistical significance, migration increase should exceed the detection limit to be assigned as relevant. Tests were two sided and probability values less than 0.05 were considered significant.

Results

Clinical findings

No intra-operative or early postoperative complications occurred. However, in nine patients an intra-operative fracture of the opposite tibial cortex was diagnosed on postoperative radiographs: 8 in the CW HTO group and 1 in the OW HTO group. There were no differences between the OW HTO and CW HTO patients in time to regain knee function and full weight bearing. On average, the clinical outcome was between 'satisfactory' and 'good' (Table I).

There were no differences in the mean Lysholm scores preoperative and at the different postoperative follow-up evaluations between the two groups. The function had improved postoperatively; at the 24-month follow-up, the mean Lysholm score of both groups had increased ($p < 0.05$) significantly compared to the preoperative score, from 58 ± 13 to 80 ± 18 in the CW HTO and from 63 ± 16 to 86 ± 14 in the OW HTO group. The preoperative VAS scores were equal in the CW HTO and OW HTO group, 59 ± 16 and 56 ± 22 respectively. The pain diminished without difference between groups and the VAS score had decreased ($p < 0.05$) at 24 months to 23 ± 32 in the CW HTO and 15 ± 25 in the OW HTO.

The average varus angle preoperatively was 6.8° ± 3.1 (CW) and 5.0° ± 2.6 (OW).The average planned correction angle preoperatively was 9.7° ± 2.9 (CW) and 8.1° ± 3.1 (OW). The average angle of achieved correction on the whole leg standing radiograph postoperatively was 0.9° ± 2 (CW) and 3.4° ± 3.0 (OW). The under correction, from the aim of 3° valgus, in the CW group was statistically significant. There was an absolute under correction, i.e. leg alignment still in varus postoperatively, in 5 (CW) and 1 (OW) respectively. The clinical outcome in these patients ranged from 'fair' through 'good' and 'excellent'. There was no correlation between the postoperative leg alignment and the clinical outcome. All osteotomies had fully healed at 12 months on follow-up radiographs.

Table I. The overall outcome at the 24-month follow-up moment in the OW HTO, CW HTO with intact cortex and CW HTO with fractured cortex Groups.

Group	OW	CW-i	CW-f
Poor	2	1	0
Fair	1	2	1
Satisfactory	3	2	0
Good	5	3	3
Excellent	9	3	2
missing	3	0	2

OW: opening-wedge; CW-i, closing-wedge with intact cortex; CW-f, closing-wedge with fractured cortex.

RSA

Mean translations at 24 months were smaller than 0.4 mm and the axial rotations were minimal (< 0.2°) in both groups (Table II). Mean varus rotations were smaller than 1°; largest movement was seen in the rotation around the x-axis, i.e. dorsal tilting. On average dorsal tilting of the proximal tibial part at 6 weeks in the OW HTO group was larger than in the CW HTO group (Table II); but the difference was not statistically significant. In both groups the dorsal tilt increased significantly between 6 weeks and 12 months, resulting in a more or less equal dorsal tilting in both groups after one year (Table III). No changes occurred at the 24 month-follow-up.

The rotation in varus direction showed different patterns in both groups. In the CW HTO group the largest results were seen 6 weeks postoperative. In the OW HTO group the largest varus rotations were found between 6 weeks and 12 months. In both groups varus rotation stabilized in the second year. Final results showed a slightly larger, not significant, overall migration in the CW HTO group compared to the OW HTO group.

The number of osteotomies with micro motion during the first year was not significantly different between both groups. In the second year of follow-up all osteotomies stabilized (Table IV).

In the patient (OW), with the fractured lateral cortex the proximal tibial part tilted 6.1° in dorsal direction during the first 3 months. In the following period of the first year, it tilted 1.5° in opposite direction. At 12 months, varus rotation of 2° and dorsal translation of 2 mm were also observed. The patients' clinical overall judgment was 'satisfactory'. In the second year of follow-up the osteotomy became stable.

In CW HTO, in the group of 8 patients with broken cortices, 2 patients showed possibly clinically significant migration of the proximal tibial part (Table IV); in one patient translation as well as rotation increased during the first 12 months, with 8.4° of dorsal tilt as the largest movement. In the second year the proximal tibial part tilted slightly (1.8°) in the opposite direction, which is not considered to be a relevant migration. Clinical outcome slightly improved in the second year; however the patient's clinical overall outcome was 'poor'. Knee alignment at 1 year was 3° of varus. The micro motions in the other patient were smaller and over a shorter period of time: 1.8° dorsal tilt and 3.9° of varus rotation during the first 3 months, after which the osteotomy stabilized. Knee alignment at 12 months was 2° of varus. No clinical complaints were seen.

Table II. The migration* in the OW- and CW HTO Groups at three follow-up moments.

6-Week Follow-up

	CW HTO							OW HTO					
Axis	Mean	Sd	Median	Min	Max	N#	Axis	Mean	Sd	Median	Min	Max	N#
Tx	-0.10	0.29	-0.17	-0.40	0.83	18	Tx	0.17	0.24	0.12	-0.09	0.84	22
Ty	-0.29	0.32	-0.26	-0.83	0.20	18	Ty	-0.15	0.19	-0.13	-0.64	0.19	22
Tz	-0.06	0.26	-0.03	-0.64	0.56	18	Tz	-0.19	0.37	-0.21	-0.79	0.46	22
Rx	-0.23	1.16	-0.38	-3.05	1.78	18	Rx	-0.57	0.89	-0.49	-3.20	1.03	19
Ry	-0.02	0.66	0.05	-1.41	1.10	18	Ry	-0.15	0.60	-0.13	-1.70	0.80	19
Rz	0.61	0.91	0.60	-0.73	3.13	18	Rz	0.05	0.66	0.12	-1.79	1.10	19

12-Month Follow-up

	CW HTO							OW HTO					
Axis	Mean	Sd	Median	Min	Max	N	Axis	Mean	Sd	Median	Min	Max	N
Tx	-0.02	0.42	-0.06	-0.66	1.36	19	Tx	0.07	0.25	0.00	-0.43	0.58	23
Ty	-0.37	0.48	-0.27	-1.38	0.62	19	Ty	-0.29	0.49	-0.13	-1.83	0.14	23
Tz	-0.21	0.41	-0.17	-1.06	0.36	19	Tz	-0.23	0.32	-0.21	-0.76	0.53	23
Rx	-1.11	2.37	-0.63	-8.37	1.53	19	Rx	-1.18	1.12	-0.99	-4.45	0.73	20
Ry	0.04	1.19	0.18	-3.50	2.08	19	Ry	0.12	0.67	0.13	-0.78	2.06	20
Rz	0.87	1.26	0.83	-0.73	4.10	19	Rz	0.45	0.86	0.22	-0.68	2.06	20

24-Month Follow-up

	CW HTO							OW HTO					
Axis	Mean	Sd	Median	Min	Max	N	Axis	Mean	Sd	Median	Min	Max	N
Tx	-0.03	0.39	-0.04	-0.72	1.12	19	Tx	0.07	0.24	0.06	-0.43	0.57	23
Ty	-0.33	0.49	-0.25	-1.76	0.61	19	Ty	-0.29	0.48	-0.12	-1.74	0.21	23
Tz	-0.16	0.34	-0.06	-0.98	0.26	19	Tz	-0.26	0.40	-0.18	-1.02	0.43	23
Rx	-1.10	1.93	-0.83	-6.53	1.32	19	Rx	-1.21	1.20	-1.02	-5.11	0.83	20
Ry	0.07	0.91	0.27	-1.94	2.23	19	Ry	0.15	0.75	0.21	-1.16	2.13	20
Rz	0.97	1.30	0.89	-0.99	4.44	19	Rz	0.45	0.93	0.24	-1.11	2.25	20

*Translation along the x-axis, y-axis, and z-axis (Tx, Ty, and Tz) are in mm; rotations about the x-axis, y-axis, and z-axis (Rx, Ry, and Rz) are in degrees.

#The postoperative RSA radiograph of two patients, one in each group were missing; for these patients, the 6-week results served as baseline.

In 3 patients of the OW HTO group, evaluation of rotation was not possible because only two paired bone or prosthesis markers could be identified in the radiographs.

Table III. The Migration* Increases (Mean and SD) in the OW HTO and CW HTO Groups from 0 to 6 Weeks, 6 weeks to 12 Months, and 12 to 24 Months Postoperatively.

	CW HTO						OW HTO					
	0-6w		6w-12m		12m-24m		0-6w		6w-12m		12m-24m	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Tx	-0.10[1]	0.29	0.08	0.20	-0.01	0.14	0.17[2,3]	0.24	-0.09[3]	0.25	0.00	0.11
Ty	-0.29[1]	0.32	-0.02	0.28	0.00	0.11	-0.15[2]	0.19	-0.15	0.43	0.00	0.06
Tz	-0.06	0.26	-0.16[1]	0.31	0.05	0.29	-0.19[2]	0.37	-0.04	0.27	-0.03	0.22
Rx	-0.23	1.16	-0.99[1]	1.56	-0.03	0.59	-0.57[2]	0.89	-0.62[2]	0.90	-0.03	0.31
Ry	-0.02	0.66	0.02	1.08	0.02	0.55	-0.15	0.60	0.30	0.64	0.03	0.29
Rz	0.61[1]	0.91	0.28	0.73	0.10	0.22	0.05	0.66	0.42[2]	0.64	0.01	0.19

*Translation along the x-axis, y-axis, and z-axis (Tx, Ty, and Tz) are in mm; rotations about the x-axis, y-axis, and z-axis (Rx, Ry, and Rz) are in degrees.

[1,2] Significant increase (2-sided, $p < 0.05$) during the time intervals within [1] the CW HTO and [2] the OW HTO groups, tested with the Wilcoxon test.

[3] Significant increase (2-sided, $p < 0.05$) in the OW HTO group compared with the CW HTO group, tested with the Mann–Whitney U test.

Table IV. The number of stable or migrating osteotomies in the OW HTO, CW HTO with intact cortex and CW HTO with fractured cortex Groups.

Time period	**0-6w**			**6w-12m**			**12m-24m**		
group	OW	CW-i	CW-f	OW	CW-i	CW-f	OW	CW-i	CW-f
stable < 1mm and/or < 2°	21	10	6	20	8	7	23	11	8
micro motion > 1mm and/or > 2°	1	0	2	2	2	1	0	0	0
missing	1	1	0	1	1	0	0	0	0

OW: opening-wedge; CW-i, closing-wedge with intact cortex; CW-f, closing-wedge with fractured cortex.

In two other patients in the CW HTO group with intact cortices, very distinct migration results were seen. In one patient rotations in all directions during the first 3 months were measured: 5.2° dorsal tilt, 2.1° internal rotation and 1.6° varus rotation, after which the osteotomy stabilized. At 12 months, knee alignment was 1° of varus, pain was increased and function was decreased, scores which stabilized in the second year and resulted in a 'fair' overall score. The other patient showed an increasing varus rotation up to 4.1° during the first year, which stabilized in the second year. Knee alignment was 1° of varus; however this patient showed no clinical complaints, pain abated and function increased, and the overall score at 24 months was 'excellent'.

Although dorsal tilting (1.1°) and varus rotation (0.7°) were slightly larger in the 'fractured' group, significant differences in the mean migration results between the CW HTO group with fractured cortices and the CW HTO with intact cortices were not found. The number of osteotomies, which showed micro motion during the first year of follow-up, did not differ significantly between both groups (Table IV).

Discussion

Dorsal tilt was the direction in which there was the largest amount of displacement in both groups. In both groups this displacement increased significantly after 6 weeks. Possibly because at that time patients were allowed to bear full weight, causing increased pressure on the tibia plateau, creating a posterior directed force. Displacement in this direction influences tibial slope, ventral tilt decreases the slope, and dorsal tilt increases it (Fig. 3). However in both groups on average the slope increase because of this displacement was small; dorsal tilt was on average 1.1° in the CW group and 1.2° in the OW group at 24 months FU.

Lateral closing-wedge osteotomies supposedly offer greater initial stability because of the larger cortical contact area [1]. Medial opening-wedge techniques are nowadays preferred because they are safer and easier to perform [1, 19]. Postoperative stability however greatly depends on the ability of the fixation method to withstand the forces that act upon the proximal tibia. Biomechanical studies have demonstrated great differences between the various available fixation methods in HTO [7, 9-11]. According to Agneskirchner et al [7] rigid plates with locking bolts offer superior stability. Flamme et al [9] tested several lateral implants in CW HTO in a tibia model and found that staples and an external fixator offered greatest initial stability, compared to a blade plate and a semi-tubular plate. Angle-stable implants were not tested.

RSA has been used by Gaasbeek et al [16] to compare medial to lateral techniques using the same fixation method in both, a rigid plate and locking bolts. They tested initial stability in a cadaver model, in a material testing system; there was no difference in initial stability between OW en CW HTO. Pape et al [17] and Magyar et al [13] used RSA clinically to measure stability in HTO. Pape et al [17] compared stability in patients that had an accidental fracture of the opposite medial cortex to patients with an intact cortex in lateral closing-wedge osteotomy, but did not compare medial to lateral techniques. Fracture of the opposite cortex caused increased instability. Magyar et al [13] compared lateral staple fixation to hemicallotasis medially and found that there was less displacement in the hemicallotasis group. In this series, as in the experimental setup used by Gaasbeek et al [16], OW en CW were compared using the same fixation method, allowing direct and exact comparison between both. There were no differences in stability measured by RSA between the OW and CW groups. According to our RSA data and our criteria for stability all osteotomies became stable after 12 months in both groups.

Few randomized trials exist that compare opening- to closing-wedge techniques. Brouwer et al [12] compared staples for lateral fixation to a Puddu plate for medial fixation in a series of 92 patients undergoing HTO. They concluded that closing-wedge osteotomy achieves a more accurate correction with less morbidity, but found no difference in outcome. Pain and knee function improved in both groups. Magyar et al [28] compared lateral staples to hemicallotasis and found that hemicallotasis gave more precise and predictable results, and less loss of correction, but again no difference in clinical results. In a prospective cohort study Van den Bekerom et al [18] compared a lateral AO/ASIF L-plate to a medial Puddu plate. They found a higher rate of non-union, loss of correction and implant failure in the OW group. Patients were less satisfied in the OW group. In all three studies however different techniques for fixation are compared; differences can be attributed to both osteotomy technique and fixation method. In our series no difference in complication rate, bone healing rate, clinical outcome and pain improvement at short term follow-up was found. Pain and knee function improved significantly at short term follow-up in both groups.

Miller et al [29] studied the influence of the integrity of the opposite lateral cortex in medial OW HTO in a replicate tibia model; disruption of the opposite cortex led to increased micro-motion. Repair using staples restored stability. Clinically fracture of the opposite cortex has been studied by Van Raaij et al [30] and, as mentioned, by Pape et al [17]. Van Raaij et al found in a series of CW and OW HTO that fracture of the opposite cortex occurred more often in their CW group, without major consequence, and no resultant mal-alignment. In their OW group fracture of the lateral cortex led to a re-varus mal-alignment more often. Similar to what van Raaij et al reported more opposite cortices fractured in our CW group, 8 to 1. This caused increased movement initially in 3 (in 2 of 8 in the CW group). All osteotomies became stable at 12 months and in spite of the fractured cortex and the increased movement no difference in clinical outcome was found in these patients. Fracture of the opposite cortex causes either a varus (medial fracture) or valgus directed force on the construct. In contrast to what Pape et al [17] reported, 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 [6, 17, 20-25, 31]; this depends on correct preoperative planning and an accurate amount of correction during surgery. In addition it also depends on the ability of the construction to retain the correction. Gaasbeek et al [16] and Brouwer et al [12] both reported under correction in their OW groups. In contrast, in our series there was under correction in the CW group and a more exact correction was achieved in the OW group. No significant differences in migration between both groups were seen at the different intervals of the 24 months follow-up. It can thus be assumed that the different fixation technique is not the cause of the loss of correction. It therefore seems that the under correction in the CW group is caused at the time of operation. In spite of the under correction in the CW group and the small difference in posterior tilt there were no differences in clinical outcome.

Weight bearing was started at the same time in both groups; 15 kg in the first 6 weeks and full weight bearing at 6 weeks postoperatively. Whereas closing-wedge osteotomies are supposed to have higher initial stability because of a larger bone contact area and faster postoperative stability because of faster bone healing, the opening-wedge technique fixated with the TomoFix implant is equally stable. As no difference in migration was seen between both groups it can be concluded that opening-wedge osteotomies fixated with the medial implant provides enough initial stability to withstand the force exerted on the tibia plateau. With this implant even faster full weight bearing seems possible; Takeuchi reported no loss of correction in a series of patients that had simultaneous bilateral OW HTO and were mobilized fully weight bearing immediately postoperative [32]. A second RSA study on stability in early full weight bearing after HTO is currently under way at our institution.

In conclusion, in this series both opening- and closing-wedge techniques fixated with angle-stable implants, resulted in significantly reduced pain and improved function in patients with medial compartment osteoarthritis of the knee. There were no differences in fixation stability on repetitive RSA measurements, i.e. the medial opening-wedge technique offered equal stability as the lateral closing-wedge technique. Although not of clinical significance in this series, the under correction in the CW group is a cause for concern. It is recommended that HTO is performed using a medial opening-wedge technique and an angle stable implant for fixation.

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Chapter 3

Early full weight bearing is safe in opening-wedge high tibial osteotomy

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Abstract

In opening-wedge, valgus osteotomy of the upper tibia, there are concerns regarding the initial stability and ability to retain the correction. Rehabilitation protocols vary depending on the osteotomy technique and the fixation method. Angle-stable implants offer superior initial stability. Early full weight bearing appears to be possible using these implants. In this prospective cohort study, we measured migration in opening-wedge osteotomy in patients following an early full weight bearing protocol and compared the results to those from a historical cohort of opening-wedge osteotomy patients who followed a standard protocol (full weight bearing after 6 weeks) using radiostereometry.

Fourteen opening-wedge osteotomies fixated with the angle-stable Tomofix implant were performed; patients were allowed full weight bearing as soon as pain and wound healing permitted. Radiostereometry was used to measure motion across the osteotomy at regular intervals. Improvement in pain and functional outcome were assessed postoperatively. The results were compared to those from a group of 23 patients who had undergone the same operation but had used a standard rehabilitation protocol.

There were no adverse effects because of the early full weight bearing protocol and no differences in motion at the osteotomy between groups. Pain and function improved substantially without any differences between groups. Patients in the early weight bearing group achieved the same result but in a shorter time. Interpretation: Tomofix-plate-fixated opening-wedge high tibial osteotomy allows early full weight bearing without loss of correction.

Introduction

Medial osteoarthritis of the knee can be treated with opening-wedge, valgus, high tibial osteotomy (OW HTO) [1]. There are concerns, however, regarding the ability of the fixation technique to withstand the forces that act on the proximal tibia [1]. Loss of correction leads to poorer results [2].

Ideally, the fixation technique used should be strong enough to allow early joint motion and early full weight bearing postoperatively. Initially, 15 kg of weight bearing is often allowed for 6 weeks. Depending on the fixation technique used, time to full weight bearing can take up to 3 months [3].

Angle-stable fixation plates with locking bolts have been designed for use in OW HTO. Osteotomies fixated with these plates offer superior initial stability compared to other medial fixation plates and equal stability compared to similar plates used for CW HTO [4, 5]. With these implants, immediate full weight bearing appears to be possible [6, 7].

Radiostereometric analysis (RSA) has been used to document motion at the osteotomy in OW HTO using standard weight bearing protocols [8]. The aim of this study was to measure migration at the osteotomy using RSA in patients after OW HTO that were rehabilitated with an early full weight bearing protocol (E). The primary research question was whether there would be a difference in motion at the osteotomy because of the early full weight bearing, as measured by RSA, compared to a historical cohort of patients rehabilitated using a standard protocol (S). Secondary research questions were whether there was a difference in time to walking without aid, and improvement in pain and knee function.

Patients and methods

After approval of the study by the institutional medical ethics committee (registration number 2005/217), we prospectively recruited patients aged between 18 and 60 who were scheduled for HTO between December 2005 and December 2006. They formed the E group. The patients in the standard weight bearing group (S) (n = 23) had previously been enrolled in a randomized controlled trail of opening-wedge versus closing-wedge HTO, between December 2001 and August 2004, based on the same inclusion criteria as used in this study [8].

Both groups involved patients with medial knee osteoarthritis, with a varus deformity smaller than 12°. Exclusion criteria were rheumatoid arthritis, insufficiency of the medial collateral ligament, patella-femoral complaints, previous knee surgery, and/or a BMI of > 30. The aim was an overcorrection to a mechanical axis of 3° valgus.

Two experienced surgeons performed all osteotomies in both groups using standard surgical techniques. In the resultant opening, a ChronOS β-tricalcium phosphate wedge (Mathys, Bettlach, Switzerland) was inserted to facilitate bone growth. All osteotomies were fixated with the medial TomoFix plate (Fig. 1) and screws (Synthes GmbH, Oberdorf, Switzerland).

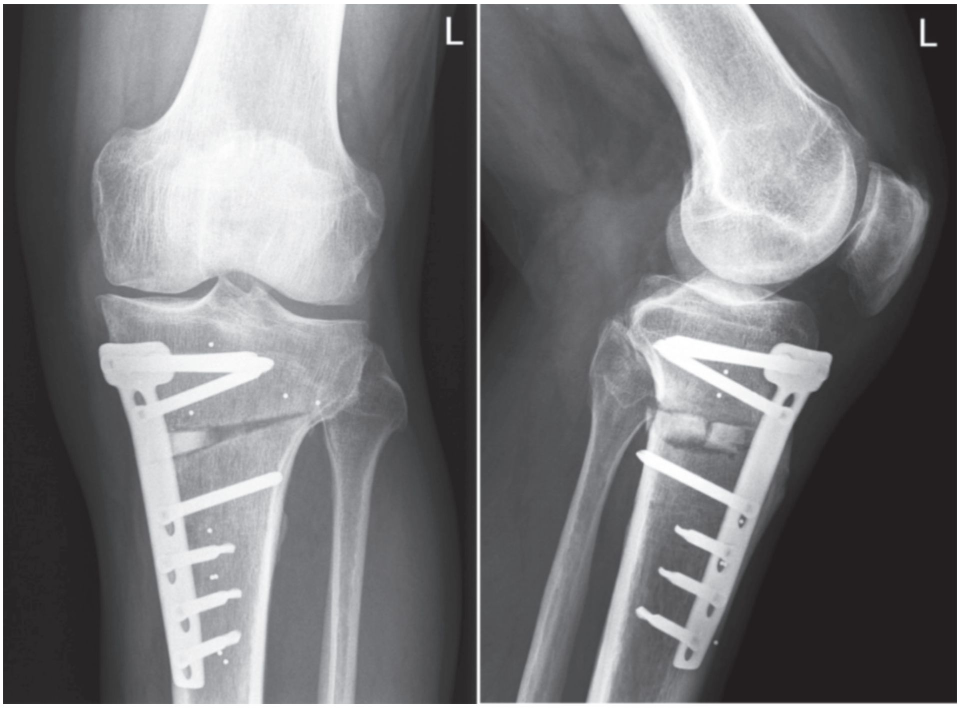

Figure 1. The OW HTO, Tomofix implant and tantalum beads used for RSA.

In the S group, a standard postoperative weight bearing protocol was used: 10–15 kg for 6 weeks and full weight bearing thereafter. The patients in the E group were allowed partial weight bearing (15 kg) until pain and wound healing permitted full weight bearing during the first 2 weeks. All patients were asked to record weight bearing in a diary to document time to full weight bearing.

Migration was measured using RSA; 5 to 9 tantalum beads (1.6 mm) were inserted in the proximal and distal ends of the osteotomy with a special instrument (Mathys, Bettlach, Switzerland) at the time of operation (Fig. 1). Digital baseline RSA radiographs (165 d.p.i. and 11-bit gray scale resolution) were made with a digital radiology system (Agfa-Gevaert AG, Rijswijk, the Netherlands), within 1 week postoperatively after mobilization of the patient. Follow-up images were planned at 3 and 6 weeks, and 3 and 12 months postoperatively. RSA-CMS software (version 4.3.1.0 20041006 beta; Medis, Leiden, the Netherlands) was used to analyze the radiographs and calculate migration [9]. Migration was defined as motion of the center of gravity of the proximal tibial part relative to the distal tibial part in mm, in all 3 directions and in degrees (°) around all 3 axes (Fig. 2) [10]. The mean migration in all directions was calculated at all postoperative follow-up moments, as was the increase in migration during three intervals: from 0 to 6 weeks, from 6 weeks to 3 months, and from 3 months to 12 months. Movement was classified as: < 1 mm or 2° in any direction, stable, or > 1 mm or 2° in 1 or more directions, which is (possibly) clinically relevant migration.

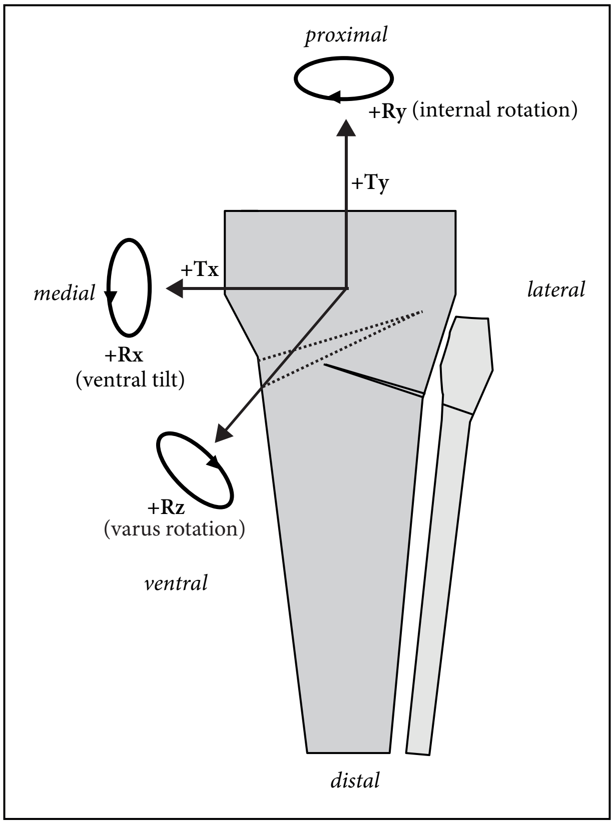

Figure 2. The 6 possible directions of migration are shown schematically. T: translation in mm; R: rotation in degrees; x: transverse axis; y: longitudinal axis; z: sagittal axis.

To assess the detection limit, double examinations were done in all patients at the 6-week follow-up evaluation. These radiographs were used to calculate the upper limits of the 99% confidence interval (CI) [11]. The detection limit was 0.2 mm, 0.1 mm, and 0.3 mm for the translations in the x, y, and z directions and 0.8°, 0.8°, and 0.4° for the rotations about the x, y, and z axes, respectively, which is sufficient to detect motion considered possibly clinically relevant.

Knee function was measured clinically preoperatively, at 6 weeks and at 3, 6, and 12 months postoperatively using the WOMAC, Lysholm and KOOS scores; pain was assessed on a visual analog scale (VAS). Patients documented the amount of weight bearing and use of a walking aid (crutches or cane) in a diary each day during the first 6 weeks and every week thereafter until they walked without any aid. Standard AP and lateral radiographs were taken postoperatively during the first week and after 6 and 12 months to assess bone healing.

The time until walking without a walking aid, VAS pain score, Lysholm knee function score, and motion at the osteotomy at the 6-week, 3-month, and 12-month follow-up and measurement intervals on RSA analysis from the E group were compared to the data from the S group.

Statistics

To detect a significant difference in migration of 0.7 mm and/ or 1.1° between the groups, sufficient to detect a clinically relevant difference in migration, 13 individuals in the E group would be required, according to an a priori performed power calculation with $\alpha = 0.05$, power = 90%, and n = 23 in the S group. To find possible confounding factors, Student's t-test was used to detect preoperative differences in the patient characteristics between the groups. The non-parametric Wilcoxon signed rank sum test was used to detect increases in clinical scores and migration between 2 consecutive follow-up times within each group. The Mann-Whitney U test was used to compare the clinical scores, pain, and migration exceeding the detection limit between groups at different preoperative and postoperative follow-up times. Fisher's exact test was used to analyze differences between both groups in the number of patients with clinically relevant migration at the osteotomy, patients with a walking distance of less than 1 km, and patients using a walking aid. Tests were two-sided and probability $p < 0.05$ were considered statistically significant. SPSS software version 12.0.1 was used to perform the statistical analyses.

Results

Fourteen osteotomies were performed in 14 patients (10 males) with a mean age of 49 years (SD 9), a mean weight of 81 kg (SD 11), without any complications. The mean varus angle preoperatively was 6° (SD 3). The mean angle of correction was 9° (SD 2). The preoperative patient characteristics of the early weight bearing (E) group did not differ statistically significantly from those of the standard weight bearing (S) group (Table I).

Also, the distance patients could walk preoperatively and the preoperative VAS and Lysholm scores were not statistically significantly different. Postoperatively, one complication occurred. A wound infection was diagnosed 5 weeks postoperatively and treated successfully with antibiotics and wound debridement. All osteotomies had healed at 12 months.

Table I. Pre-operative patient characteristics for the early weight bearing (E) and standard weight bearing (S) groups. Mean (SD)

	EWB	SWB	p-value
Age	49 (8)	53 (8)	0.1
Weight	81 (11)	86 (12)	0.3
Height	177 (8)	176 (11)	0.4
BMI	26 (3)	28 (3)	0.1
Varus angle pre-op	6.0° (2.8°)	5.0° (2.6)	0.3
Planned correction	8.9° (2.4°)	8.1° (3.1)	0.3
VAS Pain	51 (25)	56 (22)	0.6
Lysholm	57 (16)	63 (16)	0.3

The time to full weight bearing in the E group ranged between 15 and 39 days (mean 26, SD 8). Pain during walking at the moment of full weight bearing ranged from 0 to 40 (mean 21, SD 14). Two patients walked without crutches within 3 weeks of surgery. Six weeks postoperatively, 7 patients walked without the support of a walking aid, 6 patients walked with a cane, and the patient with the wound infection used 2 crutches. There was no association between the use of a cane and the KOOS pain score or KOOS function score at 6 weeks. At 8 weeks, 3 more patients stopped using the cane and within 3 months, none of the patients needed support. This was statistically significantly different from the S group at 3 months ($p = 0.005$). All the patients in the S group used crutches at the 6-week follow-up, as prescribed in the protocol. At 3 months, 12 of the 23 patients did not use crutches, and at 6 months all patients except one were able to walk without support. In the E group, 10 patients could walk a distance of more than 1 km at 3 months; this was statistically significantly more than in the S group ($p = 0.04$), in which 7 patients could walk more than 1 km. Pain decreased statistically significantly ($p < 0.005$) in all E-group patients during the first year, from a mean of 51 (SD 25) to a mean of 14 (SD 12) – a mean decrease of 38 (SD 28) points. This was not statistically significantly different ($p = 0.3$) compared to the improvement in the S group (mean 25, SD 28). The improvement in the Lysholm score in the E group at 6 weeks (mean 7, SD 31) was not statistically significant ($p = 0.4$); nor did it differ significantly from the improvement in the S group (mean 2, SD 23) ($p = 0.6$). At the 6-month and 12-month follow-up, the mean Lysholm score had improved statistically significantly ($p = 0.009$ and $p = 0.003$, respectively). At 12 months, the improvement in the Lysholm score in the E group (mean 19, SD 20) was not statistically different from that in the S group (mean 20, SD 14) ($p = 0.9$).

The overall satisfaction of the patients at the 12-month follow-up was "excellent" in 9 patients, while 4 patients scored "good". 1 patient scored "fair", and as joint degeneration progressed, he received a total knee arthroplasty 14 months postoperatively. Sixteen patients in the S group were satisfied, 5 of whom scored "good" and 5 of whom scored "excellent". The other 9 patients scored "satisfied"; 5 patients scored "fair" and 2 patients scored "poor". In the

E group, all KOOS scores and all WOMAC scores had improved statistically significantly at the 6-month follow-up ($p < 0.05$) (Table II).

Table II. KOOS, WOMAC and Tegner scores pre-operative and at the postoperative follow-up moments for the early weight bearing (E) group. Mean (SD)

Score		Pre-op	6w	3m	6m	12m
KOOS	Pain	43 (17)	67* (23)	68* (22)	78* (21)	74* (19)
	Symptom	47 (14)	54 (12)	52 (14)	58* (11)	60* (15)
	ADL	47 (18)	67 (18)	69* (21)	77* (26)	76* (19)
	Sport/Rec	21 (20)	20 (22)	37 (30)	47* (32)	41* (27)
	QOL	35 (11)	36 (12)	40 (18)	44* (16)	49* (11)
WOMAC	Total	49 (16)	30* (17)	28* (20)	21* (22)	17* (14)
	Pain	11 (4)	6* (4)	6* (5)	4* (4)	4* (4)
	Stiffness	3 (1)	2* (1)	2* (1)	1* (1)	1* (1)
	Function	36 (12)	23* (12)	21* (14)	15* (18)	16* (13)
TEGNER		1.9 (1.4)			2.9 (1.6)	3.1 (1.5)

ADL, activities of daily living; Rec, recreation; QOL, quality of live * $P < 0.05$ relative to the preoperative score

RSA results

The mean migrations in the E group found at 3 follow-up times (Table III) and the mean migrations found during the time intervals (Table IV) were small and within the measurement error in all directions.

At 1 year, 12 patients had migration grade 1 (less than 1 mm or 2° in one or more directions) and 2 patients (14%) had grade 2 (more than 1 mm or 2° in one or more directions). At any of the follow-up times, there were no statistically significant differences between groups in the number of osteotomies that migrated more than what was considered clinically significant (grade 2). In both grade-2 cases of the E group, the only possibly clinically relevant migration was rotation in the dorsal direction around the x-axis (posterior tilting). Both had different migration patterns during the follow-up period, which resulted in a posterior tilt of over 2° at 1 year. In one case, the posterior tilt was 0.3° at 3 weeks, then increased to 1.1° at 6 weeks, and to 2.1° at 3 months; thereafter, it stabilized. This patient started full weight bearing at day 34 and was using a cane until week 11. In the other case, the posterior tilt was 1.0° in the first 3 weeks, increasing gradually to 1.2° at 6 weeks and 1.5° at 3 months, and with a further increase to 2.3° at 1 year. This patient started full weight bearing at day 31 and was using a cane until week 12.

Table III. Migration* in the early weight bearing (E) and standard weight bearing (S) groups at 3 follow-up moments.

6-Week Follow-up

	EWB		SWB	
Axis	Mean (SD)	(Min – Max)	Mean (SD)	(Min – Max)
Tx	-0.02 (0.36)	(-0.70 - 0.60)	0.17[2] (0.24)	(-0.09 - 0.84)
Ty	-0.10 (0.24)	(-0.75 - 0.27)	-0.15[2] (0.19)	(-0.64 - 0.19)
Tz	-0.01[3] (0.14)	(-0.20 - 0.30)	-0.19[2,3] (0.37)	(-0.79 - 0.46)
Rx	-0.16 (0.74)	(-1.18 - 1.78)	-0.57[2] (0.89)	(-3.20 - 1.03)
Ry	-0.16 (0.52)	(-0.92 - 0.60)	-0.15 (0.60)	(-1.70 - 0.80)
Rz	-0.01 (0.67)	(-1.69 - 1.04)	-0.05 (0.66)	(-1.79 - 1.10)

3-Month Follow-up

	EWB		SWB	
Axis	Mean (SD)	(Min – Max)	Mean (SD)	(Min – Max)
Tx	-0.01 (0.40)	(-0.86 - 0.69)	0.14[2] (0.24)	(-0.27 - 0.71)
Ty	-0.13 (0.22)	(-0.75 - 0.19)	-0.17[2] (0.25)	(-0.74 - 0.22)
Tz	-0.05 (0.20)	(-0.50 - 0.32)	-0.17[2] (0.33)	(-0.78 - 0.40)
Rx	-0.41 (0.99)	(-2.11 - 2.17)	-0.88[2] (1.47)	(-6.14 - 1.49)
Ry	-0.09 (0.58)	(-1.18 - 0.94)	-0.05 (0.47)	(-0.84 - 0.73)
Rz	0.06 (0.75)	(-1.72 - 1.42)	0.16 (0.54)	(-0.79 - 1.04)

12-Month Follow-up

	EWB		SWB	
Axis	Mean (SD)	(Min – Max)	Mean (SD)	(Min – Max)
Tx	-0.03 (0.40)	(-0.81 - 0.73)	0.07 (0.25)	(-0.43 - 0.58)
Ty	-0.18[1] (0.27)	(-0.97 - 0.16)	-0.29[2] (0.49)	(-1.83 - 0.14)
Tz	-0.08 (0.21)	(-0.53 - 0.35)	-0.23[2] (0.32)	(-0.76 - 0.53)
Rx	-0.73[1] (0.88)	(-2.26 - 0.60)	-1.18[2] (1.12)	(-4.45 - 0.73)
Ry	-0.07 (0.51)	(-0.89 - 0.75)	0.12 (0.67)	(-0.78 - 2.06)
Rz	0.19 (0.82)	(-1.76 - 1.46)	0.45 (0.86)	(-0.68 - 2.06)

*Translation along the x-axis, y-axis, and z-axis (Tx, Ty, and Tz) are in mm; rotations about the x-axis, y-axis, and z-axis (Rx, Ry, and Rz) are in degrees.

In 1 patient in the SWB group, the postoperative RSA radiograph was missing; for this patient, the 6-week result served as baseline.

[1,2] Significant migration (2-sided, $p < 0.05$) at the follow-up moment within [1] EWB and [2] the SWB groups, tested with the Wilcoxon test, but not clinically relevant.

[3] Significant difference in migration (2-sided, $p < 0.05$) in the SWB group compared with the EWB group, tested with the Mann–Whitney U test, but migrations were below the detection limit.

Table IV. Migration* increases in the early weight bearing (E) and standard weight bearing (S) groups from 6 weeks to 3 months, and 3 to 12 months postoperatively.

	EWB		SWB	
	6w-3m	3m-12m	6w-3m	3m-12m
Tx	0.01 (0.08)	-0.02 (0.09)	-0.03 (0.23)	-0.07 (0.21)
Ty	-0.04[1] (0.06)	-0.04[1] (0.07)	-0.02 (0.24)	-0.13 (0.37)
Tz	-0.07 (0.17)	-0.02 (0.11)	0.02 (0.20)	-0.06 (0.23)
Rx	-0.25[1] (0.35)	-0.30[1] (0.47)	-0.29 (0.82)	-0.40 (0.89)
Ry	0.07 (0.48)	0.02 (0.25)	0.06 (0.45)	0.21 (0.55)
Rz	0.07 (0.20)	0.12[1] (0.18)	0.10 (0.39)	0.29[2] (0.55)

*Translation along the x-axis, y-axis, and z-axis (Tx, Ty, and Tz) are in mm; rotations about the x-axis, y-axis, and z-axis (Rx, Ry, and Rz) are in degrees.

[1,2] Significant increase (2-sided, $p < 0.05$) during the time intervals within [1] EWB and [2] the SWB groups, tested with the Wilcoxon test, but not clinically relevant.

The RSA data of the E group were compared to the RSA data of the S group (Tables III and IV). In the S group of 23 patients, 7 cases showed grade-2 migrations at 1 year. In 1 of these 7, the lateral cortex of the tibia fractured intra-operatively. During the first 6 weeks of partial weight bearing, the proximal tibial part tilted 3.0° posteriorly. This posterior tilt increased between 6 weeks and 3 months to 6.1°. After that, it rotated in the opposite direction. At 12 months, this had resulted in a migrated position of 4.4° posterior tilt, a varus rotation of 2°, and 2 mm of posterior translation. In 4 osteotomies, migrations gradually increased until 6 months, with small increases in the second half-year, resulting in a posterior tilt ranging between 2.0 and 2.4. 3 of the patients only stopped using crutches between 3 and 6 months postoperatively. Two cases showed migration, which gradually increased during the first year, resulting in varus rotation (2.1° and 2.0°) around the z-axis. One patient who stopped using crutches between 3 and 6 months postoperatively also had 2.1° of medial rotation around the y-axis. As in the E group, the 7 grade-2 cases in the S group did not migrate more than what was considered possibly clinically significant in the second half-year, and were considered stable at 1 year.

There were no statistically significant differences in mean migration between groups at any of the follow-up times for RSA measurement or time intervals between the follow-ups.

Discussion

In this series of OW HTO patients, full weight bearing was allowed as soon as wound healing and pain permitted it, but no loss of correction and no adverse effects occurred. There was no difference in motion at the osteotomy between groups at any of the time points, as measured by RSA. At the 1-year follow-up in the E group, varus rotation which might influence leg alignment was small (mean 0.2°, SD 0.8) and posterior tilt which might influence slope was also small (mean 0.7°, SD 0.9).

Because of the early weight bearing, patients regained knee function in a shorter time. Pain and knee function scores were not, however, influenced by the weight bearing protocol; in both groups, they improved statistically significantly and were nearly equal at 1 year.

In HTO, the implant used for fixation should be able to retain the correction achieved at the time of surgery. RSA has been used in vitro as well as in clinical studies to measure initial fixation stability and postoperative stability at specific intervals after HTO [4, 8, 12, 13]. Using RSA in a cadaver model comparing initial stability in OW and CW using medial and lateral angle stable plates for fixation, Gaasbeek et al [4] found no difference in motion at the osteotomy. Similarly, in a prospective randomized clinical trial comparing stability in CW and OW HTO fixated with TomoFix implants, Luites et al [8] found no difference in initial stability and ability to retain the correction at 1-year follow-up. In our series, no differences in motion (measured by RSA at the osteotomy) were seen between groups. No relation between the amount of weight bearing or the use of crutches and migration was found.

Rehabilitation protocols and time to full weight bearing after HTO vary. The amount of initial weight bearing that is allowed postoperatively depends strongly on the type of fixation used. Noyes et al [14] reported that full weight bearing was possible after 8 weeks in OW HTO fixated with a Puddu plate. In their series, rigid autologous grafts were used to increase initial stability and a long leg brace was prescribed for the first 8 weeks. Also using a Puddu plate for fixation together with iliac crest autografts or frozen allografts and a knee-hinged immobilizer to increase stability, Asik et al [3] reported that full weight bearing was possible after 3 months. Lobenhoffer et al [15] and Staubli et al [16], using Tomofix for fixation in OW HTO without filling the gap and without using a brace or cast, found that full weight bearing was possible at 8 weeks and 10 weeks, respectively. More recently, a shorter time to full weight bearing after OW HTO has been reported; in a series of 57 OW HTOs again using Tomofix for fixation, Takeuchi et al [7] allowed full weight bearing after 2 weeks. As with our findings, they did not observe any loss of correction or implant failure. Patients in Takeuchi's series were older on average: 69 years as compared to 49 years in this series.

Gap filling in OW HTO may be used to increase initial stability and facilitate or promote bone healing. Takeuchi et al [7] used tri-calcium phosphate (β-TCP) and hydroxyapatite wedges to help distribute the stress at the osteotomy across the wedge and the plate. No mention was made of bone healing time or time to full bone remodeling of the porous bone substitutes; however, no non-unions were reported. The porous β-TCP bone substitute inserted into the gaps created in our patients in the E and S groups is not shaped to fill the gap, and does not provide added initial stability. No non-unions were seen in either group, and bone healing was complete in all patients at the 1-year follow-up. Furthermore, full resorption of bone substitute was found to be present in almost all patients, as has been described in a previous histological analysis on the resorption of β-TCP in OW HTO [17]. Lobenhoffer et al [15] and Staubli et al [16] did not use grafts or bone substitutes to fill the gap, and reported that full remodeling of the medial cortex can take up to 1 year. They reported 2 cases of non-union in 262 patients and 1 non-union and two re-varisations in 92 patients, respectively. It can be concluded that bone healing occurs with or without filling of the gap. Furthermore, bone healing times do not vary. It can therefore be debated whether the gap should be filled at all. We conclude that fixation stability in our series of patients was solely dependent on the stability provided by the Tomofix plate; this did not lead to delayed healing or loss of correction.

Although early weight bearing appears to be safe in OW HTO fixated with Tomofix plates, other factors influence the actual time at which patients start full weight bearing. Remarkably, the use of a walking aid was not related to pain or the function score at that time; patients in the E group did not experience more pain because of the early weight bearing, and their function score did not improve faster. In this group patients did have a shorter period of time to full weight bearing; furthermore, their walking distances increased more quickly. Although the patients in the E group had a shorter time to full weight bearing and were walking longer distances earlier in their recovery, this was not reflected in their Lysholm scores.

Criticisms that can be leveled at this study include the small sample size of the E cohort and the fact that the patients were from different cohorts of OW HTO. They were from the same patient population, however, and patients in both groups were recruited based on the same criteria. Inclusion criteria were stringent to minimize the influence of factors other than the amount of weight bearing on the primary outcome measurement, i.e. motion at the osteotomy. Demographics were similar. Furthermore, all patients in both groups were operated on by the same surgeons using standardized technique.

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Chapter 4

Osteotomies around the knee: patient selection, stability of fixation and bone healing in high tibial osteotomies

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Abstract

New developments in osteotomy techniques and methods of fixation have caused a revival of interest in osteotomies around the knee. The current consensus on the indications, patient selection and the factors influencing the outcome after high tibial osteotomy is presented. This paper highlights recent research aimed at joint pressure redistribution, fixation stability and bone healing that has led to improved surgical techniques and a decrease of postoperative time to full weight bearing in high tibial osteotomy.

Introduction

Osteotomies around the knee were once well-established procedures in the treatment of uni-compartmental osteoarthritis of the knee [1]. Later they were almost entirely replaced because of the success of total- and uni-compartmental knee replacement (TKR and UKR). Compared to replacements, osteotomies were considered demanding procedures with an unpredictable outcome and associated with significant complications.

In the 1990s, in sports medicine, the role of correction of varus malalignment in the treatment of ligamentous injuries and imbalance of the knee led to a re-appreciation of osteotomies [2]. Furthermore, new knowledge led to renewed interest in the influence of malalignment on the development and symptoms of osteoarthritis [3-5].

Recently, better guidelines for the selection of candidates for osteotomy (as well as for UKR) have been formulated by The International Society of Arthroscopy, Knee Surgery and Orthopedic Sports Medicine (ISAKOS) [6]. New medial opening-wedge osteotomy techniques [7] and specially designed fixation plates based on the locking-compression-plate (LCP) concept, providing superior initial stability, are now available [8-12].

All these factors have led to a trend back towards osteotomy around the knee. In this current concept paper the current views on high tibial osteotomy (HTO) are discussed.

Indication, patient selection and prognosis

The main indication for HTO is the correction of varus malalignment in medial uni-compartmental osteoarthritis of the knee. The goal is to unload the medial compartment by slightly overcorrecting into valgus, in order to reduce pain, slow the degenerative process and delay joint replacement [1, 13-20]. A second indication is the correction of load imbalance in ligamentous instability in patients with a varus thrust in order to change the axial alignment, thereby reducing the varus thrust and unloading any ligament reconstruction. A possible secondary goal in these patients is to change the tibial slope in order to reduce translational forces and improve the antero-posterior stability of the knee.

Typical initial assessment consists of weight bearing antero-posterior (AP) and lateral radiographs and axial views of the patello-femoral joint as well as whole-leg standing radiographs in order to assess alignment. Abnormal ligamentous laxity is noted on clinical examination and on optional stress radiographs. The presence of a constitutional varus morphotype and previous meniscal procedures is documented; the tibial bone varus angle (TBVA) (Fig. 1) and the patellar height should also be measured.

With regard to patient selection, in 2004 the place of osteotomies and UKR in the management of osteoarthritis of the knee was formulated by ISAKOS [6]. For each treatment option ideal patients, possible patients and which patients were not suited for surgery were defined (Table I). In addition to those guidelines, in our opinion patients younger than 40 years of age can benefit from realignment alone, or combined with a secondary cartilage procedure such as micro-fracture for osteochondritis or early osteoarthritis. Furthermore ligamentous reconstructions can be combined with osteotomy to modify frontal and sagittal planes [2, 21]. Corrections of > 15° can be performed with current techniques of fixation of the osteotomy.

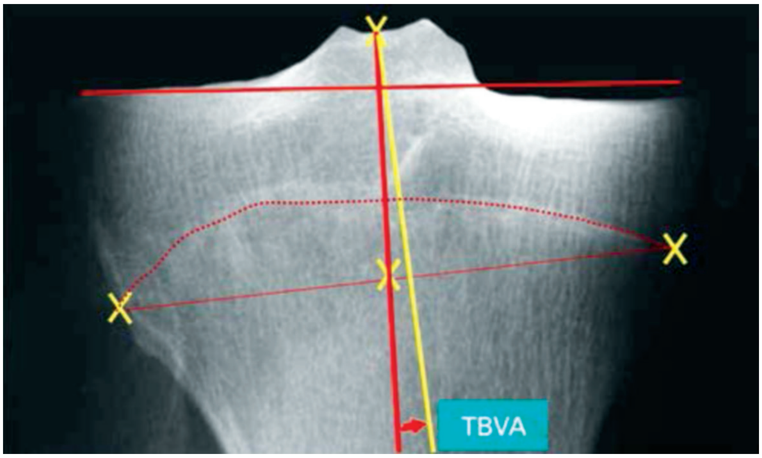


Figure 1. Radiograph showing the tibial bone varus angle (TBVA) (arrow), which is the angle between the mechanical axis of the tibia (red line) and the epiphyseal axis of the proximal tibia (yellow line) [22].

Table I. Ideal and possible patients for high tibial osteotomy and patients not suited for the procedure according to the International Society of Arthroscopy, Knee Surgery and Orthopedic Sports Medicine [6].

Ideal*	Possible**	Not suited
Isolated medial joint line pain	Flexion contracture < 15°	Bi-compartmental (medial and lateral) OA***
Age (years) 40 to 60	Previous infection	Fixed flexion contracture >25°
BMI < 30	Age 60 to 70 or < 40	Obese patients
High-demand activity but no running or jumping	ACL, PCL or PLC insufficiency	Menisectomy in the compartment to be loaded by the osteotomy
Malalignment < 15°	Moderate patello-femoral arthritis	
Metaphyseal varus, i.e. TBVA > 5°	Wish to continue all sports	
Full range of motion		
Normal lateral and patello-femoral compartments		
IKDC (A),B,C,D/Ahlback I to IV80		
No cupula		
Normal ligament balance		
Non-smoker		
Some level of pain tolerance		

*BMI, body mass index; TBVA, tibia bone varus angle; IKDC, International Knee Documentation Committee osteoarthritis classification. **ACL, anterior cruciate ligament; PCL, posterior cruciate ligament; PLC, postero-lateral corner. ***OA, osteoarthritis

For UKR, ISAKOS defined the ideal patient as aged ≥ 65 years, with a sedentary lifestyle, an osseous deformity (TBVA) < 5°. The varus leg deformity should be correctable by physical examination and should be assessed on stress radiographs. Ligamentous stability, a full range of movement and absence of tibio-femoral subluxation were all defined as prerequisites. Regarding prognosis, Bonnin and Chambat [22] looked at tibial deformities and measured the TBVA, concluding that it was an important prognostic factor, with an HTO being more or less curative in patients with an abnormal TBVA (> 5°). The osteotomy corrected the congenital deformity in these patients and normalized the obliquity of the joint line while it was palliative in patients with a normal TBVA (< 5°). In well selected osteotomy patients based on the TBVA survival is > 90% at 10 years follow-up [22]. Jenny et al [23] found the same results with respect to the TBVA and prognosis after HTO.

Babis et al [24] also looked at obliquity of the joint line as a prognostic factor. In a series of patients with large varus deformities and osteoarthritis of the medial compartment, they demonstrated in a computer model that, with a double osteotomy, i.e. combining a distal femoral with a proximal tibial osteotomy, normal obliquity of the joint line was preserved and tension of stabilizing ligaments remained normal after correction of a varus leg alignment into slight valgus. The 29 simulated double osteotomies were performed in 24 patients and resulted in a 96% survival rate at a mean follow-up of 82.7 months. They concluded that preservation of obliquity of the joint line within narrow boundaries of 0° (SD 4) was the key to success. This has been confirmed in a recent short-term follow-up study by Hofmann and van Heerwaarden [25]. Few studies that have documented the survival of HTO however use survival curves calculated by the Kaplan-Meier method. The endpoint is usually the placement of a TKR; prognostic factors for survival are rarely used. Coventry et al [26] recorded a survival rate of 87% at five years and 66% at ten years. They found a lower survival rate in patients who were obese (51% *vs* 91%) and a higher survival in patients who had a valgus alignment ≥ 8° five weeks' postoperatively, compared to those who had a valgus alignment ≤ 5° (94% *vs* 63%). Similarly, Naudie et al [27] found obesity and failure to achieve the proper amount of correction to be negative prognostic factors. Holden et al [28] and Odenbring et al [29] found an age of < 50 years to be a positive prognostic factor.

Correction of the deformity

Classically, the correction will almost always be performed in the tibia. This is contraindicated in knee joints that have an oblique joint line, as the subsequent tibial osteotomy causes an increase in obliquity, or similarly in patients where a distal femoral deformity causes the varus malalignment [30]. Generally, the principles of deformity correction as formulated by Paley [31] should be respected. A lateral closing-wedge, a medial opening-wedge or a dome-type tibial osteotomy may be used [15, 32]. Many studies have shown good short- and mid-term follow-up results for the various techniques of osteotomy [19, 26, 33-37]. The outcome, however, strongly depends on an optimal and exact amount of correction [38]. Too little correction leads to poor results and a recurrence of the varus malalignment; too much leads to a valgus overload and osteoarthritis of the lateral compartment [18-20].

In valgus HTO, postoperative corrections from 8° to 10° valgus relative to the anatomical axis, and 3° to 5° valgus relative to the mechanical axis, have been proposed in the literature [18, 19, 39-43]. All recommendations however are from the articles authors own individual experience.

More recent authors have used the position of the mechanical leg axis relative to the width of the tibial plateau, pre- and postoperatively, as a guideline for the amount of correction needed [44]. Their recommendations are based on the work of Fujisawa et al [17] who concluded that, for optimal results, the corrected axis should run through the lateral 30% to 40% of the tibial plateau. Based on this clinical work, it is recommended by many that the postoperative mechanical axis should run laterally through the tibial plateau, at 62% of its entire width, measured from the medial side [45-47].

Some experimental data [48] on the effect of different axes of loading after osteotomy on the pressure distribution across the surface of the knee joint, measured using pressure-sensitive films, is available. In the only study performed under reproducible dynamic loading conditions, Agneskirchner et al [47] measured the pressure distribution across the joint, before and after an opening-wedge HTO, with the corrected axis running through the 'Fujisawa point' [17], with an intact medial collateral ligament (MCL), and after stepwise cutting of the MCL (Fig. 2). In varus alignment, most pressure was medial (65%), in neutral alignment it was also medial (60%), and in valgus alignment it was lateral (65%). After an opening-wedge osteotomy with an intact MCL, the pressure increased medially (71%), only after complete transection of the MCL did the pressure change to 64% laterally. They concluded that decompression of the medial compartment in an opening-wedge osteotomy is possible and effective by using a slight valgus overcorrection, i.e. through the Fujisawa point, but not without a release of the MCL.

With respect to correction of the slope, joint pressure and translational forces in the sagittal plane can be strongly influenced by changing the tibial slope. Neyret et al [49] found a strong relationship between increased tibial slope and increased anterior tibial translation, with a normal slope being 10° (SD 3). Generally, reducing the slope will correct for the increased anterior tibial translation in anterior cruciate ligament (ACL)-deficient knees and will reduce stresses on the ACL reconstruction improving antero-posterior stability; increasing the slope vice-versa will reduce translation in posterior cruciate ligament (PCL)-deficient knees. Agneskirchner et al [50] found that changes in tibial slope have a strong effect on the kinematics of the knee. They measured contact pressure after tibial flexion osteotomies which increased the tibial slope, and found a reduction of pressure in the posterior part of the tibial plateau. This effect can be used to unload secondary cartilage damage in an ACL-deficient knee, which is usually located in the posterior compartment. They concluded that valgus osteotomies can be combined with a flexion component of the proximal tibia, addressing complex knee pathologies which might possibly comprise damage to the posteromedial cartilage and antero-posterior and postero-lateral instability, in one procedure. There is further recent evidence that the slope increases after opening-wedge osteotomy and decreases after closing-wedge osteotomy [51].

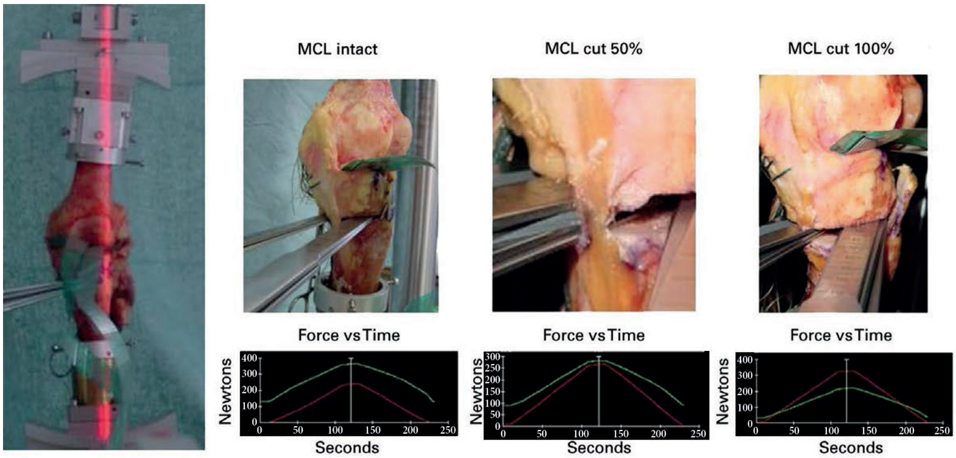


Figure 2. Photographs showing cartilage pressure distribution in high tibial osteotomy (HTO). Biomechanical test set-up for pressure-film measurements in the medial and lateral compartments of the knee while simulating an opening-wedge HTO. A vertically projected laser beam shows that the loading axis passes the knee joint at the Fujisawa point [17].
The graphs show the pressure distribution in the medial (green line) and lateral (red line) compartments, after a valgus opening-wedge osteotomy with an intact medial collateral ligament (MCL), and after dividing the MCL by 50% and 100%. Only a full release of the MCL distal to the opening-wedge HTO will cause cartilage pressure redistribution to the lateral compartment [47].

Techniques of osteotomy and methods of fixation

Most techniques of HTO are lateral-based closing-wedge osteotomies [15]. All require either a fibular osteotomy or a release of the proximal tibio-fibular joint; require osteosynthesis on the lateral side of the tibia and cause shortening of the leg. Especially larger corrections may cause marked shortening of the leg and a large offset of the proximal tibia, which may compromise later placement of the tibial component of a TKR. Furthermore two saw cuts are needed, and only malalignment in the frontal plane can be corrected. The exposure required on the lateral side includes release of the extensor musculature and has the risk of damage to the common peroneal nerve. Damage to this nerve is said to occur in between 3.3% and 11.9% of patients; electromyography shows damage in up to 27% of patients [52, 53].

Medial opening-wedge HTO techniques avoid muscle detachment, peroneal nerve dissection, shortening of the leg and don't require a fibular osteotomy. They require only one saw cut and corrections in the frontal plane can be combined with adjustments in the sagittal plane. In spite of these advantages these procedures have been less popular, mainly because implants for internal fixation have, until recently, been unable to withstand the axial and torsion forces in the proximal tibia. Several implant-related complications have been reported (Table II). Another cause of failure is that if the osteotomy cut is made above the tibial tuberosity, little room is left for proximal fixation. In recent years a modification of the opening-wedge technique has been proposed; a bi-plane osteotomy in which a transverse cut is combined with a second ascending cut behind the tuberosity [7]. With this technique more room is left for proximal fixation and a buttress is created which provides stability in the sagittal and transverse planes. Various methods of fixation have been used and these are summarized in Table II.

Table II. Comparison of fixation methods

Method	Advantages	Disadvantages
Cylinder cast only	Simple Cheap Exposure only required for saw cuts	Delayed bone healing[81] Loss of correction[82] Immobilization and its complications*
External fixation	Gradual correction of large deformities possible Angle of correction can be changed[32,83]	Bulky device Inconvenient for patients Pin-tract related complications[84]
Lateral osteotomy with staple fixation	Simpler and quicker than plate fixation Larger contact area after osteotomy closure	Requires casting Poor holding power of staples[32] Loss of correction[85] Complications of lateral approach** Large offset created in lateral proximal tibia[86,87]
Lateral osteotomy with plate fixation	More stable than staples[85] No casting required Immediate knee movement allowed Large contact area after osteotomy closure	Complications of lateral approach** Large offset created in lateral proximal tibia
Medial osteotomy with plate fixation	No lateral approach Simpler medial approach Only one saw cut needed Transverse/sagittal plane corrections possible No offset created	High initial demand on implant No large contact area Small lateral hinge[88] No compression of osteotomy possible Fixation failure[74,89]
Angle stable implants; applied either lateral or medial	Less damage to soft tissues and periosteum[56] No rigid compression needed Higher initial stability[58,59]	Relatively bulky implants Expensive

*arthrofibrosis, increased risk of venous thrombosis, stiffness, muscle atrophy, **muscle detachment, peroneal nerve dissection, fibular osteotomy required, leg shortening

Based on the principle that bone healing is induced by the micro-motion that occurs across a splinted zone, a variety of plates have been developed over the last 20 years, including locking compression plates (LCP), the point contact fixation system (PC-fix) and the less invasive stabilization system (LISS) [10, 11, 54-56], they all consist of an angle-stable plate-screw interface of locking bolts, which increase the stiffness of the construct and obviate the need for rigid compression of the plate against bone. With the LCP concept a combination screw hole was introduced which can be used both for conventional fixation with rigid compression, and for splinting. Good clinical results using these plates have been reported in treating fractures [9, 57]. These principles have been applied to the fixation of osteotomies. Plate fixators have been developed based on the LCP concept for opening- and closing-wedge osteotomies. For an opening-wedge osteotomy a long, T-shaped fixator plate is available (Tomofix, Synthes GmbH, Solothurn, Switzerland) [8]. The initial stability provided by this implant has been investigated in a biomechanical study by Agneskirchner et al [58] using third generation composite tibiae as a model, four different plates were tested: three types of spacer plate of different lengths, two with locking bolts, and the Tomofix plate fixator (Fig. 3).

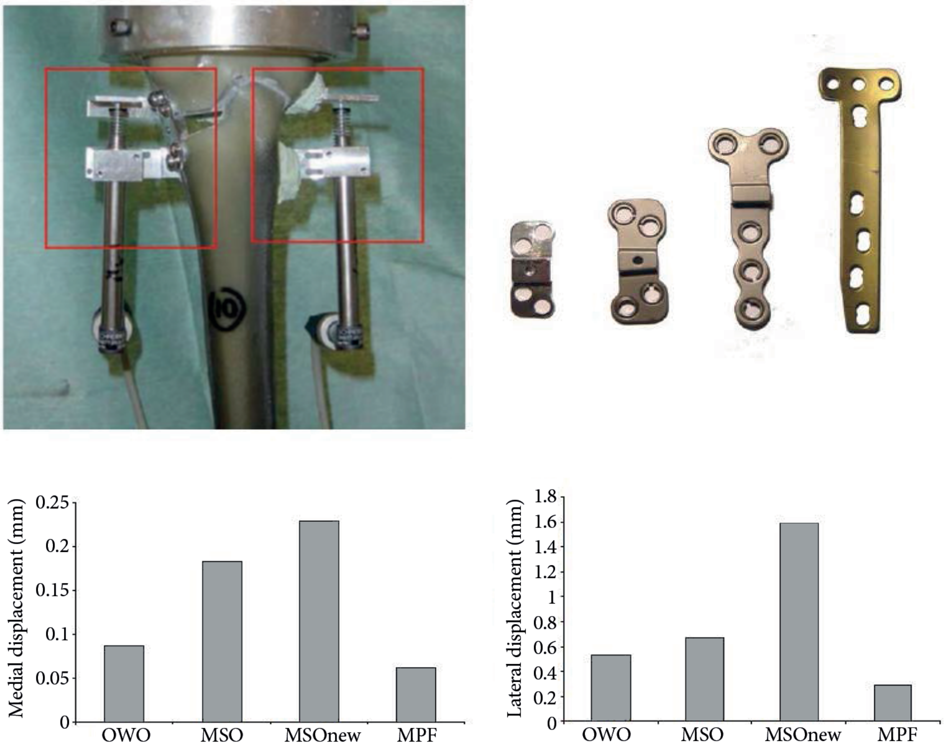


Figure 3. Top left) biomechanical test set-up for the measurement of displacement at the medial and lateral sides of a medial opening-wedge HTO during axial loading of third-generation composite tibiae and, top right) the different plates used. Bottom left) medial and lateral linear displacement transducer measurements of the four tested implants: conventional spacer plate (OWO), short spacer plate with multi-directionally-insertable locking bolts (MSO), long spacer plate with multi-directionally insertable locking bolts (MSOnew), and medial tibial plate fixator (MPF). The MPF shows significantly less displacement during axial loading than the other implants [58].

They applied axial compression on the tibiae using a materials testing machine under standardized alignment of the loading axis. Single load-to-failure tests and load-controlled cyclical tests to failure were performed. Failure occurred at the bone bridge of the lateral cortex in all tested implants. In the single load-to-failure tests the Tomofix plate resisted the most force and in the cyclical load-to-failure tests it resisted more than twice the amount of loading cycles than did the short spacer plates. The movement at the osteotomy gap was smallest in the Tomofix, with a reduction in displacement of between 65% and 88% compared to the various spacer plates. The highest residual stability after failure of the lateral cortex was also observed with the Tomofix plate. These results suggest that the design of the implant strongly influences the primary stability of a medial opening-wedge tibial osteotomy. They concluded that a rigid long plate fixator with locking bolts yielded the best results [58].

The clinical results seem to correlate with these biomechanical observations by Agneskirchner et al [58]. Lobenhoffer et al [7] reported a 6% rate of implant failure with loss of correction in a series of 101 HTOs using a spacer plate. Spahn [59] compared spacer plates with an angle-stable implant and found that 11.7% of patients treated with a spacer plate needed additional lateral osteosynthesis and loss of correction related to the implant was seen only in patients treated with a spacer plate. Staubli et al [8] investigated 92 HTOs treated with a Tomofix plate and observed 2% loss of correction and 2% delayed union. Lobenhoffer et al [60] reported on 262 consecutive HTOs using a Tomofix plate; there was no loss of correction, although two patients developed a pseudo-arthrosis, both successfully treated with cancellous bone graft.

Operative technique

At the author's institutions for valgus HTO a bi-plane medial based opening-wedge osteotomy is performed, fixation is with the Tomofix fixator plate (Fig. 4) [61].

Arthroscopy may be performed routinely before HTO in order to debride the degenerative compartment and to check the integrity of the lateral compartment. In some cases the arthroscopic assessment will lead to a change in surgical intervention, and therefore, arthroscopy is regarded by some as indispensable before HTO [62]. The starting position of the procedure is with the knee flexed to 90°. A fluoroscope is mandatory, with visualization possible in two directions. The medial side of the tibia is exposed through either a transverse or alternatively a longitudinal incision. The superficial fibres of the medial collateral ligament are mobilized and a distal release is performed. The upper border of the pes anserinus marks the starting point of the osteotomy. Two Kirschner wires are placed under fluoroscopic control to mark the saw cut. The lateral aiming point is the upper third of the proximal tibio-fibular joint, 10 mm medial to the lateral cortex. This is the hinge point of the osteotomy. Only the posterior two-thirds of the tibia are cut. The separate ascending cut of the bi-planar osteotomy is performed 1.5 - 2 cm behind the tibial tuberosity in the frontal plane, parallel to the anterior tibial margin (Fig. 4). The osteotomy is opened gradually using chisels and a specially-calibrated spreading device. The gap is then measured and compared with the planned length of the base of the wedge. If the desired correction is achieved, and checked further with a rigid bar projected over the centers of the hip and ankle, a laminar bone spreader is inserted. It is of utmost importance to obtain full extension during these measurements which sometimes means that the lateral hinge may be fractured and later compressed during fixation. The plate fixator is introduced into the wound and then pushed distally into a subcutaneous tunnel until its long arm is aligned with the tibial shaft. Eight locking bolts are used in the Tomofix device, four proximal and four distal, of which three are uni-cortical. An additional lag screw is applied through the first distal hole below the osteotomy after proximal fixation, inducing compression on the lateral hinge point of the osteotomy and eliminating any potential distraction or instability in this area (Fig. 4).

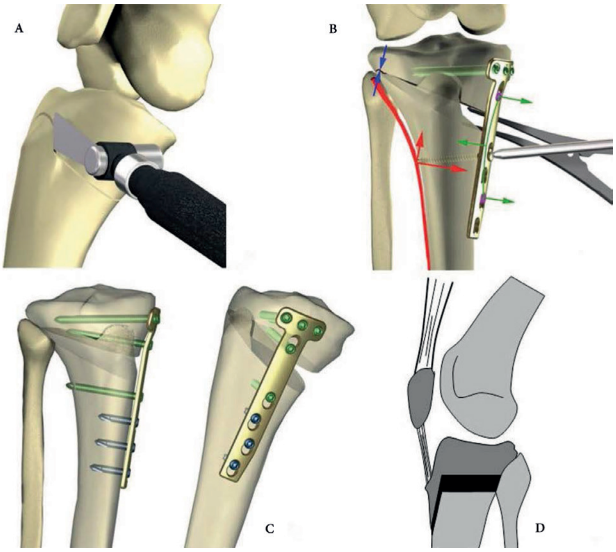


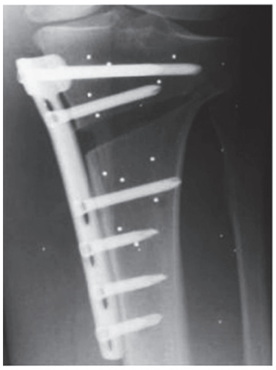
Figure 4. Diagrams that show the surgical technique for a bi-plane opening-wedge HTO fixated by an internal fixator plate. The ascending cut of the bi-plane osteotomy is performed behind the tibial tuberosity (**A**). A lag-screw is (green arrow) inserted causing a force vector upwards (red arrows) with lateral hinge-point compression (blue arrows) (**B**). Configuration of the final fixation configuration in frontal and sagittal views (**C**). Modification of surgical technique: distal tuberosity cut to prevent patella infera in large opening-wedge corrections (**D**) [63].

A modification of the bi-planar osteotomy can be used, especially in large opening-wedge corrections, or in cases of pre-operative patella baja. Instead of making the second osteotomy cut proximally, the tibial tuberosity is cut distally (Fig. 4) [63].

The supposed effects of alterations in patellar height in HTO [64-66] have been studied by Gaasbeek et al [63]. They compared the effects on patellar height, calculated using the Caton Index [67] in patients who had undergone a standard proximal-tuberosity osteotomy (PTO) and a modified distal-tuberosity osteotomy (DTO). They found that patellar height does not change with the latter, but in PTO it decreased significantly. In the PTO group, patellar height and the angle of correction were related: the larger the correction angle, the lower the postoperative patellar height. Based on these results, they concluded that a DTO can prevent changes in patellar height, and recommended that it should be performed in patients who require a large correction. In a recent study by Stoffel et al [68] both techniques were compared by measuring patello-femoral contact stress. A DTO produced significantly less contact stress than did the PTO technique. We use a DTO in those patients with a pre-existing low patella, and consider it in opening-wedge corrections larger than 8° to 10°.

Postoperative care and weight bearing protocol

Postoperative cryotherapy and intermittent venous compression are recommended to reduce swelling. Starting on the first postoperative day, partial weight bearing (15 kg to 20 kg) is allowed. From four to six weeks the amount of weight bearing allowed is based on the amount of pain, although after six weeks full weight bearing is permitted. Full range of active and passive movement is allowed and started with the help of a physiotherapist.



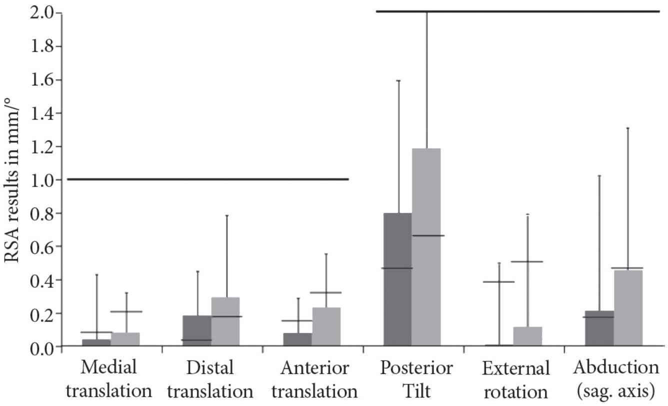


Figure 5. Radiostereometry (RSA) measurements of fixation stability in postoperative rehabilitation. Left) Radiograph showing RSA bone markers inserted proximal and distal of an opening-wedge HTO Right) bar chart showing the mean displacements of RSA markers inserted proximal and distal to an opening-wedge HTO during the first 12 months after surgery. Rehabilitation, with early postoperative full weight bearing (dark grey bars) compared to full weight bearing after six weeks (light grey bars) [69, 70].

Regarding weight bearing two studies have been performed to investigate the weight bearing protocol and the stability of fixation. Luites et al [69] in a randomized controlled trial, compared stability between opening-wedge and closing-wedge HTO with the Tomofix plate fixator in 42 patients, using radiostereometry (RSA) (Fig. 5). All patients were allowed partial weight bearing for a period of six weeks and full weight bearing thereafter. RSA measurements made immediately after surgery and at six weeks, three, six and 12 months postoperatively were compared to measured micro-movements at the osteotomy. They found no difference between the two techniques and no significant displacement compared to measurements made immediately after surgery. In a second study, Brinkman et al [70] measured the stability of fixation using the same RSA technique in 14 opening-wedge osteotomies with full weight bearing starting two weeks after surgery. Again, no significant movement at the osteotomy was recorded (Fig. 5). They concluded that fixation was stable without loss of correction with early weight bearing. Based on this research early weight bearing can be started depending on pain and wound healing; which means that most patients are fully weight bearing after 2 to 3 weeks.

Bone healing in HTO

The general principles of bone healing apply to closing-wedge osteotomies. They can be considered optimally controlled fractures that are treated according to the principles of fracture treatment. With radiographs taken at distinct intervals, e.g. at six weeks, three, six and 12 months, progression of bone healing can be monitored.

Bone healing in opening-wedge osteotomies differs, however, because of the distraction and the gap which is created. Staubli [71] extensively studied bone healing in HTO performed without filling the gap and found that on plain radiographs healing occurs from lateral to medial, starting at the laterally-based hinge point (Fig. 6). On MRI scans, at six weeks the hematoma in the gap is replaced by connective tissue, which provides a scaffold for further callus formation and ossification, visible by three months postoperatively (Fig. 6).

Based on the assessment of standard radiographs, approximately 75% of the gap has filled with new bone by six months. CT scans at this point show progression in bone mineralization but no signs of full consolidation, indicating that bone healing is overestimated at six months on standard radiographs, with the CT scans showing progression at a slower pace (Fig. 6). One year after operation full consolidation can be found in approximately 90% of patients on radiographs, MRI and CT scans. Based on this the current authors do not advise removal of the plate before 1.5 years after osteotomy. Many surgeons, however, prefer to fill the gap with bone graft, based on various arguments; reduction in local blood loss, an increase in mechanical stability and an increase in bone healing [72-77]. In one of the authors centers (Sint Maartenskliniek, Nijmegen, The Netherlands) opening-wedge HTO has been performed using Tomofix plates and porous tri-calcium phosphate (TCP) as a filling material. Resorption of TCP, bone ingrowth and bone remodeling were studied on plain radiographs [78] and on bone biopsies from the areas of the opening-wedge at the time of removal of the plate [79]. It was found that the TCP was resorbed, with complete incorporation and remodeling into new bone [79]. Based on this, our view is that when using a stable implant in bi-planar opening-wedge HTO, only gaps > 20 mm should be filled; for this purpose autologous grafts are recommended. If filling material is preferred, porous TCP is a safe option that will not interfere with normal bone healing. However, no prospective randomized trials have yet been published that compare the various filling materials with no filling at all.

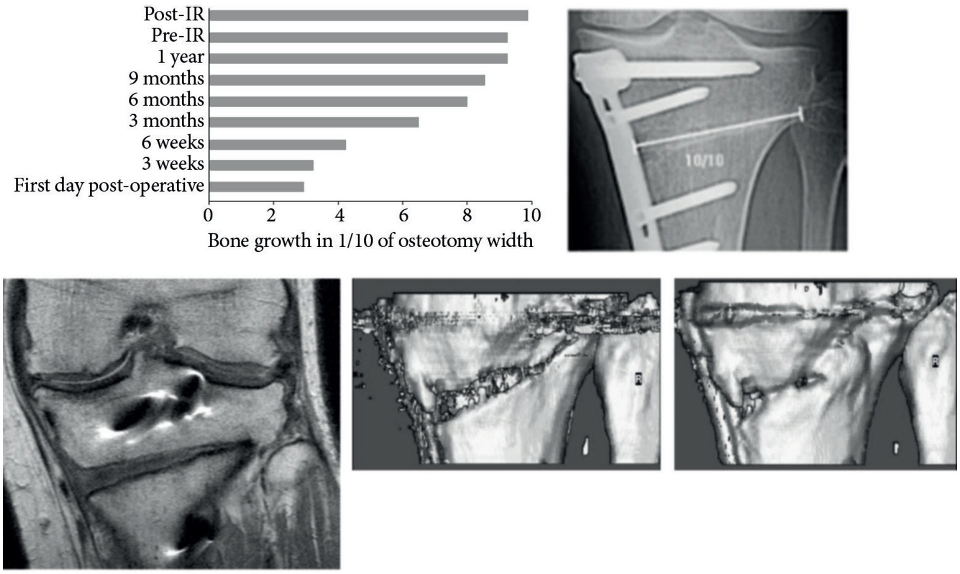


Figure 6. Bone healing in an opening-wedge HTO. Bar chart showing (top) progression of bone growth in an osteotomy gap related to the width of the osteotomy starting at the laterally based hinge point. 71 IR, implant removal, MR (T1) image showing (bottom left) callus formation and ossification three months after HTO and (bottom right) three-dimensional CT images six weeks (left) and six months (right) after an opening-wedge HTO (postero-lateral view) showing progression in bone mineralization but no full consolidation at six months postoperatively (arrow).

In conclusion, high tibial osteotomy is a viable treatment option for a well-defined patient group suffering from osteoarthritis of the medial compartment and ligamentous imbalance of the knee. Based on new data obtained by biomechanical testing and clinical research, the biplanar osteotomy fixed with an internal plate fixator is very stable. Although bone healing in opening-wedge osteotomies may take from as little as three up to 12 months, early full weight bearing is possible with these angle-stable LCP concept based plates and good bone healing is achieved without loss of correction.

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Chapter 5

Axial and torsional stability of supracondylar femur osteotomies: biomechanical comparison of the stability of five different plate and osteotomy configurations

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Abstract

Little is known regarding the biomechanical stability and stiffness of implants and techniques used in supracondylar femur osteotomies (SCO). Therefore, fixation stability and stiffness of implants to bone was investigated under simulated physiological loading conditions using a composite femur model and a 3D motion-analysis system.

Five osteotomy configurations were investigated: (1) oblique medial closing-wedge fixated with an angle-stable implant; (2) oblique and (3) perpendicular medial closing-wedge, both fixated with an angled blade plate; and lateral opening-wedge fixated with (4) a spacer plate and (5) an angle-stable lateral implant. The motion measured at the osteotomy was used to calculate the stiffness and stability of the constructs.

The least amount of motion and highest stiffness was measured in the medial oblique closing-wedge osteotomy fixated with the angled blade plate. The lateral opening-wedge techniques were less stable and had a lower stiffness compared with the medial; the oblique saw cuts were more stable and had a higher stiffness than the perpendicular.

The data on the differences in the primary stability of bone-implant constructs used in SCO in this study can be used as reference for future testing of SCO techniques. Furthermore, it is recommended that based on the differences found, the early postoperative rehabilitation protocol is tailored to the stability and stiffness of the fixation method used.

Introduction

Distal femoral supracondylar osteotomy (SCO) is a well-established surgical procedure for the treatment of lateral compartment osteoarthritis of the knee with a valgus leg alignment [6, 11, 13, 16-18]. Stability of the plate and osteotomy construct after SCO is crucial in order to retain the achieved correction during functional postoperative rehabilitation. An oblique closing-wedge osteotomy direction has been suggested to enhance stability [17]. Devices used for the fixation of supracondylar fractures have been previously investigated biomechanically using both cadaver and composite bone [3, 5, 25]. The artificial bones used provided reproducible bone properties and allowed the circumvention of the problems of availability and inter-specimen variability associated with cadaver specimens. The structural equivalence of these composite femurs with human bones has been validated [9, 22].

In this study, the stability and stiffness of four implant devices for opening-wedge and closing-wedge SCO techniques were tested. Simulated physiological loading and subsequent loading to failure were applied using a material testing machine (MTS), and osteosynthesis gap measurements were performed using a three-dimensional (3D) motion-analysis system. The specific research goals of the study were to compare (1) the standard medial closing-wedge SCO technique using an angled blade plate and rigid compression and a new medial distal femur plate based on the locking compression plate (LCP) principles [8], (2) the lateral opening-wedge technique using both a conventional and an LCP lateral distal femur plate and closing-wedge techniques and (3) the medial closing-wedge oblique SCO and medial closing-wedge perpendicular SCO technique.

Materials and methods

Thirty short-glass-fiber-reinforced (SGFR) third-generation composite replicate femurs (Sawbones Europe AB, Malmo, Sweden) were used in five test modalities: (1) ABPobl: oblique medial closing-wedge SCO with a 90°-angled blade plate (AO/ASIF, Davos, Swiss), (2) MDF: oblique medial closing-wedge SCO with a medial LCP (Tomofix, Synthes, Bettlach, Swiss), (3) ASP: lateral opening-wedge SCO with a non-angle-stable spacer plate (Arthrex spacer plate, Naples, FL, USA), (4) LDF: lateral opening-wedge SCO with a lateral LCP (Tomofix, Synthes, Bettlach, Switzerland) and (5) ABPperp: perpendicular medial closing-wedge SCO with a 90°-angled blade plate (AO/ASIF, Davos, Swiss) (Fig. 1 and Table I). Six femurs were available for each test modality, 3 for axial testing and 3 for torsional testing; all 30 femurs were subsequently tested to failure (Table I).

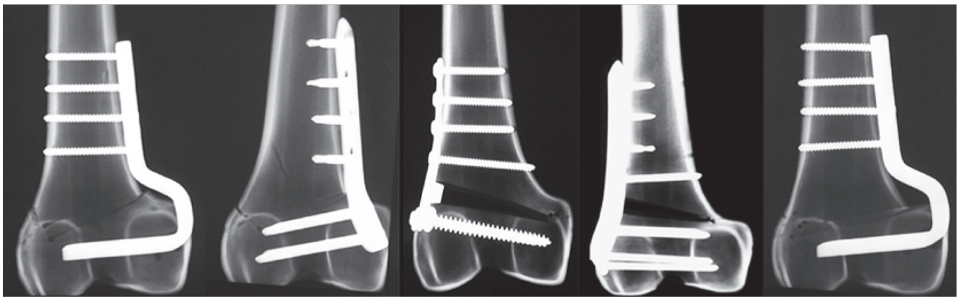

Figure 1. Overview of the five configurations tested. AP radiographs of all implants, from left to right: ABPobl angled blade plate oblique osteotomy, MDF angle-stable implant oblique osteotomy, ASP nonangle-stable lateral implant, LDF angle-stable lateral implant and ABPperp angled blade plate perpendicular osteotomy.

Table I. Overview of the configurations and test protocols

Total No	Implant type	SCO technique	No femurs	Test runs per femur	Cycles	Axial Pre-load	Axial Loading	Torsional Pre-load	Torsional Loading
	Axial loading			**Axial loading**					
15	Blade plate	oblique	3	1	100	10N	150N	-	-
	Blade plate	perpendicular	3	2	100	10N	800N	-	-
	MDF	oblique	3	3	1	-	failure	-	-
	LDF	lateral open	3						
	ASP	lateral open	3						
	Torsional loading			**Torsional loading**					
15	Blade plate	oblique	3	1	100	-	-	0.5 Nm	5 Nm
	Blade plate	perpendicular	3	2	100	150N	-	0.5 Nm	5 Nm
	MDF	oblique	3	3	100	800N	-	0.5 Nm	5 Nm
	LDF	lateral open	3	4	1	-	-	-	failure
	ASP	lateral open	3						

An overview of the number of femurs, the different implants, and SCO techniques (left) and loading protocols that were used in the tests is shown (right).

Experimental set-up

The osteotomies were performed, and the plates implanted according to the standard surgical procedure for each implant. A wedge of 10° was either removed in the closing-wedge SCO or created in the opening-wedge SCO. To achieve this, all composite femurs were aligned in a standardized way using an alignment jig and a femur saw guide (Balansys, Mathys Medical, Bettlach, Swiss) that provided a reproducible osteotomy position, osteotomy direction and wedge size. The lateral opening-wedge and the oblique medial closing-wedge were directed

20° oblique to the distal femur condylar line, whereas the medial perpendicular wedge was directed parallel to the distal femur condyles. The bone deformation needed for the opening or closing of the wedge and the implant fixation were performed without producing a fracture in the opposite bone bridge. The femur head and trochanter and the distal femur end were thereafter embedded in a polyurethane-based cold-curing resin (Ureol FC 53, Vantico GmbH, Wehr, Germany) in a specially constructed fixture; the fixture allowed for mounting of the femur in a materials testing machine (MTS)(Mini Bionix, MTS Systems Corporation, Eden Prairie, MN, USA) (Fig. 2). The fixture was designed in such a way that the axis of loading of the replicate femur in the MTS was through the centre of the femur head proximal and through a point 18-mm medial from the mid-condylar distance, creating a mechanical femur axis of 2°; reproducing loading in the normally aligned human knee after a SCO for valgus osteoarthritis [10, 12] (Fig. 2). The fixture allowed the MTS to apply both an axial load along and a torsion load around the mechanical axis of the femur (Fig. 2).

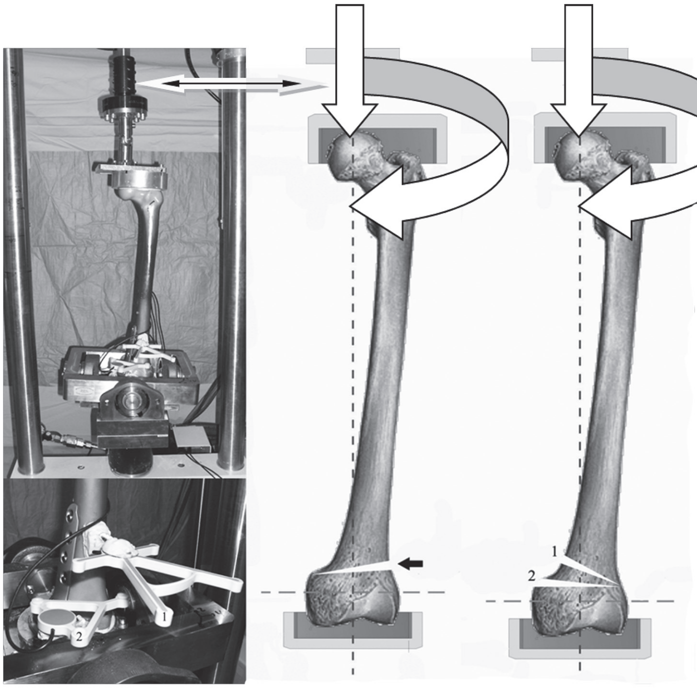

Figure 2. Schematic representation and a photograph of the test setup that was used are shown. Top left the setup in the MTS. Bottom left close up of the 3D measuring system; 1 and 2, microphone and speaker. Right corresponding schematic view of the setup and loading axis used in the MTS, a loading axis just medial from the midcondylar distance is used, corresponding with a mechanical loading axis of 2° varus. The white arrows show the direction of force applied by the top half of the MTS. Also shown are the lateral opening-wedge osteotomy (black arrow), and the (1) Oblique osteotomy and (2) Perpendicular osteotomy.

Measuring system

The principles of rigid body motion were used to measure (micro) motion across the SCO. Reference point pairs, relative to which motion was measured, were defined on the replicate femur both proximal and distal to the osteotomy gap; two points across the midpoint of the intact cortical bridge, two points midway across the osteotomy at the level of the deepest point of the trochlea and two points just posterior of the plate on the femur.

Motion (displacement) of the diaphysis of the femur proximal to the osteotomy was measured relative to the femur condyles distal to the osteotomy using an ultrasound 3D motion-analysis system (CMS20S, Zebris Medizintechnik, GmbH, Isny, Germany). This system is based on the travel time measurement of ultrasonic pulses that are emitted by miniature speakers on a marker-triplet to microphones on a second marker-quartet (Fig. 2). Its use has been validated in cervical spine kinematics analysis [4, 24]. Its current use has, to the best of our knowledge, not been documented previously. The accuracy of the system as reported by the manufacturer is 0.01 mm (Zebris Medizintechnik, GmbH, Isny, Germany). The sensor and emitter markers were rigidly fixed to the femur using bone cement (Palacos, Biomet, Inc, Warsaw, IN, USA). After mounting of the femur in the MTS with the microphone template attached, a coordinate system was defined based on landmarks on the distal femur using a calibrated pointer device temporarily attached to the emitter-marker. The coordinate axes were defined in such a way that the anatomical medial-lateral axis corresponded to the Y-axis, the anterior posterior axis to the X-axis and the proximal-distal axis to the Z-axis. The coordinates of the point pairs relative to which motion was measured were then registered. Before the start of the loading cycles, the MTS was first calibrated to the 0 position, meaning it was not putting any pressure on the loaded femur. In this state, the Zebris system was calibrated to the 0 position. This process was repeated for each femur for each test run. During testing, the motion-analysis system continuously measured displacement at a rate of 20 Hz. Force and moment data were recorded by the materials testing machine at a rate of 20 Hz.

Loading protocol

The replicate femurs were subjected to axial and torsional loading protocols designed to simulate physiological loading (Table I). Cyclical axial loading was performed at two loading levels (150 and 800 N) on 3 femurs per SCO configuration simulating partial and full weight bearing in an 80-kg patient. After an axial preload of 10 N was achieved, the femurs were tested during 100 cycles for each load at a rate of 0.5 Hz. Each femur was subsequently tested to failure under displacement control at a rate of 0.1 mm per second. Failure was defined by a drop of actuator loading, either because of failure of the bone, bone-implant construct, or of the implant itself. Cyclical torsional loading was also performed in 3 femurs per SCO modality using a 0.5 Nm torsional preload. Internal rotation around the Z-axis with a cyclical moment loading of 5 Nm at a rate of 0.25 Hz was applied during 100 cycles, with an increasing axial pre-load (Table I). The different axial preloads were used to simulate no, partial and full weight bearing. After completion of all three runs, each femur was tested to failure under displacement control at a rate of 0.25° per second. Criteria for failure were the same as used for the axial loading failure tests.

Statistical analysis

The displacement data recorded were computed using a custom-written program in Mathematica (version 5.0, Wolfram research, Inc, Champaign, IL, USA); the change in position and the angle of rotation around all axes for each measuring point and the change in absolute distance between the measuring points were calculated. Displacement at the SCO was calculated using the change in the (absolute) distance between the measuring points per loading cycle. The amount of motion that occurs at the SCO was defined as the difference between the maximum increase and maximum decrease in the distance between measuring points; determined for each cycle and per measuring point. A greater mean difference calculated over 100 cycles and 3 measuring points indicates more motion allowed by the bone-implant construct. Stability was subsequently defined as the amount of motion allowed by the construct. A similar approach was used in the torsional tests. The amount of motion was calculated by determining the amount of rotation around the Z-axis that is allowed by the bone-implant construct during each cycle. Stability in torsion was defined as the amount of rotation allowed by the construct.

The stiffness under axial compression of the construct was calculated by plotting displacement at the SCO during the failure test, defined as the average amount of movement on the Z-axis of the 3 previously defined point pairs, against the force data. Stiffness of the bone–implant construct was defined as the slope of the linear portion of the force osteotomy deformation curve (i.e. the force required per millimeter of displacement). Stiffness under torsion loading was calculated by plotting the rotation around the Z-axis over time against the moment (Nm) applied by the MTS and defined as Nm required for one degree of rotation.

Statistical analysis was performed using SPSS statistical software (Version 11.5, SPSS, Inc, Chicago, IL, USA); one-way ANOVA was used to measure statistical differences between modalities, and P values <0.05 were considered significant using a 95% confidence interval (CI95).

Results

Axial loading

No visible damage to bone, bone–implant construct or implant was found during the axial loading tests. During each cycle of loading and unloading, a corresponding movement at the osteotomy was observed to occur. The displacement data showed that there were varying differences between the configurations tested, with varying levels of statistical significance. (Table II, III and Fig. 3). The oblique OT (ABPobl) allowed statistically significantly less motion than the perpendicular OT (ABPperp) in the 800 N test (Table III). ABPobl compared with MDF allowed less motion in all tests, but to a statistically significant level only in the 150 N axial tests (Table III).

Table II. Axial and torsion test results

Axial	OT type	Preload	Axial load	N	Mean	SD ±	95% CI for Mean Lower-Upper Bound		Min	Max
	ABPobl		150N	300	0.057	0.038	0.052	0.061	0	0.143
	MDF			300	0.070	0.043	0.065	0.075	0	0.256
	ASP			300	0.094	0.046	0.089	0.100	0	0.239
	LDF			300	0.068	0.044	0.063	0.073	0	0.226
	ABPperp			300	0.038	0.065	0.030	0.045	0	0.178
	ABPobl		800N	300	0.100	0.043	0.095	0.105	0.057	0.720
	MDF			300	0.105	0.030	0.101	0.108	0.037	0.183
	ASP			300	0.170	0.034	0.166	0.173	0.093	0.336
	LDF			300	0.108	0.025	0.106	0.111	0.013	0.191
	ABPperp			300	0.112	0.032	0.109	0.116	0	0.241
Torsion										
	ABPobl	0N		300	0.049	0.018	0.047	0.051	0.009	0.136
	MDF			300	0.053	0.017	0.051	0.055	0.015	0.111
	ASP			300	0.043	0.018	0.041	0.045	0.010	0.093
	LDF			300	0.055	0.016	0.053	0.057	0.017	0.114
	ABPperp			300	0.060	0.026	0.057	0.063	0.020	0.158
	ABPobl	150N		300	0.042	0.014	0.041	0.044	0.014	0.079
	MDF			300	0.045	0.018	0.043	0.047	0.006	0.104
	ASP			300	0.052	0.021	0.049	0.054	0.011	0.093
	LDF			300	0.047	0.014	0.045	0.048	0.011	0.084
	ABPperp			300	0.061	0.013	0.060	0.062	0.030	0.102
	ABPobl	800N		300	0.041	0.015	0.040	0.043	0.000	0.082
	MDF			300	0.044	0.015	0.042	0.045	0.014	0.130
	ASP			300	0.045	0.017	0.043	0.047	0.010	0.094
	LDF			300	0.053	0.017	0.051	0.055	0.014	0.094
	ABPperp			300	0.056	0.015	0.054	0.058	0.022	0.095

Results for the axial and torsion tests are shown; osteotomy type, axial load, total number of cycles, and the mean displacement, including the standard deviation (SD), CI_{95} and Minimum and Maximum, are detailed.

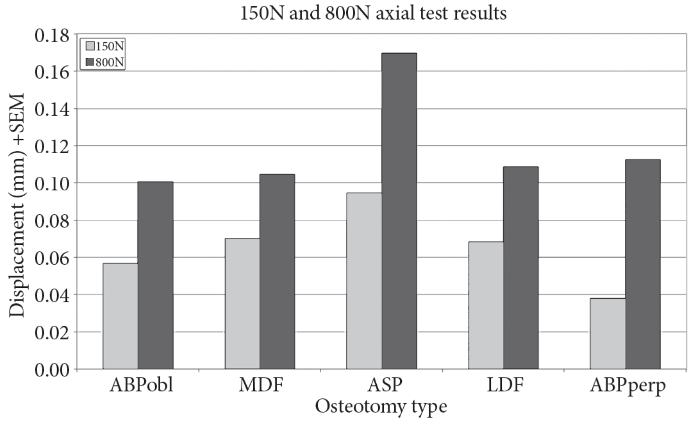

Figure 3. Graphic view of the axial test results is shown. Results for both the 150 and 800 N axial compression-tests; results for each test is displayed for each modality; displacement is displayed in millimetres (mm).

Table III. Statistical comparison of the axial and torsion test results

		Axial tests		Torsion tests			Axial tests		Torsion tests		
		150N	800N	0N	150N	800N	150N	800N	0N	150N	800N
ABPobl	MDF	>	>	>	>	>	0.0001	-	-	-	-
	ASP	>	>	<	>	>	0.0001	0.0001	0.001	0.0001	-
	LDF	>	>	>	>	>	0.035	0.03	0.004	0.014	0.0001
	ABPperp	<	>	>	>	>	0.0001	0.0001	0.0001	0.0001	0.0001
MDF	ASP	>	>	<	>	>	0.0001	0.0001	0.0001	0.0001	-
	LDF	>	>	>	>	>	-	-	-	-	0.0001
	ABPperp	<	>	>	>	>	0.0001	0.038	0.0002	0.0001	0.0001
ASP	LDF	<	<	>	<	>	0.0001	0.0001	0.0001	0.002	0.0001
	ABPperp	<	<	>	>	>	0.0001	0.0001	0.0001	0.0001	0.0001
LDF	ABPperp	<	<	>	>	>	0.0001	-	0.009	0.0001	-

The motion data of each configuration is compared to the other configurations. On the left, the arrows indicate which configuration is more stable, and on the right, the statistical level of significance of the differences is shown.
For example the first row shows that the ABPobl is more stable than the MDF in all tests, but only in the 150N axial test is the difference statistically significant. Only p values < 0.05 are displayed (- indicates no statistical significance).

Axial failure tests

All 15 failure tests resulted in a per-trochanteric femoral neck fracture; failure occurred proximally to the osteotomy. No macroscopically observable failure at the bone-implant interface or of the implant itself was observed. Fracture of the medial opposite cortex bone-bridge occurred during the failure test in all ASP femurs, as well as in 1 LDF. No fractures of the opposing lateral cortex bone-bridge were observed in the medial closing-wedge SCOs. During the axial failure tests, the force time course of loading typically demonstrated an increasing axial compression load with a sudden drop in load at failure. Calculated stiffness was found highest in the ABPobl configuration (Table IV and Fig. 4).

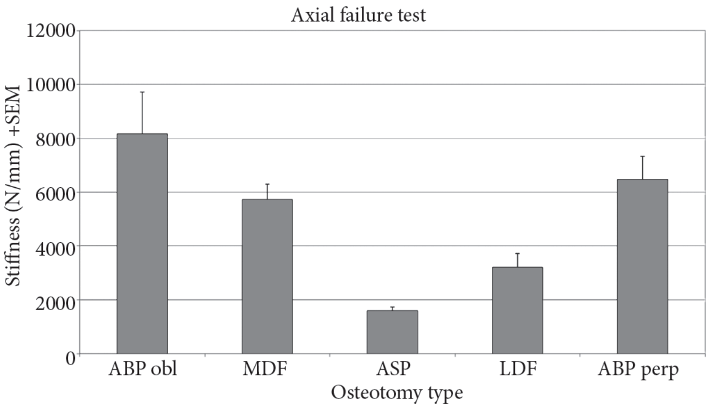

Figure 4. Graphic view of the axial failure test results is shown. Results for the axial failure tests; stiffness is displayed in Nm per millimeter displacement on the Z-axis.

Table IV. Axial and torsional failure test results

	Axial Stiffnes					Torsional Stiffness				
Osteotomy type	**N**	**Mean**	**SD ±**	**Min**	**Max**	**N**	**Mean**	**SD ±**	**Min**	**Max**
ABPobl	3	8170	2682	6021	11176	3	31.7	4.5	26.9	35.9
MDF	3	5723	990	4618	6528	3	28.4	3.2	26.0	32.1
ASP	3	1601	220	1350	1758	3	21.8	16.9	4	37.3
LDF	3	3197	895	2227	3989	3	23.9	18.3	3.2	37.8
ABPperp	3	6464	1521	4875	7906	3	22.6	4.2	17.9	26.2

Results for the axial and torsional failure tests are shown; the number of femurs (N), mean stiffness and minimum and maximum are detailed. Axial stiffness is in N/mm and torsional stiffness in Nm/°.

Torsional loading

No visible damage to bone, bone-implant construct or implant was found during the torsion tests. The lateral opening-wedge SCO techniques (ASP and LDF) showed more motion compared with ABPobl and MDF (Table II and Fig. 5). Maximum motion was measured in all tests in ABPpp; it allowed statistically significantly more motion than the ABPobl and MDF in all tests (Table III).

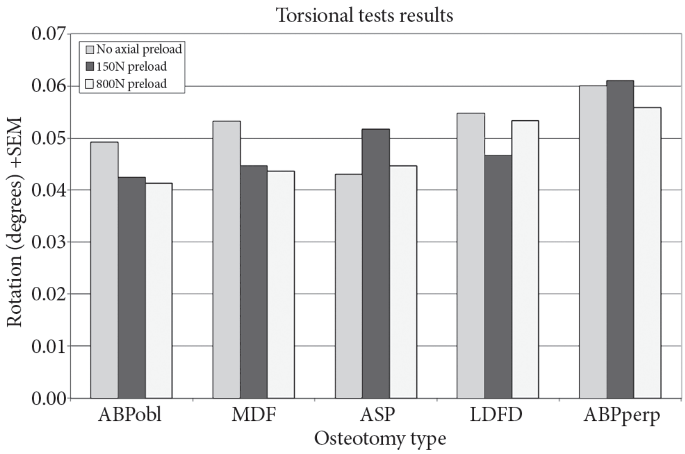

Figure 5. Graphic view of the torsional test results is shown. Results for the torsional test runs; results for each test are displayed for each modality; rotation is displayed in degrees rotation.

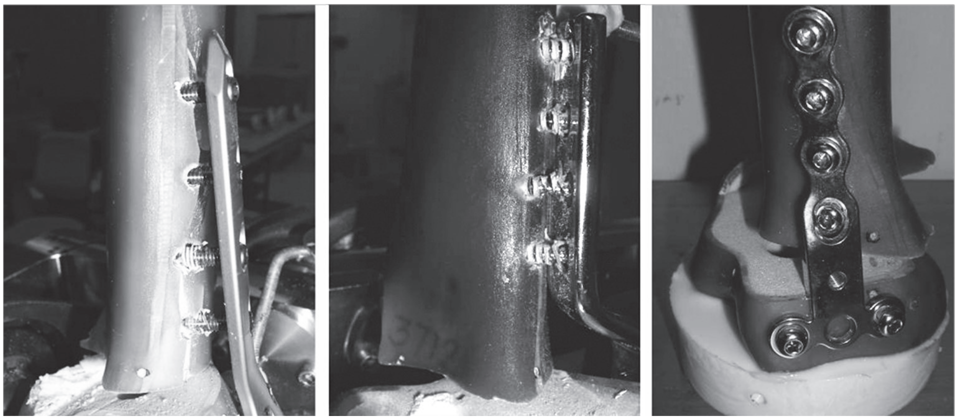

Figure 6. Detailed view of the failure patterns in the torsional failure tests. Fracture of the femur at the screw-bone interface in the MDF in the torsional failure tests (left).The screws have clearly been bent at the screw-bone interface in the ABPperp in the torsional failure test (middle). The ASP itself has been bent in the torsional failure test (right).

Torsional failure tests

In all medial closing-wedge SCO techniques, the opposing lateral cortex bone-bridge fractured first. Thereafter, in the ABPobl configuration, a subsequent spiral fracture occurred just proximal from the plate, whereas in ABPperp no fracture occurred, the proximal femur end kept turning clockwise; with bending of the screws at the screw-bone interface clearly visible (Fig. 6). In the MDF configuration, a fracture occurred at the screw-bone interface in all femurs (Fig. 6). In both ASP and LDF configurations, the opposite medial cortex fractured almost immediately after the start of the test in one femur (* in Table IV). Thereafter, in ASP, the proximal femur end kept turning inward as the plates themselves bend (Fig. 6). In LDF, subsequently, there was a spiral fracture just proximal of the plate in one femur, a spiral fracture that extended to the bone-screw interface in the second, and there was failure in the third because the screws were pulled out of the bone. Calculated stiffness was greatest in the ABPobl configuration (Table IV and Fig. 7).

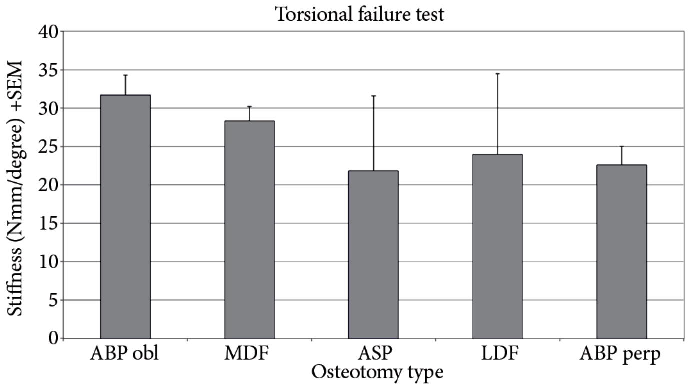

Figure 7. Graphic view of the torsional failure test results. Results for the torsional failure tests; stiffness is displayed in Nm/degree rotation around the Z-axis.

Discussion

In this comparative biomechanical study, the oblique closing-wedge osteotomy with conventional angled blade plate and rigid compression was found to be the most stable configuration. In the current study, an attempt was made to simulate physiological loading, unlike the non-physiological uniaxial stress and fatigue testing often done by the plate manufacturer. A physiological mechanical loading axis of 2° varus of the femur was used, the entire femur was loaded, loading was applied through the center of the femoral head and loads simulating partial and full weight bearing were used in the axial loading tests. Furthermore, an attempt was made to simulate the natural torque moment that occurs during flexion-extension of the femur, during walking with partial and full weight bearing. It is the authors' opinion that the data provided in this study can therefore be used for decision-making in clinical practice regarding functional rehabilitation.

The superior stability and stiffness of the angled blade plate (ABPobl) when compared with the LCP concept based MDF configuration is not unexpected. LCP concept based plates in general act as an internal fixator, whereas the angled blade plate is compressed rigidly against the cortex allowing for less motion at the fracture site, or in the case of a SCO, the osteotomy. Subsequently, bone healing in LCP fixation is fundamentally different from bone healing with rigid fixation: secondary versus primary bone healing. The various biological advantages of LCP fixation versus rigid compression apply to LCP fixation in osteotomies [23]. The clinical use of angle-stable implants (LCP) in tibia osteotomies has been reported, and their biomechanical properties have been documented [1, 7, 19-21, 23]. The biomechanical properties of LCP used in SCO have, on the other hand, not been documented previously. Furthermore, exact comparison of bone-healing rates between LCP fixation and rigid fixation in SCO is not available.

In this study, only the primary fixation strength in a composite femur model was tested. It is therefore unknown how the results in this study translate to actual bone-healing rates, loss of correction and clinical outcome in patients treated using LCP fixation in SCO. The two opening-wedge plate and osteotomy configurations tested performed less well than the closing-wedge configurations. This may be due either to the biomechanical properties of the implant and the bone-implant construct or to the opening-wedge technique itself, with the lack of bone compression at the osteotomy site and a difference in load-bearing capacity of the bone bridge of the opposite cortex in opening-wedge when compared with closing-wedge SCO. The observed poor stiffness in the torsional failure tests in the two opening-wedge techniques, with observed immediate fracture of the opposite cortex in both axial and torsional failure tests, suggests that the strength of the intact cortex plays a significant role in the stability of implants used in these plate and osteotomy configurations.

In this study, the defect created by the opening-wedge osteotomy was not filled with a graft, which might influence the initial stability. This may lead to load sharing in axial and rotational testing of which the effects are unknown. In clinical use, grafts are primarily inserted to promote bone healing, and the contribution to initial stability of a graft is questionable. Until now, its use has only been recommended in larger defects. Franco et al [6] using the spacer plate tested in this study recommended filling of the gap only if the defect was larger than 7.5 mm. In proximal opening-wedge tibia osteotomies, clinical results show that when an LCP is used for fixation, filling of the gap is not necessary to retain the achieved correction [2].

In this study, it was found that an oblique osteotomy is more stable than a perpendicular osteotomy. This is in accordance with the observation of Stahelin who suggested that a larger cortical contact area after closing of the wedge enhances stability [17]. The difference between perpendicular and oblique saw cuts became apparent in the torsional tests, the configuration with the perpendicular saw cut clearly showing less stability (Table III).

In patients who undergo SCO, postoperative functional rehabilitation is paramount to regain knee function. Furthermore, maintaining the angle of correction is essential in obtaining good long-term clinical results. A bone-implant construct that has optimal biomechanical and biological fixation characteristics and allows for functional rehabilitation and partial to full weight bearing will improve clinical outcome in patients who undergo

SCO. On the basis of the stability and stiffness found in this study, no clear recommendation for the use of LCP (MDF) over the rigid compression technique (ABPobl) can be made.

From a surgical standpoint, as well as from the aforementioned biological standpoint, MDF has several advantages over the an angled blade plate. Medial closing-wedge SCO with an angled blade plate is a demanding surgical technique; it has been associated with complications including plate and screw failure, non-union, and loss of correction during bone healing [11, 13-17]. Fixation using MDF is a less demanding surgical procedure with better control of the amount of deformity correction and less complications [8]. Opening-wedge SCO techniques are technically even less demanding than the closing-wedge techniques and allow for precise deformity correction. However, in the present study, stability of fixation of the opening-wedge techniques is significantly lower than the closing-wedge techniques. Additional stability can be provided by hinged orthoses, or a cast. Functional rehabilitation in the current authors' opinion should be performed at a slower rate than in closing-wedge techniques. Future clinical studies will, however, have to prove all these supposed advantages, because to date no information on the long-term clinical results and the complications of the use of LCP in SCO is available.

Important limitations of this study are the limited amount of femurs available for the failure tests; standard deviations are fairly large in these tests. There might not be enough data to draw definitive conclusions on the behavior of the constructs in the failure tests. Test runs had to be limited to 100 cycles for practical reasons; data storage requirements would otherwise be too high. Furthermore, in an experimental setup like the one used, the effect of the soft tissues on stability and stiffness of course cannot be taken into account.

Conclusion

This experimental study presents baseline data on the differences in the primary stability of bone-implant constructs used in SCO. The data in this study can be used as reference for future testing of SCO techniques. Furthermore, it is recommended that based on the differences found, the early postoperative rehabilitation protocol is tailored to the stability and stiffness of the fixation method used.

Acknowledgments

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Chapter 6

Axial and torsional stability of an improved single-plane and a new bi-plane osteotomy technique for supracondylar femur osteotomies

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Abstract

An important disadvantage of the standard medial closing-wedge distal femur osteotomy for lateral compartment osteoarthritis of the knee is the immediate effects on the extensor mechanism function. Therefore, a novel bi-plane osteotomy technique was developed.

The stability and stiffness of this newly developed technique and a modification of the proximal screw configuration were tested in a composite femur model and compared to the standard single-plane technique. Research question was if the new bi-plane technique and/or modified screw configuration would improve the stability and stiffness of the construct.

In 12 femurs, motion at the osteotomy under axial and torsion loading was measured using a 3D motion analysis system. All were subsequently tested to failure. The data recorded were used to calculate stability and stiffness of the constructs.

The stability and stiffness were highest in the bi-plane technique under axial loads, but were lower under torsional loading, compared to the single-plane technique. The screw configuration modification improved axial stability and stiffness, but had no influence on torsional stability.

In replicate femurs, the new bi-plane technique improved axial stability, but in contrast to what was theorized, decreased torsional stability, compared to the single-plane technique. The addition of a bi-cortical screw proximally improved stability under axial loading, but not torsion. Further clinical testing will have to prove if early full weight bearing using the new bi-plane technique is possible.

Introduction

Distal femoral supracondylar osteotomies (SCO) can be performed using either lateral opening- or medial closing-wedge techniques [4, 5, 16]. Biomechanically, the medial closing-wedge technique offers superior initial stability and stiffness [4]. An important disadvantage of the standard single-plane medial closing-wedge technique is the position of the osteotomy relative to the trochlea and the soft tissues gliding surface on the anterior side of the femur.

The saw cuts of the osteotomy need to be positioned proximal to the trochlea avoiding the patella-femoral joint. The osteotomy does disrupt the soft tissue gliding mechanism however causing a haematoma, and subsequent pain and swelling, slowing rehabilitation. Therefore, a modification of the oblique medial closing-wedge technique was developed by one of the authors (AES): the bi-plane medial closing-wedge technique [7, 11].

At our institution, we previously tested the primary stability and stiffness of different SCO configurations using axial and torsional cyclical loading, in a composite biomechanical femur model, avoiding the availability problems and inter-specimen variability associated with cadaver specimens [4]. The structural equivalence of these composite femurs with human bones has been validated [13, 19]. Compared to the single-plane technique, in the bi-plane technique, the two saw cuts for the closing-wedge are made only in the posterior 3/4 of the femur after which an ascending oblique saw cut is performed on the anterior surface of the femur, completing the osteotomy (Fig. 1). The ascending saw cut enables a more distal positioning of the closing-wedge saw cuts; the soft tissue gliding mechanism is not disrupted as the anterior ascending bone cut ends more proximal on the anterior cortex, avoiding the patella-femoral compartment (Fig. 1). Furthermore, the ascending saw cut increases the cortico-spongious contact area, which should in theory further enhance stability, especially under torsion loads, and promote bone healing. A bi-cortical proximal screw was added, instead of the four uni-cortical screws used previously, as a potential way to further enhance the stability of the construct (Fig. 1).

The use of the extra bi-cortical screw was adopted from high tibial osteotomies (HTO) fixated with Tomofix, in which the authors use one bi-cortical and 3 uni-cortical screws distal to the osteotomy [2]. The purpose of this study is to test these two modifications of the standard SCO technique with angle-stable medial distal femur plate (MDF) fixation. In the current study, using the same femur model, loading protocols and measuring technique [4], we set out to test: (1) the stability and stiffness of the newly developed bi-plane technique, (2) the influence on stability and stiffness of the modified screw configuration and (3) compare results to those from the previous biomechanical study.

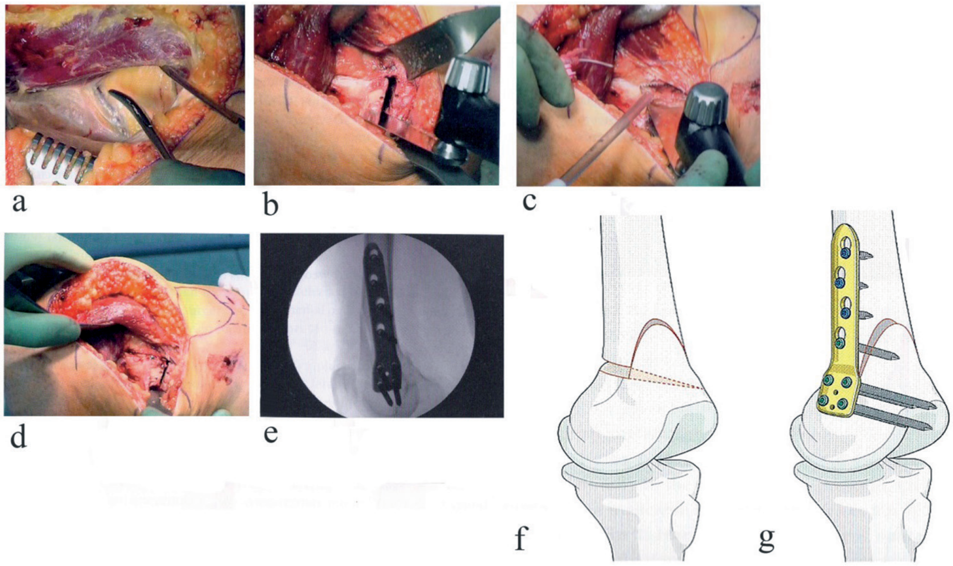

Figure 1. a–e Intra-operative view, **a** soft tissues on the anterior side of the femur, **b** standard wedge has been removed in posterior three-fourth, thin saw blade is introduced for ascending saw cut, **c** anterior saw cut, **d** osteotomy has been closed; the soft tissues are still intact, **e** per-operative lateral image intensifier view of the osteotomy. **f** and **g** schematic view of the bi-plane osteotomy, **f** before closure, **g** with the MDF plate in place, note the bi-cortical proximal screw (Fig. 1 is reprinted from [11], with permission of AO publishing, Dubendorf, Swiss).

Materials and methods

The same test set-up and loading protocols as described in detail in a previous similar biomechanical SCO study were used [4]. In the present study, twelve short-glass-fiber-reinforced (SGFR) third-generation composite replicate femurs (Sawbones Europe AB, Malmo, Sweden) were used in two configurations: (1) MDF SP: single-plane oblique medial closing-wedge SCO fixated with a medial angle stable implant (Tomofix, Synthes, Bettlach, Swiss) and (2) MDF BP: bi-plane oblique medial closing-wedge SCO (Fig. 1). Six femurs were available for each configuration, all femurs were subjected to axial and torsion loads and all were subsequently tested to failure (Table I).

Experimental set-up

The osteotomies were performed and plates implanted according to the standard surgical procedure for each implant as provided by the manufacturer [11]. Distally, 4 bi-cortical screws were used for fixation. Proximally, 3 uni-cortical screws and 1 bi-cortical screw were used. A wedge of 10 degrees (°) was removed with the distal saw cut directed 20° oblique to the distal femur condylar line. All composite femurs were aligned in a standardized way using an alignment jig and a femur saw guide (Balansys, Mathys Medical, Bettlach, Swiss), which provided a reproducible osteotomy position, osteotomy direction and wedge size. The bone deformation needed for the closing of the wedge and the implant fixation was possible without producing a fracture in the lateral bone bridge. The femur head and trochanter and the distal femur end were thereafter embedded in a polyurethane-based cold-curing resin (Ureol FC 53, Vantico GmbH, Wehr, Germany) in a specially constructed fixture; the fixture allowed for mounting of the femur in a materials testing machine (MTS) (Mini Bionix, MTS Systems Corporation, Eden Prairie, MN, USA). The fixture was designed in such a way that a mechanical femur loading axis of 2° was created [14, 15].

Table I. Overview of the number of femurs, runs, cycles and amount of loading.

Total	Implant type	Technique	No	No runs Axial loading	No cycles	Axial pre-load	Loading	Torsional pre-load	Loading
Axial									
12	MDF SP	single-plane	6	1	100	10N	150N	-	-
	MDF BP	bi-plane	6	2	100	10N	800N	-	-
				3	1	-	to failure	-	-
Torsion				**Torsional loading**					
12	MDF SP	single-plane	6	1	100	-	-	0.5 Nm	5 Nm
	MDF BP	bi-plane	6	2	100	150N	-	0.5 Nm	5 Nm
				3	100	800N	-	0.5 Nm	5 Nm
				4	1	-	-	-	to failure

An overview of the number of femurs, the different implants, and SCO techniques (left) and loading protocols that were used in the tests is shown (right).

Measuring system

The principles of rigid body motion were used to measure (micro) motion across the SCO. Reference point pairs, relative to which motion was measured, were defined on the replicate femur; two points across the midpoint of the intact lateral cortical bridge, two points midway across the osteotomy and two points just posterior of the plate on the medial side of the femur; a digital ruler was used to reproducibly determine the position of the point pairs. Motion across the osteotomy was measured using the same ultrasound 3D motion analysis system as in our previous biomechanical study (CMS20S, Zebris Medizintechnik, GmbH, Isny, Germany) [4]. The accuracy of the system as reported by the manufacturer is 0.01 mm (Zebris Medizintechnik, GmbH, Isny, Germany). The sensor and emitter markers were rigidly fixed to the femur using bone cement (Palacos, Biomet, Inc, Warsaw, Indiana, USA), at the same position on each femur (Fig. 2). After mounting of the femur in the MTS with the microphone template attached, a coordinate system was defined based on landmarks on the distal femur using a calibrated pointer device.

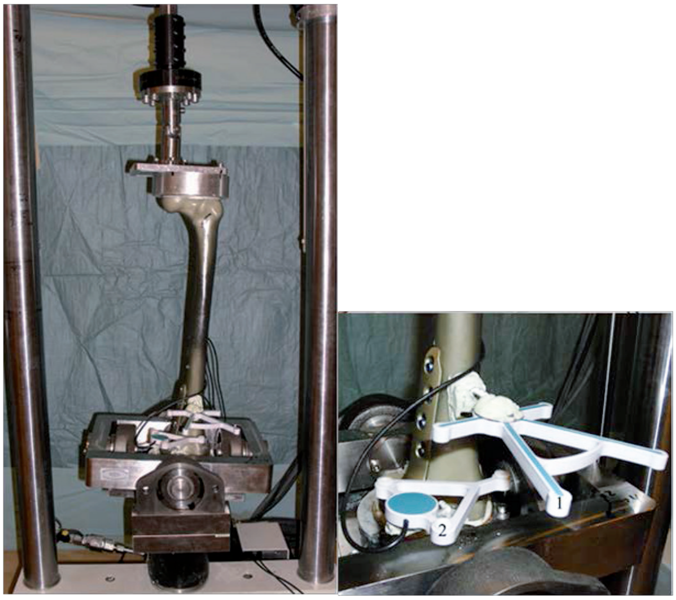

Figure 2. Left Test set-up: The replicate femur is loaded in the MTS. Right Close-up of the measuring system; microphone (1) and speaker (2) templates are rigidly fixed to the replicate femur close to the osteotomy.

Loading protocol

The replicate femurs were subjected to axial and torsional loading protocols designed to simulate physiological loading, with all femurs subjected to axial loading and torsional loading (Table I). After an axial preload of 10 N was achieved, the femurs were tested during 100 cycles for each load (150 N and 800 N) at a rate of 0.5 Hz. Six femurs (3 for each configuration) were subsequently tested to axial failure under displacement control at a rate of 0.1 mm per second. Failure was defined by a drop of actuator loading, because of failure of the bone, bone-implant construct or of the implant itself. Each femur was subjected to 100 cycles of 5Nm torque at a rate of 0.25 Hz; the first run was done without an axial preload; thereafter, two runs using 150 and 800 N axial preloads, respectively, were performed. After completion of all three runs, six femurs (3 per configuration) were tested to torsional failure under displacement control at a rate of 0.25° per second. Criteria for failure were the same as used for the axial loading failure tests.

Statistical analysis

The displacement data recorded using the 3D measuring system were computed using a custom-made program in Mathematica (Version 5.0, Wolfram research, Inc, Champaign, IL, USA). Displacement at the SCO was calculated using the change in the (absolute) distance between the measuring points per loading cycle. The amount of motion that occurs at the

SCO was defined as the difference between the maximum increase and maximum decrease in the distance between measuring points determined for each cycle and per measuring point. A greater mean difference calculated over 100 cycles and three measuring points indicates more motion allowed by the bone-implant construct. Stability was defined as the amount of motion allowed by the construct in the axial and torsion tests. The axial stiffness of the construct was calculated by plotting displacement at the SCO during the failure test, defined as the average amount of movement on the Z-axis of the three previously defined point pairs, against the force data. Stiffness of the bone-implant construct was defined as the slope of the linear portion of the force-osteotomy deformation curve (i.e., the force required per mm of displacement). Similarly, stiffness in torsion was calculated by plotting the rotation around the Z-axis over time against the moment (Nm) applied by the MTS and defined as Nm required for one degree of rotation. Results of both techniques were compared to the motion data from our previous biomechanical SCO study; the data from the single-plane oblique medial closing-wedge SCO fixated with the same angle stable implant (MDF) using the old screw configuration were used for comparison [4].

Statistical analysis was performed using SPSS statistical software (Version 17, SPSS, Inc., Chicago, IL, USA); the independent samples T test was used to measure statistical differences between configurations, and P values < 0.05 were considered significant using a 95% confidence interval (CI95). The data collected in this study were not statistically compared to that from the previous study because the measurements were performed at different study periods.

Results

Axial and torsion test results are displayed in the tables and figures; for comparison purposes, the results from the single-plane, medial closing-wedge OT, with 4 uni-cortical screws proximally (MDF) from the previous SCO study, are also displayed.

Axial loading

No visible damage to bone, bone-implant construct or implant was found. During each cycle of loading and unloading, a corresponding movement at the osteotomy was observed to occur.

At 150 and 800 N, the MDF BP allowed less motion than the MDF SP, and the difference in motion was statistically significant ($P<0.005$) at both loading levels (Table II and Fig. 3).

Table II. Axial and torsion test results

OT type	Axial load	Torsion load	Axial preload	N Cycles	Mean	SD ±	95% CI for Mean Lower-Upper bound		Min	Max	Std Error
MDF SP	150N			600	0,054	0,025	0,052	0,056	0,020	0,192	0,00103
MDF BP	150N			600	0,044	0,018	0,043	0,046	0,016	0,135	0,00070
MDF	150N			300	0,070	0,043	0,065	0,075	0	0,256	0,00249
MDF SP	800N			600	0,061	0,019	0,059	0,062	0,030	0,222	0,00080
MDF BP	800N			600	0,056	0,017	0,055	0,058	0,025	0,114	0,00071
MDF	800N			300	0,105	0,030	0,101	0,108	0,037	0,183	0,00171
MDF SP		5Nm	0N	600	0,0490	0,0127	0,0480	0,0500	0,0182	0,1229	0,0005
MDF BP		5Nm	0N	600	0,0685	0,0158	0,0672	0,0698	0,0318	0,1347	0,0006
MDF		5Nm	0N	300	0,0533	0,0172	0,0513	0,0552	0,0148	0,1111	0,0010
MDF SP		5Nm	150N	600	0,0502	0,0148	0,0491	0,0514	0,0188	0,1449	0,0006
MDF BP		5Nm	150N	600	0,0685	0,0159	0,0672	0,0698	0,0296	0,1390	0,0006
MDF		5Nm	150N	300	0,0446	0,0183	0,0425	0,0467	0,0057	0,1040	0,0011
MDF SP		5Nm	800N	600	0,0489	0,0119	0,0480	0,0499	0,0175	0,1053	0,0005
MDF BP		5Nm	800N	600	0,0707	0,0163	0,0694	0,0720	0,0305	0,1526	0,0007
MDF		5Nm	800N	300	0,0436	0,0147	0,0420	0,0453	0,0138	0,1298	0,0009

Results for the axial and torsion tests are shown; osteotomy type, axial load, total number of cycles, and the mean displacement, including the standard deviation (SD), CI_{95} and Minimum and Maximum, are detailed.

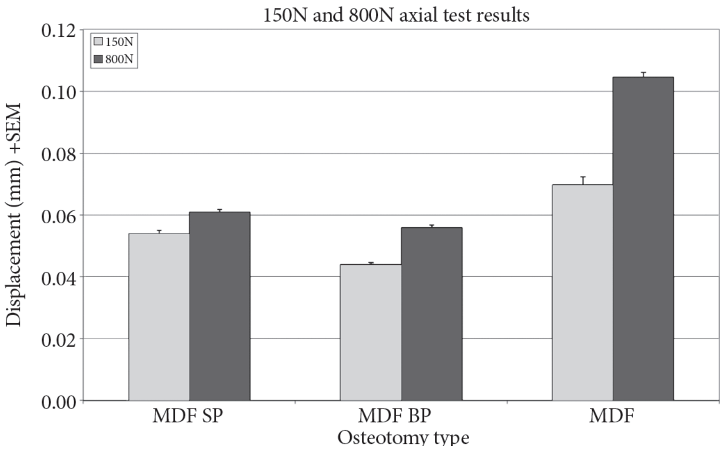

Figure 3. Results for both the 150 and 800 N axial compression tests; results for each test is displayed for each modality; displacement is displayed in millimeters (mm). The standard error of the mean is also shown (SEM).

Axial failure tests

All 6 failure tests resulted in a per-trochanteric femoral neck failure, i.e. failure occurred proximally to the osteotomy in the replicate femurs. No macroscopically observable failure at the bone–implant interface or of the implant itself was observed. No fractures of the opposing lateral cortex bone bridge were observed in both techniques. During the axial failure tests, the force time course of loading typically demonstrated increasing motion with increasing axial compression load with a sudden drop in load at failure. Calculated stiffness was highest in the MDF BP configuration, and the difference was statistically significant (P = 0.013) (Table III and Fig. 4).

Table III. Axial and torsion failure test results

	Axial Stiffness					Torsional Stiffness				
Osteotomy type	N	Mean	SD ±	Min	Max	N	Mean	SD	Min	Max
MDF SP	3	7169	3303	4850	10952	3	44,4	10,4	26,4	35,8
MDF BP	3	19363	3746	17164	23690	3	31,9	4,9	33,4	54,3
MDF	3	5723	990	4618	6528	3	28,4	3,2	26,0	32,1

Results for the axial and torsional failure tests are shown; the number of femurs (N), mean stiffness and minimum and maximum are detailed. Axial stiffness is in N/mm and torsional stiffness in Nm/°.

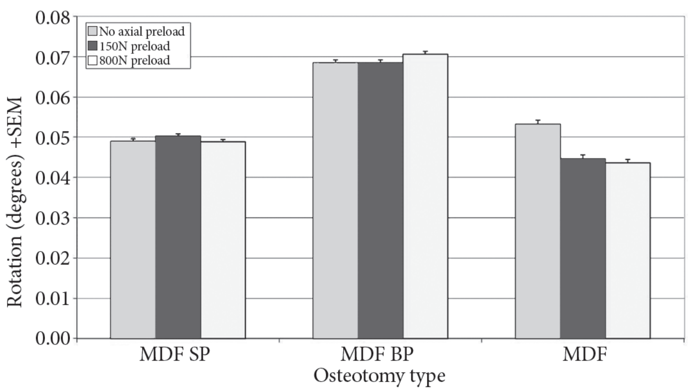

Figure 4. Results for the torsional test runs; results for each test are displayed for each modality; rotation is displayed in degrees rotation. The SEM is also shown.

Torsional loading

No visible damage to bone, bone-implant construct or implant was found. In all tests, the MDF SP configuration allowed less motion; differences were statistically significant (P < 0.005) in all tests (Table II and Fig. 5).

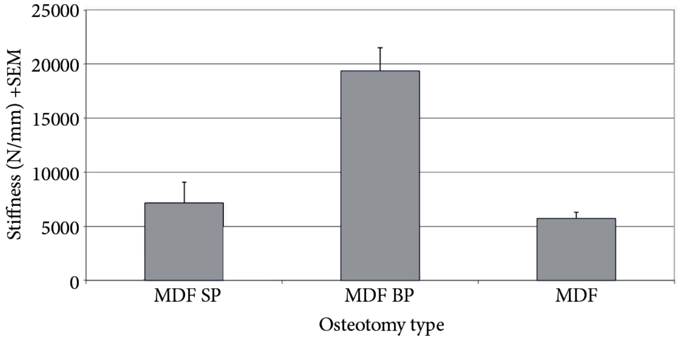

Figure 5. Results for the axial failure tests; stiffness is displayed in Nm per millimeter displacement on the Z-axis. The SEM is also shown.

Torsional failure tests

In all six femurs, similar patterns of failure were observed, the opposing lateral cortex bone bridge fractured first, after which a fracture occurred at the screw–bone interface in all femurs. Calculated stiffness was greatest in the MDF SP configuration, the difference was not statistically significant (Table III and Fig. 6).

One important difference was observed: in the MDF BP, the fracture at the lateral cortex started at the point where the anterior part of the bi-plane osteotomy ends at the intact lateral cortical hinge of the femur and ran into the lateral femur condyle; concurrently, the anterior portion of the bi-plane osteotomy fractured off (Fig. 7).

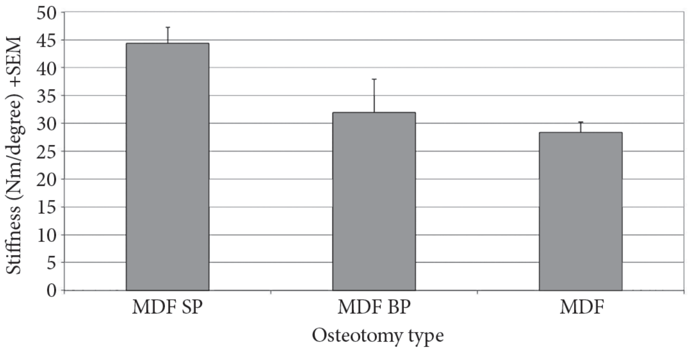

Figure 6. Results for the torsional failure tests; stiffness is displayed in Nm per degree rotation around the Z-axis. The SEM is also shown.

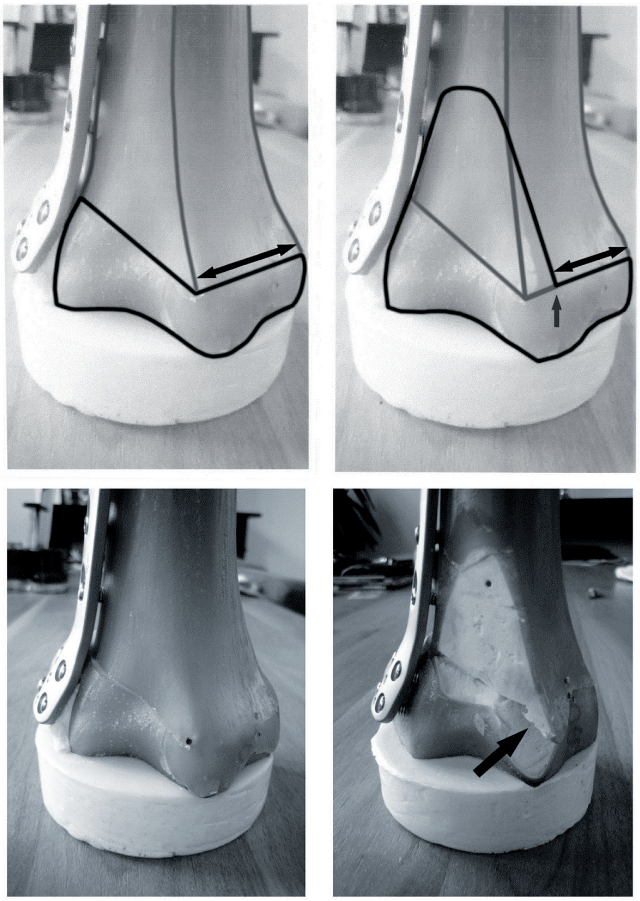

Figure 7. View of SP (left) and BP (right) techniques, outlined in black is the shape of the distal part of the OT. Grey arrow (top right): the ascending saw cut endpoint on the lateral cortex. Black arrows (top left and right): the size of the intact lateral cortical hinge. Clearly visible (bottom left and right) is the difference in fracture pattern of the lateral cortex in the torsion failure test. Black arrow (bottom right): the lateral cortex fracture at the endpoint of the ascending saw cut.

Discussion

The most important finding in the present study is that the new bi-plane technique improved axial stability, but in contrast to what was theorized, had a decreased stability in torsion, compared to the single-plane technique. The MDF in the previous study only differs from the MDF SP in this study in the screw configuration used proximally; four uni-cortical screws, instead of three and one bi-cortical in the current set-up [4]. Comparison shows that the MDF in the previous study is less stable under axial loading than both configurations in the current study (Fig. 3). This is in part because of the extra bi-cortical screw. However, the MDF BP has a statistically significant higher stability than the SP technique under axial loading. Thus, the bi-plane osteotomy itself also increases axial stability. Furthermore, in the axial failure tests, MDF BP has a much higher calculated stiffness than MDF SP and MDF (Fig. 5). A possible explanation is that the energy is distributed and absorbed across a larger area in the bi-plane technique. In contrast to the axial stiffness and stability, and instead of what was theorized, the bi-plane technique showed decreased stability in the torsion tests (Fig. 4). Possible explanations for this are that on the lateral cortex in the AP direction, forces are distributed across a smaller area (Fig. 7). The fracturing off of the anterior part of the osteotomy suggests that it does not contribute to stability. Furthermore, judging from the fracture pattern in the torsional failure tests, the point where the standard oblique and new anterior saw cut join on the lateral side of the femur is not very stable. In the MDF SP, there is no disruption of the lateral cortex because of the second saw cut, and the two flat ends of the osteotomy lie rigidly against each other, and the entire AP diameter of the lateral cortex contributes to stability (Fig. 7). The MDF and MDF SP perform similarly in the torsion tests; it therefore appears that the bi-cortical screw does not improve stability in torsion. MDF SP does have a higher calculated stiffness in the torsion to failure test; however, this might be because it has no weak hinge point and has the extra bi-cortical screw proximally. Interestingly, in contrast to its torsional stability, MDF BP has a higher calculated stiffness than MDF. The bi-cortical screw therefore appears to influence stiffness but not stability in torsion.

In biomechanical tests of high tibial osteotomies (HTO) using replicate tibia sawbones, Agneskirchner et al found significantly improved stability using the TomoFix HTO plate [1]. Based on these results and clinical observations of patients starting full weight bearing earlier than prescribed in the rehabilitation protocol, clinical studies were performed comparing an early full weight bearing protocol to a standard weight bearing protocol after HTO [3]. Subsequently, early full weight bearing has been introduced as standard protocol after HTO [3, 20, 21].

For SCO in clinical studies reporting on the single-plane technique with the angle stable TomoFix MDF implant used in this study, no bone-healing problems have been reported with a standard rehabilitation protocol consisting of 6–8 weeks of partial weight bearing [6, 7, 10]. No bone-healing problems have been observed in the first cohort of 30 patients operated on with the bi-plane technique either [8]. After introduction of the bi-plane technique, a faster recovery of knee function was observed when compared with the single-plane patient groups, and patients themselves increased the amount of weight bearing within the first 6 weeks after the osteotomy, although full weight bearing was allowed after 6–8 weeks only if clear signs of bone healing were visible. Repeatedly, instead of what was advised, patients were bearing full weight without crutches at the time of their first follow-up. In these patients, no corrections loss and no impaired bone healing had been found [8]. The findings regarding torsional stability in the current study are to some extent in contrast with the observation that patients experience their osteotomy as stable.

The amount of motion observed in the torsion test may be the cause for concern; however, no damage to the construct was observed during the various torsion tests and in the failure tests, stiffness appeared to be less affected negatively by the bi-plane osteotomy. It might be that stability in torsion is less important than axial stability, with the decreased torsion stability still being in the range of what is required for the construct to be stable. However, no fatigue tests were performed, so no conclusions on longer-term effects of repeated torsion loading on the osteotomy can be drawn. Therefore, postoperatively, physical activities, which produce high torsional loads on the femur, such as leg movements in breaststroke swimming, are probably best avoided until bone healing has been observed. Specific limitation of torsional motion has not been described after osteotomies around the knee. Knee braces have been used to limit rotation in knees with ligamentous laxities, i.e., preventing torsion of the tibia relative to the femur [17, 23].

The use of braces for additional stability after SCO has been documented by various authors; Healy et al used a brace if the fixation of the osteotomy was questionable; both Wang et al and Miniaci et al also used braces [9, 18, 22]. All three authors in their series of patients used an angled blade plate for fixation and a limited weight bearing protocol initially, varying from non-weight bearing to toe touch for 6 weeks, full weight bearing being allowed after 12 weeks or if clear signs of consolidation were present on follow-up radiographs. Based on the results of the present study, a clinical study has been started at our institution using early full weight bearing and a hinged brace until full bone healing in patients after bi-plane SCO fixated with the angle stable implant used in this study [12].

Important limitations of the study are, as in the previous study, the limited amount of femurs available for the failure tests; exact conclusions on stiffness might not be possible. Also, because of the size of the data collected by the 3D measuring system, no fatigue tests could be performed. Furthermore, no test-retest reliability measurements were performed. Ideally, the MDF data should have come from the same series of tests, not the previous study. Because of this, no statistical comparison to the current data was performed.

Conclusion

In the current test configuration, the new bi-plane technique improved axial stability, but in contrast to what was theorized, decreased torsional stability, compared to the single-plane technique. The addition of a bi-cortical screw proximally improved stability under axial loading, but not torsion. Further clinical testing will have to prove if early full weight bearing using the new bi-plane technique is possible.

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Chapter 7

Biomechanical testing of distal femur osteotomy plate fixation techniques: the role of simulated physiological loading

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Abstract

In many cases regulatory authorities require that implants for fracture and/or osteotomy fixation are tested according to rudimentary mechanical test models such as open gap tests or four point bending tests. Such test models may be suitable to compare different implants on a purely mechanical basis, but they are not always representative of the postoperative situation, which in the end is decisive when it comes to bone healing.

In the current study the Knee Expert Group of the Association for the Study of Internal Fixation has compared the available open gap test results of the latest version of the TomoFix Medial Distal Femoral Plate and of the antecedent plate design, with the test results of a more physiological and life-like test model, which simulated postoperative conditions for medial closing-wedge supracondylar osteotomies.

In contrast to the open gap test model, the physiological tests in the current study show that the performance of both plates is equal. It is argued that the difference in results between the two loading models is due to differences in test design and that as life like conditions as possible should be used for biomechanical testing of implants.

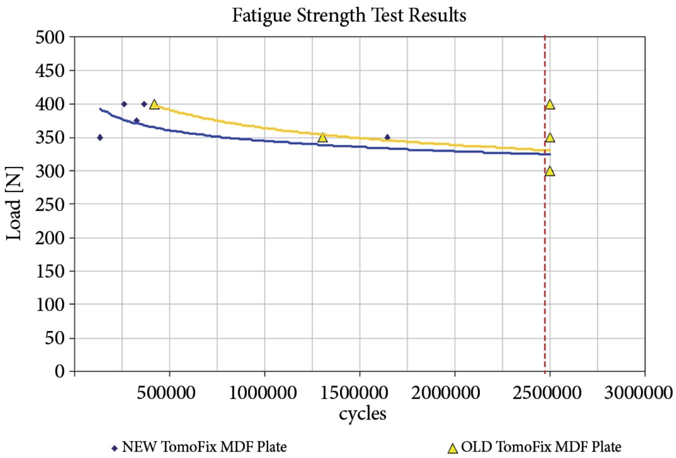
Introduction

Implants for fixation of fractures and osteotomies have since long been tested for clinical approval and have been compared to each other in so called open gap biomechanical test models [1-6]. In many cases regulatory authorities require that implants are tested according to rudimentary mechanical test models such as these open gap tests or four point bending tests. The biomechanical loading protocols used aim at testing construct stability and fixation strength to bone and include in general axial and torsion loading, stiffness and fatigue testing. Although the open gap model purposely represents a worst case scenario of implant loading in unstable fractures, for many fractures and closing-wedge osteotomies however this model represents a non-physiological test situation. The reduced fracture fragments or closed osteotomy gap are likely to improve the overall stability and stiffness of the construct [7, 8].

In recent years so called Locking Compression Plates (LCP) have been developed specifically for fixation of osteotomies around the knee. Various factors have been identified to influence construct stability of LCP in plate fixation techniques; working length (i.e. distance of the first screw to the fracture), number of screws, distance of the plate to the bone, gap size and plate length [2]. Increased working length, less screws, a greater distance of the plate to the bone, an increased gap size and a shorter plate all negatively influenced the stability of the construct [2]. These parameters have been investigated using composite cylinders and finite element analysis (FEA) under simulated non-physiological loading conditions [2].

The latest version of the TomoFix Medial Distal Femoral Plate (MDF)(Synthes GmbH, Switzerland), has shown equal static strength but inferior stiffness and fatigue strength when compared to the antecedent plate design under these non-physiological testing conditions (Fig. 1A and 1B).

Figure 1. A. New design plate fixated in composite cylinder blocks for open gap model testing.



B. Condensed schematic representation of the open gap fatigue tests as provided by the manufacturer (Synthes GmbH).
Both plates were setup to be tested over 2500000 cycles (red vertical line=end point of test runs), 2 of 5 OLD design plates (▲) and 5 of 5 NEW design plates (◆) failed before reaching the tests end at the various loading levels used (300, 350 and 400N, OLD plate and 350,375 and 400N, NEW plate). Trend lines for both are also shown (Blue=NEW plate, Yellow=OLD plate).

These results were evaluated by a group of osteotomy experts involved in the development of plates for fixation of osteotomies around the knee; the Knee Expert Group (KNEG) of the Association for the Study of Internal Fixation (AO/ASIF). They questioned the validity and the clinical relevance of the open gap model in the testing of closing-wedge osteotomy techniques.

A validated biomechanical testing model with life like simulated loading conditions has been previously used to compare the construct stability of different types of plate fixation techniques for distal femur osteotomies, one of which was the antecedent version of the MDF plate [7]. The new design MDF plate has a different shape than its predecessor; it has a more anatomical preformed shape resulting in an improved fit to the distal femur which reduces the distance of the plate to the bone, subsequently reducing leverage forces resulting on the plate (Fig. 2). It has an optimized screw-hole orientation, providing a better fit for the screws in the femur. It has also been made slightly shorter and slimmer in favor of reduced prominence, while the thickness of both plates is the same.

In this study both designs were tested under axial and torsion loads in a material testing machine (MTS) in a composite replicate femur model, under simulated physiological loading conditions. The composite bone model provided reproducible bone properties and avoided the availability problems and variability associated with cadaver specimens. The mechanical properties of these bones have been validated [9]. The study hypothesis was that, in contrast to the open gap model test results, there is no difference in stability and stiffness between the two designs using a simulated physiologic postoperative test model for comparison.

Figure 2. The latest design (NEW), top, and the antecedent design (OLD), bottom. The NEW plate has an optimized shape, to better fit the distal femur; it has improved screw-hole directions, and is shorter and slimmer, but equally thick.

Materials and methods

The same test protocol as has been previously used by Brinkman et al was used in the current study [7]. Fourteen femurs in total were available; 7 for each plate type (NEW and OLD). Bi-plane closing-wedge distal femur osteotomies were performed, and the plates implanted according to standard surgical technique [10]. All femurs were aligned in a standardized way using an alignment jig and a femur saw guide (Balansys, Mathys Medical, Bettlach, Swiss), the closing-wedge osteotomy was directed 20° oblique to the distal femur condylar line, a wedge of 10° was removed. The bone deformation needed for the closing of the wedge and the implant fixation were performed without producing a fracture in the opposite bone bridge. The femur head and trochanter and the distal femur end were thereafter embedded in a polyurethane-based cold-curing resin (Ureol FC 53, Vantico GmbH, Wehr, Germany) in a specially constructed fixture; the fixture allowed for mounting of the femur in a materials testing machine (MTS) (Mini Bionix, MTS Systems Corporation, Eden Prairie, MN, USA) (Fig. 3). The fixture was designed in such a way that the axis of loading of the replicate femur in the MTS was through the center of the femur head proximal and through a point 18-mm medial from the mid-condylar distance, creating a mechanical femur axis of 2°; reproducing loading in the normally aligned human knee after a SCO for valgus osteoarthritis.

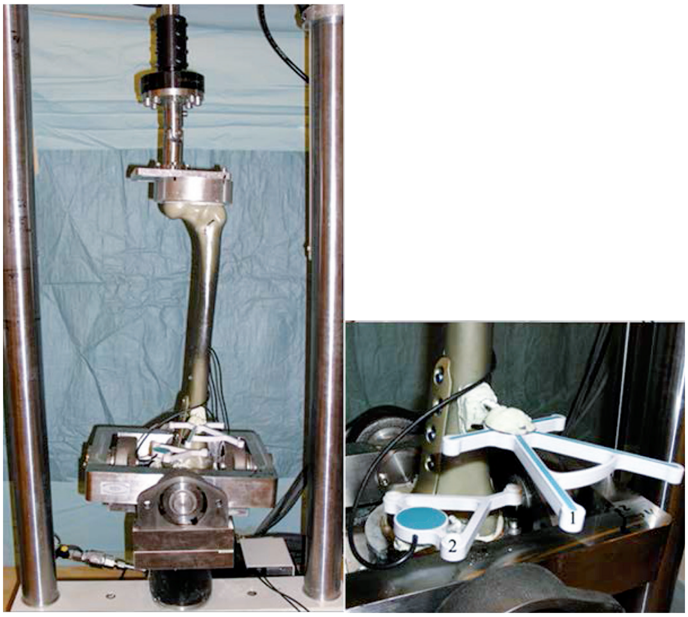


Figure 3. Overview of the test setup used. Left: the entire setup, the femur loaded in the MTS. Right: Close-up of the measuring system; 1 and 2, microphone and speaker templates.

Measuring system

The principles of rigid body motion were used to measure (micro) motion across the SCO. Reference point pairs, relative to which motion was measured, were defined on the replicate femur both proximal and distal to the osteotomy gap; two points across the midpoint of the intact cortical bone bridge, two points midway across the osteotomy and two points just posterior of the plate on the femur. Motion (displacement) of the diaphysis of the femur proximal to the osteotomy was measured relative to the femur condyles distal to the osteotomy using an ultrasound 3D motion-analysis system (CMS20S, Zebris Medizintechnik, GmbH, Isny, Germany). This system is based on the travel time measurement of ultrasonic pulses that are emitted by miniature speakers on a marker-triplet to microphones on a second marker-quartet (Fig. 2). It has been previously used by Brinkman et al in biomechanical testing of various osteotomy techniques [7, 11].

Loading protocol

The replicate femurs were subjected to axial and torsional loading protocols designed to simulate physiological loading (Table I). Cyclical axial loading was performed at two loading levels (150 and 800 N) on all femurs, during 100 cycles for each load at a rate of 0.5 Hz. Cyclical torsional loading was thereafter performed in all femurs. Internal rotation around the Z-axis with a cyclical moment loading of 5 Nm at a rate of 0.25 Hz was applied during 100 cycles, with an increasing axial pre-load (Table I).

Table I. Overview of the configurations and test protocols

	Implant type	Axial loading		Torsional loading		
		Axial loads		5NM torsion load with axial pre load		
Femurs	test runs	1	2	3	4	5
		150N	800N	0N	150N	800N
7	MDF OLD	100	100	100	100	100
7	MDF NEW	100	100	100	100	100
14						

Overview of the test runs: axial tests at 150N and 800N both 100 cycles per test run, torsion tests at 5Nm, with 0N, 150N and 800N axial pre-load, again 100 cycles per test run.

The different axial preloads were used to simulate no, partial and full weight bearing.

Four femurs were subsequently tested to failure under axial compression, with displacement control at a rate of 0.1 mm per second. Failure was defined by a drop of actuator loading, either because of failure of the bone, bone-implant construct, or of the implant itself. Three femurs were tested to failure under torsion, with displacement control at a rate of 0.25° per second. Criteria for failure were the same as used for the axial loading failure tests.

Statistical analysis

The displacement data recorded was computed using a custom-written program in Mathematica (version 5.0, Wolfram research, Inc, Champaign, IL, USA); the change in position and the angle of rotation around all axes for each measuring point and the change in absolute distance between the measuring points was calculated. Displacement at the SCO was calculated using the change in the (absolute) distance between the measuring points per loading cycle. The amount of motion that occurs at the SCO was defined as the difference between the maximum increase and maximum decrease in the distance between measuring points; determined for each cycle and per measuring point. A greater mean difference calculated over 100 cycles and 3 measuring points indicates more motion allowed by the bone-implant construct. Stability was subsequently defined as the amount of motion allowed by the construct. A similar approach was used in the torsional tests. The amount of motion was calculated by determining the amount of rotation around the Z-axis that is allowed by the bone-implant construct during each cycle. Stability in torsion was defined as the amount of rotation allowed by the construct. The stiffness under axial compression of the construct was calculated by plotting displacement at the SCO during the failure test, defined as the average amount of movement on the Z-axis of the 3 previously defined point pairs, against the force data. Stiffness of the bone-implant construct was defined as the slope of the linear portion of the force – deformation curve (i.e. the force required per millimeter of displacement). Stiffness under torsion loading was calculated by plotting the rotation around the Z-axis over time against the moment (Nm) applied by the MTS and defined as Nm required for one degree of rotation. Statistical analysis was performed using SPSS statistical software (Version 11.5, SPSS, Inc, Chicago, IL, USA); the independent sample T-test was used to measure statistical differences between the two configurations, P values <0.05 were considered significant using a 95% confidence interval (CI95).

Results

Axial tests

No visible damage to bone, bone-implant construct or implant was found in any of the test runs. During each cycle of loading and unloading, a corresponding movement at the osteotomy was observed to occur. At 800N the NEW plate allowed statistically significantly less motion than the OLD plate, at 150N there was no difference (Table II).

Table II. Axial and torsion test results

			Total runs	Mean	SD	
Axial tests	150N	NEW plate	700	0.085651	0.054997	
		OLD plate	700	0.087737	0.056193	
	800N	NEW plate	700	0.088803	0.048292	
		OLD plate	700	0.096411	0.044069	*
Torsion tests	0N	NEW plate	700	0.077263	0.022999	
		OLD plate	700	0.080334	0.025255	*
	150N	NEW plate	700	0.076817	0.02146	
		OLD plate	700	0.078167	0.023	
	800N	NEW Plate	700	0.076932	0.021548	
		OLD plate	700	0.077137	0.02275	

*Statistically significantly less motion with the NEW design. Results for the axial and torsion test runs, movement is in mm for the axial tests and in degrees for the torsion tests.

Torsion tests

Again no visible damage to bone, bone-implant construct or implant was found in any of the test runs. In the test run with no axial preload the NEW plate allowed statistically significantly less motion than the OLD plate; in the other runs there was no difference between the two (Table II).

Axial failure tests

Seven failure tests (4 OLD, 3 NEW) resulted in a per-trochanteric femoral neck failure, *i.e.* failure occurred proximally to the osteotomy in the replicate femurs. In one femur with the NEW plate a two level femur fracture occurred; a femoral neck fracture as in the other tests, but a femur shaft fracture just proximal to the plate occurred as well. No macroscopically observable failure at the bone-implant interface or of the implant itself was observed in any of the tests. No fractures of the opposing lateral cortex bone-bridge were observed with both plates. During the axial failure tests, the force time course of loading typically demonstrated increasing motion with increasing axial compression load with a sudden drop in load at failure. Calculated stiffness was similar in both plate types (Table III).

Table III. Axial and torsion failure test results

Femur	NEW Axial	OLD	NEW Torsion	OLD
1	4313.10	4240.50	31.00*	32.10*
2	4242.90	4193.50	33.40	37.20
3	4011.20	5002.10	29.50	26.50
4	3607.60	4084.80		
Average	4043.70	4380.23	31.30	31.93
Significance (p<0.05=sign)	P=0.27		P=0.78	

Results for the axial and torsion failure tests, axial force is in N/mm, torsion force is Nm/°; differences are not statistically significant. *femurs in which the drive-shaft of the MTS came loose.

Torsion failure tests

In the 6 femurs that were tested to failure under torsion loads, different patterns of failure were observed. Two femurs (one NEW, one OLD) did not fail, the test ended because the drive-shaft of the MTS itself came loose, which became apparent by a sudden drop in load on the femur. In those two there was no visible damage to the construct, their calculated stiffness did not differ from the other femurs. In two (again one NEW, one OLD) the test ended because of a fracture at the bi-plane hinge on the lateral cortex bone-bridge. And in two (one NEW, one OLD) a spiral fracture occurred just proximal of the osteotomy, just anterior of the proximal screw-bone interface. Calculated stiffness again was similar in both plates (Table III).

Discussion

The most important finding in this study was that, overall, there was very little difference in stability and stiffness between the two plates. In two test runs the NEW plate allowed statistically significantly less motion than the OLD plate (800N axial test and the torsion test with no axial pre-load). In all the other tests there was no statistically significant difference between the two. Again as in previous studies the axial failure tests ended because of pertrochanteric femoral neck fractures, not because of failure at the osteotomy [7]. Stiffness in the current tests also was very similar in both plates, with the OLD plate on average showing a slightly higher stiffness, but not statistically significant. In the torsion failure tests, the failure modes differed somewhat between femurs, but again there was no difference between the two plates. Again the OLD plate showed a slightly higher stiffness on average, but not statistically significant.

In these tests, as in previous tests by Brinkman et al, the postoperative situation after medial closing-wedge SCO was reproduced as "life-like" as possible, with simulated partial and full weight bearing and simulated leg alignment as in patients that undergo SCO [7, 11]. In the open gap model which is often used to compare the mechanical strength of osteosynthesis implants, a composite cylinder is cut in half and both ends are fixated with a plate (Fig. 1A). That construct is then tested under axial and torsion loads, with motion measured across the gap. As documented by Stoffel et al gap size and plate length are important factors in the overall stability [2]. It is therefore not unexpected that under these circumstances a shorter and slimmer plate has a lower stiffness and fatigue strength than a plate that is longer and that has an expanded shaft.

Various authors have compared different types of plates and nails, and different types of screw configurations, using sawbones or human cadaver bones, in distal femur and proximal tibia fracture models [1, 3, 6, 8]. Almost all use some form of gap model; with the gap representing the unstable fracture [1, 3-6]. David et al used anatomic reduction without fracture gaps in a cadaver study testing a locked nail and an angled blade plate [8]. They stated that direct bony opposition more closely approximates the clinical situation, in which fracture fragments are reduced anatomically before placement of the fixation device. So as a consequence of the fracture reduction in most fractures stability is likely to be increased, which is not simulated in gap models. Similarly in closing-wedge SCO there is no gap, both ends of the osteotomy are rigidly compressed against each other. And because of the controlled nature in which the SCO is created, closed and fixated there is inherent stability of the construct. Furthermore because of the gap in gap model testing the loading conditions at the plate are completely different, in a gap model the plate is loaded under tension, in the current setup under compression, because it is on the medial side of the femur. In SCO the load at the knee is shifted from lateral to medial, therefore after SCO the compressive forces will be on the medial side, as is the case in the current test setup.

The above arguments can also be made against concerns over the inferior results of the NEW plate in the fatigue tests using an open gap test model; they were not performed under simulated postoperative conditions. Fatigue testing with an open gap model may give a better understanding of the plate's failure mode. However it is questionable whether fatigue test results are representative of the clinical situation in SCO, because ongoing bone-healing will stabilize the construct as the implant fatigues, i.e. load sharing takes place decreasing the loading on the plate. Closing-wedge SCO typically heal in 6–12 weeks, specific postoperative rehabilitation protocols provide for partial and full weight bearing tailored to stability of fixation construct and time to full bone healing [12]. In our experience bone healing using a bi-plane osteotomy technique is fast and increased stability through bone healing occurs quickly [10]. This whole process is not simulated in any biomechanical test setup and can only be documented in in-vivo bone healing studies.

Limitations of the study are that, because of the small number of femurs available, the failure data set is small in size. No fatigue tests were performed, due to data size collection and time limitations. The MTS is not able to reliably load the construct quickly therefore fatigue testing of a single femur would have taken weeks. Furthermore the data is not comparable to the two previously published biomechanical studies by Brinkman et al, because 4th generation sawbones were used instead of 3rd as the 3rd generation sawbones are no longer commercially available [7, 11]. According to Heiner et al the 4th generation bones mirror human bones more closely than the 3rd [9]. Tests with the 4th generation bones should therefore, if anything, be more representative of the postoperative situation after SCO.

Conclusion

The current test results show that under simulated physiological loading conditions there is no difference in stability between the two plates; the latest design Tomofix MDF provides as much, if not more, stability and equal stiffness compared to the antecedent design. These test results in our opinion stress the importance of as life like as possible test conditions for any form of biomechanical testing.

Conflicts of interest

A grant was provided by Synthes GmbH and received by the Medizinischen Hochschule Hannover, Germany, to perform the current study. They had no influence whatsoever on its outcome and the data published in this study.

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Chapter 8

The safety and feasibility of a less invasive distal femur closing-wedge osteotomy technique: a cadaveric dissection study of the medial aspect of the distal femur

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Abstract

To investigate the feasibility and safety of a less invasive surgical approach to the distal medial aspect of the femur in supracondylar medial closing-wedge osteotomy for the treatment of lateral compartment osteoarthritis of the knee. The aim of a less invasive approach is to minimize soft tissue disruption, reduce damage to neurovascular structures and thereby prevent muscle atrophy and optimize bone healing potential.

A human cadaver dissection study on the vascular and neural structures of the medial side of the distal femur was conducted. Surgical dissection (n = 4), cryomicrotomy and subsequent 3D reconstruction of the anatomy (n = 1), and surgical dissection after performance of a supracondylar osteotomy through a less invasive approach (n = 1) were performed in 6 legs in total.

A branch of the femoral artery, the distal genicular artery, supplies the distal area of the vastus medialis (VM) muscle. Crucial in the presented less invasive approach is its musculo-articular branch, which has an oblique course through the VM to the supero-medial pole of the patella. The femoral nerve and saphenous nerve innervate the VM. These structures are at risk in the traditional subvastus approach, whereas no major damage was observed in the leg in which a less invasive approach was performed.

In this cadaveric dissection study, a less invasive approach to the medial side of the distal femur proved to be feasible and safe. Damage to the VM and its neurovascular structures is minimized as compared to the traditional subvastus approach.

Introduction

Lateral compartment osteoarthritis of the knee with a valgus leg alignment can be treated with a supracondylar varus osteotomy (SCO), using either medial closing- or lateral opening-wedge techniques [10, 15-18, 20, 21, 26, 29]. A lateral approach similar to the Minimally Invasive Percutaneous Plate Osteosynthesis (MIPPO) technique in fracture surgery can be used, minimizing soft tissue damage and vascular disruption, optimizing bone healing potential [5, 6, 12–14, 31]. An important disadvantage of the standard subvastus approach for medial SCO is that a large incision is needed. The vastus medialis (VM) needs to be stripped of its septum severing neurovascular structures causing VM hypotrophy (Fig. 1a–c) [16, 29].

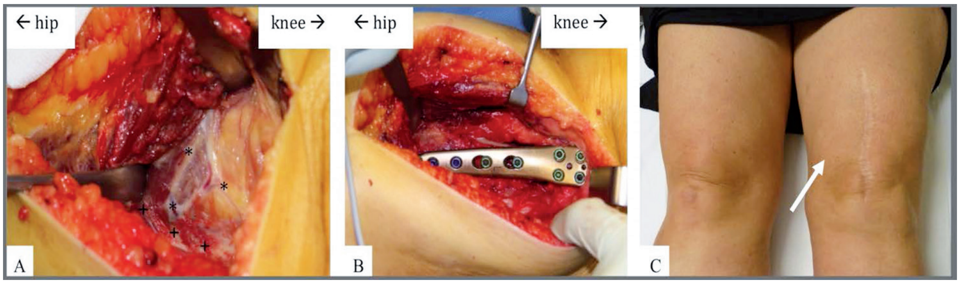

Figure 1. Medial view of traditional medial subvastus approach in a left leg.

A) Distal part of the m.vastus medialis is retracted supero-lateral with Hohman retractors. Neurovascular bundles (*) originating from the dorsal intermuscular septum prevent further exploration proximally and need to be cut to sufficiently expose area for bi-plane osteotomy and plate fixation.

B) Vastus medialis retracted supero-laterally after stripping the muscle from the intermuscular septum severing neurovascular bundles; plate fixation after osteotomy.

C) Vastus medialis atrophy (arrow) after standard subvastus approach in the left leg of a patient after supracondylar osteotomy.

This may be prevented with a less invasive approach analogous to the lateral MIPPO technique using a distal incision large enough for the osteotomy and distal plate fixation combined with a stab incision for proximal plate fixation.

The neurovascular anatomy of the medial side of the distal femur has been studied in the midvastus approach in total knee replacement surgery [1, 22] and for vascular tissue grafts of the medial femoral condyle [4, 9, 30], but not with respect to SCO [1, 4, 9, 22, 30]. The VM's main blood supply is from the descending genicular artery (DGA) which branches off from the distal femoral artery [30]. Innervation of the middle and distal part of the VM is provided by the medial branch of the femoral nerve along the posterior edge of the VM, with branches into the VM, and the VM obliquus [11, 27]. The standard single-plane medial closing-wedge SCO has been modified to a bi-plane osteotomy with an angle-stable implant (LCP) for fixation (Fig. 1) [2, 3, 7, 28, 29]. It is the preferred technique because it provides increased axial stability and stiffness, less soft tissue disruption, and a shorter rehabilitation time [7, 28]. Although fixation with a LCP does allow for a less invasive approach until now, only a traditional subvastus approach has been used. Only one other report on a less invasive approach to the femur for SCO exists but is lacking an anatomical foundation [25].

Therefore, to potentially minimize soft tissue damage and neurovascular disruption in the medial approach to the distal femur in SCO, the current study was designed to investigate the safety and feasibility of a less invasive approach. For this purpose, six human cadaver legs were investigated. Specific research questions were as follows: (1) what variations are there in the vasculature of the distal medial aspect of the femur, (2) is there a clearly distinguishable plane between the VM obliquus (VMO) and VM longus (VML) and if so does this plane and the neurovascular structures allow dissection through it, and (3) is a less invasive approach for a bi-plane medial closing-wedge SCO technically feasible and safe regarding neurovascular structures at risk, and what risk of neurovascular damage exists if screws are placed percutaneous through the VM?

Materials and methods

Six legs of four different human cadavers were obtained from the Department of Functional Anatomy of the University Medical Center Utrecht (Table I). First in cadavers 1–5, blood was removed with a soap solution, the leg was perfused with 1 L of 10% formalin solution, and then, Araldite was introduced into the femoral artery, coloring all arterial structures red [23]. Each leg was then amputated from the trunk about 10 cm below the hip joint, the skin was removed, and the foot was amputated at the level of the conjoint fascia of the soleus and gastrocnemius muscle. Thereafter, the legs were dehydrated in six baths with increasing concentrations of alcohol (50–70–80–96–96%), each step taking 1 week. In the final preparation step, after dehydration, the specimens were immersed for a few months in methylbenzoate, which makes the soft tissue slightly transparent. A less invasive SCO was performed in the sixth leg. To mimic the physiologic elastic properties of the vessels, in this leg the vessels were not filled with Araldite, which makes them solid, but were filled with a mixture of gelatin and gouache. No dehydration was performed in this leg.

Table I. Demographics of human cadaveric legs and dissection methods.

Specimen	Gender, age	Procedure	DGA	VMO-VML
1	Male, 93, left	Dissection	+	-
2	Male, 88 left	Dissection	+	+
3	Male, 93, right	Dissection	+	+
4	Male, 88, right	Dissection	+	-
5	Female, 65, left	Cryomicrotome sectioning	+	-
6	Male, 50, right	Dissection after SCO	+	-

The descending genicular artery (DGA) was present in all specimens. A different fiber alignment between the vastus medialis obliquus (VMO) and the vastus medialis longus (VML) was identified in only two specimens.

Dissection and sectioning

In legs 1–4, the medial structures covering the distal femur were dissected manually using regular sharp surgical dissecting techniques. The arteries were solid, red, and easily dissectible from the other structures. This resulted in a clear overview of all branches of the femoral artery and their location in the VM muscle. All sectioning layers were photographed. In the images, the angle of the musculo-articular branch of the DGA related to the longitudinal axis of the femur and its external diameter were measured using ImageJ software (ImageJ 1.45 s, National Institutes of Health, USA). The longitudinal axis of the femur was determined in the sagittal plane by the line from the midpoint of the medial condyle to the middle of the femoral shaft at the proximal end of the specimen. External diameter of the musculo-articular branch was measured directly after branching off the femoral artery.

Cryomicrotomy was used in the fifth leg. The leg was frozen in carboxy-methyl-cellulose gel at -25°C. Using a heavy duty sledge cryomicrotome (PMV 450; LKB Instruments, Stockholm, Sweden), consecutive sagittal sections using 25-micrometer intervals were obtained. The surface of each section was photographed (Nikon D1X; Nikon Corporation, Chiyoda-ku, Tokyo, Japan) at a resolution of 300 pixels/inch. The exact dimension of the part of the leg that appeared on the photographs was documented and was the same for each picture taken; in total 1,043 sequential images were collected. Thereafter, the coronal and transverse planes were reconstructed using Enhanced Multi-planar-reformatting Along Curves software (E-AC Group, Department of Information and Computing Sciences, Utrecht University, Utrecht, The Netherlands). Using this technique, it is possible to show all three dimensions of a specimen in which surfaces can then be measured while the topographic relations remain unaltered [19]. Via synchronous display of all planes using a custom made Interactive Image Sequence Viewer program (N. Moayeri and G. J. Groen, Utrecht, The Netherlands) and E-MAC, all soft tissue structures of the medial aspect of the distal femur were visualized and analyzed in a 3D model [19] (Fig. 2). Using this software, surface areas were measured of arteries, veins, and nerves in the coronal section 12 cm above the knee joint line (Fig. 2).

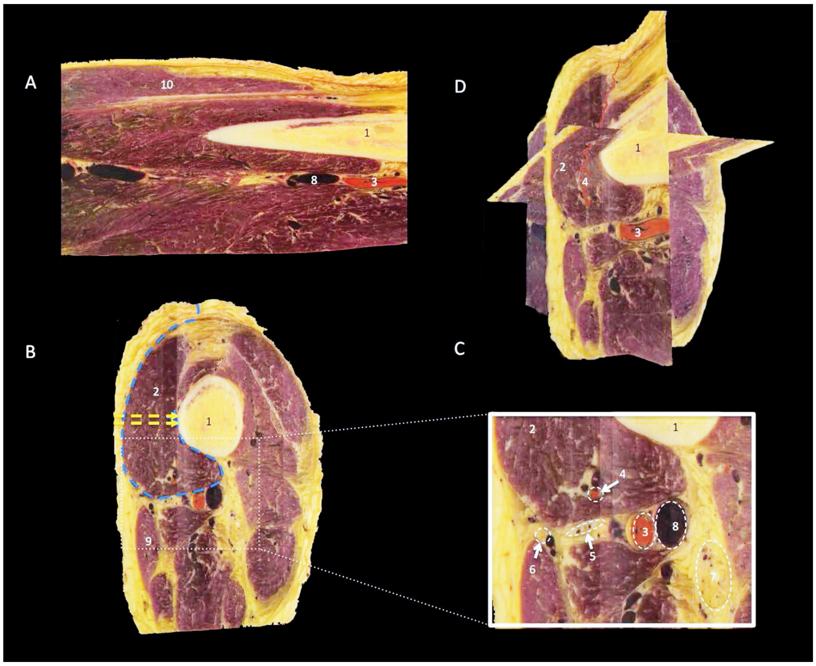

Figure 2. Three-dimensional reconstruction of a left femur after cryomicrotome sectioning (specimen 5). **1** femur; **2** vastus medialis muscle; **3** femoral artery; **4** DGA; **5** adductor magnus tendon; **6** saphenous nerve; **7** femoral nerve; **8** femoral vein; **9** sartorius muscle; **10** rectus femoris muscle

(**A**) Sagittal sections were made initially. Transversal and coronal sections were reconstructed using E-MAC software.
(**B**) In a coronal section 12 cm above the knee joint line, the traditional subvastus approach (blue line) and the percutaneous approach (yellow line) are projected. In the percutaneous approach, the VM is not stripped of the intermuscular septum at this level in order to spare branching nerves and vessels.
(**C**) Magnification of the coronal section. Structures in the intermuscular septum are encircled. Surface areas of arteries, veins, and nerves were measured: **3** femoral artery: 22.8 mm^2; **4** DGA: 2.6 mm^2, **6** saphenous nerve: 2.3 mm^2; **7** femoral nerve: 56.7 mm^2, **8** femoral vein: 46.8 mm^2.
(**D**) Perspective caudal view of left upper leg, femoral condyles removed for better view. The course and caliber of the Descending Genicular Artery (DGA) in the m. vastus medialis is shown.

Osteotomy

In the sixth leg, a medial closing-wedge bi-plane SCO was performed using a LCP for fixation (Tomofix MDF, Synthes, Bettlach, Switzerland). A 4.5-cm longitudinal incision positioned over the distal part of the VM halfway between the ventral and dorsal aspect of the leg was used (Fig. 3).

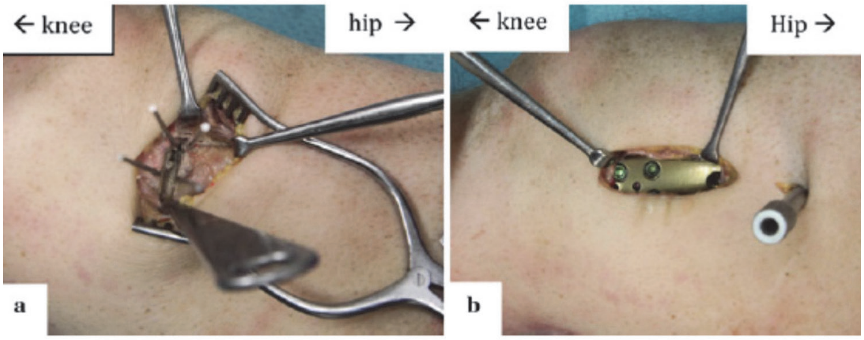

Figure 3. Medial view of less invasive approach in a cadaveric right leg.

(**A**) Distal part of the m. vastus medialis is retracted supero-lateral with small soft tissue retractors. K-wires inserted to guide sawcuts of biplanar osteotomy cuts, and small Hohman retractor protects posterior soft tissues.

(**B**) Plate fixation: distal screws and first screw proximal of osteotomy inserted, drill sleeve positioned in most proximal plate hole through stab incision.

This incision and a limited subvastus approach using the natural opening under the distal part of the VM leaving as much as possible of the VM's attachment, including the neurovascular structures, to the septum intact, enabled sufficient exposure of the osteotomy area. Thereafter, a blunt retractor was positioned sub-periostially to protect the dorsal neurovascular structures, and with a small muscle elevator, the vastus muscle belly was elevated enough to expose the bone for the osteotomy cuts (Fig. 3a). K-wires were inserted in the bone to guide the 0.8-mm 90/65 saw blade used to make the transverse osteotomy cuts starting 6.5 cm proximal to the medial knee joint line as well as the bi-plane anterior osteotomy cut [7]. After wedge removal, the osteotomy was closed. Through the same incision insertion of the plate under the vastus muscle belly, distal plate fixation and insertion of the compression screw proximal of the osteotomy were possible (Fig. 3b). A stab incision positioned over the most proximal plate hole was then made, and after blunt dissection with a clamp, a drill guiding sleeve was positioned on the plate (Fig. 3b), while its position was controlled by the surgeon's index finger slid under the muscle belly. The three proximal plate holes could be reached by repositioning the drill sleeve through the same proximal incision. After pre-drilling through the drill sleeve, uni-cortical screws were inserted, and as a final step, the compression screw was exchanged for a bi-cortical screw through the distal incision. After standard surgical closure of the wounds, the area of surgery was dissected to assess the disruption of vascular structures.

Institutional review board approval (University Medical Center Utrecht, Utrecht, The Netherlands) was obtained for this study.

Results

In the four manually dissected cadavers, the descending genicular artery (DGA) and its branches that supply the distal part of the VM, the distal femur and the knee joint, could be clearly identified. In all cadavers, a musculo-articular branch was present running to the supero-medial pole of the patella. The external diameter of this branch was 1.9 ± 0.3 mm; the average angle with the longitudinal axis of the femur was 35 ± 9 degrees. More proximal muscular branches were also identified in the VM muscle. The course of these vessels in the muscle is projected on the femur in Fig. 4 in which the position relative to the femoral artery, the femur and the adductor magnus tendon, the osteotomy, and the LCP is also shown (Fig. 4).

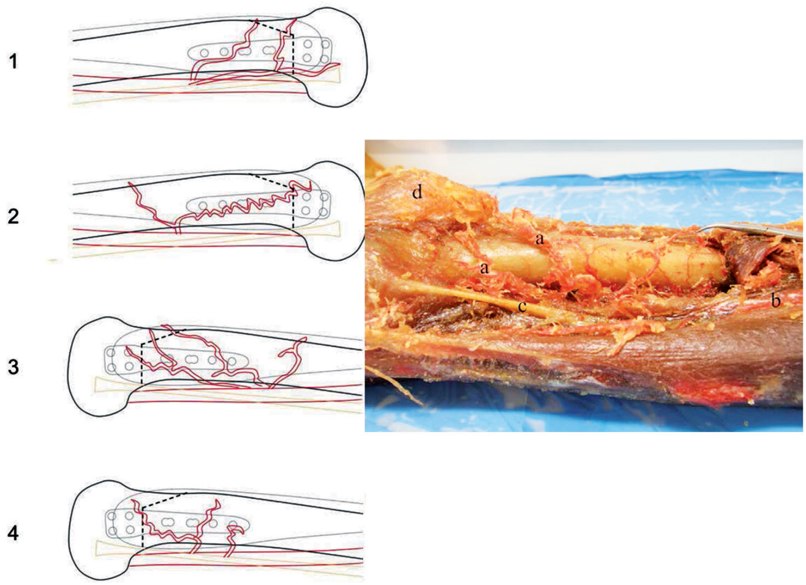

Figure 4. Schematic representation of the descending genicular artery (DGA) and its branches as found within the VM muscle in the manually dissected cadaver legs (specimen 1–4) projected on the femur. Femoral artery, adductor magnus tendon, bi-plane osteotomy and LCP are also projected on the femur. Right: original image after dissection of specimen 3 (**a** DGA, **b** femoral artery, **c** adductor magnus tendon, **d** patella).

A border between the VMO and the VML could be objectified as a different alignment of the muscle fibers in only two specimens. No intramuscular septum was found between the VMO and VML in the specimens in this study. A perspective view of the cryomicrotome dissected specimen was created to show the course of the musculo-articular branch (Fig. 2d). Its maximal surface was 2.7 mm^2. The saphenous nerve, its course running along the medial side of the femur, was found located in the septum posterior from the VM muscle. The surface areas of relevant arteries, veins, and nerves were measured 12 cm above the medial knee joint line: DGA: 2.6 mm^2; saphenous nerve: 2.3 mm^2; femoral artery: 22.8 mm^2; femoral vein: 46.8 mm^2; femoral nerve: 56.7 mm^2 (Fig. 2c). At this level, the DGA has already branched off the femoral artery. This is the level of percutaneous entry through the VM for proximal plate fixation (Fig. 2b). In the traditional subvastus approach, the muscle needs to be stripped of the intermuscular septum up to this level in order to perform the proximal plate fixation.

The minimally invasive bi-plane SCO in the sixth leg was technically feasible: a 4.5cm incision was sufficient to perform the osteotomy and placement of the distal screws and the most distal of proximal screws. Via one stab incision, the three proximal screws could be inserted. On dissection of the surgically exposed area, the DGA was found unharmed in its course through the VM as was expected from the other specimens. One small vessel branch from the DGA appeared to be damaged by the stab incision and preparations for proximal percutaneous screw insertions (Fig. 5).

Figure 5. Dissection of the medial aspect of the femur after bi-plane SCO and plate removal in specimen 6. Disruption of arteries in the vastus medialis muscle caused by the distal stab incision (arrow) was analyzed. A smaller branch of the DGA was damaged by the stab incision.

Discussion

The most important finding in this study is that a less invasive approach for medial SCO is a feasible surgical technique without causing damage to the main neurovascular supply of the VM. This approach preserves neurovascular structures branching from the inter-muscular septum into the VM that are damaged in the traditional subvastus approach. Several patterns of vascularization of the medial distal part of the femur were identified, all dependent on the course of the DGA and its branches. These arteries are all potentially at risk for damage in less invasive plate fixation in medial SCO (Figs. 1, 4). However, no major vascular damage was found in the SCO that was performed using the presented less invasive approach.

Variations in vascularization

At risk in medial SCO is the branch from the femoral artery that runs an oblique course to the supero-medial pole of the patella (Fig. 4) and is referred to in the literature as the articular, the osteo-articular, the musculo-articular branch, or DGA [1, 4, 9, 22, 30]. The data in this study are in accordance with the variable course of the DGA and its branches that have been previously described [1, 4, 9, 22, 30] (Table II).

Table II. Overview of cadaveric studies concerning the anatomy of the descending genicular artery and its branches. Many patterns were identified: the branch running to the supero-medial pole of the patella, which is potentially at risk in the less invasive approach, was given several names and was nearly always present.

	N	purpose	result	artery to patella	presence
Schneibel et al 2002	32	Subvastus approach TKA	9 patterns	Musculo-articular branch	always
Basirar et al 2006	15	Midvastus approach TKA	Average angle and distance to patella	Descending Genicular Artery (DGA)	always
Dubois et al 2010	25	Composite tissue flap	5 patterns	Osteo-articular branch	always
Yamamoto et al 2010	19	Composite tissue flap	Presence of branches, location and diameter	Osteo-articular branch	89%
Huang et al 2011	34	Composite tissue flap	4 patterns	Articular branch	always

It branches off into multiple perforating smaller vessels and runs distally and superiorly to the medial femoral condyle and supero-medial pole of the patella. Dubois et al [4] presented five patterns of the DGA in a study on the options for a cortico-periosteal medial femoral supracondylar flap (Table II). In a similar study on flap applications, Huang et al [9] recently presented a comparable DGA branching classification. Yamamoto et al [30] in a study on vascularized medial femoral condyle bone grafts found that the DGA was present in 89% of human cadavers; it originated on average 13.7 cm proximal to the medial femoral condyle and had an average internal diameter of 1.1 mm. In the current study, the DGA was present in all with a comparable location of origin and course and had an external diameter of 1.9 mm (±0.3). In defining a safety zone for the midvastus approach for total knee arthroplasty, Basirar et al [1] measured a 20°–40° entry angle of the DGA to the supero-medial pole of the patella, measured in the frontal plane. In the current study in the sagittal plane, similar angles of the DGA in relation to the longitudinal axis of the femur were found (35° ± 9°), which is easily recognizable during surgery. In all specimens, branches of the DGA project over the LCP from a medial point of view (Fig. 4). But the most proximal plate hole was found to be located outside the DGA branching pattern. The stab incision for proximal screw insertion should be made in this area.

Cryomicrotome sectioning was used in the current study to produce 3D images of the medial aspect of the distal femur. Although very elaborate, it is an accurate and therefore invaluable technique. A high resolution camera was used to photograph sequential 25-micrometer coupes. Since each layer of sectioning is photographed in true full color, different contrast agents can be used to highlight structures, as was done with Araldite for the arteries in the current study. Because the leg was frozen, subsequent sectioning did not alter the position of anatomical structures. After software reconstruction of the two other anatomical planes, synchronous display of all three planes allowed 3D visualization of the specimen. Surfaces and distances can be measured exactly, and by defining a region of interest in consecutive slides, the course of independent structures can be reconstructed as was done with the DGA (Fig. 2d).

VMO-VML interval and surgical access

Recently, Smith et al [24] presented a systematic review of 26 mostly cadaveric studies on the existence of the VMO and the VML. They concluded that there is insufficient evidence to suggest that the VM is composed of two separate components. In the majority of the included studies, the muscles could not be distinguished by a different alignment in fibers. In addition, in only 19–24% of the cadavers studied, an actual fibro-fascial plane between the muscles could be found. The findings in the six legs that were dissected in the present study are in accordance with their analysis; no fibro-fascial plane was seen in any of the specimens, and a different alignment of fibers was objectified in only two cases. In addition to that, Jojima et al [11] found small nerve fibers of the medial branch of the femoral nerve crossing between the main body of the VM and distal oblique portion furthermore indicating that there is no clear watershed or cleavage plane in innervation between the two; creating such a plane might even cause damage to neural structures.

Safety and feasibility of the less invasive approach

The SCO in the sixth leg using a less invasive approach proved to be safe and feasible. The vascular damage was in accordance with what can be expected from the course of the DGA and its small muscular branches. One smaller vessel was disrupted, whereas the main DGA branch was intact. Using this new technique, the more proximal part of the VM that is otherwise also stripped of the septum and femur remained intact, which is likely to preserve the blood supply in that part of the VM. Stahelin and Hardegger [25] also were able to use a less invasive approach by using a small malleable implant through a single medial incision but they did not provide a detailed anatomical description of the approach used, and there is no biomechanical data that support the use of a soft short malleable implant for medial SCO.

There is no literature on bleeding complications in percutaneous pins and wires placed at the medial side of the distal in placing external fixators near and/or over the knee joint; safe corridors can be created using drill sleeves. To minimize the risk of damaging an artery in the presented less invasive approach, the VM should not be retracted ventrally at the distal incision site while making the stab incision proximally because in most vascularization patterns the DGA is then pulled into the area of penetration of the stab incision, whereas the stab incision is likely to pass the DGA ventrally with the muscle belly left in place. Distally large nerve branches from the femoral nerve that run from dorsal to ventral relative to the septum innervating the VM either need to be cut in the traditional subvastus approach or are at risk for damage by stretching (Fig. 1). What's more, besides the most distal nerves that branch from the septum to the VM, a motor nerve sometimes branches off from the saphenous nerve, innervating the oblique part of the VM [8]. It is not known how much stretching of these nerve branches is allowed before permanent nerve damage occurs and muscle atrophy will sustain. In the less invasive approach, only the most distal part of the VM is lifted. This reduces the stretch on these nerves. In the area of the proximal stab incision, the size of the nerves was too small to visualize, because of that only little damage can be expected.

In addition, after the stab incision is made, blunt dissection to the plate and drilling through drill sleeves will further reduce the risk of damage. It is the current author's impression that using these techniques, the risk of vascular damage can be minimized. It should be noted, however, that just proximal to the most proximal part of where the current plate will sit on the femur, there is considerable risk of neurovascular damage at the location of the adductor canal (Hunter's canal). In this anatomic location, the femoral artery and vein as well as the muscular branch of the femoral nerve and saphenous nerve are at risk when performing stab incisions. MIPPO techniques for plate fixation on the medial side of the femur with plates longer than the plate in the current study used for medial SCO are therefore ill advised.

Important limitations of this study are the limited amount of legs that were investigated. This is mainly due to the fact that the preparation process applied is lengthy and expensive and the collection of data using the cryomicrotome is very time-consuming. It is the first time, however, that an anatomical study on the medial aspect of the femur has been performed specifically with respect to SCO. Furthermore, three modalities were combined: anatomic dissection, 3D analysis using a cryomicrotome, and the actual application of the less invasive surgical technique. Clinical relevance of the less invasive approach described here is the potential for decreased neurovascular and muscular damage in SCO, while optimizing bone healing potential, subsequently shortening rehabilitation time without increasing complication risk. Plate removal can be performed through the same incision and approach to the femur with palpation over the plate from distal to proximally helping to locate the screws through the stab incision scar. Future placement of a total knee arthroplasty can be performed through a separate standard median incision and para-patellar approach to the femur. The clinical application of the less invasive technique described in the present study in patients that undergo a SCO will have to prove its safety though.

Conclusion

The vascularization of the medial aspect of the femur as documented in this study allows for a medial closing-wedge SCO to be performed using a less invasive subvastus approach to the femur. Inserting the plate through the septum between the VMO and the VML is not feasible as a fibro-fascial septum exists in only a limited number of cases. The less invasive approach is technically feasible and safe and damage to the VM and its neurovascular structures is minimized as compared to the traditional subvastus approach.

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Chapter 9

Osteotomies around the knee: patient selection, planning, operative techniques, stability of fixation, and bone healing in Supracondylar Femur Osteotomies

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Abstract

Supracondylar femoral varus osteotomy for lateral compartment osteoarthritis of the knee is a demanding procedure that has a less favourable outcome compared to tibial valgus osteotomy. The biomechanics of valgus osteoarthritis appear to be very different compared to varus osteoarthritis. New surgical techniques and new implants specifically designed for femoral varus osteotomies have been developed and biomechanical data on the stability of these techniques and implants is now available. These developments warrant a re-appreciation of this treatment modality. Therefore indication, planning and surgical technique for supracondylar femoral varus osteotomy are discussed with special attention to these new developments in surgical technique.

Introduction

Varus supracondylar osteotomy (SCO) for lateral compartment osteoarthritis (OA) of the knee has not had the same success or widespread use as valgus high tibial osteotomy (HTO) [1-6]. The goal in SCO is similar to HTO, to shift the load from the diseased to the healthy compartment, in order to reduce pain, improve function and delay placement of a total knee replacement (TKR) [7].

Valgus OA however occurs much less frequently than varus OA and varus SCO is considered a technically more demanding procedure [4, 5, 8, 9]. In the past the surgical techniques for SCO were mainly dependant on difficult to use implants making the procedure more complex. Complication rates related to the failure of fixation up to 16% have been reported [10]. Similar to the re-appreciation of HTO, SCO has gained renewed interest as new knowledge has become available on the influence of malalignment on the development and symptoms of OA [11]. Furthermore knowledge on the etiopathology of lateral compartment OA has improved and better guidelines for the selection of candidates for osteotomy have been formulated by The International Society of Arthroscopy, knee surgery and Orthopaedic Sports Medicine (ISAKOS) [6, 12, 13].

New techniques for medial closing-wedge osteotomy and specially designed fixation plates based on the locking-compression-plate (LCP) concept, providing superior initial stability, are now available [14, 15]. This paper discusses the current views on varus SCO.

Etiopathology, indication and patient selection

A valgus leg alignment can be present congenitally or occur after lateral menisectomy, growth plate disturbances and/or post traumatically [16]. The presence of lateral compartment OA itself will often cause a valgus leg alignment. Lateral compartment OA is most often located postero-laterally in the knee whereas medial compartment osteoarthritis is located antero-medially. Anatomically the lateral tibia plateau is convex, instead of concave medially; congruency of the lateral compartment is to a much larger extent maintained by the shape of the lateral meniscus, and loss of the integrity of the lateral meniscus decreases this congruency [17]. Various authors have looked at the differences between lateral and medial OA to explain aetiology and pathology [6, 18-21]. Recent research on cartilage forces and associations between variations in anatomy around the hip and leg alignment better explain why cartilage in lateral OA deteriorates more rapidly in specific patients (Table I) [22-28].

The main indication for SCO is the correction of frontal plane valgus malalignment in lateral uni-compartmental OA of the knee. A second indication is the correction of load imbalance in ligamentous instability due to chronic medial collateral ligament insufficiency to reduce the valgus thrust and to unload any ligament reconstruction. A third indication is the correction of lateral patello-femoral mal-tracking due to the valgus leg alignment and associated abnormal trochlear orientation, to reduce the lateral displacement forces acting on the patella.

Table I. Causes of rapid lateral compartment OA progression.

Author	Study	Conclusions
Cartilage forces		
Pena et al [24]	Difference in effect on cartilage of lateral *vs* medial menisectomy using finite element analysis.	Percentage increase in cartilage stress in lateral compartment higher after lateral menisectomy then medial.
Yang et al [25]	Combined effect of tibio-femoral knee angle and meniscectomy on cartilage contact stress.	Greater percentage increase of cartilage contact stress after lateral and meniscectomy compared to medial meniscectomy with pre existing abnormal tibio-femoral angle.
Bretin et al [49]	Influence of femoral fracture malrotation malunion on knee joint cartilage forces.	Internal rotation malunions are associated with lateral mechanical axis deviation and lateral shift of cartilage forces.
Anatomy and leg alignment		
Allen et al [23]	Follow-up of late changes after menisectomy in a series of 210 patients.	Increased knee OA after meniscectomy in patients with pre existent abnormal (valgus) tibio-femoral alignment and lateral menisectomy compared to medial.
Weidow et al [26]	Motion and moments in hip and knee in medial and lateral knee OA compared to control group.	Association between lateral knee OA and biomechanics of the hip joint, but unknown if reason for development of lateral OA or caused by its presence.
Weidow et al [27]	Relationship between lateral knee OA and anatomical differences in the hip region.	Association between lateral knee OA and wider pelvis, shorter neck, shorter head-shaft distance, shorter lever arm of the hip in lateral OA compared to medial OA.

Initial assessment is done using weight bearing antero-posterior (AP) and lateral radiographs and axial views of the patello-femoral joint are taken, as well as whole leg standing radiographs and postero-anterior (PA) weight bearing radiographs in 45° of knee flexion[7, 16, 29-31]. The latter is used to visualize the degenerative changes in the posterior part of the lateral tibia plateau (Fig. 1). Optional varus stress views may be used to show a sufficient lateral collateral ligament and adequate joint space in the medial compartment [32].

The ISAKOS guidelines on HTO in the management of knee OA can also be applied to SCO (Table II) [12]. In addition to these guidelines, it is the current authors' opinion that patients younger than 40 years of age can also benefit from realignment, alone, or combined with a secondary cartilage procedure such as micro fracturing. Furthermore patients with medial compartment cartilage changes up to Outerbridge [33] grade 3 and patients with an intact remnant of the medial meniscus after partial menisectomy may be suitable candidates, provided that the leg is not overcorrected into varus. In addition to frontal plane corrections > 15˚, corrections up to 15˚ in the sagittal plane can be performed using current fixation techniques.

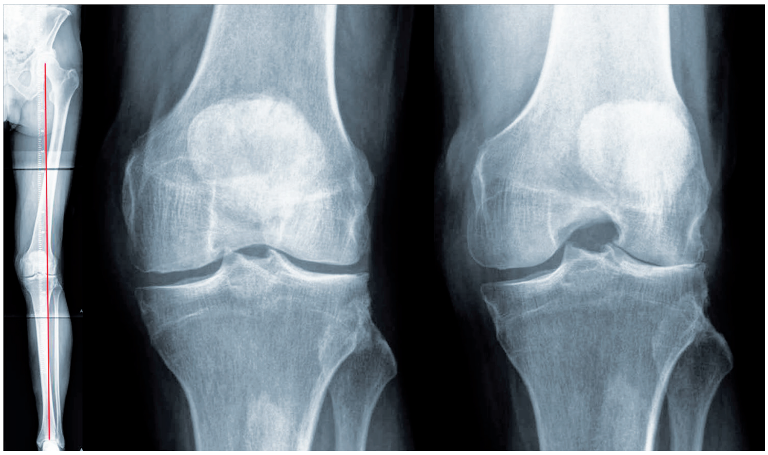

Figure 1. Typical lateral compartment osteoarthritic left knee. Valgus leg alignment on full leg weight bearing radiograph with weight bearing line (in red) passing through the lateral compartment (left), weight bearing AP knee radiograph in extension shows small lateral joint space narrowing (middle), weight bearing PA knee radiograph in 45˚ flexion (Rosenberg view) shows severe lateral joint space narrowing (right).

Table II. ISAKOS guidelines [12] for selection of patients suitable for SCO.

Ideal	Possible	No candidate
Isolated lateral joint line pain	Flexion contracture < 25°	Flexion contracture > 25°
Age 40-60	Age < 40, 60-70	Bi compartmental disease
BMI < 30	Moderate, symptomatic PF OA	Previous meniscectomy in compartment to be loaded by SCO
Non smoker	Instability of ACL/PCL/PLC	Prior knee infection
High demand activity but no running/jumping	Wants to participate in all sports	Rheumatoid arthritis
Alignment < 15° valgus		Obesity
Deformity in distal femur		Possible non compliance
Full range of motion		Heavy smoker
< 10° extension loss, > 90° flexion		Soft, atrophic appearing bone on X-ray
Normal medial and PF compartments		Severe femoral bone loss
Normal ligament balance		
OA classification IKDC (A),B,C,D		
No notch osteofytes		

BMI, body mass index; PF, patella femoral; IKDC, International Knee Documentation Committee osteoarthritis classification; ACL, anterior cruciate ligament; PCL, posterior cruciate ligament; PLC, posterolateral corner; OA, osteoarthritis; SCO, supra condylar femur osteotomy.

Correction of the deformity

In knee joints with distal femoral deformities and valgus joint line obliquity a femoral correction not only corrects the leg alignment but also normalizes the knee joint line obliquity. In many patients however the valgus malalignment may be found to be caused by a tibial or a combined tibial and femoral deformity [34]. The principles of deformity correction as formulated by Paley [35] dictate that in these cases either a tibial correction or a double level osteotomy should be performed with a resultant normal knee joint line orientation. Planning of correction using present and desired weight bearing lines provides for the angle of correction as well as the length of the wedge base on the cortex (Fig. 2).

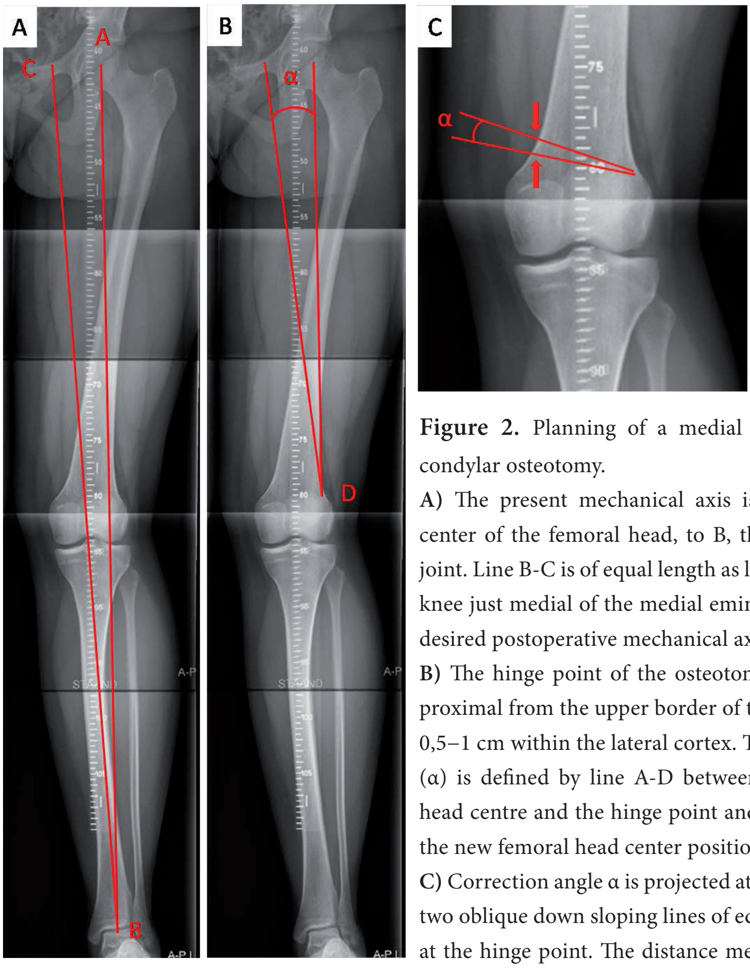

Figure 2. Planning of a medial closing-wedge supracondylar osteotomy.

A) The present mechanical axis is drawn from A, the center of the femoral head, to B, the centre of the ankle joint. Line B-C is of equal length as line A-B and passes the knee just medial of the medial eminence representing the desired postoperative mechanical axis.

B) The hinge point of the osteotomy (D) is marked just proximal from the upper border of the lateral condyle and 0,5–1 cm within the lateral cortex. The angle of correction (α) is defined by line A-D between the present femoral head centre and the hinge point and line C-D connecting the new femoral head center position and the hinge point.

C) Correction angle α is projected at the distal femur using two oblique down sloping lines of equal length converging at the hinge point. The distance measured between those 2 lines at the level of the medial cortex (arrows) represents the osteotomy wedge base length to be removed during surgery.

While a varus SCO is biomechanically efficient in the extended knee, it should be noted that in flexion the osteotomy has no effect [36]. In 90 degrees of flexion the contact point of the loaded posterior condyles on the tibia remains unchanged by the SCO. Patients therefore should be warned that while excellent symptoms relief may be expected in extension and during gait, symptoms are likely to persist during activities that load the knee in high flexion.

In the literature results vary from relatively poor to good at mid to long term follow-up; from 57% satisfactory results at 6.5 years follow-up, to 83% at 99 months (approximately 9 years) and 92% good results at 4 year follow-up, as reported by McDermott et al [1, 2, 4, 5]. The endpoint of survival is usually placement of a TKA; survival up to 87% at 99 months has been reported [1].

Well-designed studies, let alone RCT's, comparing the various available surgical options and factors that determine the outcome in SCO are not available. There is no consensus in varus SCO on the optimal amount of correction. A correction of the anatomical femoro-tibial axis to 6–10° [1, 3, 4, 9, 37, 38] or mechanical femoro-tibial axis between 0 and 3 degrees have all been recommended [2, 6, 7, 29, 38, 39]. Shoji and Insall [40] identified the remaining obliquity of the knee joint line after valgus correcting osteotomies as a major prognostic factor. In a series of patients with valgus deformities and lateral compartment OA, they performed an HTO and found that if the joint line obliquity produced after the tibial correction exceeded 15°, especially in combination with over- or under-correction of the frontal malalignment, rapid further degeneration ensued. Several clinical studies on double osteotomies to prevent pathological joint line obliquity have since confirmed these early observations by Shoji and Insall [34, 41, 42].

Other authors stated that poor results were associated with failure to correct the tibia-femoral angle to 0° while on the other hand no correlation between alignment and outcome has been reported as well [2, 4]. Teitge [6] noted that with correct alignment deterioration was slow and that those with a less than good result were poor from the start; in those the indication to perform an osteotomy might not have been correct. Increased body weight and an increasing amount of previous surgeries have also been found to be prognostic factors for a less than optimal outcome. Regarding overcorrection into varus after SCO, Sharma et al [11] in a study on the role of knee alignment in OA disease progression and functional decline found a 4 fold increase in the odds of disease progression if a varus alignment was present, and a malalignment greater than > 5° was associated with a significantly greater functional deterioration over the period of follow-up.

The current authors correct the mechanical axis to a line passing the knee joint just medial to the deepest point of the trochlea. In severe lateral OA in the presence of a normal medial compartment a line slightly medial to that, i.e. just medial of the medial eminence of the tibia plateau, is used. Alternatively in the presence of a normal contralateral leg that mechanical axis can be used as reference. Furthermore rather than planning the closing-wedge osteotomy cuts parallel to the joint line, the cuts are planned obliquely down sloping from the medial cortex (Fig. 2).

Osteotomy techniques and methods of fixation

In SCO, medial closing-wedge and lateral opening-wedge techniques can be used [6, 17, 29, 30, 38, 39, 43]. For fixation an angled blade plate, a Dynamic Condylar Screw and side plate (DCS), a malleable implant, staples, a plaster cast only, and an external fixator have all been used with various amounts of success [5, 10, 16, 38]. The medial closing-wedge technique, with saw cuts either parallel to the joint line or oblique down sloping from the medial cortex to the lateral cortex hinge point, fixated with an angled blade plate, has had the most widespread use [1-4, 6, 9, 37, 43, 44]. More recently angle stable implants specifically designed for the fixation of SCO have become available and a new so called bi-plane SCO technique has been developed [7, 29, 30, 39].

The various osteotomy techniques and fixation methods all have their advantages and disadvantages (Table III). An important limitation of the single-plane medial closing-wedge technique is the position of the osteotomy relative to the trochlea and the soft-tissues gliding surface on the anterior side of the femur [15,29].

While in the standard single-plane technique the patello-femoral (PF) joint is avoided by proximal positioning of the saw cuts, the osteotomy does disrupt the soft-tissue gliding mechanism causing a haematoma with subsequent pain and swelling slowing rehabilitation. A modification was therefore developed by the current authors: the bi-plane medial closing-wedge technique [15]. In this technique the two saw cuts for the closing-wedge are made only in the posterior 3/4 of the femur after which an ascending saw cut is performed on the anterior surface of the femur, completing the osteotomy. By avoiding the trochlea this technique enables a more distal positioning of the lateral hinge point in better healing metaphyseal bone. As the soft tissue gliding mechanism is not disrupted rehabilitation is faster [29]. Furthermore, the ascending saw cut increases the cortical contact area, which enhances stability and bone healing potential [15, 45].

By changing the fixation technique to a plate fixator the difficulties encountered using an angled blade plate, which caused surgeons to refrain from SCO altogether, are avoided. Inaccurate positioning of the seating chisel and loss of stability after repositioning, the high frequency of hinge fractures causing secondary displacements while removing the seating chisel and inserting the angled blade plate are all avoided.

Lateral plate positioning on the tension side, rather than the compression side, in medial closing-wedge SCO has been advocated by some. In that scenario the plate is loaded under tension which in turn would prevent lateral distraction during weight bearing [17].

The downside of lateral fixation in medial SCO however is an increase in load on the plate, it is further away from the postoperative weight bearing line (WBL), increasing the load lever arm and bending moment. This may lead to instability of fixation, delayed bone healing, implant failure and loss of reduction [6, 32]. Stahelin[10] showed by measurement of bone diameters at the level of the bone cuts that, using oblique directed bone cuts of equal length forming an isosceles triangle, the bone diameter at the level of the osteotomy cuts is equal

(Fig. 2). After closure of the osteotomy the medial cortex can be compressed without change of correction, contrary to bone cuts aligned parallel to the joint line resulting in unequal bone diameters causing impaction and overcorrection after compression of the osteotomy.

Table III. Comparison of different osteotomy and fixation techniques with respect to surgical technique, bone healing and fixation stability.

Osteotomy	advantage	disadvantage
Medial closing-wedge SCO Fixation technique		
Medial Closing-wedge SP SCO	– good bone healing potential – oblique saw cuts increase stability	– supratrochlear area disrupted
Medial angled blade plate	– plate closer to WBL, lower stress/strain – high construct stability [14]	– prone to hinge fracture by blade insertion – blade location dictates reduction/correction – difficult
Dynamic Condylar Side plate (DCS) (applied laterally)		– plate further from WBL, higher stress/strain – screw location dictates reduction/correction – prone to hinge fractures with dislocation
LCP based fixation	– ease of plate application – high construct stability [14, 15]	
Medial Closing-wedge BP SCO	– in metaphyseal bone area with highest bone healing potential – highest axial stability [14] – smallest wedge volume [45]	– extra saw cut

Osteotomy	advantage	disadvantage
Lateral opening-wedge SCO Fixation technique		
Lateral open wedge SP SCO	– single cut – easier approach to femur – easily adjustable correction	– supratrochlear area disrupted – weak medial hinge point [6, 14] – plate location complaints [7, 48] – very unstable if hinge point fractures [6] – slowest bone healing, role of grafts unclear
Blade plate/DCS + screw fixation		– prone to hinge fracture by blade insertion – plate/screw dictates reduction/correction [6] – difficult
Spacer plate	– spacer supports correction [17, 31] – ease of plate application	– low construct stability [14]
LCP based fixation	– ease of plate application	– low construct stability [14]

SP, single-plane (or uni-planar); BP, bi-plane; SCO, supracondylar femur osteotomy; LCP, Locking compression plate; WBL, weight bearing line.

Baseline data on the initial stability of the various SCO techniques has become available [14, 15, 46]. In three biomechanical studies partial and full weight bearing conditions after SCO corrections in replicate bones were studied. In the first study the biomechanical properties of 5 different SCO techniques (Fig. 3) have been evaluated [14].

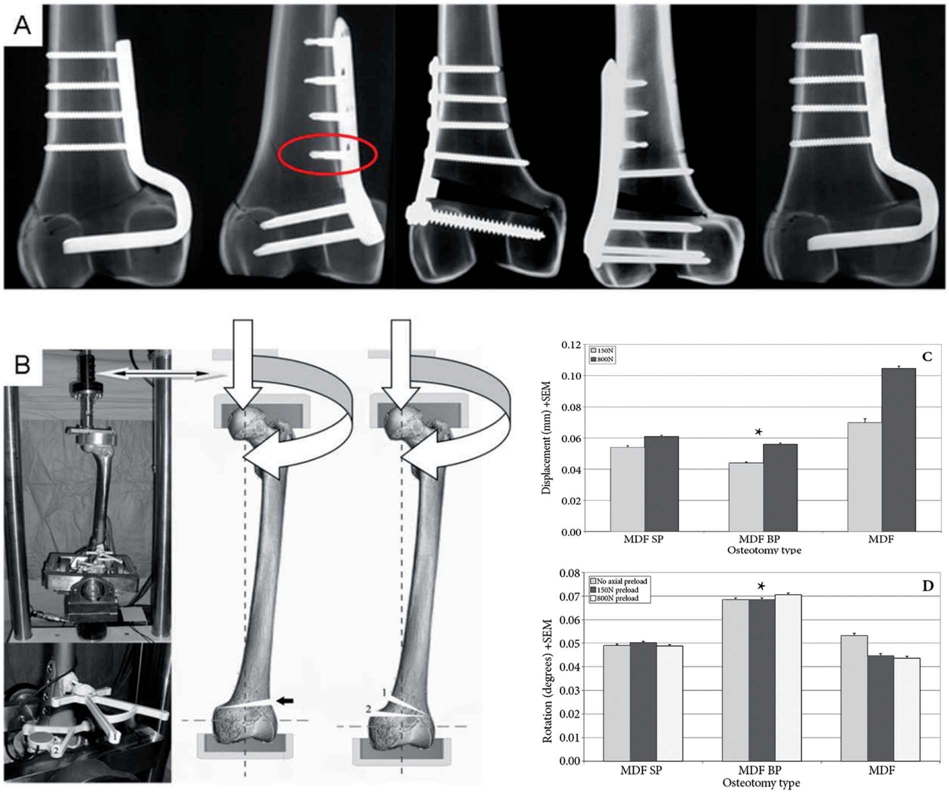

Figure 3

A) Overview of the 5 osteotomy configurations initially tested, from left to right: medial closing-wedge oblique saw cut AO blade plate, medial closing-wedge oblique saw cut LCP (Tomofix MDF), lateral opening-wedge spacer plate, lateral opening-wedge LCP (Tomofix LDF), medial closing-wedge perpendicular saw cut AO blade plate [14]. Red circle: the uni-cortical screw initially used was replaced by a bi-cortical screw in the second series of tests [15].

B) Overview of the test setup, the replica femur is loaded in an MTS with the 3D measuring system attached (bottom left: 1 and 2). The direction and position of the osteotomy cuts (bottom middle) creating a 10° opening (black arrow) or a 10° closing-wedge oblique (1) or perpendicular (2) osteotomy. The load applied to the femur is also shown (middle: white arrows) [14]. **C)** Results of the axial loading tests and **D)** torsion loading tests, comparing the single-plane SCO with modified proximal screw configuration (red circle in **A,** bi-cortical instead of uni-cortical) (MDF SP), the new bi-plane SCO (MDF BP) and the old single-plane SCO (MDF). Motion is in millimeters (mm). MDF BP is statistically significantly more stable under axial loads and statistically significantly less stable under torsion loads (* in A and B) [15].

The angled blade plate and the Tomofix Medial Distal Femur plate (Synthes GmbH, Solothurn, Switzerland), using an oblique osteotomy direction provided the largest amount of initial stability. The parallel osteotomy compared to the oblique osteotomy, and the lateral opening-wedge technique, whether fixated with an angle-stable or a spacer plates, were clearly less stable. In a second study the aforementioned bi-plane osteotomy was found to be more stable than the standard single-plane SCO [15]. Subsequently, in a third study previous results on bi-plane SCO stability were reconfirmed using an improved, more anatomically shaped version of the angle stable (Tomofix) plate and latest 4th generation replicate bones [46].

Operative technique

The current authors preferred SCO technique is a bi-plane medial closing-wedge osteotomy fixated with the Tomofix-plate (Fig. 4) [29]. Arthroscopy can be performed prior to the osteotomy to assess the cartilage and menisci; if needed additional procedures, including micro-fracturing, can be performed. The whole leg should be draped free and on personal preference a sterile tourniquet can be applied. The starting position of the knee is in full extension. An image intensifier fluoroscope is mandatory, with visualisation possible in two directions. The medial side of the distal femur can be either exposed by a median or antero-medial incision and a subvastus approach. In the standard subvastus approach the muscle needs to be stripped of the septum severing vessels and nerves at a length enabling plate fixation. Alternatively a less invasive technique can be used as described by Visser et al [47]. A small medial incision is made at the level of the osteotomy and instead of stripping the (VM) of its septum, the natural interval between the distal femur and VM is used to lift the muscle ventrally.

After exposure of the femur a blunt Hohmann retractor is positioned dorso-medially at the level of the osteotomy to protect the neurovascular structures. The height and direction of the osteotomy cuts are marked with K-wires using fluoroscopy. The first K-wire for the distal saw cut is inserted at the medial cortex aimed at an approximately 20° down sloped direction ending a few millimetres (mm) above the upper portion of the lateral femur condyle and 5–10mm medial to the lateral cortex (Fig. 2). The second K-wire is inserted proximally at the pre-planned wedge base distance on the medial cortex, the ends of both K-wires meet at the hereby created hinge point of the osteotomy. Ideally, the K-wires form an isosceles triangle which can be checked by measuring the remaining length of the K-wires outside the bone. Two additional K-wires can be positioned more posterior at the same height to guide the saw blade. Alternatively, a special saw guide can be used to precisely determine wedge size and direction. Two saw cuts are made parallel to and within the K-wires, but only in the posterior three quarters of the femur. A third ascending saw cut is than performed to complete the osteotomy, parallel to the posterior cortex, usually at an angle of 90–95° to the other saw cuts. After wedge removal, the osteotomy is closed by applying gentle pressure; this can take up to a couple of minutes, to allow for plastic deformation of the bone. All bone should be removed from the gap before closure to prevent incomplete closure and lateral cortex fracture. After closure, the alignment is checked using a rigid bar over the centre of the femoral head and centre of the ankle joint, the new mechanical axis should run as pre-operatively planned; if needed adjustments can still be made to the osteotomy at this time.

An angle stable Tomofix plate is slid proximally under the vastus medialis muscle until it is aligned with the femur shaft and then positioned antero-medially on the distal femur. After distal fixation with 4 locking bolts the osteotomy is compressed manually. For additional compression an eccentrically placed screw in the dynamic part of the combination-hole directly proximal to the osteotomy is used. The plate is secured proximally using three uni-cortical locking bolts, and one bi-cortical screw just proximal from the osteotomy replacing the compression screw. In the less invasive technique the distal locking bolts and the osteotomy-compression screw are inserted through the medial incision whereas the remaining proximal screws are inserted through a separate transmuscular stab incision positioned at the most proximal plate hole avoiding damage to major neurovascular structures [47]. The wound is closed after placement of a low suction drain under the vastus medialis.

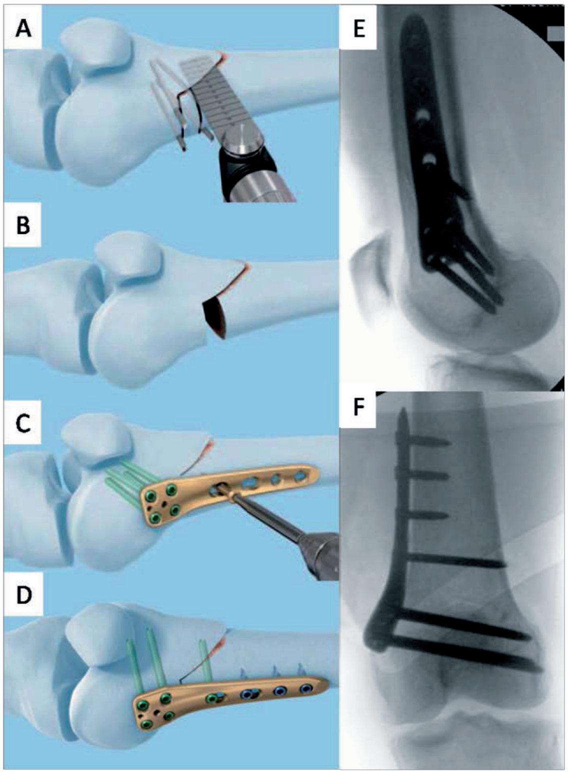

Figure 4. Diagrams and radiographs showing surgical technique for a bi-plane closing-wedge SCO with fixation by an internal fixator plate. After the transverse cuts have been made, the ascending cut of the bi-plane osteotomy is performed parallel to the posterior cortex (**A**). The wedge is removed before closure (**B**). After distal plate fixation a lag-screw is inserted to compress the osteotomy (**C**). Final fixation configuration (**D**). Intraoperative sagittal fluoroscopy view (**E**). Intraoperative frontal fluoroscopy view (F).

Postoperative care and weight bearing protocol

Postoperative cryotherapy and intermittent venous compression are recommended to reduce swelling. Starting on the first postoperative day, partial weight bearing (15 kg to 20 kg) is allowed for the first 6 weeks, it is increased thereafter depending on pain and signs of bone healing on follow-up radiographs.

For SCO in clinical studies reporting on the single-plane technique with the TomoFix implant, no bone healing problems have been reported with a standard rehabilitation protocol consisting of 6–8 weeks of partial weight bearing [29, 39]. Clinical results seem to correlate with the biomechanical observations concerning construct fixation strength and the bi-plane osteotomy technique. Van Heerwaarden et al [39] reported no loss of correction related to the implant and no failures of fixation material in 59 single-plane osteotomies fixated with the Tomofix MDF plate. Freiling et al [29] reported on 60 medial closing-wedge osteotomies half of which were bi-plane and found 3 non-unions overall, none of which were related to implant failure.

However, after introduction of the bi-plane technique a faster recovery of knee function was observed by the current authors as compared with the single-plane patient groups; patients themselves increased the amount of weight bearing within the first 6 weeks after the osteotomy as they experience sufficient stability to allow full weight bearing.

Although Brinkman et al [15] demonstrated that the bi-plane OT is much more stable than single-plane OT under axial loads, they did find torsional stability to be slightly decreased. Therefore postoperatively physical activities, which produce high torsion loads on the femur are probably best avoided until bone healing has been observed.

The use of braces to improve stability and protect the osteotomy has been documented by various authors; Healy et al [3] used a brace if the fixation of the osteotomy was questionable, Wang et al [1] and Miniaci et al [44] both also used braces. All three authors in their series of patients used an angled blade plate for fixation and a limited weight bearing protocol initially, varying from non-weight bearing to toe touch for 6 weeks, full weight bearing being allowed after 12 weeks or if clear signs of consolidation were present on follow-up radiographs.

Based on the results of the biomechanical studies [15, 45, 46] and clinical experience a clinical study has been started using early full weight bearing (after 2 weeks) and a hinged brace preventing torsional loading until full bone healing in patients after bi-plane medial closing-wedge SCO fixated with the Tomofix implant [32] For lateral opening-wedge SCO patients rehabilitation should be more careful because the osteotomy construct is less stable [14] and bone healing is slower [6, 29, 48].

Bone healing in SCO

The general principles of bone healing apply to closing-wedge osteotomies, which can be considered optimally controlled fractures treated according to standard protocols for fracture treatment. With radiographs taken at intervals, e.g. at 6 weeks, three and 6 months, progression of bone healing can be monitored.

Bone healing in closing-wedge osteotomies however may be faster than in fractures if after closure of the wedge the hinge point remains intact, i.e. if initial stability is optimal. Bone healing in the distal femur then normally is complete after 6–8 weeks (Fig. 5). Methods to prevent hinge point fracture are careful clearance of uneven saw cut surfaces and bone remnants after wedge removal, weakening of the lateral cortex before closure by chisels or small bur holes, and a slow paced wedge closure. Initial stability can be furthermore optimized by using oblique saw cuts and by compressing the osteotomy using either a compression device or the compression screw technique (Fig. 4).

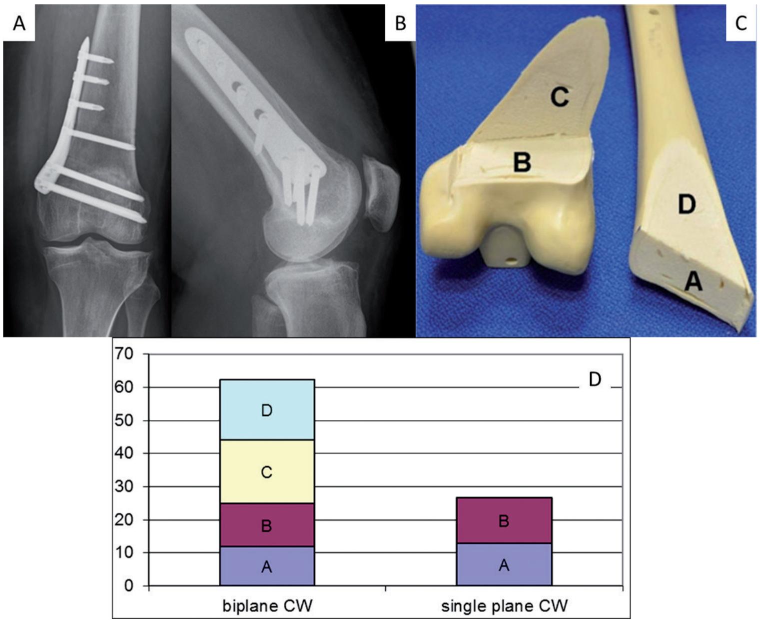

Figure 5. Radiographic follow-up of bone healing (radiographs at t = 0 presented in figure 2) and bone surfaces after bi-plane supracondylar osteotomy in a saw bone model. **A**. Lateral view shows full consolidation of ascending cut at 6 weeks follow-up. **B**. AP view shows full consolidation at 6 weeks follow-up. **C**. Bone surfaces following a medial closing-wedge bi-plane osteotomy in a saw bone model: Transverse osteotomy plane surfaces A (proximal) and B (distal), frontal osteotomy plane surfaces C (ventral) and D (dorsal). D. Summation of femoral surface square centimeter (cm^2) stratified by anatomical location of the different osteotomy planes in single-plane and bi-plane closing-wedge (CW) supracondylar osteotomy (C and D adapted from [45] with permission).

Similar to fractures, bone healing in osteotomies is slowed down by smoking and instability, e.g. by insufficient implant fixation strength and/or hinge fracture.

Van Heerwaarden et al [45] studied bone geometry and wedge volume after SCO, comparing lateral open and single- and bi-plane medial closing-wedge techniques and found the bi-plane medial closing-wedge SCO to have the best bone healing potential compared to other SCO techniques. They found that using the bi-plane technique a smaller wedge volume and a larger bone surface contact area are created, arguing that this would improve bone healing and stability (Fig. 5).

In the lateral opening-wedge technique concerns exist regarding the stability of fixation and ability of the construct to retain the correction; bone healing has been documented to take longer, time to full weight bearing is longer and often an iliac crest graft is needed to fill the defect [7, 14, 39, 48]. Various authors could not recommend this technique, because of a large number of non-unions and ilio-tibial band irritation because of plate location [7, 48].

Varus supracondylar osteotomy is a viable treatment option for a well-defined patient group suffering from valgus malalignment and osteoarthritis of the lateral compartment, and in addition may be considered in ligamentous imbalance and lateral patello-femoral maltracking. Based on new data obtained by biomechanical testing and clinical research, the bi-plane osteotomy fixed with an internal plate fixator is very stable. Bone healing potential is optimal using this technique and takes 6–8 weeks; full weight bearing before full bone healing is possible without loss of correction.

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Chapter 10

General Discussion, Summary and Answers to the questions

In this thesis, in a number of studies, new surgical techniques for corrective distal femur and proximal tibial osteotomy are introduced and a scientific basis for choosing between the various surgical options and postoperative rehabilitation protocols is provided. Furthermore, the primary stability of the osteotomy construct after surgery is addressed and guidelines for surgical treatment and rehabilitation are offered.

Chapter one provides a general introduction to the topic and raises a number of research questions to be addressed in the subsequent chapters.

In chapter two, in a randomized controlled trial (RCT), the stability of opening- and closing-wedge osteotomies (OW and CW) stabilized using the widely used TomoFix (Synthes GmbH, Oberdorf, Switzerland) implants for fixation was measured, using an accurate three-dimensional imaging modality named Radiostereometry (RSA), in a series of 42 patients. There were no differences between the OW and CW groups in the time to regain knee function and full weight bearing. Pain and knee function were significantly improved in both groups without any differences between them. All osteotomies united within one year. RSA showed no clinically relevant movement of bone or the implant, nor could differences between the two groups be established. It can be concluded that Tomofix-plate-fixated medial Opening-Wedge High Tibial Osteotomy offers equal stability to a lateral Closing-Wedge technique. Both demonstrate excellent initial stability and provide significantly improved knee function and reduction in pain, although the OW technique appeared more critical in obtaining the intended correction.

In chapter three, in a prospective cohort study, Opening-Wedge High Tibial Osteotomy stabilized with the angle-stable Tomofix implant in 14 knees were documented in patients that were allowed unrestricted weight bearing as soon as pain and wound healing permitted. Again RSA was used to measure motion across the osteotomy at regular intervals. Improvement in pain and functional outcome were also assessed postoperatively. The results were compared to those from a group of 23 patients who had undergone the same operation but had used a standard rehabilitation protocol with restricted weight bearing. There were no adverse effects because of the early full weight bearing. There were no differences in motion at the osteotomy between groups as measured by RSA. In both groups, pain and function improved substantially without any differences between groups. Patients in the early weight bearing group achieved the same result but in a shorter period of time. It can be concluded that Tomofix-plate-fixated Opening-Wedge High Tibial Osteotomy allows early full weight bearing without loss of correction, and that the full weight bearing regime leads to an earlier return to function and a shorter rehabilitation time.

In chapter four, an overview of new developments in osteotomy techniques and methods of fixation is presented for high tibial osteotomy. This chapter highlights recent research aimed at joint pressure redistribution, fixation stability and bone healing that has led to improved surgical techniques and a decrease of postoperative time to full weight bearing. The current consensus on HTO-indications and patient selection and the factors influencing the outcome after HTO are presented.

In chapter five the fixation stability and stiffness of implants used in various commonly used supracondylar femur osteotomy (SCO) techniques was investigated. Under simulated physiological loading conditions a composite femur model and a 3D ultrasound travel-time based motion-analysis system was used. The osteotomy configuration options that were investigated were: LCP concept based and conventional rigid compression based fixation techniques, medial closing-wedge and lateral opening-wedge techniques, and obliquely and perpendicularly directed osteotomy saw cuts (relative to the joint line).

In 5 configurations these variables were investigated: (1) an oblique medial closing-wedge osteotomy stabilized with an angle-stable implant (Tomofix MDF, Synthes GmbH, Oberdorf, Switzerland); (2) an osteotomy with an oblique and (3) a perpendicular saw cut, both medial closing-wedge, and both fixated with a rigid compression based 90° angled blade plate (AO/ASIF, Davos, Swiss); and two lateral opening-wedge osteotomies fixated with (4) a spacer plate (Arthrex spacer plate, Naples, FL, USA) and (5) an angle-stable lateral distal femur plate (Tomofix LDF, Synthes GmbH, Oberdorf, Switzerland).

The motion measured at the osteotomy was used to calculate the stiffness and stability of the constructs. The least amount of motion and highest stiffness were measured in the medial oblique closing-wedge osteotomy stabilized with the angled blade plate and the Tomofix MDF plate. The lateral opening-wedge techniques were less stable and had a lower stiffness compared with the medial closing-wedge ones, and the oblique saw cuts were more stable and had a higher stiffness than the perpendicular ones. The baseline data documented in this study on the differences in the primary stability of bone-implant constructs used in SCO can be used as reference for future testing of SCO techniques. Furthermore, it is recommended that, based on the differences found, the early postoperative rehabilitation protocol is tailored to the stability and stiffness of the fixation method used, i.e. opening-wedge osteotomies should be rehabilitated at a slower pace than closing-wedge osteotomies.

In chapter six, a novel bi-plane distal femur osteotomy technique was introduced, aimed at better preserving the patella-femoral joint and improving initial stability. The stability and stiffness of this newly developed technique and a modification of the proximal screw configuration of the current Supracondylar Osteotomy technique using Tomofix MDF for fixation were tested in a composite femur model and compared to the standard single-plane technique. The research question was if the new bi-plane technique and/or modified screw configuration would improve the stability and stiffness of the construct. In 12 composite replicate femurs, motion at the osteotomy under axial and torsion loading was measured using a 3D ultrasound travel-time based motion analysis system. All were subsequently tested to failure. The motion data recorded were used to calculate stability and stiffness of the constructs. Results showed that the stability and stiffness were highest in the bi-plane technique under axial loads, but were lower under torsional loading, compared to the single-plane technique. The screw configuration modification improved axial stability and stiffness, but had no influence on torsional stability. In the replicate femurs used in this study, the new bi-plane technique improved axial stability, but in contrast to what was theorized, decreased torsional stability, compared to the single-plane technique. The addition of a bi-cortical screw proximally improved stability under axial loading, but not the torsional stability.

In chapter seven the validity of rudimentary mechanical test models such as open gap tests and four point bending tests was discussed. In many cases, regulatory authorities require that implants for fracture and/or osteotomy fixation are tested according to these test models. Such test models may be suitable to compare different implants on a purely mechanical basis, but they are not always representative of the postoperative situation after supracondylar osteotomy, which in the end is decisive when it comes to bone healing. The available open gap test results of the latest version of the Tomofix Medial Distal Femoral Plate and of the antecedent plate design, are compared with the test results using a more physiological and life-like test model, which simulated postoperative conditions for medial closing-wedge supracondylar osteotomies. The same test setup as used and documented in detail in chapters five and six was used. The results in this chapter showed that in contrast to the open gap test model the performance of both plates is equal. It is argued that the difference in results between the two loading models is due to differences in test design and that as life-like conditions as possible should be used for biomechanical testing of implants.

In chapter eight a human cadaver dissection study on the vascular and neural structures of the medial side of the distal femur was described. Surgical dissection, cryomicrotomy and subsequent 3D reconstruction of the anatomy, and surgical dissection after performance of a SCO through a less invasive approach were performed in 6 legs in total. A branch of the femoral artery, the distal genicular artery, supplies the distal area of the vastus medialis (VM) muscle. This artery has several branching patterns; crucial in the presented less invasive approach is its musculo-articular branch, which has an oblique course through the VM to the supero-medial pole of the patella. The femoral nerve and saphenous nerve innervate the VM. These structures are at risk in the traditional subvastus approach, whereas no major damage was observed in the leg in which a less invasive approach was performed. In this cadaveric dissection study, a less invasive approach to the medial side of the distal femur proved to be feasible and safe and able to respect relevant anatomy. Damage to the VM and its neurovascular structures is minimized as compared to the traditional subvastus approach.

In chapter nine, current concepts of SCO for lateral compartment OA of the knee were discussed. SCO is a demanding procedure that has historically been associated with a less favorable outcome compared to valgus HTO. The biomechanics of lateral OA of the knee appear to be very different compared to medial OA. This chapter highlights research on the etiopathology of lateral compartment OA, fixation stability and bone healing that has led to improved surgical techniques and a decrease of postoperative fixation stability problems. These new surgical techniques and new implants specifically designed for femoral varus osteotomies, and the biomechanical data on the stability of these techniques and implants are presented. The current consensus on SCO-indications and patient selection, and the factors influencing the outcome after SCO are presented.

Answers to the specific research questions

1) Which High Tibial Osteotomy technique, Closing-Wedge or Opening-Wedge, is more stable initially?

Analysis of the RSA motion data presented in chapter two showed no difference in migration at the osteotomy between CW and OW. Therefore it can be concluded that both provide equal initial stability.

2) Is immediate full weight bearing after Opening-Wedge High Tibial Osteotomy safe?

Comparison of the RSA motion data measured in 14 knees in which patients used immediate full weight bearing after OW HTO to a historical control group of patients using a standard protocol showed no difference in migration at the osteotomy between both groups. Therefore it can be concluded that early full weight bearing after OW HTO is safe.

3) Which Supracondylar Osteotomy technique has the highest initial stability?

Comparison of the 3D motion data of 5 different SCO techniques showed that an oblique, medial closing-wedge osteotomy fixated with an angled blade plate or with an angle-stable implant provided the highest amount of initial stability.

4) Which effect does our newly designed bi-plane technique have on initial stability?

Analysis of the 3D motion data showed that the bi-plane osteotomy greatly increases axial stability, while slightly and unexpectedly reducing torsional stability.

5) What is the influence of the test model used on the outcome of the tests; does using simulated physiological loading change the outcome in biomechanical testing of implants for SCO?

Comparison of the initial stability as measured by a 3D motion measuring system using simulated postoperative conditions comparing two different versions of the same plate showed no difference in initial stability. In contrast, in a rudimentary open gap model comparing the same two plates, the older version of the two designs was found to provide more initial stability. Therefore it can be concluded that the type of test model greatly influences the outcome and it is advised that as life-like conditions as possible should be used as a basis for testing implants.

6) Is a less invasive approach to the medial distal femur feasible, safe, and can it be used for a Supracondylar femur Osteotomy?

The results of the cadaveric dissection study in chapter eight show that a less invasive approach to the medial aspect of the distal femur is not only feasible and safe, it reduces the risk of damage to the neurovascular structures that supply the vastus medialis muscle.

Chapter 11

Algemene discussie, samenvatting en beantwoording van de vragen

In dit proefschrift wordt in een aantal studies nieuwe chirurgische technieken geïntroduceerd en wordt een wetenschappelijke basis gegeven voor de keuze tussen de verschillende operatie technieken en revalidatie protocollen. Bovendien wordt er ingegaan op de primaire stabiliteit van de osteotomie constructie en worden richtlijnen voor behandeling en revalidatie gegeven.

In hoofdstuk één wordt een introductie gegeven over het onderwerp osteotomiën rond de knie en wordt een aantal onderzoeksvragen geformuleerd die in de daaropvolgende hoofdstukken behandeld worden.

In hoofdstuk 2 werd in een gerandomiseerde klinische trial het verschil in primaire stabiliteit tussen Open- en Gesloten-wig valgiserende tibiakop osteotomiën (OW en GW VTKO) gefixeerd met behulp van de algemeen gebruikte Tomofix (Synthes, Zwitserland) plaat onderzocht door middel van een zeer nauwkeurig 3D-meetsysteem genaamd radiostereometrie (RSA).

In een serie van 42 patiënten werden geen verschillen gevonden tussen beide groepen in de tijd tot het terug krijgen van de volledige kniefunctie en tijd tot volledige belasting. Pijn en de knie functie verbeterden beiden statistisch significant in beide groepen, zonder verschil tussen de groepen. Alle osteotomiën in beide groepen waren binnen 1 jaar volledig geconsolideerd. RSA toonde geen verschil in klinisch relevante beweging ter plaatse van de osteotomie en geen verschil in beweging tussen de beide groepen. De conclusie is dat een met een Tomofix plaat gefixeerde Open Wig Valgiserende Tibia Kop Osteotomie dezelfde stabiliteit heeft als een laterale Gesloten Wig Valgiserende Tibia Kop Osteotomie. Beiden geven een prima initiële stabiliteit en geven statisch significante verbetering van pijn en functie van de knie. Als enige verschil werd gevonden dat de Open Wig techniek preciezer is in het behalen van de vereiste correctie.

In hoofdstuk 3 werd in een serie van 14 opeenvolgende patiënten de invloed van vroege volledige belasting na een Open Wig Valgiserende Tibia Kop Osteotomie op de stabiliteit van de constructie onderzocht, met de vraag of er een onbedoelde negatieve invloed was door die vroege belasting op de stabiliteit.

De beweging ter plaatse van de osteotomie werd opnieuw gemeten met behulp van RSA. Volledige belasting was toegestaan zodra wondgenezing en pijn dat toelieten. Verbetering van functie en vermindering van pijn werd op verschillende momenten gemeten. De resultaten werden vergeleken met een historische controle groep van 23 patiënten, die dezelfde operatie hadden ondergaan, maar nabehandeld werden met een standaard postoperatief belastingsprotocol. In de groep van 14 patiënten werden geen nadelige gevolgen gezien als gevolg van de vroege volledige belasting. Er was geen verschil in beweging ter plaatse van de osteotomie gemeten met behulp van het 3D RSA meet systeem tussen beide groepen. In beide verbeterde de pijn en functie statistisch significant zonder verschil tussen de groepen. De patiënten in de vroege volledige belasting groep behaalden dezelfde resultaten sneller.

De conclusie is dat vroege volledige belasting in een met Tomofix gefixeerde Open Wig Valgiserende Tibiakop Osteotomie veilig is.

In hoofdstuk 4 werd een overzicht gegeven van nieuwe ontwikkelingen op het gebied van osteotomie techniek en methode van fixatie in proximale (valgiserende) tibia kop osteotomiën. De nadruk lag op nieuw onderzoek over druk verdeling in het knie gewricht, fixatie stabiliteit en botgenezing, dat geleid heeft tot verbeterde chirurgische technieken en een vermindering in de tijd tot volledige belasting na de operatie. De huidige consensus over indicaties, patiënt selectie en de factoren die de uitkomst na een VTKO beïnvloeden werden in dit hoofdstuk gepresenteerd.

In hoofdstuk 5 werd de stabiliteit en stijfheid van verschillende Distale Femur Osteotomie (DFO) fixatie technieken onderzocht met behulp van een replica femur model en een op ultrageluid reistijd gebaseerd 3D meetsysteem. Onder nagebootste postoperatieve omstandigheden werden op LCP concept gebaseerde en op rigide compressie gebaseerde fixatie technieken, mediaal Open- en lateraal Gesloten-wig osteotomie technieken en technieken waarbij een schuine en een rechte zaagsnede ten opzichte van het gewrichtsoppervlak gebruikt worden, met elkaar vergeleken.

Hiertoe werd de stabiliteit en stijfheid van vijf verschillende DFO configuraties onderzocht: (1) mediaal gesloten DFO met een schuine zaagsnede gefixeerd met een hoekstabiele plaat (Tomofix MDF, Synthes), (2) mediaal gesloten osteotomie met schuine zaagsnede (2) en (3) mediaal gesloten met de zaagsnede parallel aan de gewrichtslijn, beide gefixeerd met een AO hoekplaat, (4) lateraal Open-wig osteotomie gefixeerd met een conventionele spacerplaat (Arthrex 'Puddu' plaat) en (5) een hoekstabiele plaat voor laterale fixatie in DFO (Tomofix 'Lateral Distal Femur' plaat, Synthes). De bewegelijkheid ter plaatse van de osteotomie gemeten met het 3D meetsysteem werd gebruikt om de stabiliteit en de stijfheid van de verschillende constructies te berekenen. De minste beweging en dus hoogste stabiliteit werd gemeten in de constructie met de mediaal gesloten DFO met schuine zaagsnede, gefixeerd met een hoekplaat of een hoekstabiele plaat. De lateraal open constructies al dan niet met conventionele of hoekstabiele plaat en de constructie met de zaagsnede parallel aan het gewrichtsoppervlak waren alle 3 duidelijk minder stabiel. De data gepresenteerd in dit hoofdstuk kan gebruikt worden als referentie in verder onderzoek van DFO technieken. Het verdient verder aanbeveling het postoperatieve revalidatie schema aan te passen aan de stevigheid van de gebruikte techniek, dat wil zeggen, patiënten waarbij een lateraal open techniek gebruikt wordt moeten langzamer gerevalideerd worden.

In hoofdstuk 6 werd een nieuwe zogenaamde 'bi-plane' osteotomie techniek geïntroduceerd, met als doel het patello-femorale gewricht meer te sparen en de initiële stabiliteit te vergroten. Deze nieuwe techniek en een aanpassing van de schroefconfiguratie van de bestaande standaard mediaal gesloten wig Distale Femur Osteotomie techniek werd onderzocht in een replica femur model en vergeleken met de standaard 'single-plane' techniek. De onderzoeksvraag was in welke mate de 'bi-plane' techniek en de veranderde schroef configuratie de stabiliteit van de constructie beïnvloedden.

In twaalf replica femurs werd de bewegelijkheid ter plaatse van de osteotomie onder compressie en rotatie krachten gemeten met een 3D meetsysteem gebaseerd op ultrageluid reistijd. Alle 12 werden tenslotte getest tot het falen van de constructie. De data verzameld door het 3D meetsysteem werd gebruikt om de stabiliteit en stijfheid van de constructie te berekenen.

Resultaten toonden dat de stabiliteit en stijfheid in de 'bi-plane' techniek onder axiale compressie krachten hoger waren, maar lager bij rotatie krachten, vergeleken met de standaard techniek. De veranderde schroef configuratie verbeterde de stabiliteit en stijfheid onder axiale compressie, maar had geen invloed bij torsie krachten. De conclusie is dat de nieuwe 'bi-plane' techniek de axiale stabiliteit in grote mate verhoogt, maar in tegenstelling tot de verwachting de torsie stabiliteit wat verminderd.

In hoofdstuk 7 werd de validiteit van basale testmethoden, zoals 'open gap' testen, voor het testen van implantaten en hun fixatie stevigheid ter discussie gesteld. Vaak zijn dergelijke testen verplicht voor het op de markt kunnen brengen van een product. Hoewel dit soort testen geschikt zijn om de materiaal eigenschappen van implantaten te testen, zijn ze niet altijd even representatief voor de postoperatieve situatie na een uitgevoerde Distale Femur Osteotomie, hetgeen wel van belang is als het aankomt op botgenezing.

In dit hoofdstuk werden de resultaten van de 'open gap' test resultaten, van een nieuwe versie van de Tomofix MDF plaat, verricht door de fabrikant, vergeleken met die van een test model met zo goed mogelijk nagebootste postoperatieve omstandigheden. Hetzelfde testmodel als in detail beschreven in hoofdstuk 5 en 6 werd gebruikt. In tegenstelling tot de tests verricht door de fabrikant was de nieuwe versie in het in dit hoofdstuk gebruikte test model even stabiel en stevig als de oude versie. De resultaten van deze tests geven het belang aan van het zo precies mogelijk nabootsen van de postoperatieve situatie bij het testen van nieuwe implantaten.

In hoofdstuk 8 werden de resultaten beschreven van een anatomische studie naar de vasculaire en neurologische structuren van het mediale distale deel van het femur. Chirurgische dissectie, cryomicrotoom dissectie en 3D reconstructie, en een Distale Femur Osteotomie via de minder invasieve benadering werden verricht in 6 kadaver benen.

Een tak van de arteria femoralis, de arteria genicularis, voorziet het distale deel van de vastus medialis spier van bloed. Deze arterie heeft verschillende vertakkingpatronen, die in dit hoofdstuk beschreven worden. Van cruciaal belang in de minder invasieve benadering is de musculo-articulaire tak die schuin naar de mediale bovenpool van de patella loopt. De nervus femoralis en de nervus saphenus innerveren de vastus medialis spier. Al deze structuren lopen gevaar bij de standaard subvastus-benadering van het femur. In het femur waarin een DFO verricht werd via de minder invasieve methode werd geen schade gevonden aan deze structuren. De conclusie was dat een minder invasieve benadering van het mediale distale deel van het femur mogelijk en veilig is. Schade aan de neurovasculaire structuren blijft beperkt in vergelijk met de standaard benadering.

In hoofdstuk 9 werden de huidige inzichten rondom Distale Femur Osteotomiën (DFO) besproken. Een DFO is een moeilijke chirurgische ingreep die zeker in het verleden geassocieerd werd met een minder gunstig resultaat dan VTKO. De biomechanische basis van laterale knie artrose is dan ook waarschijnlijk totaal verschillend van mediale artrose. In dit hoofdstuk werd recent onderzoek naar de eti-pathologie van laterale knie artrose, fixatie stabiliteit en de botgenezing van DFO behandeld. Dit heeft geleid tot nieuwe en verbeterde chirurgische technieken en daardoor minder postoperatieve fixatiestabiliteit en botgenezings problemen. De huidige consensus over indicaties, patiënt selectie en factoren die de uitkomst beïnvloeden na DFO werden besproken met de nadruk op deze nieuwe ontwikkelingen.

Beantwoording van de onderzoeksvragen

1) Welke Valgiserende Tibia Kop Osteotomie techniek, Gesloten Wig of Open Wig, geeft de meeste initiële stabiliteit?

Analyse van de Radiostereometrie (RSA) data in hoofdstuk 2 toonde dat er geen verschil in migratie ter plaatse van de osteotomie is tussen GW en OW. De conclusie is dus dat beide even stabiel zijn.

2) Is vroege volledige belasting na een Open Wig Valgiserende Tibia Kop Osteotomie veilig?

Vergelijk van de RSA data in hoofdstuk 3 van een groep van 14 patiënten die vroeg volledig mochten belasten na een Open Wig VTKO met een historische controle groep patiënten die een standaard postoperatief belastingsprotocol volgden, toonde geen verschil in migratie ter plaatse van de osteotomie. De conclusie is dus dat vroege volledige belasting na een Open Wig Valgiserende Tibia Kop Osteotomie veilig is.

3) Welke Distale Femur Osteotomie techniek geeft de meeste initiële stabiliteit?

Vergelijk in hoofdstuk 5 van de bewegingsdata van 5 verschillende DFO technieken gemeten door het 3D meetsysteem toonde dat de mediaal gesloten wig DFO met schuine zaagsnede gefixeerd met of de AO hoekplaat of een hoekstabiel implantaat de meeste initiële stabiliteit geeft.

4) Welk effect heeft de nieuw ontwikkelde 'bi-plane' osteotomie techniek op de initiële stabiliteit?

Analyse in hoofdstuk 6 van bewegingsdata gemeten met een 3D meetsysteem toonde dat de 'bi-plane' techniek de axiale stabiliteit sterk verhoogt en de torsie stabiliteit verlaagt.

5) Wat is de invloed van het testmodel op de uitkomst van de test; verandert het gebruik van nagebootste postoperatieve omstandigheden de uitkomst van de test?

Vergelijking in hoofdstuk 7 van de stabiliteit gemeten door een 3D meetsysteem in een test omgeving waarbij de postoperatieve situatie is nagebootst toonde geen verschil tussen twee verschillende versies van de Tomofix MDF plaat. Dit in tegenstelling tot de 'open gap' tests uitgevoerd door de fabrikant waarbij de resultaten aangaven dat de nieuwe versie van de plaat minder stabiel was dan de oudere versie. De conclusie is dat het wel of niet gebruiken van nagebootste postoperatieve omstandigheden van grote invloed is op de test uitkomst.

6) Is een minder invasieve benadering van het mediale distale deel van het femur mogelijk, veilig en kan het gebruikt worden voor een Distale Femur Osteotomie?

De resultaten van de in hoofdstuk 8 beschreven anatomische kadaver dissectie studie tonen dat een minder invasieve benadering van het mediale distale deel van het femur niet alleen mogelijk en veilig toepasbaar is in DFO, het vermindert bovendien de kans op schade aan neuro-vasculaire structuren.

Chapter 12

Recommendations for future research

While the studies presented in this thesis aim to further enhance knowledge on High Tibial Osteotomy (HTO) and Supracondylar Osteotomy (SCO) in the treatment of unicompartmental knee osteoarthritis, many questions remain to be answered.

Although there is excellent data on pressure distribution changes in articular cartilage after HTO using cadaver knees loaded in a material testing machine (MTS) and pressure sensitive films to record pressure changes, such data is lacking for SCO [1]. Therefore similar experiments need to be performed to analyze pressure distribution changes in articular cartilage after SCO. As an alternative, finite element analysis might be used in such a study instead of cadaver knees.

Fujisawa documented the location on the tibia plateau of the ideal new mechanical axis after HTO [2]. No one has, to the best of my knowledge, ever reproduced the data in his study from 1979. Performing a similar experiment as Fujisawa did for HTO detailing the optimum postoperative alignment after SCO is another challenge that remains. To avoid the medical ethical difficulties in performing such an experiment, i.e. performing medically unnecessary arthroscopies, again finite element analysis or alternatively a gait lab analysis might be used to solve the question of the location of the optimal mechanical axis after SCO.

Finally, while the Radiostereometry data in chapters two and three provide a clinical validation of the work by Agneskirchner et al on the initial stability of HTO using composite tibias [3] such studies using RSA are lacking for SCO. What's more, there are no clinical studies comparing the various SCO techniques. In my opinion an RSA based RCT comparing the various SCO techniques is needed to provide a definitive answer as to what the optimal SCO technique is.

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Chapter 13

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Chapter 14

Curriculum Vitae

Justus-Martijn Brinkman was born on June 21st 1975 in Bracknell, Great Britain, where he would spend the first four years of his life. After living in Haarlem and Heemstede for a brief period of time, the Brinkman family settled in Apeldoorn. He attended the 'Stedelijk Gymnasium Apeldoorn', where his father was an ancient language teacher.

He moved to Utrecht after his graduation in 1993 to study medicine and completed his university education in 2000 becoming a doctor of medicine. After two years in general surgery, he started work in the VU Medical Centre in Amsterdam as an unaccredited orthopedic registrar. In 2004 he began working in the Sint Maartenskliniek Nijmegen where he would first meet the Co-Promotor of this thesis, Ronald van Heerwaarden. Later that year he worked in Hannover as a researcher in the Biomechanical laboratory of the Hannover University. In 2005 he finally got accepted into the orthopedic training program. He was subsequently trained at the Deventer Hospital, Sint Maartenskliniek Nijmegen, Rijnstate Hospital in Arnhem, UMCN Sint Radboud, finishing his training in 2011 back in the Sint Maartenskliniek. Thereafter he spent a year overseas in Australia, doing a Hip- and Knee primary and revision arthroplasty fellowship. He now lives in Utrecht, with his girlfriend Valeria and their three sons Jens, Fedde and Pepijn. He is working as a consultant orthopedic surgeon specializing in osteotomy around the knee and revision hip- and knee arthroplasty in the Maartenskliniek Woerden.