JOINT PRESERVATION OF UNICOMPARTMENTAL KNEE OSTEOARTHRITIS

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CHAPTER 1

Introduction

General introduction osteoarthritis

Approximately 1.2 million people suffered from osteoarthritis (OA) in the Netherlands in 2015. It can be seen in any of the joints, but the knee is the most commonly affected joint. OA of the knee joint has an incidence of 6.2 per 1.000 per year in the Netherlands [1]. OA is a multi-factorial joint disorder. Although OA is often characterized as a degenerative disease, low-grade inflammation constitutes an important aspect of OA's pathological pathway [2]. OA is strongly correlated with aging: approximately 80-90% of patients with OA are 50 years of age or older [1]. Other than increasing age, risk factors for OA are multiple, such as the presence of other joint diseases, lifestyle variables (e.g. obesity, a history of manual labor, sports activities, cigarette smoking), comorbidities, sex and ethnicity [2]. Also, genes (e.g. GDF5, ASPN, eDG2) that predispose to OA severity, in conjunction with environmental factors, are recently discovered [3]. OA causes considerable pain and reduced mobility and is a burden for society because of its chronic nature and high costs of interventions [1, 2, 4-6]. The prevalence and incidence of OA continue to increase. The general aging of the population and increasing level of obesity contribute to OA in the knee joint, whereas in the younger population, this is mainly sport-related [1, 6-8].

Osteoarthritis of the knee

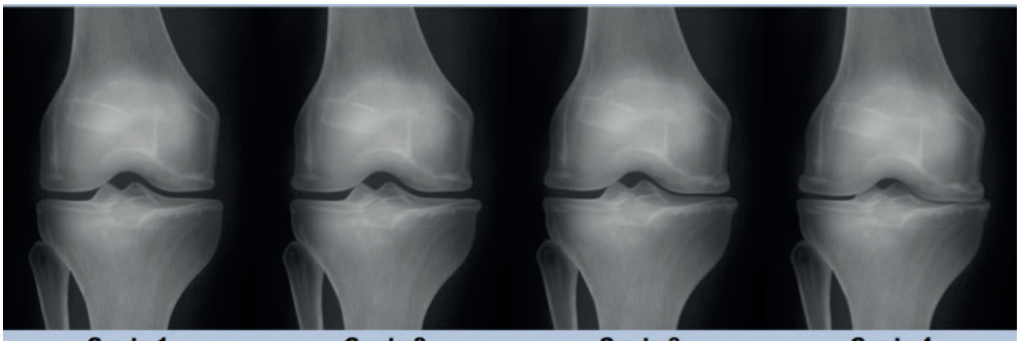
OA of the knee occurs in the tibiofemoral compartment (medial and/or lateral) and/or in the patellofemoral compartment. In the knee, besides the previous mentioned multi-factorial origin, a malaligment of the leg can lead to unicompartmental OA (medial or lateral). Normally the anatomical load-bearing axis of the knee ranges from 5 to 7 degrees of valgus. In most normal knees, approximately 60% of the weight-bearing force is transmitted through the medial compartment and 40% through the lateral compartment. Malalignment of the leg in the coronal plane leads to a disturbed load distribution and thereby overloading of a compartment. This increases the risk of progression of knee OA and causes a subsequent decline in physical function and progression of pain [4, 9, 10]. The other way around, unicompartmental knee OA can also lead to malalignment due to substance loss of the medial or lateral compartment. Medial (or varus) knee OA is more common than lateral (or valgus) knee OA. Varus or valgus alignment causes additional force on the medial or lateral compartment, respectively, and changes in the forces and moments acting on the knee during walking [11].

In general, OA of the knee is treated either conservatively (non-operatively) or surgically. Treatment goals are decreasing pain and improving function. The treatment options are outlined in the following sections.

Non-operative treatment

The conservative treatment is usually useful for mild to moderate OA (Kellgren and Lawrence Grade I-III (Figure 1) [12]). Also, operative treatment is not suitable for every patient, because of medical comorbidity, old age or other circumstances. Possible conservative treatment options are analgesics, nutraceuticals (e.g. glucosamine, chondroitin), intra-articular injections with glucocorticosteroids or hyaluronic acid (HA), lifestyle modification (e.g. weight loss), physical therapy (muscle strengthening and core stability), unloading bracing and orthoses. Most options are beneficial for short-term treatment. The efficacy of intra-articular injections is debated. Intra-articular injections with corticosteroids has shown significant short-term improvement, when compared to placebo. However, the repeated use of corticosteroids could facilitate tissue atrophy, joint destruction, cartilage degeneration, or joint infection [13]. Intra-articular injections with HA has a small, clinically irrelevant benefit over intra-articular placebo. Moreover, intra-articular HA is associated with high costs and potential side effects such as pain flare-ups and joint infection, although the latter is a rare complication [13]. In the guidelines as formulated by the Dutch Orthopaedic Association, intra-articular injections with HA is not recommended [14]. A multidisciplinary treatment of knee OA is preferred [13].

Figure 1 Kellgren and Lawrence classification knee osteoarthritis



CLASSIFICATION	Normal	Doubtful	Mild	Moderate	Severe
DESCRIPTION	No features of OA	Minute osteophyte: doubtful significance	Definite osteophyte: normal joint space	Moderate joint space reduction	Joint space greatly reduced: subchondral sclerosis

Unloading braces

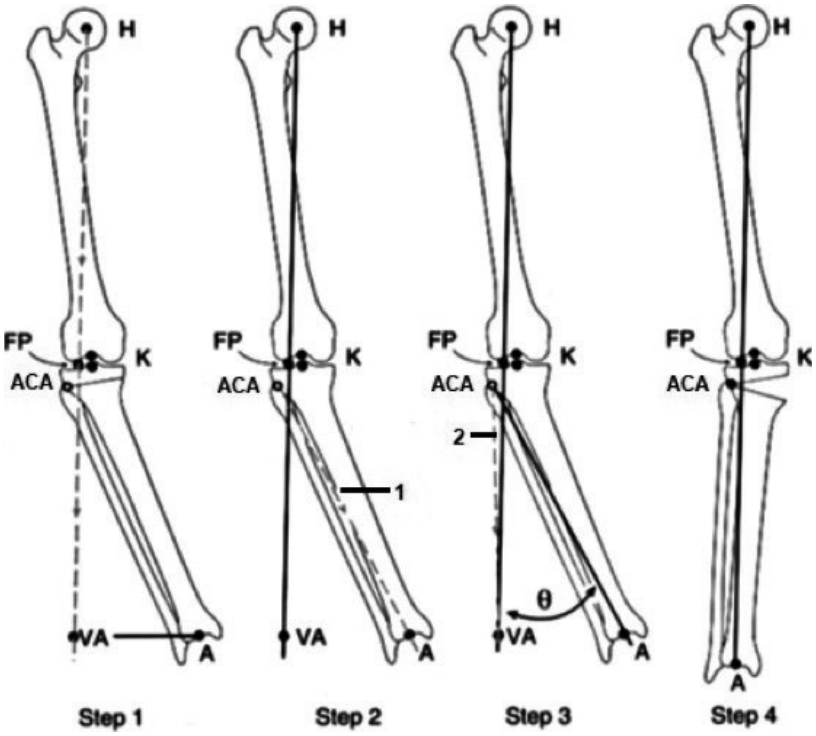
Unloading braces offer a conservative treatment option in realigning the varus or valgus knee in patients with medial or lateral knee OA. More than 30 commercially available braces are produced nowadays, with all kinds of different brace designs [15-19]. Most braces unload the medial or lateral compartment by applying an external 3-point force (valgus or varus moment acting on the knee) which distracts the medial or lateral compartment and transfers the weight bearing axis towards the lateral or medial compartment of the knee [20, 21].
Literature suggests that these unloading braces decrease disease progression which could delay the need for operative treatment, which is desirable particularly in young patients (<60years of age) [22, 23]. In several patient studies, OA related symptom-relief and functional improvement were found after treatment with unloading bracing [15, 16, 22, 24-29]. A recent Cochrane review, however, concluded that there is only little low-quality evidence for the effectiveness of bracing in the treatment of medial compartment knee OA [30]. Treatment with an unloading brace seems to be effective in selected patients, but it is still unknown which type of brace is preferred. An important problem is that the compliance to use the unloading brace is poor. As most unloading braces are expensive it is important to know why patients become non-compliant, and if there is a difference in non-compliance between various kinds of braces. Therefore, we investigated the differences in outcome between two different types of valgus unloading braces in a randomized controlled trial. We also investigated the clinical and radiological outcomes of both braces after 3 months follow-up (Chapter 2).

Operative treatment

When conservative treatment is no longer succesful, several operative treatment options are possible. Surgical treatment of unicompartmental knee OA consists of native joint preserving procedures (e.g. knee joint distraction, correction osteotomies) and arthroplasties (unicompartmental knee arthroplasty (UKA) and total knee arthroplasty (TKA)). Knee joint distraction is a surgical procedure in which an external fixation frame is used to distract the tibio-femoral joint for 6–8 weeks. This seems to be a promising treatment option in the young patients with knee OA [31-34]. However, it should be noted that some reservation is required as there is little literature about knee joint distraction and only shortterm outcomes are publiced [35]. Another joint preserving procedure is a correction osteotomy, which may be considered for the young (<60 years of age) and active patients with unicompartmental knee OA and a leg malalignment [4]. The purpose of a correction osteotomy is to realign the weight bearing lines while maintaining normal knee joint line orientation (Figure 2) [36]. A correction osteotomy can be performed in either the femur or tibia or in both bones, i.e. a double osteotomy. In patients with a medial (or varus) knee OA a valgus osteotomy is a

treatment option and in patients with a lateral (or valgus) knee OA a varus osteotomy can be considered.

Figure 2 Rationale of an open-wedge osteotomy in varus correction surgery



H hip, K knee, A ankle, VA virtual ankle, FP Fujisawa point.

1. Measurements were taken from long leg standing AP radiographs. The varus deformity originated within the knee joint and therefore this was where the centre of rotation of angulation (CORA) was located. The "new" mechanical axis line was first plotted from the centre of the femoral head passing through the desired point in the medial third of the lateral tibial plateau (FP). This line was continued out to a theoretical point VA (virtual ankle) at the level of the patient's ankle joint. The line of the intended tibial osteotomy was then drawn.
2. A further line (line 1) was drawn from the centre of the tibial surface of the talus to the anatomical correction axis (ACA) at the lateral edge of the proposed tibial osteotomy.
3. A final line (line 2) was drawn from the ACA to the VA point.
4. The angle (θ) between line 1 and line 2 was the angle of the correction [37].

Valgus osteotomy

In patients with medial knee OA and a varus leg alignment, a valgus high tibial osteotomy is a treatment option. A valgus osteotomy unloads the medial compartment and shifts the loading to the lateral compartment.

In several studies, different techniques have been evaluated, each with their own advantages, disadvantages, and complications [38-41]. The most commonly used techniques include open-wedge osteotomy (OWO) (Figure 2 and 3) and closed-wedge osteotomy (CWO) (Figure 4) [42-44].

Figure 3 An open-wedge high tibial osteotomy

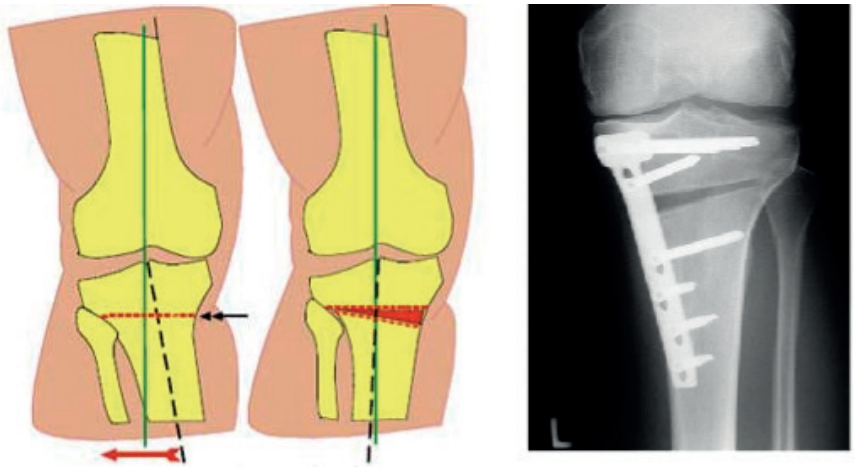
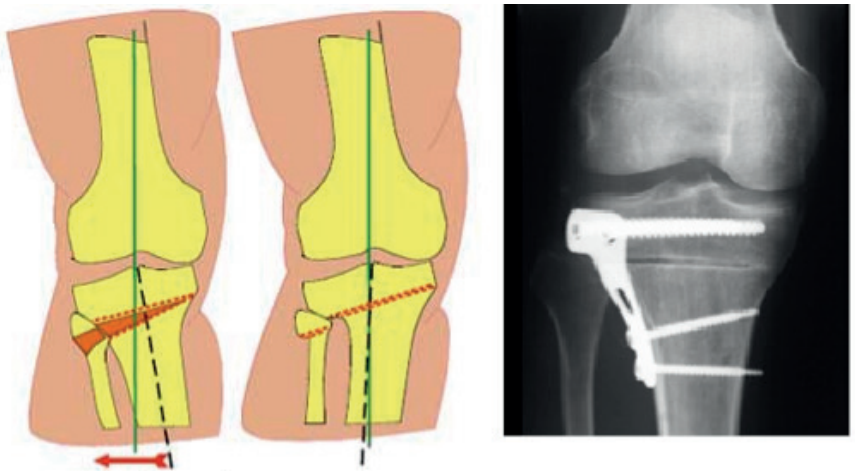


Figure 4 A closed-wedge high tibial osteotomy

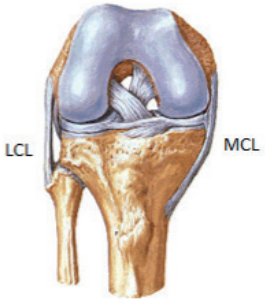


Long-term (10–20 years) survival of CWO is well documented in the literature, varying between 74% and 97.6% after 10 years [45-49], 56% to 93.2% at 15 years [45-49], and 66.9% to 85.1% at 20 years [46, 49]. The survival rates of OWO are not as frequently documented, but are reported to be between 88.9% and 97% at 5 years [42, 50, 51], and 74% to 89% at 10 years [51, 52]. For both techniques, good clinical and radiographic results are described [44, 49, 51-57]. Disadvantages of CWO include the need for a fibular osteotomy, the relatively high rate of peroneal neuropathies, bone stock loss, and a more demanding subsequent TKA [39, 40]. The TKA may be technically more demanding due to the difficulty of surgical approach (e.g. a quadriceps snip and tibial tuberosity osteotomy were performed more frequently compared to TKA after OWO, and difficulty of patella eversion in TKA), loss of proximal tibial bone stock and impingement of the stem of the tibial component on the lateral tibial cortex [58, 59]. An OWO has been associated with high non-union rates, donor site morbidity (if an autograft is used), loss of correction due to unstable fixation, and increased posterior tibial slope [39, 40].

OWO has gained popularity in recent years, due to more predictable corrections in the coronal and saggital planes. Furthermore, there is no need for a fibular osteotomy and it is relative easy to combine with additional procedures. In both techniques it is important to use a (extended) midline incision instead of a short medial or lateral oblique incision to prevent soft tissue and wound healing problems when a revision to a TKA is needed. Although an OWO has gained popularity in recent years compared to a CWO, direct comparisons of these two techniques are rare, and mid- and long-term comparisons are almost completely lacking. We therefore performed a clinical study comparing these two techniques with midterm follow-up (Chapter 7).

In an OWO the medial proximal tibia has to be exposed, however the superficial medial collateral ligament (MCL) is overlying this area (Figure 5).

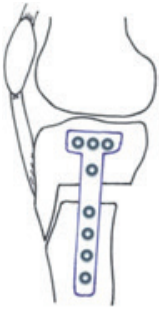
Figure 5 MCL is overlying the medial proximal tibia



LCL Lateral collateral ligament MCL Medial collateral ligament

For exposure in an OWO the superficial MCL can be left intact by elevating it subperiostally, or it can be partially or completely released from its distal insertion [60, 61]. However, it is important to preserve the normal soft tissue envelope as much as possible, especially the ligaments of the knee, which play an important role in the biomechanics of the knee. There is still debate whether or not to release the superficial MCL in an OWO. For exposure and unloading the medial compartment it is advised to release the superficial MCL [60-62]. On the other hand a release could have influence on the stability of the knee [61]. It is known that ligaments show stress relaxation over time [63, 64]. Theoretically, stress relaxation of the MCL after an OWO could contribute to unloading the medial compartment, and the release of the superficial MCL, on that account, may not be necessary. The relaxation of the MCL, the release of the superficial MCL and the effect on the cartilage pressure and stability of the knee are therefore important interactive parameters to assess. We therefore performed a study which investigated these issues (Chapter 3).
The OWO can be performed by a single (Figure 3) or biplanar technique. A biplanar osteotomy preserves the tibial tubercle and on that account it preserves the patellar height (Figure 6) [65].

Figure 6 Biplanar open-wedge tibial osteotomy

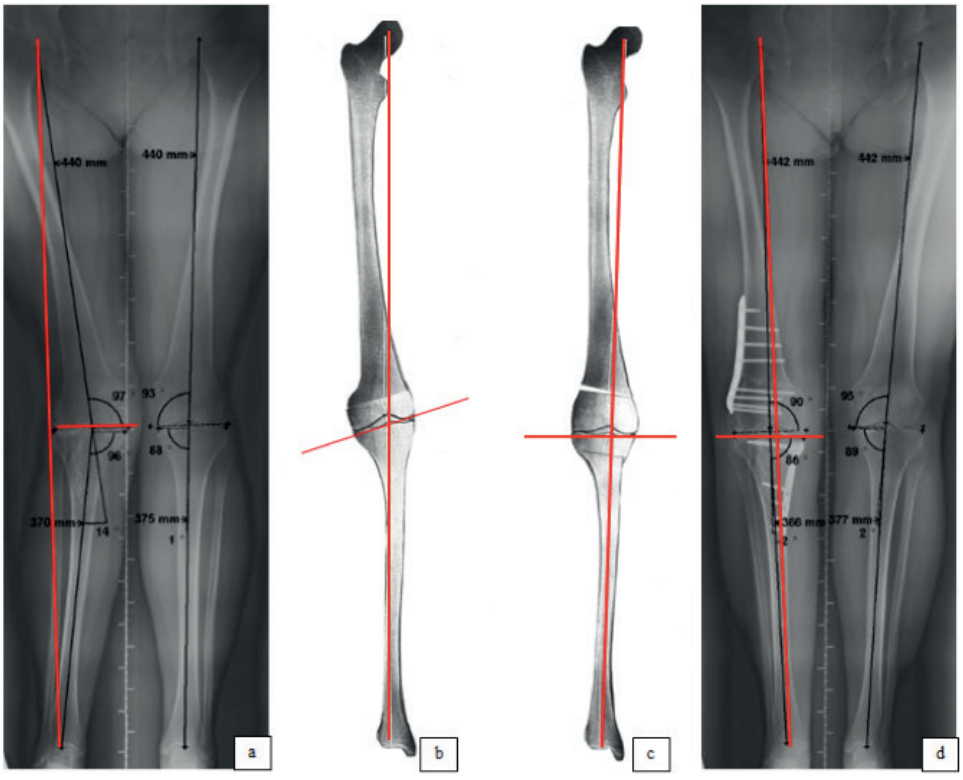


The osteotomy gap can be filled with an autograft, allograft or a (synthetic) bone substitute material, such as tricalciumphosphate (TCP). In addition, depending on type of osteosynthesis material, the gap can be left empty [66]. Many implants have been designed for an OWO [62, 66-68]. Regularly new implants with innovative features are introduced to the orthopaedic market. Important aspects to consider are fixation strength, endurance of the reconstructive stability untill osseous consolidation has occurred. Furthermore, new implants should yield low clinical complication rates. We therefore assessed these aspects of a novel implant system (FlexitSystem implant) designed for an OWO in a biomechanical cadaver study and subsequently in a clinical and radiographic safety study (Chapter 5 and 6).

Varus osteotomy

Lateral (or valgus) knee OA is less common than medial (or varus) knee OA. In patients with lateral knee OA and a valgus alignment a varus osteotomy is a treatment option. A varus osteotomy unloads the lateral compartment and shifts the loading to the medial compartment. The main options include distal femoral medial closing wedge osteotomy, distal femoral lateral open wedge osteotomy, proximal tibial medial closing wedge osteotomy or a double osteotomy, depending on the type and location of the deformity (Figure 7) [69].

Figure 7 Rationale of a double osteotomy in valgus correction surgery



Weight bearing long leg radiographs and planning drawings including weight bearing lines (WBL) and knee joint orientation lines (KJOL).

a. Preoperative valgus leg alignment caused by femoral and tibial bone deformity, WBL lateral and KJOL neutral

b. Planning drawing of medial closing wedge distal femur osteotomy resulting in neutral WBL and severe valgus KJOL

c. Planning drawing of double osteotomy, i.e. lateral open wedge distal femur and medial closing proximal tibial osteotomy, resulting in neutral WBL and neutral KJOL

d. Postoperative leg alignment after double osteotomy

As mentioned earlier, varus/valgus alignment causes additional force on the medial/lateral compartment and changes in the forces and moments acting on the knee during walking [11]. The kinetics and kinematics of gait of a medial (varus) osteoarthritic knee and the effect of a valgus osteotomy on these gait characteristics are well described in the literature. It is proven that a valgus producing osteotomy is able to improve the kinetics and kinematics of gait, causing improvements in clinical results and quality of life. In contrary, the detailed kinetic and kinematics of gait of a lateral (valgus) osteoarthritic knee and the effect of a varus osteotomy on these gait characteristics are not described in the literature. We performed a study which evaluated the changes in gait and clinical outcomes after a varus producing osteotomy in patients with lateral OA of the knee and a valgus leg alignment and compared these to a normal control group (Chapter 4).

Outline of this thesis

The objective of this thesis was to evaluate aspects of non-arthroplasty treatment options for patients with unicompartmental knee osteoarthritis (OA) and a malalignment.

The following research goals for this thesis were formulated

1. Chapter 2: Determine the differences in outcome between two different types of valgus unloading braces in a randomized controlled trial
2. Chapter 3: Determine the effect of MCL relaxation after an OWO on the contact pressure (CP), peak contact pressure (peakCP) and contact area (CA), in the medial- and lateral compartment of the knee
3. Chapter 3: Determine the effect of a complete release of the superficial MCL after an OWO on the CP, peakCP and CA in the medial and lateral compartment of the knee
4. Chapter 3: Determine the effect of a complete release of the superficial MCL after an OWO on the valgus laxity of the knee
5. Chapter 4: Evaluate the changes in gait and clinical outcomes after a varus producing osteotomy in patients with lateral OA of the knee and a valgus leg alignment and compare these to a normal control group
6. Chapter 5: Compare the biomechanical properties of an OWO fixated with the novel FlexitSystem implant to an OWO fixated with the well recorded TomoFix implant
7. Chapter 6: Report the clinical and radiographic safety (loss of correction, revision rate, complication rate) of the novel FlexitSystem implant
8. Chapter 7: Report the mid-term follow-up clinical and radiographic results of an OWO compared to a CWO in the treatment of patients with a medial knee OA and a varus leg alignment

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CHAPTER 2

Is there a difference in outcome between two valgus unloading braces for varus medial knee osteoarthritis? A randomized controlled trial

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Abstract

Purpose The short-term clinical and radiographic outcomes of two different valgus unloading braces were compared in patients with medial knee osteoarthritis (OA) and a varus leg alignment.

Methods A RCT was performed in 100 patients (50 Bledsoe Thruster brace, 50 SofTec OA brace) with symptomatic medial knee OA and a varus leg alignment. Outcomes were the visual analogue scale pain and satisfaction, Dutch Western Ontario and McMaster Universities Osteoarthritis Index, SF-12, 6-Minutes Walking Test, hip-knee-ankle alignment, analgesic use, complications and compliance after a follow-up of 2 and 12 weeks.

Results The clinical and radiographic outcomes were not significant different between both groups. Almost all clinical outcomes improved in both groups at follow-up compared to baseline. 24% of the patients discontinued using the brace.

Conclusions No significant differences in clinical and radiographic outcomes were found between both groups after 2 and 12 weeks follow-up. Both braces were effective in the treatment of varus medial knee OA. Complications and compliance remains a problem.

Level of evidence II

Keywords Valgus unloading brace, Osteoarthritis, Knee, RCT

Introduction

Knee osteoarthritis (OA) is more prevalent in the medial than the lateral compartment and is often accompanied by a varus alignment. This malalignment causes an overload of the medial compartment with increasing pain and immobility during weight bearing, increases the risk of knee OA progression and predicts decline in physical function [14, 29].

Valgus unloading braces offer a conservative treatment option in realigning the varus knee in patients with medial knee OA. More than 30 commercially available braces are produced nowadays, with all kinds of different brace designs [4, 11, 22-24]. Most braces unload the medial compartment by applying an external 3-point valgus force which distracts the medial compartment and transfers the weight bearing axis towards the lateral compartment of the knee [7, 28].

Literature suggests that these unloader braces decrease disease progression which could delay the need for operative treatment, which is desirable in young patients [1, 3]. Operative treatment is not suitable for every patient, because of medical comorbidity, old age or other circumstances. In several patient studies, OA related symptom-relief and functional improvement were found after treatment with valgus bracing [1, 4, 9, 11, 15, 18-20, 26, 32]. A recent Cochrane review, however, concluded that there is only little low-quality evidence for the effectiveness of bracing in the treatment of medial compartment knee OA [6].

Another problem is, that the compliance to use the brace is poor [6, 31, 33]. As most unloading braces are expensive it is important to know what the reason is of non-compliance, and if there is a difference in non-compliance between different kinds of braces.

To our knowledge no other study has compared the effectiveness, complications and compliance of two different kinds of valgus unloading braces in a RCT. Therefore, the objective of this study was to compare the effectiveness of two different kinds of valgus unloading braces (the Bledsoe Thruster brace (B&Co Inc. N.V., Sint-Antelinks, Belgium) and the SofTec OA Brace (Bauerfeind AG, Zeulenroda-Triebes, Germany)) in the management of patients with medial knee OA and varus leg alignment after 2 and 12 weeks follow-up.

The Bledsoe Thruster brace has a dual-hinged strut and a larger moment than the SofTec OA brace and on that account it is expected to be a mechanical stronger brace. The SofTec OA brace has airchambers for valgus force and on that account it is expected to be a more comfortable brace. Because of the differences in brace design we therefore hypothesised that the Bledsoe group would show a significant lower VAS pain (primary outcome) compared to the SofTec OA group at 2 and 12 weeks.

As to our secondary outcomes we hypothesised that the Bledsoe group would have superior scores considering the Dutch Western Ontario and McMaster Universities Osteoarthritis

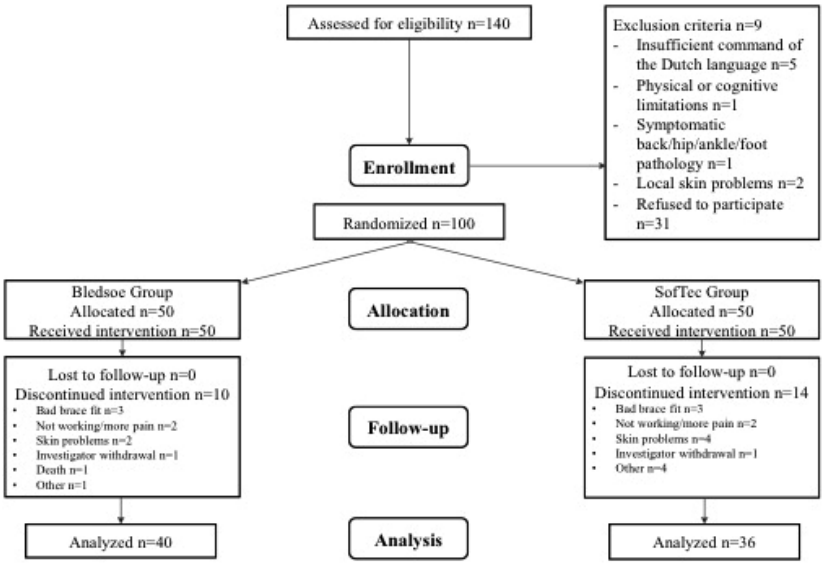
Index (WOMAC), SF-12, 6-Minutes Walking Test, hip-knee-ankle alignment and analgesic use. On the other hand, we hypothesised that the SofTec OA group would over class the Bledsoe group in VAS satisfaction, number of complication and compliance.

Patients and methods

Study design and patients

This prospective double-armed RCT was carried out between January 2011 and March 2014 in the orthopedic outpatient clinic (Rijnstate Hospital, Arnhem, the Netherlands). Approval of the Medical Ethics Committee (Radboud University Medical Centre Nijmegen, ID-number 2010/200, ABR nr.: NL32412.091.10, 27-09-2010) was obtained. Inclusion criteria were medial knee pain, radiological evidence of medial knee OA Grade 1 or higher (confirmed on X-ray using the Kellgren-Lawrence classification [16]), having a whole-leg radiographic hip–knee–ankle (HKA) varus alignment and age between 18-70 years. Exclusion criteria were insufficient command of the Dutch language, the inability to apply a brace because of physical or cognitive limitations, symptomatic back/hip/ankle/foot pathology which makes it impossible to improve pain, function, quality of life or satisfaction by wearing a brace and pre-existing local skin problems. A total of 100 patients (50 patients each comprised the Bledsoe and SofTec OA group) were included. Informed consent was obtained for all participants. One patient in the Bledsoe group died during follow-up, but this was not related to wearing the brace. No other patients were lost to follow-up, however a total of 14 patients discontinued intervention after 2 weeks follow-up (Bledsoe group: 6, SofTec OA group: 8) and another 9 patients after 12 weeks follow-up (Bledsoe group: 4, SofTec OA group: 6), leaving 76 patients for analysis at final follow-up (Fig. 1).

Figure 1 Flowchart



Randomization and blinding

Patients were randomized according to a computer induced randomization table (blocking randomization, block size 4). The randomization codes were held in sequentially numbered opaque sealed envelopes by an independent observer. The patients were allocated to the Bledsoe group or the SofTec OA group by an independent investigator and all demographic and baseline measurements (Table 1 and 2) were completed. An independent investigator who analysed the data was blinded.

Table 1 Demographics

Parameter	Bledsoe Group (n=50)	SofTec OA Group (n=50)
Male/Female (*n (%)*)	30 (60)/ 20 (40)	28 (56)/ 22 (44)
Age (*years*)	55 (40-70)[a]	57 (41-68)[a]
BMI (*kg/m²*)	28.3 (24-46.2)[a]	29.6 (4.9)[b]
Side L/R (*n (%)*)	24 (48)/ 26 (52)	24 (48)/ 26 (52)
Comorbidities (*n (%)*)	24 (48)	24 (48)
- **Diabetes Mellitus**	7 (14)	7 (14)
- **Peripheral vascular disease**	2 (4)	6 (12)
- **Decompensatio Cordis**	0 (0)	1 (2)
- **Rheumatic Arthritis**	1 (2)	0 (0)
- **Fractures ipsilateral leg**	4 (8)	2 (2)
- **Other**	10 (20)	8 (16)
Surgery ipsilateral leg (*n (%)*)	27 (54)	30 (60)
- **Arthroscopy ± (partial) meniscectomy**	19 (38)	22 (44)
- **ACL repair ± (partial) meniscectomy**	0 (0)	2 (4)
- **Micro fracturing**	1 (2)	0 (0)
- **Correction osteotomy tibia**	2 (4)	1 (2)
- **Total hip arthroplasty**	1 (2)	1 (2)
- **Other**	4 (8)	4 (8)

[a] values given as median (range)
[b] values given as mean (standard deviation)

Table 2 Baseline parameters

Parameter	Bledsoe Group (n=50)	SofTec OA Group (n=50)
VAS pain	4.4 (2.7)[b]	4.7 (2.7)[b]
VAS satisfaction	4.4 (0.0-10.0)[a]	4.1 (2.6)[b]
WOMAC	51.7 (17.5)[b]	47.8 (16.2)[b]
- **Pain**	10.7 (3.8)[b]	10.0 (3.8)[b]
- **Stiffness**	4.0 (0.0-7.0)[a]	3.0 (0.0-8.0)[a]
- **ADL**	37.1 (12.7)[b]	34.2 (11.5)[b]
SF-12		
- **PCS**	33.3 (7.6)[b]	31.7 (7.1)[b]
- **MCS**	50.8 (9.8)[b]	52.7 (20.4-65.1)[a]
6MWT		
- **Distance (*meters*)**	387.5 (90.0-520.0)[a]	358.8 (45.0-543.0)[a]
OA classification (*n (%)*)		
- **I**	7 (14)	6 (12)
- **II**	20 (40)	21 (42)
- **III**	14 (28)	16 (32)
- **IV**	9 (18)	7 (14)
HKA alignment (°)	5.4 (3.3)[b]	5.7 (0.9-23.5)[a]
Analgesic use (*n of tablets*)	0.0 (0.0-9.0)[a]	0.5 (0.0-14.0)[a]
Analgesic use (*n of patients (%)*)	16 (32)	25 (50)
-Paracetamol	10 (20)	14 (28)
-NSAID	7 (14)	12 (24)
-Tramadol	1 (2)	0 (0)
-Morfin	1 (2)	3 (6)
-Pregabalin	0 (0)	1 (2)

[a] values given as median (range)
[b] values given as mean (standard deviation)

Braces

The patients in the Bledsoe group received the Bledsoe Thruster brace, which uses muscle power to place a medially directed force against the knee during terminal extension. The brace uses a dual-hinged adjustable strut fixed to the brace shell at the calf and thigh (Fig. 2). The patients in the SofTec OA group received the SofTec OA brace, which has been constructed with only a lateral hinge including an air chamber that enables adjustment of the valgus force by the patient (Fig. 3). Brace explanation and fitting were executed by a specialized orthopedic technician. The brace was adjusted so that there was a pressure on their knee, but the patient could still wear it comfortable for several hours.

Figure 2 Bledsoe Thruster Brace

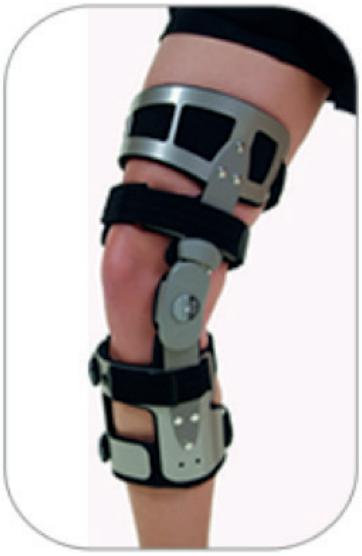
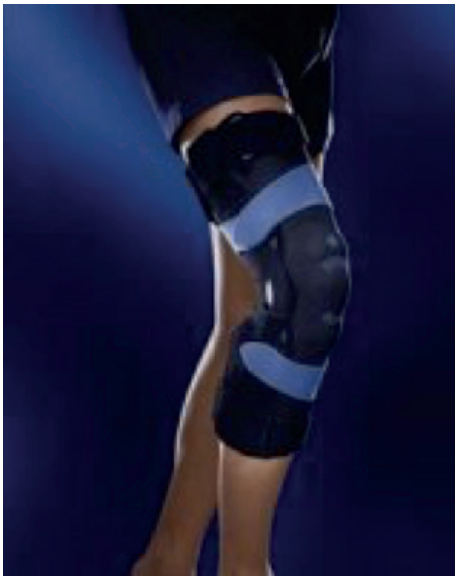


Figure 3 SofTec OA brace



Clinical outcomes

The primary outcome was VAS pain (range 0-10) at 2 and 12 weeks. Secondary outcomes were VAS satisfaction (range 0-10), WOMAC (0-96 scale, with zero as optimum score) [25],

the SF-12® (Quality Metric, Lincoln, RI, mental component summary (MCS) and a physical component summary (PCS), range 0-100, mean score 50, SD 10) and the 6-Minutes Walking Test (6MWT) (distance in meters) at 2 and 12 weeks. During the 12 weeks follow-up period, patients kept a diary in which they recorded analgesic use, complications and compliance (the mean number of hours per week they used the brace).

Radiographic outcomes

At 12 weeks the severity of OA of the knee was determined on weight bearing anteroposterior and true lateral radiographic views at 30° of flexion, using the Kellgren and Lawrence grading system [16]. Furthermore, the mechanical axis (varus alignment) was measured on a double-limb stance whole-leg radiographic HKA, with the brace applied, following the method described by Dugdale et al. [5].

Statistics

At baseline, 2 and 12 weeks total test scores (mean or median, standard deviation (SD) or range, frequencies or percentages) were calculated for continuous and categorical variables for each of the 2 treatment groups. To assess normality, we used the Kolmogorov–Smirnov and Shapiro–Wilk tests. The Levene test was used to check the assumption of equal group variance. The Student's t-test or Mann–Whitney U test was used to analyse differences in continuous data at 2 and 12 weeks follow-up between treatment groups. The Fisher's exact test or Chi-squared test was used in case of categorical variables. The paired t test or Wilcoxon signed rank test was used to analyse differences in numerical data between baseline and 12 weeks follow-up per treatment group. A $P < 0.05$ was considered significant. All data were analysed with SPSS version 20.0 (SPSS Benelux BV, IBM Company Nieuwegein, The Netherlands).

The sample size calculation was based on a baseline mean score for pain (VAS, 0-10) of 6.0 and a standard deviation SD of 2.2 (2). We estimated that a 1.5-point difference in VAS between both groups would represent a clinical relevant difference. To detect such a difference with two-sided testing ($\alpha=0.05$ and power of 80%) 34 patients in each group would be needed. With the assumption of 15% rate of loss to follow-up 80 patients should be included. After almost 2 years of study execution, the actual loss to follow-up was 30% and higher than anticipated. Approval of the Medical Ethics Committee (Radboud University Medical Centre Nijmegen, ID-number 2010/200, ABR nr.: NL32412.091.10) was obtained to include 100 instead of 80 patients to generate the necessary power for this study.

Results

The demographic and baseline parameters are shown in Table 1 and 2. There were no significant differences between both groups. At 2 and 12 weeks follow-up the VAS pain was not significant different between the Bledsoe and the SofTec OA group (p=0.816 and p=0.658, respectively). Furthermore, at 2 and 12 weeks follow-up all other secondary clinical and radiographic outcomes were also not significant different between the Bledsoe and the SofTec OA group (Table 3). However, with the exception of the SF-12 MCS, all clinical outcomes significantly improved in both brace groups after 12 weeks follow-up compared to baseline. HKA alignment remained unchanged (Table 4).

Table 3 Results at 2 and 12 weeks follow-up (between group differences)

2 weeks follow-up				
Parameter	**Bledsoe Group (n=44)**	**SofTec OA Group (n=42)**	**Differences Mean (95%CI)**	***p* value**
VAS pain	2.7 (0.0-9.4)[a]	3.0 (2.1)[b]	1.2 (-0.9-1.2)	0.816[d]
VAS satisfaction	6.3 (2.7)[b]	6.2 (2.6)[b]	0.1 (-1.0-1.3)	0.847[d]
WOMAC	62.0 (20.8)[b]	61.9 (16.6)[b]	0.1 (-8.0-8.3)	0.972[d]
- Pain	13.0 (4.4)[b]	13.2 (3.4)[b]	-0.2 (-1.9-1.5)	0.818[d]
- Stiffness	4.7 (1.9)[b]	4.6 (1.8)[b]	0.1 (-0.7-0.9)	0.855[d]
- ADL	44.3 (15.4)[b]	44.0 (12.8)[b]	0.3 (-5.9-6.4)	0.931[d]
SF-12				
- PCS	38.3 (7.8)[b]	37.9 (9.9)[b]	0.4 (-3.5-4.2)	0.851[d]
- MCS	52.5 (27.5-65.3)[a]	53.4 (16.0-64.3)[a]	NA[e]	0.965[c]
6MWT				
- Distance (*meters*)	390.0 (80.0-495.0)[a]	390.9 (78.2)[b]	-4.6 (-38.1-29.1)	0.788[d]
12 weeks follow-up				
Parameter	**Bledsoe Group (n=40)**	**SofTec OA Group (n=36)**	**Differences Mean (95% CI)**	***p* value**
VAS pain	2.7 (0.0-10.0)[a]	3.2 (0.2-8.9)[a]	NA[e]	0.658[c]
VAS satisfaction	5.7 (3.1)[b]	5.5 (2.7)[b]	0.3 (-1.1-1.6)	0.709[d]
WOMAC	68.0 (1.0-95.0)[a]	58.3 (20.3)[b]	1.9 (-8.2-12.0)	0.704[d]
- Pain	14.0 (0.0-20.0)[a]	12.0 (4.3)[b]	0.2 (-2.0-2.5)	0.844[d]
- Stiffness	4.5 (1.0-8.0)[a]	4.6 (1.9)[b]	0.0 (-0.9-1.0)	0.933[d]
- ADL	48.5 (0.0-68.0)[a]	41.7 (15.1)[b]	1.7 (-5.8-9.1)	0.658[d]
SF-12				
- PCS	36.1 (9.4)[b]	36.1 (9.0)[b]	-0.0 (-4.3-4.2)	0.986[d]
- MCS	54.2 (20.6-62.9)[a]	53.6 (8.5)[b]	2.3 (-6.6-2.0)	0.295[d]
6MWT				
- Distance (*meters*)	420.0 (0.0-540.0)[a]	388.7 (93.2)[b]	4.2 (-39.6-47.9)	0.850[d]
HKA alignment (°)	5.0 (3.2)[b]	4.8 (3.1)[b]	0.1 (-1.3-1.6)	0.855[d]

[a] Values given as median (range)
[b] Values given as mean (standard deviation)
[c] Mann-Whitney U test
[d] Student's t test
[e] Non-parametric test

Table 4 Results at 12 weeks follow-up (within group differences)

	Baseline	Results at 12 weeks		
Parameter	**Score**	**Score**	**Differences Mean (95%CI)**	**Within group difference *p* value**
VAS pain				
- **Bledsoe**	4.4 (2.7)[b]	2.7 (0.0-10.0)[a]	0.9 (0.2-1.6)	0.013[c]
- **SofTec**	4.7 (2.7)[b]	3.2 (0.2-8.9)[a]	0.7 (-0.2-1.5)	0.125[c]
VAS satisfaction				
- **Bledsoe**	4.4 (0.0-10.0)[a]	5.7 (3.1)[b]	-1.3 (-2.4- -0.1)	0.036[c]
- **SofTec**	4.1 (2.6)[b]	5.5 (2.7)[b]	-1.4 (-2.6- -0.3)	0.013[c]
WOMAC				
- **Bledsoe**	51.7 (17.5)[b]	68.0 (1.0-95.0)[a]	-9.9 (-14.7- -5.0)	<0.001[c]
- **SofTec**	47.8 (16.2)[b]	58.3 (20.3)[b]	-8.9 (-14.4- -3.4)	0.002[c]
WOMAC pain				
- **Bledsoe**	10.7 (3.8)[b]	14.0 (0.0-20.0)[a]	-1.9 (-3.0- -0.7)	0.002[c]
- **SofTec**	10.0 (3.8)[b]	12.0 (4.3)[b]	-1.6 (-3.2- -0.1)	0.041[c]
WOMAC Stiffness	4.0 (0.0-7.0)[a]	4.5 (1.0-8.0)[a]	NA[e]	0.006[d]
- **Bledsoe**	3.0 (0.0-8.0)[a]	4.6 (1.9)[b]	-0.9 (-1.6- -0.2)	0.010[c]
- **SofTec**				
WOMAC ADL				
- **Bledsoe**	37.1 (12.7)[b]	48.5 (0.0-68.0)[a]	-7.0 (-10.6- -3.4)	<0.001[c]
- **SofTec**	34.2 (11.5)[b]	41.7 (15.1)[b]	-6.4 (-10.2- -2.6)	0.002[c]
SF-12 PCS				
- **Bledsoe**	33.3 (7.6)[b]	36.1 (9.4)[b]	-3.1 (-5.5- -0.7)	0.013[c]
- **SofTec**	31.7 (7.1)[b]	36.1 (9.0)[b]	-4.4 (-7.0- -1.7)	0.002[c]
SF-12 MCS				
- **Bledsoe**	50.8 (9.8)[b]	54.2 (20.6-62.9)[a]	-0.2 (-4.1-3.7)	0.918[c]
- **SofTec**	52.7 (20.4-65.1)[a]	53.6 (8.5)[b]	-1.3 (-3.7-1.0)	0.259[c]
6MWT Distance (*meters*)				
- **Bledsoe**	387.5 (90.0-520.0)[a]	420.0 (0.0-540.0)[a]	NA[e]	0.004[d]
- **SofTec**	358.8 (45.0-543.0)[a]	388.7 (93.2)[b]	-21.9 (-58.3- 14.6)	0.231[c]
HKA alignment (°)	5.4 (3.3)[b]	5.0 (3.2)[b]	0.2 (-3.4-0.7)	0.466[c]
- **Bledsoe**	5.7 (0.9-23.5)[a]	4.8 (3.1)[b]	0.3 (-0.1-0.7)	0.153[c]
- **SofTec**				

[a] Values given as median (range)
[b] Values given as mean (standard deviation)
[c] Paired t test
[d] Wilcoxon signed rank test
[e] Non-parametric test

Complications and compliance

Analgesic use, compliance and complications at 2 and 12 weeks follow-up are shown in Table V. Patients reported complications mainly at 2 weeks (Bledsoe group 78.0%, SofTec OA group 73.0%), but this reduced at 12 weeks (Bledsoe group 40.5%, SofTec OA group 46.9%). Only minor complications were reported. There were no significant differences between the Bledsoe and the SofTec OA group. 24% of the patients discontinued using their brace for several reasons.

Table 5 Analgesic use, compliance and complications at 2 and 12 weeks follow-up

Parameter	Bledsoe Group	Softec OA Group	*p* value
Analgesic use (*n (%)*)			
0 vs 2 weeks			0.610[b]
- **More**	4 (9.8)	5 (13.5)	
- **Equal**	32 (78.0)	26 (70.3)	
- **Less**	5 (12.2%)	6 (16.2)	
0 vs 12 weeks			0.719[b]
- **More**	6 (15.8)	3 (9.4)	
- **Equal**	25 (65.8)	22 (68.8)	
- **Less**	7 (18.4)	7 (21.9)	
Compliance (*hours/day*)[a]			
- **2 weeks**	8.2 (3.7)	7.9 (3.1)	0.710[c]
- **12 weeks**	6.7 (3.4)	6.8 (4.3)	0.977[c]
Complications (*n (%)*)			
2 weeks	32 (78.0)	27 (73.0)	0.602[b]
- **Red skin**	16 (39.0)	18 (46.8)	0.392[b]
- **Blisters**	2 (4.9)	3 (8.1)	0.664[d]
- **Skin laesons**	4 (9.8)	4 (10.8)	1.000[d]
- **Bad brace fit**	17 (41.5)	8 (21.6)	0.061[b]
- **Not comfortable/pain**	13 (31.7)	9 (24.3)	0.469[b]
- **Other**	12 (29.3)	9 (24.3)	0.623[b]
12 weeks	15 (40.5)	15 (46.9)	0.597[b]
- **Red skin**	4 (10.8)	8 (25.0)	0.121[b]
- **Blisters**	0 (0.0)	1 (3.1)	0.464[d]
- **Skin laesons**	2 (5.4)	1 (3.1)	1.000[d]
- **Bad brace fit**	5 (13.5)	3 (9.4)	0.716[d]
- **Not comfortable/pain**	8 (21.6)	4 (12.5)	0.319[b]
- **Other**	9 (23.7)	7 (21.9)	0.857[b]

[a] values given as mean (standard deviation)
[b] Chi-squared test
[c] Student's t test
[d] Fisher's exact test

Discussion

The most important finding of our study is that there was no difference in clinical and radiographic outcomes between the Bledsoe Thruster brace and the SofTec OA brace after 2 and 12 weeks follow-up. Both groups showed improvement in the clinical outcomes after 12 weeks follow-up compared to baseline, thereby proving their short-term effectiveness.
No differences in clinical outcomes between two types of valgus unloading braces were shown in this study. No study compared two different kinds of valgus unloading braces before, but Dessery et al. [4] conducted a crossover trial in 24 patients, with three different types of braces, of which one was a valgus unloading brace: an ACL brace (ACL Orthoconcepts Inc.), a valgus unloading brace (V3P Orthoconcepts Inc.) and an unloader brace with valgus and external rotation (VER Orthoconcepts Inc.). They found that the three braces provide similar pain relief and improvement in function and gait. The VER brace seemed to offer a slight comfort advantage.
Although no differences in clinical outcomes between the two valgus unloading braces were found, their effectiveness at 12 weeks was proven. Our results are confirmed in previous literature [1, 2, 12, 15, 32]. Brouwer et al. (2) performed a RCT comparing an intervention group of 60 patients (conservative treatment with additional brace (OAsys valgus unloader brace) treatment) with a control group of 57 patients (conservative treatment alone) and found significant better results in VAS pain, functional outcome, walking distance and quality of life in the intervention group after a follow-up of 3, 6 and 12 months. Hunter et al. [12] compared an active treatment (DonJoy OAdjuster valgus unloader knee brace with customised neutral foot orthoses and motion control shoes) with a control treatment (a neutral knee brace with unsupportive foot orthoses and shoes with a flexible mid-sole) in 80 patients with symptomatic medial knee OA. They concluded that a multi-modal realignment treatment (i.e. the active treatment) is the most effective treatment in patients with medial knee OA.
The mean HKA in both groups did not significant change from baseline to 12 weeks, and there was no significant difference between both groups. These results were also found in studies of van Raaij et al. [32] (MOS genu valgus unloader brace) and Horlick et al. [8] (GII valgus unloader brace). Although valgus unloader braces seem to fail in changing malalignment on whole leg radiographs, this is only a static measurement. Dynamic gait studies showed reduction in adduction moment of the knee in patients wearing a valgus unloading brace [18, 19, 21, 30]. So the improvement of our clinical results could therefore be explained by unloading the medial compartment during gait and not by changing the HKA on whole leg radiographs.
Although literature shows that valgus unloading braces are an effective conservative treatment

[1, 2, 12, 15, 20, 32], compliance is a known issue [6, 8, 9, 20, 31, 33]. Studies, however, rarely register the duration of brace wear. Also definitions for patient compliance varied widely [19]. This makes compliance comparison between studies difficult and complicates guideline modification aiming at compliance improvement. Hurley et al. [13] found that the clinical outcomes (WOMAC and SF-36) were not substantially influenced by the dosage of brace wear. Our patients mean brace usage at 12 weeks was 6.7 hours (SD, 3.8 hours) per day. The mean brace use is slightly longer compared with most former literature [10, 13, 32]. It needs further investigation to establish sound principles for brace wear guidelines.

Although unloading braces are a cost-effective treatment intervention [27], they are expensive. It is therefore important to known which factors influence compliance. In our study 86% of the patients still used their brace after 2 weeks follow-up and 76% after 12 weeks follow-up. This was not significant different between the two braces. So, it seems that the real efficacy was in the first 2 weeks. This could be an explanation of the high percentages of patients who stopped wearing the brace. Squyer et al.[31] investigated whether patients continued to use an unloader brace more than 1 year after it was prescribed and they found that only one in four patients did (25%). They were, however, unable to identify any patient or radiographic factors that predicted discontinued use of the brace. Giori et al. [8] also found no association between compliance and weight, BMI or radiographic factors, although they found that brace compliance was better in patients younger than 50 years after 2.5 years follow-up. In a study of Brouwer et al. [2] a significant amount of patients stopped brace treatment after a follow-up of 12 months, mainly due to noneffectiveness. They also found a nonsignificant trend towards better clinical outcomes with unloader braces in younger patients (<60 years). In our study, 26.2% of the patients were younger and 73.8% of the patients were older than 50 years. As we looked at the age of the patients who discontinued using the brace, 12.5% were younger than 50 years. It is possible that young age has a positive influence on compliance and clinical outcomes, but this is not at all conclusive yet.

It is likely that patients with higher BMI are more difficult to brace and that in these patients the brace could be less effective due to the large subcutaneous layer [17]. It is possible that BMI had an influence on the number of complications and noncompliance in our study, as 87% of our patients had a BMI over 25. Only one of the 24 (4.2%) patients who discontinued wearing the brace had a BMI under 25. Although this hypothesis is not supported by some other authors in previous literature: Squyer et al. [31] and Giori et al. [8] did not find any correlation with BMI or weight and brace use (dis)continuation.

Also the high percentage of minor complications (e.g. bad fit, skin irritation, blisters) could have contributed to non-compliance in both braces. Main reasons for discontinue using the braces were mostly these minor complications (bad brace fit (n=6), more pain (n=4) and skin

problems (n=6), Fig. 1). Squyer et al. [31] suggested that some patients may be easier to fit than others and that bad brace fitting leads to non-compliance and complications. The type and number of complications in our study are in line with those reported in previous literature, were a complication rate of approximately 42% is reported [2, 19, 20, 31, 32].

This study had some limitations. First, 24% of the patients discontinued using their brace, which could have introduced selection bias. This percentage is however not higher when compared to previous literature [2, 8, 19, 31, 33]. Second, some information bias could have been introduced, because blinding of the patient and investigator was not possible due to the type of intervention. The investigator who analysed the intervention effect was however blinded, reducing information bias to its minimum. Third, we did not to use a control group (or a placebo treatment) to establish the changes in outcome that are entirely due to the intervention. However, the main purpose of this study was to determine the difference in effectiveness between two different kinds of valgus unloading brace types. Fourth, the follow-up was only 12 weeks. The long-term differences between the two brace types have still to be determined.

Conclusions

This study was the first RCT comparing two different kinds of valgus unloading braces. We found no differences between the Bledsoe Thruster brace and the SofTec OA brace in the treatment of varus medial knee OA, so it seems that the type of brace does not influence outcome. Both groups had significant improved clinical outcomes after 12 weeks of follow-up. 24% of the patients discontinued using their brace for several reasons. Age, BMI and bad brace fitting could have an influence on compliance. Complications and compliance remains a problem for both braces.

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Conflict of interest
All authors declare that they have no competing interests.

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CHAPTER 3

Relaxation of the MCL after an open wedge high tibial osteotomy results in decreasing contact pressures of the knee over time

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Abstract

Purpose The objective of this study was to investigate the effect of a medial open-wedge osteotomy (OWO) and the release of the superficial medial collateral ligament (MCL) on the tibiofemoral cartilage pressure, the MCL tension and the valgus laxity of the knee.
Methods Seven fresh-frozen, human cadaveric knees were used. Medial and lateral mean contact pressure (CP), peak contact pressure (peakCP), and contact area (CA) were measured using a pressure-sensitive film (I-Scan; Tekscan, Boston, MA). The MCL tension was measured using a custom-made device. These measurements were continuously recorded for 5 min after an OWO of 10°. After the osteotomy, the valgus laxity was measured with a handheld Newtonmeter. For one knee, the measurements were continued for 24 h. At the end, a complete release of the superficial MCL was performed and the measurements were repeated at 10°.
Results There was relaxation of the MCL after the osteotomy; the tension dropped in 5 min with 10.7% (mean difference 20.5 N (95% CI 16.1–24.9)), and in 24 h, the tension decreased by 24.2% (absolute difference 38.8 N) (one knee). After the osteotomy, the mean CP, peakCP and CA increased in the medial compartment (absolute difference 0.17 MPa (95% CI 0.14–0.20), 0.27 MPa (95% CI 0.24–0.30), 132.9mm2 (95% CI 67.7–198.2), respectively), and decreased in the lateral compartment (absolute difference 0.02 MPa (95% CI 0.03–0.01), 0.08 MPa (95% CI 0.11–0.04), 47.0 mm2 (95% CI −105.8 to 11.8), respectively). Only after a release of the superficial MCL, the mean CP, peak CP and CA significantly decreased in the medial compartment (absolute difference 0.17, 0.27 MPa, 119.8 mm2, respectively), and increased in the lateral compartment (absolute difference 0.02, 0.11 MPa, 52.4 mm2, respectively). After the release of the superficial MCL, a mean increase of 7.9° (mean difference −0.1° (95% CI −1.9 to 1.6)) of the valgus laxity was found.
Conclusions A release of the superficial MCL helps achieve the goal of reducing medial cartilage pressure in an OWO. There was considerable relaxation of the MCL after an OWO that resulted in a decrease of the mean CP in the medial and lateral compartments of the knee over time. However, cartilage pressure shifted from the medial to the lateral compartment only after release of the superficial MCL. The release of the superficial MCL caused a significant increase in the valgus laxity, which could influence stability after an OWO.

Level of evidence I

Keywords Open-wedge high tibial osteotomy, Tibiofemoral cartilage pressure, Release medial collateral ligament, Valgus laxity, Biomechanical study

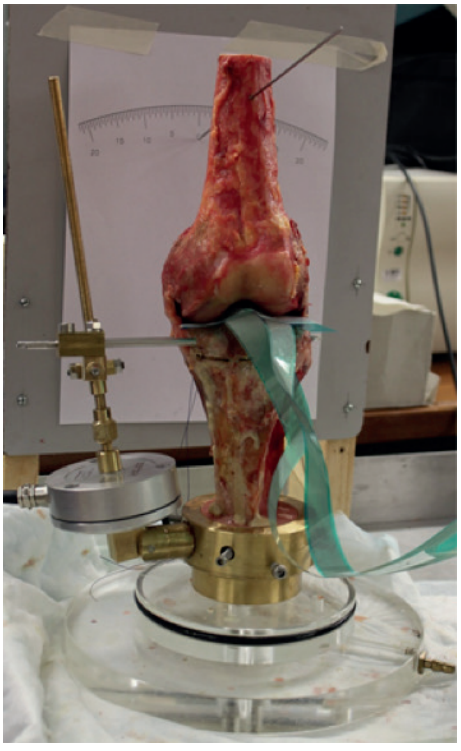
Introduction

An open-wedge osteotomy (OWO) is a successful treatment in patients with medial knee osteoarthritis (OA) and a varus leg alignment [4, 18]. An OWO unloads the medial compartment and shifts loading of the knee to the lateral compartment [1, 9, 17].
In an OWO, the medial proximal tibia must be exposed; however, the superficial medial collateral ligament (MCL) overlies this area. The superficial MCL can be left intact by elevating it sub-periostally, or it can be partially or completely released from its distal insertion [8, 11]. In literature, there is a debate as to whether or not to release the MCL when performing an OWO. Agneskircher et al. [1] concluded in their biomechanical study that if the MCL is not released after an OWO, the contact pressure in the medial compartment is even higher than in the lateral compartment. On the other hand, a release of the MCL has been shown to create a significant valgus instability [11].
It is known that ligaments show relaxation over time [5, 16], i.e. the tension in a ligament decreases over time with a constant strain. This is primarily due to maintenance of the structure in a strained condition for some finite interval of time, hence, causing some amount of plastic strain. This should not be confused with creep, which is a constant state of stress with an increasing amount of strain. The largest relaxation occurs within the first six to eight hours. After this, the effect is much smaller [5]. Theoretically, relaxation of the MCL after an OWO would result in a decrease of the cartilage pressure in the medial compartment, and the release of the superficial MCL, on that account, may not be necessary. The relaxation of the MCL and its influence on cartilage pressure has not yet been investigated.
The purpose of the present study was to investigate (1) the effect of MCL relaxation after an OWO on the contact pressure (CP), peak contact pressure (peakCP) and contact area (CA), in the medial and lateral compartments, (2) the effect of a complete release of the superficial MCL after an OWO on the CP, peakCP and CA in the medial and lateral compartments, and (3) the effect of a complete release of the superficial MCL after an OWO on the valgus laxity of the knee. It was hypothesised that (1) tension over the MCL gradually decreases, and correspondingly, the cartilage pressure in the medial compartment also decreases over time; (2) after a release of the superficial MCL, the CP, peakCP and CA in the medial compartment decreases; (3) after a release of the superficial MCL, the valgus laxity of the knee increases.

Materials and methods

Seven fresh-frozen, human cadaveric left legs were used in this study (mean age 78.9-year old (range 64–90), four men). The tibia and fibula were left as long as possible, leaving enough space for the custom-made device. The femur was cut mid-way. The cadavers were thawed over 24 h and dissected with the removal of the skin and all subcutaneous tissue. The joints were opened through a medial parapatellar approach and the quadriceps, patella, patellar tendon and anterior capsule were removed. The medial and lateral collateral ligaments (MCL and LCL), the anterior and posterior cruciate ligaments (ACL and PCL) were left intact, as was the posterior joint capsule and the popliteus tendon. The menisci were resected. The joints were visually inspected for signs of previous operations, injuries and signs of osteoarthritis. There were no signs of previous operations and injuries. Four knees had no signs of OA, one knee had mild signs of OA, and two knees had severe signs of OA, without severe osteophyte formation. None of the knees had deformities. The tibia stump was embedded in cement in a custom-made device. The femur was embedded in cement in extension, and was kept in place during cementation using a Kirschner wire (Fig. 1).

Figure 1 Experimental set-up with the custom-made device



Osteotomy

A monoplanar medial open-wedge high tibial osteotomy was carried out, without a release of the MCL. A Kirschner wire was inserted parallel to the joint line, just proximal to the tuberosity, directed to the fibular head. Along this wire the osteotomy was performed, leaving 10 millimetres of the lateral cortex intact. The osteotomy was created using a custom-made device, which was fixed to the proximal part of the osteotomy by placing screws anterior and posterior to the MCL, parallel to the osteotomy gap (Fig. 1). The gap was opened gradually until the desired osteotomy angle of 10° was reached, with one winding being equal to one millimetre. The number of millimetres c.q. windings was calculated by measuring the distance of the screw and the known desired angle (10°).

MCL tension

The custom-made device included a tensiometer incorporated within a 5 kN force transducer (Burster 8531–5000, Burster sensors and precision measurement, Gernsbach, Germany) that was used to measure the force that was produced by the MCL (MCL tension) during the opening of the osteotomy gap. The force transducer has an accuracy of ≤±0.15% (or ≤±7.5 N). In Fig. 1, the experimental set-up is shown, with the custom-made device including the tensiometer on the left side of the cadaver. The MCL tension was measured continuously for 5 min after an osteotomy of 10° in full extension. For one knee, the measurements were continued for 24 h.

Tibiofemoral cartilage pressure

A pressure-sensitive film (I-Scan Pressure Mapping Sensor 4000 (Tekscan, Boston, MA)) was inserted into the medial and lateral tibiofemoral joint and fixated to the posterior capsule using sutures. For protection of the sensor films, a thin piece of foil was placed over both sides of the sensor [20]. Before insertion into the joints, the sensors were preconditioned and calibrated using custom-made loading blocks in a mechanical testing system, as described in detail in other studies [19]. Care was taken to ensure that the sensors were seated on the cartilage without wrinkles. To ensure fixation, two sutures were placed through each sensor and the surrounding soft-tissue.

Valgus laxity

The valgus laxity was measured by applying a valgus moment of 2 Nm to the proximal femur, using a handheld force gauge. The angular change, (measured on a protractor placed behind the femur (Fig. 1)) caused by the valgus moment was taken as a measure for the laxity.

Measurements

Baseline measurements of contact pressure (CP; in MPa), peak contact pressure (peakCP; in MPa) and contact area (CA; in mm2) of the medial and lateral compartments were continuously performed at 0° gap opening, with the knee in full extension for a period of 5 min. The MCL tension and the valgus laxity were also measured at baseline. Next, the osteotomy gap was opened to 10°, and CP, peakCP and CA were measured again, as well as the MCL tension and the valgus laxity. The measurements (MCL tension, CP, peakCP and CA) were performed continuously for 5 min. For one knee, the measurements were continued for 24 h to assess the viscoelastic effects in the longer term.

After these measurements, a complete release of the superficial MCL was performed at the level of the osteotomy. All the measurements (CP, peakCP and CA, the MCL tension and valgus laxity) were repeated, at 0° and 10°.

Statistical analysis

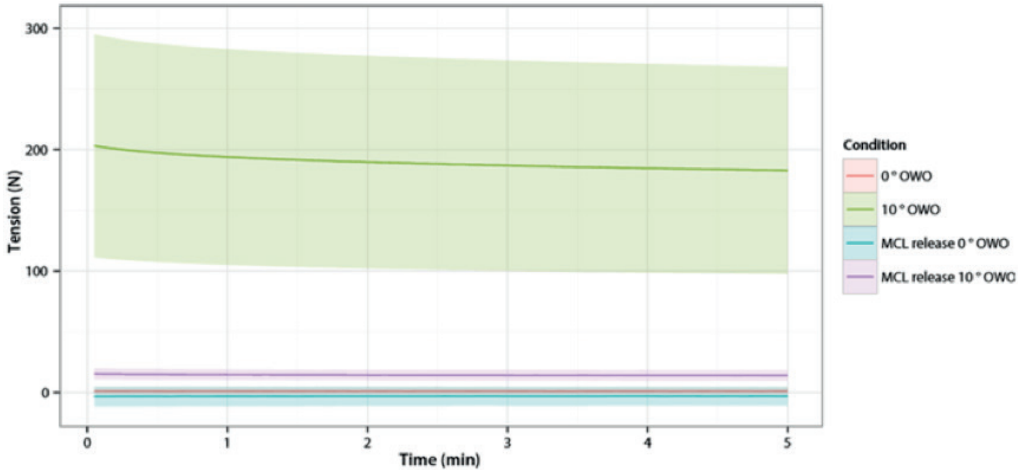
Descriptive statistics were used to summarise the data. Data were given as mean and standard deviation (SD) and differences were given as mean with 95% confidence intervals (CI). Linear mixed models were used to study the effect of condition (i.e. 0° and 10° valgus opening with and without MCL release) on CP, peakCP, CA, MCL tension and valgus laxity measurements. Patient/knee was treated as random factor. Regression parameter estimates were presented with their 95% CI. p values <0.05 were considered statistically significant. The statistical analyses were performed using R version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Tension produced by the MCL (MCL tension)

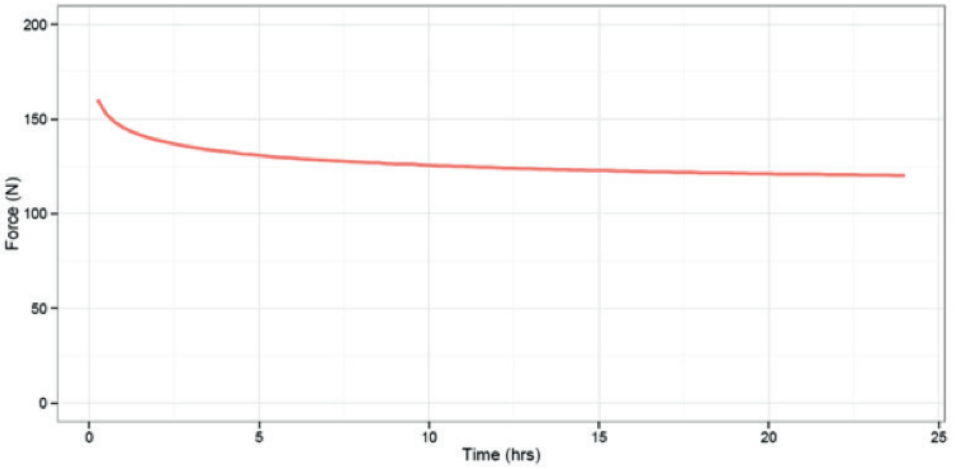
At baseline, the MCL tension was 1.2 N (SD 3.8). Opening the osteotomy gap to 10° caused an average increase in the MCL tension of 203 N (95% CI 16.1–24.9) (Fig. 2). Monitoring the MCL tension after the osteotomy revealed relaxation of the MCL. In 5 min, the tension dropped with 10.7% (mean difference 20.5 N (95% CI 16.1–24.9)). In the knee that was continuously monitored for 24 h, the MCL tension decreased with 24.2% (absolute difference 38.8 N) within 24 h. In that particular knee, within the first 5 min, the tension decreased 2.1%, and between 5 min and 24 h the tension decreased an additional 22.6% (Fig. 3).

Figure 2 Medial Collateral Ligament tension of all knees



On the X-axis is the time in minutes
On the Y-axis is the MCL tension in Newton (mean with 95% confidence interval)

Figure 3 Medial Collateral Ligament tension in 24 hours



On the X-axis is the time in hours
On the Y-axis is the MCL tension in Newton

Tibiofemoral cartilage pressures in the medial and lateral compartments

After the osteotomy, the mean CP, peakCP and CA in the medial compartment increased and in the lateral compartment decreased, compared to the situation without osteotomy (Table 1).

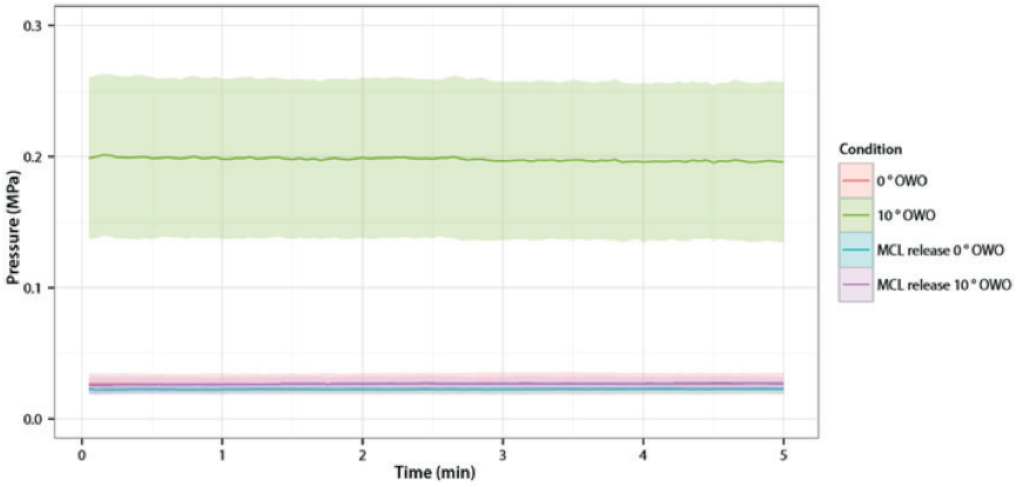
Table 1 Mean CP, peak CP, CA in the medial and lateral compartments—after 5 min compared to baseline and after MCL releas

Measurements	Baseline[a]	Osteotomy 10°[a]	MCL release 10°[a]	Absolute difference osteotomy-baseline (95% CI)	*P* value	Absolute difference MCL release-osteotomy (95% CI)	*P* value
CP medial (MPa)	0.03 (0.01)	0.20 (0.07)	0.03 (0.005)	0.17 (0.14–0.20)	<0.001	−0.17 (−0.20 to −0.13)	<0.001
CP lateral (MPa)	0.03 (0.01)	0.01 (0.00)	0.04 (0.02)	−0.02 (−0.03 to −0.01)	0.001	0.02 (0.01–0.03)	<0.001
Peak CP medial (MPa)	0.10 (0.04)	0.38 (0.05)	0.11 (0.05)	0.27 (0.24–0.30)	<0.001	−0.27 (−0.30 to −0.24)	<0.001
Peak CP lateral (MPa)	0.11 (0.05)	0.03 (0.02)	0.13 (0.07)	−0.08 (−0.11 to −0.04)	<0.001	0.11 (0.07–0.14)	<0.001
CA medial (mm^2)	193.6 (48.8)	326.5 (71.0)	203.2 (59.7)	132.9 (67.7–198.2)	<0.001	−119.8 (−185.3 to −80.6)	<0.001
CA lateral (mm^2)	112.7 (67.1)	65.7 (100.5)	120.4 (69.6)	−47.0 (−105.8 to 11.8)	N.S	52.4 (−9.2 to 114.3)	N.S

CI confidence interval, *CP* contact pressure, *CA* contact area, *MCL* medial collateral ligament, *N.S.* non-significant
[a]Values given as mean (standard deviation)

After the release of the superficial MCL, the mean CP, peakCP and CA significantly decreased in the medial compartment and significantly increased in the lateral compartment compared to the osteotomy situation. In this situation, the mean CP and peak CP in the lateral compartment increased relative to the medial compartment (Table 1).
Within the first 5 min after opening the osteotomy gap to 10°, the mean CP in the medial and lateral compartments slightly decreased (1.7% (SD1.7) and 1.6% (SD3.3), respectively) (Fig. 4).

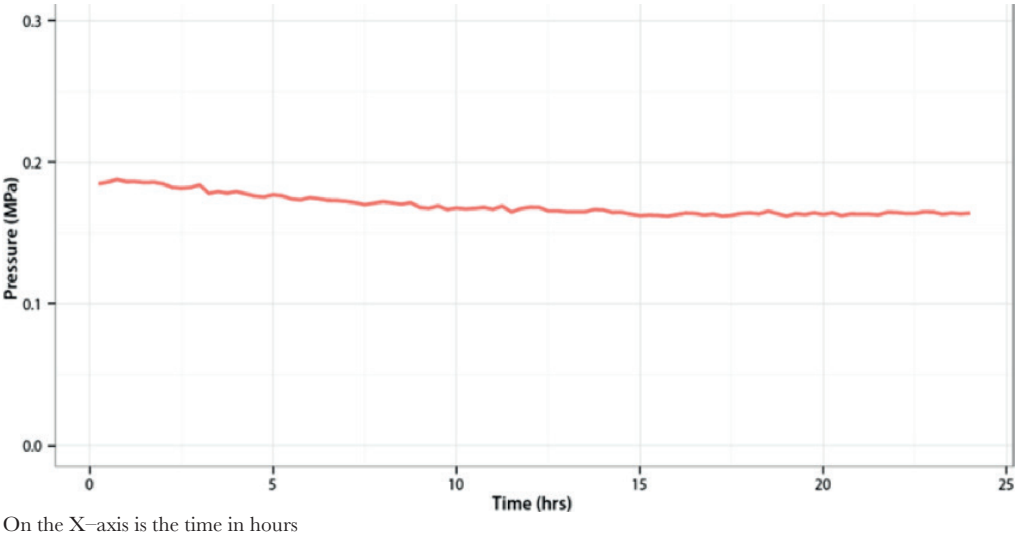
Figure 4 Contact Pressure medial compartment of all knees



On the X-axis is the time in minutes
On the Y-axis is the Contact Pressure in the medial compartment in MPa (mean with 95% confidence interval)

In the knee that was continuously monitored for 24 h, the CP decreased within 24 h with 11.3 and 10.5% in the medial and lateral compartments, respectively (Fig. 5).

Figure 5 Contact Pressure medial compartment in 24 hours

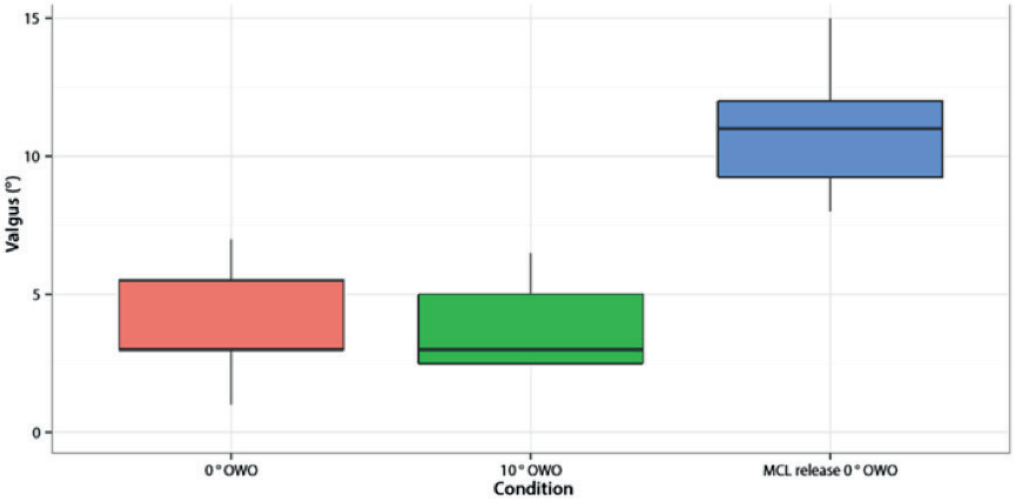


On the X–axis is the time in hours
On the Y-axis is the Contact Pressure in the medial compartment in MPa

Valgus laxity

Valgus laxity was unaffected by the osteotomy (mean difference −0.1° (95% CI −1.9 to 1.6; p = n.s.)) alone. However, after the release of the superficial MCL, the laxity was significantly increased (mean difference 7.9° (95% CI 6.1–9.6; p < 0.001)) compared to the situation without OWO (Fig. 6).

Figure 6 Valgus stability of all knees



On the X-axis are the different conditions in which the valgus stability was measured
On the Y-axis is the amount of valgus in degrees

Discussion

The most important findings of this study were as follows: Firstly, there was relaxation of the MCL after an OWO resulting in a decrease of the mean CP in the medial and lateral compartments of the knee over time. Secondly, after a complete release of the superficial MCL, there was a significant decrease of the mean CP, peakCP and CA in the medial compartment and a significant increase of the mean CP, peakCP and a non-significant increase of the CA in the lateral compartment. Thirdly, a complete release of the superficial MCL gave a significant increase in valgus laxity.

After a release of the superficial MCL, a significant decrease of the mean CP, peak CP and the CA in the medial compartment and a significant increase of the mean CP, peakCP and non-significant increase of the CA in the lateral compartment were found. These results correspond to the study of Agneskircher et al. [1]. They investigated the CP, peakCP and CA in the medial and lateral compartments with no release, a partial release and a complete release of the superficial MCL. They concluded that after a medial OWO, a complete release of the superficial MCL is required, as a shift of the cartilage pressure to the lateral compartment only occurs after this complete release. No other studies investigated the effect of a release of the superficial MCL after an OWO on the cartilage pressure. Our results confirmed the conclusions of Agneskircher et al. [1] that there is an upward mechanical lift of the medial part of the tibia plateau after an OWO without a release of the MCL, pressuring against the medial femoral condyle. They hypothesised that this leads to increased MCL tension and an associated increase of the cartilage pressure. Our results confirmed this hypothesis. We found that after an OWO of 10° there was an increase in the MCL tension of more than 200 N. The MCL consists of two components: the superficial MCL and deep MCL [12]. The tensile strength of the superficial MCL and deep MCL has been reported to be approximately 534 N and 194 N, respectively [12]. Hence, an increase of the MCL tension of more than 200 N after an osteotomy of 10° is quite a substantial amount of force.

The MCL has been described as the primary static stabiliser against valgus rotation of the knee [7, 14]. In an OWO, a release of the superficial MCL is needed for exposure and, without a release, this results in a higher cartilage pressure in the medial compartment than in the lateral compartment [1, 8]. However, a release of the superficial MCL results in a valgus instability [11, 13]. There was also a significant increase in the valgus laxity. In the present study, a complete release of the superficial MCL was performed. Pape et al. [11] investigated the presence of valgus instability after partial versus complete release of the superficial MCL by measuring the medial joint opening on stress radiographs. They concluded that the anterior fibres of the superficial MCL play a crucial role in maintaining valgus stability. Therefore, the

release of the superficial MCL for an OWO should be kept to a minimum to decrease the potential of late valgus instability.

The clinical consequence of valgus laxity after a release of the superficial MCL has been recently investigated in a study by Seo et al. [15]. They explored the changes in medial laxity of the knee joint after a complete release of the superficial MCL in patients who underwent an OWO, by measuring the medial joint space opening on radiographs before, during and after surgery. They found that a complete release of the superficial MCL during OWO increases the medial joint space opening. However, the medial joint space opening decreased to the level before the release of the superficial MCL after fixing with the TomoFix plate following the opening of the osteotomy site. No significant differences were found after 3-, 6- and 12-month follow-up. Gaasbeek et al. [4] investigated the valgus stability comparing an OWO with a closed-wedge osteotomy and found that the OWO group showed a mean postoperative decrease, and not an increase, of the mean MCL laxity of 4.5° (SD 1.5) versus 5.3° (SD 1.2) in the closed-wedge osteotomy group ($p = 0.04$). However, they did not perform a release of the superficial MCL during the OWO; they shifted the superficial MCL and pes anserinus dorsally. The clinical results were equal between both groups after one-year follow-up [4]. After a follow-up of 7.8 years, there was no difference in survival rate between the OWO and closed-wedge osteotomy group [18].

A release of the superficial MCL has been shown to lead to valgus instability [11, 13]. This is in line with the findings of the present study. However, there is a discrepancy between the biomechanical and clinical findings, as a postoperative valgus instability after an OWO and release of the superficial MCL is not a common complication [6]. There are several explanations for this discrepancy. Firstly, the muscular support of the dynamic stabilisers, such as the semimembranosus tendon and the medial head of the gastrocnemius, may partially compensate for the release of the superficial MCL [13]. Secondly, there could be a re-tensioning effect of the remaining fibres of the MCL, which could restore the valgus stability [10]. Thirdly, a tendon-to-bone healing of the superficial MCL might occur during rehabilitation, thus preventing a (late) valgus instability [11].

There are several limitations to this study. Firstly, this was an experimental set-up; the measurements were not performed in vivo. Secondly, we performed our study without axial loading of the cadavers, which would have been more comparable with a clinical situation. Hence, the lateralisation of the axial force vector due to the osteotomy was not taken into account in this study. Nevertheless, even without axial loading, we found similar results to Agneskircher et al. [1], who performed a comparable study in cadaver knees, but with loading of the cadavers. Thirdly, we tested the valgus laxity only in extension. Although the MCL is the primary static stabiliser against valgus rotation of the knee, in extension the posterior

medial capsule seems to be an important structure and in flexion it is the superficial MCL [3, 14]. Nevertheless, in extension, we found a significant increase in valgus laxity after release of the superficial MCL, so, in flexion, the valgus laxity is expected to be more pronounced. Fourthly, only the static stabilisers against valgus rotation were left intact, we resected all the dynamic stabilisers against valgus rotation, such as the semimembranosus tendon and the medial head of the gastrocnemius. As mentioned before, the dynamic stabilisers might partly compensate for the release of the superficial MCL. Ideally, this study would have been performed in a dynamic setting with all the stabilising structures intact. Fifthly, it is known that the tension in a ligament decreases over time with a constant strain [5, 16]. The largest relaxation is within the first six to eight hours, after that, the effect is much smaller [5]. We only investigated the relaxation and the effect on the cartilage pressure in 5 min, except for one knee, which we investigated for 24 h. The pattern of relaxation in the present study was similar to that described in the literature [5, 16]. It is expected that the relaxation of the MCL and the decrease in cartilage pressure would be higher after six to eight hours. Nevertheless, the cartilage pressure remained very high even after 24 h. Finally, we resected the menisci to fit in the pressure-sensitive film in the medial and lateral tibiofemoral compartments. This might have influenced our results, possibly an overestimation of the (peak) CP and an underestimation of the CA. In 1986, Baratz et al. [2] had already studied the effects of meniscectomy on contact areas and the stresses in the knee joints of human cadavers using pressure-sensitive film. Loss of the medial meniscus led to a decrease in contact areas of approximately 75% and an increase in the peak contact pressures of approximately 235%. Nevertheless, our results were comparable to Agneskircher et al. [1], who preserved the menisci.

The present study showed that a release of the superficial MCL is necessary for a successful OWO. Postoperatively, surgeons should consider the stability of the knee, as a release of the superficial MCL increased valgus laxity.

Conclusion

A release of the superficial MCL helps achieve the goal of reducing medial cartilage pressure in an OWO. A considerable relaxation of the MCL after an OWO occurred, which resulted in a decrease of the mean CP in the medial and lateral compartments of the knee over time. Cartilage pressure shifted from the medial to the lateral compartment only after a release of the superficial MCL. The release of the superficial MCL caused a significant increase in valgus laxity, which could influence stability after an OWO.

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CHAPTER 4

Gait analysis before and after corrective osteotomy in patients with knee osteoarthritis and a valgus deformity

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Abstract

Purpose In this prospective study, the changes in kinetics and kinematics of gait and clinical outcomes after a varus osteotomy (tibial, femoral or double osteotomy) in patients with osteoarthritis (OA) of the knee and a valgus leg alignment were analyzed and compared to healthy subjects.

Methods Twelve patients and ten healthy controls were included. Both kinetics and kinematics of gait and clinical and radiographic outcomes were evaluated.

Results The knee adduction moment increased significantly postoperatively ($p < 0.05$) and almost similar to the control group. Patients showed less knee and hip flexion/ extension motion and moment during gait pre- and postoperatively compared to the controls. A significant improvement was found in WOMAC [80.8 (SD 16.1), $p = 0.000$], KOS [74.9 (SD 14.7), $p = 0.018$], OKS [21.2 (SD 7.5), $p = 0.000$] and VAS-pain [32.9 (SD 20.9), $p = 0.003$] in all patients irrespective of the osteotomy technique used. The radiographic measurements showed a mean hip knee ankle (HKA) angle correction of 10.4° (95 % CI 6.4°–14.4°).

Conclusions In patients with knee OA combined with a valgus leg alignment, the varus-producing osteotomy is a successful treatment. Postoperatively, the patients showed kinetics and kinematics of gait similar as that of a healthy control group. A significant increase in the knee adduction moment during stance phase was found, which was related to the degree of correction. The HKA angle towards zero degrees caused a medial shift in the dynamic knee loading. The medial shift will optimally restore cartilage loading forces and knee ligament balance and reduces progression of OA or the risk of OA. A significant improvement in all clinical outcomes was also found.

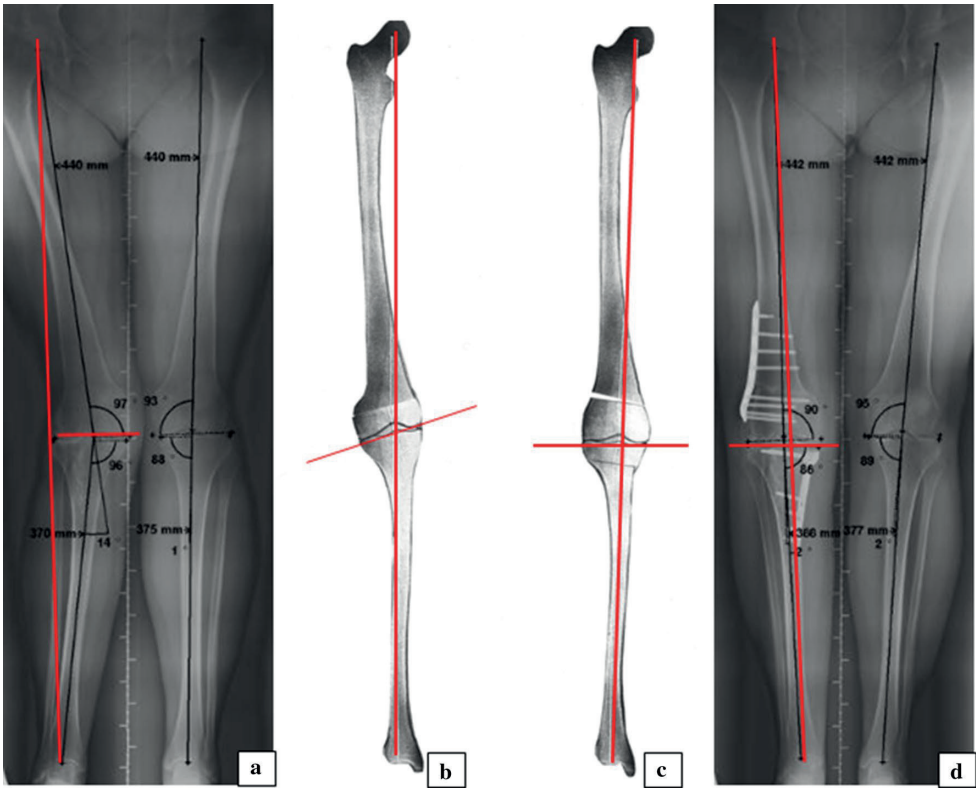
Level of evidence III

Keywords Double osteotomy, Supracondylar femoral osteotomy, Closed wedge medial high tibial osteotomy, Valgus alignment, Gait analysis

Introduction

Malalignment of the leg increases the risk of progression of knee osteoarthritis (OA) and causes a decline in physical function and progression of pain [15, 32]. One of the possible reasons for this increased risk of OA is that a malalignment of the knee influences the forces and moments acting on the knee during walking. In patients with medial knee OA and a varus alignment, an increased knee adduction moment is typically observed [17, 35, 36]. Kaufman et al. [17] found a significant difference between patients with knee OA (0.39 % BW–HT, SD 0.28) and healthy subjects (0.36 % BW–HT, SD 0.36). Turcot et al. [35] found a significant difference between patients with a varus leg alignment (0.62 Nm/kg, SD 0.19) compared to the control group (0.50 Nm/kg, SD 0.12). Moreover, the literature has shown a relationship between the degree of knee deformity and the forces acting on the knee [32, 33, 35, 36, 39, 40]. Weidenhielm et al. [39] found correlations between the hip knee ankle (HKA) angle and the peak adduction moment before surgery, after surgery and between the change in HKA angle and the change in peak adduction moment after surgery. Furthermore, varus alignment and increased knee adduction moment were associated with the progression of OA [25, 26, 32]. Sharma et al. [32] found a significant correlation between adduction moment and the Kellgren–Lawrence grade in knees. They also found significant correlations between adduction moment and joint space width in knees. In another study, Sharma and Song [33] found that a varus alignment was associated with a fourfold increase in the odds of medial progression (adjusted odds ratio 4.09, 95 % CI 2.20–7.62). Hence, malalignment of the leg alters the kinetics and kinematics in the knee, which most likely increases the risk of knee OA [32, 35]. When conservative treatment is no longer successful, corrective osteotomy is considered for young and active patients with lateral knee OA and a valgus leg alignment [15]. The purpose of a correction osteotomy is to realign the weight-bearing lines while maintaining normal knee joint line orientation (Fig. 1) [1, 2, 6, 7, 9–11, 14, 22, 23, 27, 28, 30, 34, 37]. A corrective osteotomy can be performed in either the femur or tibia or in both bones, i.e. a double osteotomy.

Figure 1 Rationale of double osteotomy in valgus corrective surgery



Weight-bearing long-leg radiographs and planning drawings including weight-bearing lines (WBL) and knee joint orientation lines (KJOL) of one of the study patients

a Preoperative valgus leg alignment caused by femoral and tibial bone deformity, WBL lateral and KJOL neutral

b Planning drawing of medial closing wedge distal femur osteotomy resulting in neutral WBL and severe valgus KJOL

c Planning drawing of double osteotomy, i.e. lateral open wedge distal femur and medial closing proximal tibial osteotomy, resulting in neutral WBL and neutral KJOL

d Postoperative leg alignment after double osteotomy

The kinetic and kinematics of gait of a varus medial osteoarthritic knee and the effect of a valgus osteotomy on these gait characteristics are well described in the literature [8, 17, 21, 25, 35, 36–39]. It is proven that a valgus-producing osteotomy is able to improve the kinetics and kinematics of gait [21, 38], causing improvements in clinical results and quality of life [4, 14]. Lind et al. [21] found a significant increase in walking speed, maximum knee flexion and a significant decrease in the mean maximum adduction moment after a valgus-producing osteotomy. Some literature addressed that the amount of adduction moment is a predictive value for the clinical results after a valgus osteotomy. Patients with a higher adduction moment

showed inferior clinical results compared to patients with a lower adduction moment [29, 38]. Also, the improvements in kinetics and kinematics of gait following a valgus osteotomy decrease the rate of the progression of medial knee OA, thereby delaying or preventing later conversion to a knee arthroplasty.

Although the kinetics and kinematics of gait in a medial varus osteoarthritic knee and the effect of a valgus osteotomy are well described [8, 36, 38, 39], the effect of a varus osteotomy on gait has been investigated only once [6]. In that study, only one parameter, the knee peak adduction moment, was studied in a subgroup of 12 patients with a lateral open wedge high tibial osteotomy and a mild valgus malalignment [mean HKA angle 2.4° (SD 2.4)] without an abnormal mechanical lateral distal femoral angle (mLDFA). The authors found a significant increase in the peak knee adduction moment during gait (mean change (95 % CI) of 0.72 % BW*Ht (0.42, 1.02) suggesting a medial shift in dynamic knee joint load. Although the peak adduction moment is an important outcome, it is a simplification of describing the effect of a varus osteotomy on gait. Detailed kinetics and kinematics of gait after a varus osteotomy have not yet been described in the literature. The spatiotemporal parameters, the flexion/extension angles, the abduction/adduction angles, the flexion/extension moments, the abduction/adduction moments of the knee and hip during the whole stance phase are important parameters in gait studies [24]. Furthermore, in contrast to the study of Collins et al. [6], patients with a large HKA angle and with an abnormal mLDFA were included. As a consequence, patients who underwent a medial closing wedge high tibial osteotomy (TKO), a medial closing wedge distal femur osteotomy (SCO) or both double osteotomy (DOT) were included. Clinical results after a varusproducing osteotomy are somewhat better described, but there is a lot of discrepancy between these studies and most studies have a low level of evidence [1, 2, 7, 10, 11, 30, 34]. Therefore, a well-performed study with a complete analysis of kinetics and kinematics of gait in combination with valid clinical scores is necessary.

The purpose of the study was to evaluate changes in gait and clinical outcomes after a varus-producing osteotomy in patients with lateral OA of the knee and a valgus leg alignment and compare these to a normal control group. Based on the previous study of Collins et al. [6], who found a significant increase in knee peak adduction moment, an increase in knee adduction moment during the whole stance phase was expected. We hypothesized that all the kinetics and kinematics of gait will improve towards that of a healthy control group postoperatively due to a correction of the valgus malalignment towards a varus alignment.

Materials and methods

This prospective study was carried out between 2006 and 2008, after approval of the Medical Ethical Board/Committee without an assigned number, as this study was in line with our normal protocol for operating these patients. A consecutive series of 12 patients participated in this study. Patients had been indicated for a single-level or double level varus osteotomy because of lateral OA of the knee and a valgus alignment. Exclusion criteria were conditions other than the OA of the knee that severely influenced gait. Ten healthy control subjects participated in the study. Written informed consent was obtained prior to participation. Patients were tested preoperatively (baseline) and 1 year postoperative, whereas control subjects were only measured once. Patient characteristics at baseline and controls characteristics are presented in Table 1.

Table 1 Patient characteristics at baseline and controls characteristics

Parameter	Patients	Controls
Number of subjects	12	10
Age, years (SD)	45 (3.3)	51 (13.2)
Sex, N		
• **Female**	8	6
• **Male**	4	4
Height, cm (SD)	176 (13)	174 (12)
Weight, kg (SD)	81 (14.0)	76 (8.9)
Side, Left/Right	5/7	
OA classification (SD)		
• **Medial**	1.4 (0.8)[a]	
• **Lateral**	2.3 (1.1)[a]	

SD Standard Deviation, *N* Number, cm Centimeter, *kg* Kilogram, *OA* Osteoarthritis Classification Kellgren and Lawrence
[a] N=11

Operation techniques

Deformity analysis according to Paley and Pfeil [28] revealed a single-level femoral valgus deformity in five patients, single-level tibial valgus deformity in three patients and double-level valgus deformity in four patients. Planning of deformity correction was aimed at correction of the lower leg to a neutral mechanical axis by angular correction of the deformed bone(s) to normal or into slight varus taking care of normal knee joint orientation (Fig. 1). All osteotomies were uniplanar closing wedge corrections, which were performed by one surgeon (RvH), five medial closing wedge distal femur osteotomies (SCO), three medial closing wedge high tibial

osteotomies (TKO) and a combination of both in the four double osteotomy patients (DOT). Preoperatively, a calibrated sawguide including a goniometer was used to enable accurate wedge resections according to the preoperative planning [22]. All osteotomies were fixed with angular stable (TomoFix®) plates. Postoperative rehabilitation consisted of immediate range of motion exercises, muscle training and partial weightbearing until 6 weeks postoperative. Subsequently, full weight-bearing was started depending on pain and radiographic proof of sufficient bone healing.

Clinical and radiographic outcomes

The clinical evaluation consisted of the Visual Analogue Scale for maximum pain (VAS-pm) and the frequency (VAS-pf) the patient experienced pain, The Dutch Western Ontario and McMaster Universities osteoarthritis index (WOMAC) [31], the Oxford Knee Score (OKS) [13], the Knee Outcome Survey Activities of Daily Living Scale (KOS) [16] and an evaluation of postoperative complications and reoperations. Whole leg standing anteroposterior radiographs were used to measure the pre- and postoperative hip knee ankle (HKA) angle, mechanical lateral distal femoral angle (mLDFA) and medial proximal femoral angle (MPTA), according to Paley and Pfeil [28]. Radiographic OA grading of the affected knee was performed by an independent investigator (NvE) using the Kellgren and Lawrence classification [18].

Gait analysis methods

The kinetics and kinematics of gait of each subject were measured using the Vicon motion analysis system (Vicon Motion Systems Ltd., Oxford, UK). The study of Koenraadt et al. [20] showed an accuracy of the system of at least 0.1 mm. The system consisted of eight infrared cameras and a computer system for data acquisition, processing and analysis. Marker positions were sampled at 200 Hz. Twenty reflective markers (14 mm in diameter) were placed according to the Helen Hayes lower limb model. Kinetic data were obtained simultaneously with the measurement of the kinematics using a Kistler force plate (Kistler Instruments, Switzerland) embedded in the floor and sampling at 2400 Hz. All subjects were instructed to walk barefoot at a self-selected speed. Subjects had a fixed starting point so that their third step was placed on the surface of the force plate [5]. At least three acceptable trials were obtained for both the right and the left leg. The gait data were processed using Vicon Workstation (version 5.2) and the Optimized Lower limb Gait Analysis (OLGA) model. A Woltering filtering routine with MSE = 25 was used to filter the data.

The gait parameters of interest were walking speed, stride length and foot progression angle. In addition, varus/valgus (adduction/abduction) and flexion/extension angle and external

moment of the knee and hip during the entire stance phase were obtained and subsequently normalized to stance time. Heel strike and toe-off were determined using the vertical ground reaction force with a threshold of 10 N. The average of three trials per subject was used. For each OA patient, these parameters were calculated for the affected leg, whereas for the control group, the leg was randomly selected. The kinetics and kinematics of gait were analyzed using custom written programs in Matlab. The accuracy of the used method in assessing the kinematics and kinetics of gait is <5 degrees as has been reported in the literature [24, 41].

Statistical analysis

Total test scores [mean, standard deviation (SD)] for the continuous variables (HKA angle, WOMAC, KSS, OKS, KOS, VAS-pm, VAS-pf) were calculated at baseline (preoperative) and 1 year postoperative. A paired t test was used to indicate differences between the preoperative and postoperative clinical outcomes and the gait characteristics walking velocity, stride length and foot progression angle. A Wilcoxon signed-rank test was used to test for significant differences in knee and hip angles and moments between the pre- and postoperative condition for each percent of the stance phase. Differences between the patients and controls were tested using a Mann–Whitney U test. To study the relation between the degree of deformity correction with the knee adduction moment, the mean knee adduction moment over the stance phase was first calculated. Subsequently, the Pearson correlation coefficient between the correction of HKA angle and increase of mean knee adduction moment was calculated. The effect of the three different surgical interventions on kinetics and kinematics were also analyzed. However, no statistical analysis has been performed on these data because the subgroups consisted of only a few patients. A $p < 0.05$ was considered significant. All data were statistically analyzed with SPSS version 18.0.

Results

Not all patients had a complete data set. One patient had no preoperative clinical measurements and was therefore left out in the analysis of clinical outcomes. Two patients had an incomplete radiographic file and were therefore left out in the radiographic analysis.

Clinical and radiographic outcomes, complications and reoperations

Postoperative all clinical results significantly improved (Table 2). The radiographic measurements showed a mean HKA angle correction of 10.4° (95 % CI 6.4°–14.4°). The mean mLDFA and MPTA are also shown in Table 2. In five patients (three DOT and two SCO), the hardware was removed within 1 year. One patient (SCO) underwent a pseudoarthrosis repair 6 months postoperative. No intraoperative or postoperative complications that could interfere with postoperative gait were found.

Table 2 Clinical and radiographic outcomes

Parameter	Mean preoperative scores (SD) N=11	Mean postoperative scores (SD) N=12	Mean difference (95% CI) N=11	p-value N=11
HKA (°)	9.3 (5.7) valgus[b]	1.1 (2.3) varus[a]	10.4 (6.4-14.4)	P=0.000
mLDFA (°)	85.0 (6.2)[b]	90.0 (2.0)[a]	4.0 (0.1-7.9)	n.s.
MPTA (°)	88.0 (7.7)[b]	89.0 (2.8)[a]	0.0 (-4.4-4.4)	n.s.
WOMAC (0-96)	57 (13)	81 (16)	-26 (-33- -19)	P=0.000
VAS-pm (0-100)	60 (19)	33 (21)	26 (11-41)	P=0.003
VAS-pf (0-100)	71 (21)	27 (22)	26 (61)	P=0.000
KOS (0-100%)	56 (15)	75 (15)	20 (35-4.2)	P=0.018
OKS (12-60)	33 (8)	21 (8)	12 (6.8-17)	P=0.000

SD Standard Deviation, *CI* Confidence Interval, *N* Number, *OA* Osteoarthritis Classification Kellgren and Lawrence, *HKA* Hip Knee Ankle angle, *mLDFA* mechanical Lateral Distal Femoral Angle, *MPTA* Medial Proximal Tibial Angle, *WOMAC* Dutch Western Ontario and McMaster Universities osteoarthritis index, *VAS-pm* Visual Analogue Scale for maximum pain, *VAS-pf* Visual Analogue Scale for how frequent the patient experienced pain, *KOS* Knee Outcome Survey Activities of Daily Living Scale, *OKS* Oxford Knee Score

[a] N=10

[b] N=12

Gait analysis

Spatiotemporal parameters

The spatiotemporal parameters are shown in Table 3. Surgery did not affect the walking velocity of the patients, leaving a significant difference with the control group after surgery ($p = 0.024$). Although the stride length did not increase postoperatively, stride length after surgery was not significantly different from controls ($p = 0.13$). There was also no significant difference

in foot progression angle between the preoperative, postoperative measurements and the controls.

Table 3 Spatiotemporal parameters

Spatiotemporal parameters	Mean preoperative scores (SD) N=12	Mean scores control group (SD) N=10	p-value[a]	Mean postoperative scores (SD) N=12	p-value[b]
Walking velocity (m/s)	0.95 (0.09)	1.25 (0.15)	p<0.001	0.93 (0.25)	n.s.
Stride length (m)	1.10 (0.18)	1.38 (0.14)	p=0.004	1.17 (0.39)	n.s.
Foot progression angle (°)	7.0° (3.8°)	6.4° (2.5°)	n.s.	5.8° (3.6°)	n.s.

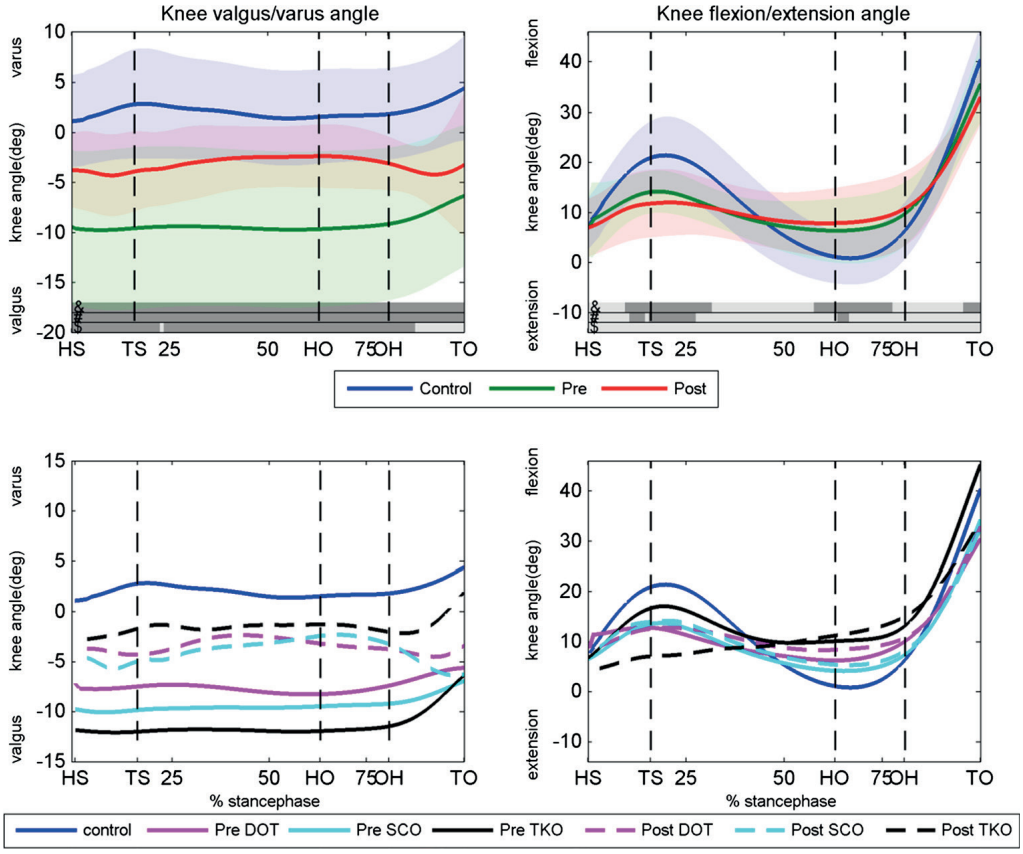
SD Standard Deviation *N* Number *n.s.* non significant
[a] Difference between preoperative scores and scores control group
[b] Difference between preoperative and postoperative scores

Knee and hip kinematics

The valgus/varus and flexion/extension angle of the knee for the preoperative condition, the postoperative condition and the control group are shown in Fig. 2. Although the valgus angle of the patients significantly decreased postoperatively (except for late stance), patients had significantly more knee valgus angle during the entire stance phase before and after surgery compared to healthy controls.

Patients had pre- and postoperatively significantly less knee flexion around toe strike and less knee extension around heel off compared to controls. Knee flexion/extension angle was not significantly different between pre- and postoperative. The three types of surgery (TKO, SCO and DOT) influenced the knee angles in almost a similar manner as can be seen in the lower panels of Fig. 2.

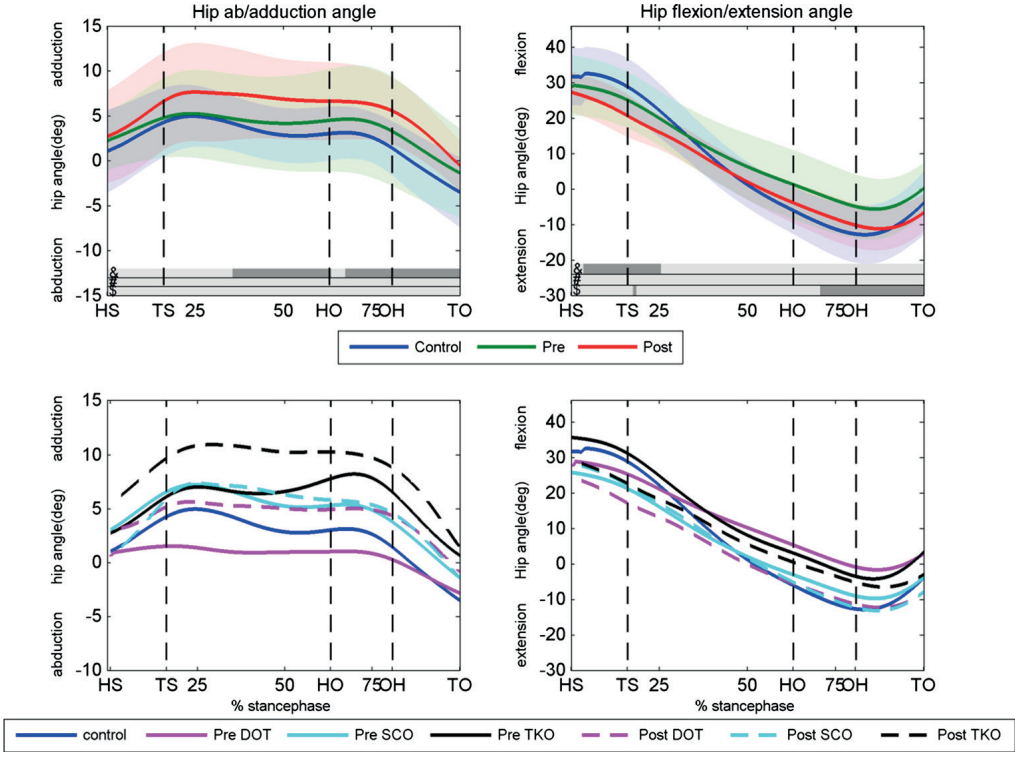
Figure 2 Knee valgus/varus and flexion/extension angles



Upper panels the knee angles of the controls, preoperative condition and postoperative condition for the valgus/varus (left panel) and flexion/extension (right panel) angle. Dark areas in the bars right above the x-axis indicate significant differences ($p < 0.05$) between: &, postoperative and controls; #, preoperative and controls; $, pre- and postoperative Lower panels knee varus/valgus and flexion/ extension angles for the DOT, SCO and TKO group. Pre- and postoperative as well as the control data are displayed
HS heel strike, *TS* toe strike, *HO* heel off, *OH* opposite heel strike, *TO* toe-off, *Deg* degrees, *Pre* preoperative, *Post* postoperative, *DOT* double osteotomy, *SCO* supracondylar osteotomy, *TKO* high tibial osteotomy

There was no significant difference in hip flexion/extension angle between the preoperative condition and the controls (Fig. 3). After surgery, the hip flexion/extension angle was significantly lower at the final part of the stance phase compared to the preoperative condition. The patients had their hip significantly more extended at the first 25 % of the stance phase and more adducted from 35 to 100 % of the stance phase in the postoperative condition compared to the controls.

Figure 3 Hip abduction/adduction and flexion/extension angles



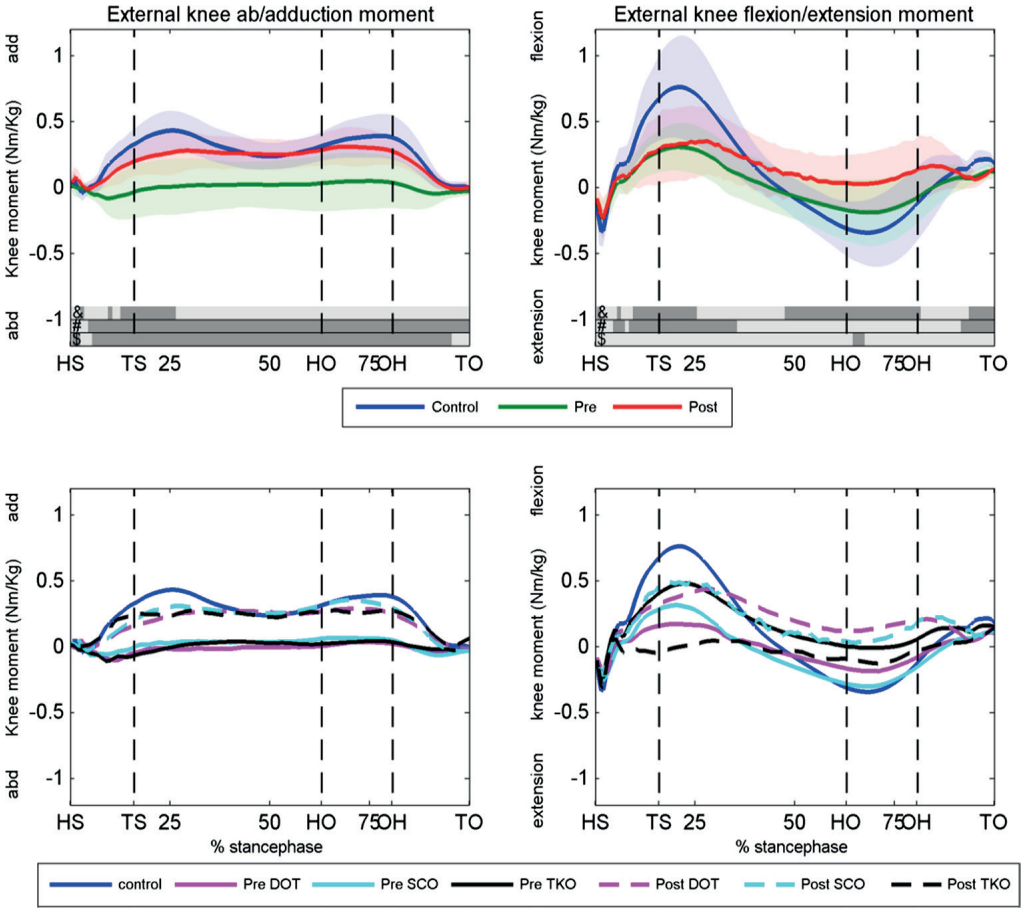
Upper panels the hip angles of the controls, preoperative condition and postoperative condition for the abduction/adduction (left panel) and flexion/extension (right panel) angle. Dark areas in the bars right above the x-axis indicate significant differences ($p < 0.05$) between: &, postoperative and controls, #, preoperative and controls, $, pre- and postoperative Lower panels hip abduction/adduction and flexion/extension angles for the DOT, SCO and TKO group. Pre- and postoperative as well as the control data are displayed
HS heel strike, *TS* toe strike, *HO* heel off, *OH* opposite heel strike, *TO* toe-off, *Deg* degrees, *Pre* preoperative, *Post* postoperative, *DOT* double osteotomy, *SCO* supracondylar osteotomy, *TKO* high tibial osteotomy

Knee and hip kinetics

The external knee and hip joint moments for the pre- and postoperative condition and the controls are shown in Figs. 4 and 5, respectively. The patients had a significant lower knee adduction moment before surgery compared to healthy controls, which increased significantly postoperative during almost the entire stance phase. The mean knee adduction moment increased significantly from 0.004 preoperative to 0.204 Nm/kg postoperative ($p = 0.004$). A power calculation based on the change in mean knee adduction moment revealed a power of 95.4 %. After surgery, patients had only a significant lower adduction moment compared to controls around toe strike. The patients had significantly lower knee flexion moment at the first 35 % of the stance phase and lower knee extension moment at toe-off (right upper panel, Fig.

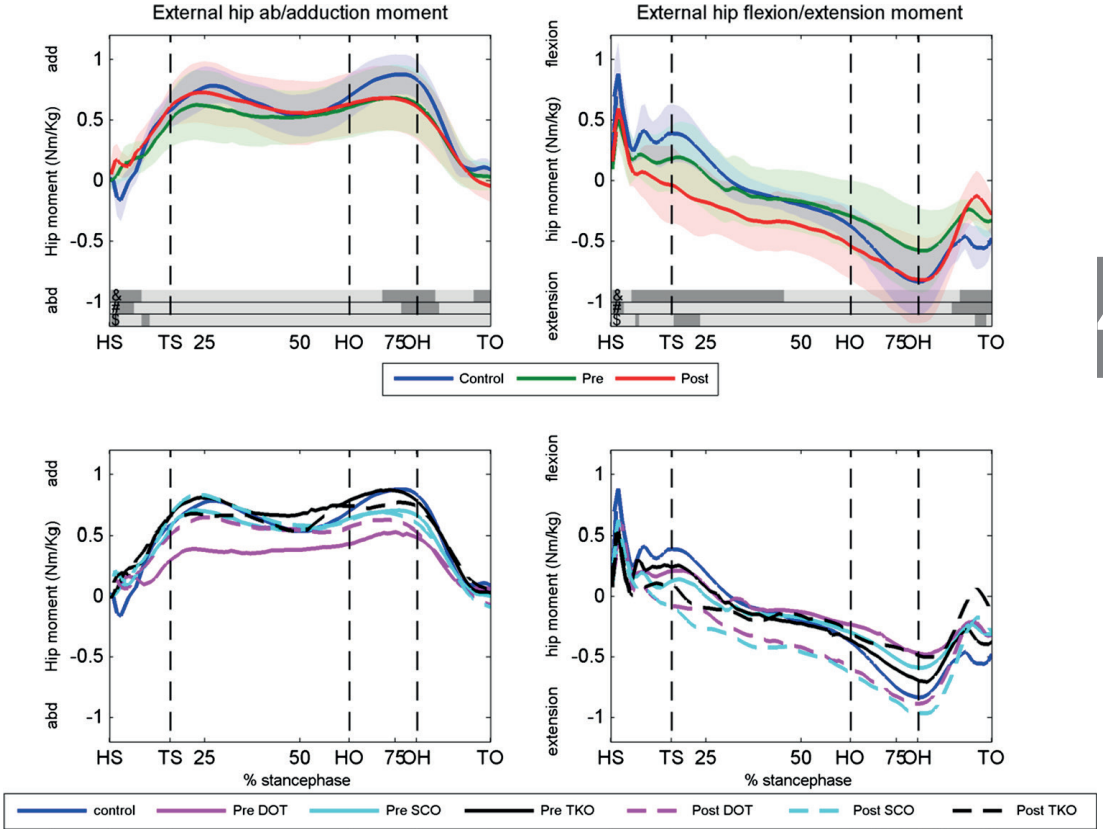
4) compared to the controls. Surgery did not affect the knee flexion/extension moment.
Hip external abduction/adduction had almost no differences between the patients (pre- and postoperative) and the controls (Fig. 5). Surgery caused a significant decrease in hip extension moment around toe strike and toe-off. The hip extension moment was significantly lower after surgery at the first 50 % of stance and at toe-off compared to controls. No clear differences were found between the three surgical techniques in knee and hip moments (lower panels of Figs. 4, 5).
A significant correlation was found between the correction of HKA angle and increase in mean knee adduction moment ($r = 0.65$; $p = 0.04$).

Figure 4 Knee external knee abduction/adduction and flexion/extension moments



Upper panels: the knee moments of the controls, preoperative condition and postoperative condition for the abduction/adduction (left panel) and flexion/extension (right panel) moment.
Dark areas in the bars right above the x-axis indicate significant differences ($p<0.05$) between:
& = postoperative and controls
# = preoperative and controls
$ = pre,- and postoperative.
Lower panels: knee abduction/adduction and flexion/extension moments for the DOT, SCO and TKO group and the controls.
HS Heel strike, *TS* Toe strike, *HO* Heel off, *OH* Opposite heel strike, *TO* Toe off, *Deg* Degrees, *Pre* Preoperative, *Post* Postoperative, *DOT* Double osteotomy, *SCO* Supracondylair osteotomy, *TKO* High tibial osteotomy

Figure 5 Hip abduction/adduction and flexion/extension moments



Upper panels: the hip moments of the controls, preoperative condition and postoperative condition for the abduction/adduction (left panel) and flexion/extension (right panel) moment
Dark areas in the bars right above the x-axis indicate significant differences ($p<0.05$) between:
& = postoperative and controls
# = preoperative and controls
$ = pre,- and postoperative
Lower panels: hip abduction/adduction and flexion/extension moments for the DOT, SCO and TKO group and controls
HS Heel strike, *TS* Toe strike, *HO* Heel off, *OH* Opposite heel strike, *TO* Toe off, *Deg* Degrees, *Pre* Preoperative, *Post* Postoperative, *DOT* Double osteotomy, *SCO* Supracondylair osteotomy, *TKO* High tibial osteotomy

Discussion

The most important finding of the present study is the significant increase in knee adduction moment during the whole stance phase postoperatively to an almost similar pattern as was found in the control group (left upper panel Fig. 4). In addition to the increase in peak adduction moment (mean change was 0.72 % BW*Ht (95 % CI 0.42, 1.02) described by Collins et al. [6], an increased mean adduction moment during the whole stance phase of 0.20 Nm/kg after three types of osteotomies was found. Collins et al. [6] investigated the gait of a subgroup of 12 patients after a lateral opening wedge high tibial osteotomy for a mild valgus malalignment [mean HKA angle 2.4° (SD 2.4)]. The authors excluded patients with an abnormal mLDFA, and they did not compare the results to a control group. In contrast to Collins et al. [6], patients with a large HKA angle [mean HKA angle 9.3 (SD 5.7)] an abnormal mLDFA were included and compared to a control group. The knee adduction moment changed postoperatively during the whole stance phase to an almost similar pattern as the control group. Our control group showed comparable results with the gait characteristics of other healthy subjects in the literature [12, 35].

As yet to our knowledge only one gait study has been performed with varus osteotomies [6], the mechanical axis seems the best predictor of the peak abduction/adduction moment, as shown in earlier studies with valgus osteotomies [8, 14, 38, 39]. Turcot et al. [35] found that subjects with varus knees had larger peak knee adduction moments than subjects with neutral or valgus knees. A valgus osteotomy causes an increase in the abduction moment and a lateral shift in the dynamic knee joint loading [8, 36, 38, 39]. Postoperatively, a mean correction of 10.4° (95 % CI 6.4–14.4) towards a mean HKA angle of 1.1° (SD 2.3) varus and an increase in the adduction moment comparable to that of healthy controls during the entire stance phase were found. It seems that a varus osteotomy, which has an opposite effect as compared to a valgus osteotomy, caused a medial shift in the dynamic knee joint load. The medial shift will optimally restore cartilage loading forces and knee ligament balance and possibly reduces the risk of OA. The mean increase in knee adduction moment during stance showed a significant correlation with the correction of the valgus malalignment.

It was showed that the other gait kinetics and kinematics improved towards that of a healthy control group after surgery, with exception of the knee and hip flexion/extension motion and moment. In general, our patients showed less knee and hip flexion/extension motion and moment during gait compared to the controls. Postoperatively these curves hardly changed compared to preoperatively. The pre- and postoperative differences between the patients and the controls could be explained by the lower walking velocities, which were significantly different between the patients and the controls. Kirtley et al. [19] already showed that the peak

knee flexion moment is strongly related to walking speed. Also Brinkmann and Perry [3] found a positive correlation between knee flexion and gait velocity.
Significant improvements in WOMAC, KOS, OKS and VAS-pm and VAS-pf were found in all patients. These clinical results are comparable with the literature, although there are a lot of discrepancies between studies and most studies have a low level of evidence [1, 2, 7, 10, 11, 30, 34]. The significant improvements of all clinical outcomes prove the effectiveness of a varus-producing osteotomy; however, long-term results are needed to confirm this conclusion.
A common limitation in studying patients with knee OA and a valgus alignment is the low prevalence of these patients [35]. In the current study, a small number of patients (12 in total) was evaluated. Nevertheless, the power appeared to be 0.95 for the difference in mean abduction moment. Another limitation is that three different operation techniques were used. However, different operation techniques are needed to maintain a normal knee joint line orientation after correction of each type of bone deformity. Maintaining a normal knee joint line orientation will optimally restore cartilage loading forces and knee ligament balance [2, 28] after correction, and this results in long-term survival of the osteotomies [2]. Although it was not possible to perform a statistical analysis of these three subgroups, the clinical evaluations, radiographic measurements as well as the kinetics and kinematics of gait were similar in all three operation techniques; therefore, the osteotomy type chosen does not seem to influence the outcome. The operated leg was compared to a control group, instead of the healthy leg. In most studies, the operated leg is compared to the healthy leg. However, the leg deformities in our study group were large, and compensatory mechanisms during gait could have been expected in the gait cycle of the contralateral leg. Therefore, the gait patterns of the operated leg were compared with that of a healthy control group in order to be able to compare it with a healthy gait cycle.

Conclusion

This study showed that different types of varus-producing osteotomies in patients with lateral knee OA and a valgus alignment are a successful treatment in correcting alignment resulting in an increase in all postoperative clinical outcomes. A significant increase in the knee adduction moment was found during stance phase postoperatively, which was related to the degree of correction. Several other gait characteristics significantly changed towards that of the healthy controls. The HKA angle towards zero degrees caused a medial shift in the dynamic knee loading. The medial shift will optimally restore cartilage loading forces and knee ligament balance and reduces progression of OA or the risk of OA.

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CHAPTER 5

Biomechanical comparison of two different locking plates for open wedge high tibial osteotomy

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Abstract

Purpose The purpose of this study was to compare the mechanical stability of a relatively thin locking plate (FlexitSystem implant) with a relatively firm locking plate (TomoFix implant), both used for opening wedge high tibial osteotomy.

Methods Seven fresh frozen paired human cadaveric tibiae were used. The opening wedge high tibial osteotomies in the left tibiae were fixated with the FlexitSystem implant and in the right tibiae with the TomoFix implant. The tibiae were CT-scanned to determine the bone mineral density. Axial loading was applied in a cyclic fashion for 50,000 cycles. We compared throughout the loading history the relative motions between the proximal and distal tibia using roentgen stereophotogrammetry analysis at set intervals. Also the strength of the reconstructions was compared using a displacement-controlled compressive test until failure.

Results One pair (with the lowest bone mineral density) failed during the preparation of the osteotomy. The FlexitSystem implant displayed a similar stability compared to the TomoFix implant, with low translations (mean 2.16±1.02mm vs. 4.29±5.66mm) and rotations (mean 3.17±2.04° vs. 4.30±6.78°), which was not significant different. Although on average the FlexitSystem reconstructions were slightly stronger than the Tomofix reconstructions (mean 4867±944N vs. 4628±1987N), no significant ($p=0.71$) differences between the two implants were found.

Conclusions From a biomechanical point of view, the FlexitSystem implant is a suitable alternative to the TomoFix implant for a high tibial open wedge osteotomy.

Level of evidence I

Keywords TomoFix implant, FlexitSystem implant, Open wedge high tibial osteotomy, Biomechanical stability

Introduction

Patients with knee osteoarthritis (OA) of the medial compartment often have a varus leg alignment which causes an overload of the medial compartment. Malalignment increases the risk for progression of knee OA and is associated with a decline in physical function and progression of pain [1-3]. In order to unload the medial compartment, a valgus high tibial osteotomy is the treatment of choice for the young and active patient [4].
The most commonly used techniques include closed-wedge osteotomy (CWO) and open-wedge osteotomy (OWO) [5, 6]. The disadvantages of a lateral closed wedge osteotomy are the need for a fibular osteotomy, the high rate of tibial neuropathies, peroneal neuropathies, bone stock loss, and a more demanding subsequent total knee arthroplasty [6]. On the other hand, OWO has been associated with high non-union rates and loss of correction due to unstable fixation [6, 7]. Therefore, fixation strength and maintenance of stability until osseous consolidation are a prerequisite of the implants used in OWO [8]. Several implants have been designed for OWO [8-11]. The TomoFix implant (Fig. 1) is widely used because of its well-reported clinical [5, 12, 13] and biomechanical [9, 11, 14] track record. The TomoFix implant is a long and rigid titanium plate with locking screws, which functions as an internal fixator [8]. Due to its size, the disadvantages of this implant have been reported to be local irritation and wound healing problems [15-18]. Therefore, implant removal after surgery is often needed [18]. The FlexitSystem implant (Fig. 1) is a novel implant to be used for OWO. The FlexitSystem implant is shorter and thinner compared to the TomoFix implant. To compensate for the smaller dimensions, a different grade of titanium alloy (stiffer and stronger) is used for the FlexitSystem. The characteristics of the implants used in these study are shown in Table 1. The potential benefit of the FlexitSystem implant is that, due to its smaller dimensions, patients may experience less discomfort from the plate, which may eliminate the necessity of implant removal after surgery. A potential concern is that the smaller dimensions of the implant may affect the primary stability of the reconstruction.

Figure 1 High tibial open wedge osteotomy implants

FlexitSystem implant (left) and TomoFix implant (right)

Table 1 Characteristics of the implants used in this study

Characteristics implants	FlexitSystem implant	TomoFix implant
Length	80mm	112mm
Width	32mm	38mm
Thickness	2.8mm	3mm
Screw holes	7	8 (7 used)
Material	Ti6Al4V	Commercially pure titanium
Modulus of elasticity	~110 GPa	~100 GPa
Yield strength	~800 MPa	~350 MPa
Designed single cut osteotomy	yes	yes
Locking screws	yes	yes

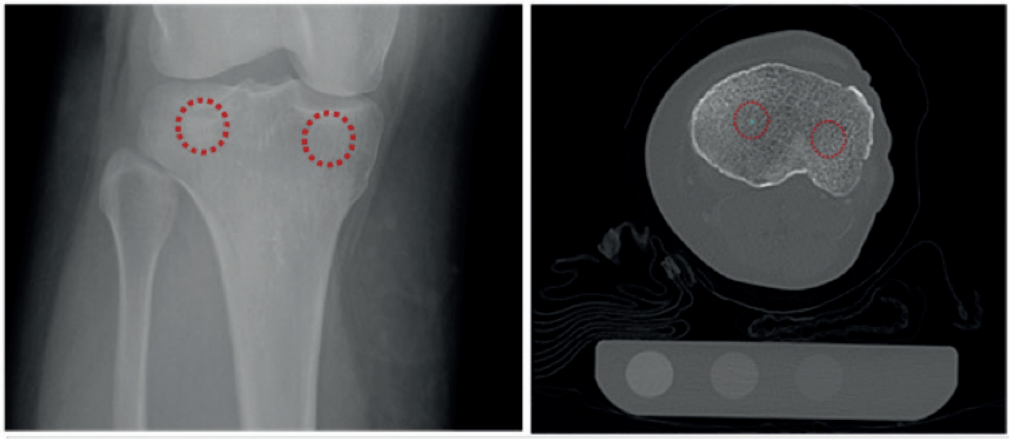
The purpose of this study was to compare the mechanical stability of the novel FlexitSystem implant to the well reported TomoFix implant based on mechanical tests (dynamically loading and compressive to failure) using fresh frozen human cadaveric tibiae. Our hypothesis was that the mechanical stability of the FlexitSystem implant was not 'inferior' to that of the TomoFix implant.

Material and methods

Specimen preparation

Seven paired human cadaveric tibiae (mean age of 74±6 years; three male, four female) were used for the study. Considering the relatively high age of the cadaveric specimens, the bone density was evaluated using quantified computed tomography (qCT). For this purpose, the bone mineral density (BMD) was measured in standardized regions of interest in the proximal tibia. These regions were defined as two spheres located in the medial and lateral compartment. The spheres had a radius of 7.8 mm (20 pixels), with the centers located at 11.7 mm (30 pixels) below the tibial plateau (Fig. 2). No significant differences ($p=0.45$) were found in BMD between the tibiae used for the FlexitSystem and TomoFix reconstructions. The exact BMD values are given in Table 2. Specimen pair 1, in which a fracture occurred during implantation of the TomoFix implant, displayed the lowest BMD.

Figure 2 Bone mineral density measurements



Medial and lateral regions of interest defined for the bone mineral density measurements, as indicated on an X-ray (left) and the calibrated CT scan (right). Notice the calibration phantom located underneath the cadaveric specimen, with different levels of calcium-equivalent densities.

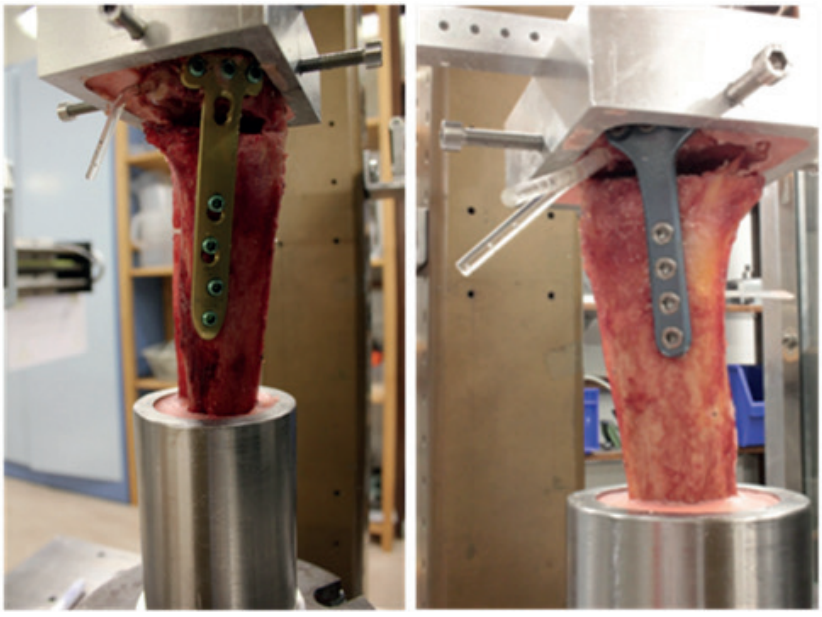
Table 2 Averaged bone mineral density in the tested specimens

Specimen	Sex	Age	BMD (mg/cm^3) FlexitSystem	BMD (mg/cm^3) TomoFix
1[a]	Female	83	51.07	18.25
2	Female	67	72.74	84.45
3	Female	78	85.52	115.04
4	Male	77	99.19	145.09
5	Male	70	152.83	129.04
6	Female	68	101.87	119.10
7	Male	70	126.59	139.28

[a] Fracture occurred during implantation, not included in experimental testing
BMD Bone mineral density

The cadavers were thawed over a time period of 24 hours and all soft tissue was removed. The OWO were performed by one orthopaedic surgeon. A Kirschner wire was inserted parallel to the joint space, ending just above the head of the fibula. Along this wire, a single-cut supra-tuberosity osteotomy was performed, leaving 10 mm of the lateral cortex intact, which was used as a hinge during the opening of the osteotomy. The gap was standardized at 10 mm by using a custom-made spacer that was used in combination with both implants. The implants were fixed on the medial side of the tibia and aligned with the tibial diaphysis to avoid anterior and cortical overhang. The proximal part was parallel to the medial tibial slope. The proximal screws were placed in the proximal tibia just above the osteotomy gap. First the proximal screw holes were drilled bicortical holding the implant in the correct position. The screw length was measured using the depth cauge. The correct size self-tapping locking screws were inserted. After that the four distal correct size self-tapping locking screws were placed bicortical. The osteotomies in the left tibiae were fixated with the FlexitSystem implant (Neosteo, Nantes, France), while in the right tibiae the TomoFix implant (TomoFix Osteotomy system, DePuy Synthes, West Chester, PA, USA) was used (Fig. 3).

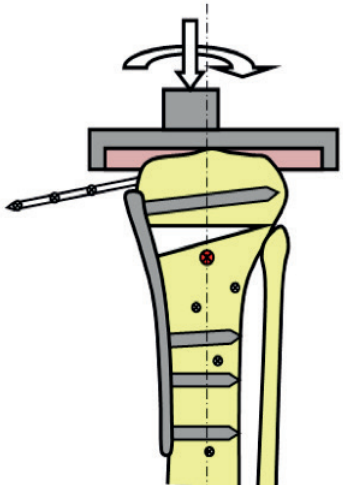
Figure 3 Tibial osteotomies with the implants



Tibial osteotomies with the TomoFix (left) and FlexitSystem (right) implants. Notice the plastic tracers attached to the proximal tibia, containing tantalum roentgen stereophotogrammetry analysis (RSA) markers.

After preparation of the osteotomy, the distal tibia was resected and potted using polymethylmethacrylate (PMMA), at a level of 30 mm distally to the lowest position of the TomoFix implant (the longest plate of the two systems). The contralateral tibiae with the FlexitSystem implants were resected at the same level (Fig. 3). Next, a custom load applicator was attached to the proximal tibia, which was aligned perpendicular to the long axis of the tibia using a goniometer. The load applicator was fixed using four screws, after which additional fixation was provided by potting the proximal tibiae using PMMA (Fig. 4). Care was taken that the osteotomy plates were not embedded in the cement. The custom load applicator was fixed perpendicularly to the tibial shaft.

Figure 4 Schematic representation of the experimental set-up



A load applicator (top part) was fixed to the proximal tibia using screws and bone cement (in pink). The crossed circles indicate locations of RSA markers. The red circle, located at the tibial tuberosity, indicates the origin of the coordinate system, around which all rotations and translations were calculated. Markers were attached to the proximal tibiae using a tracer (left).

Mechanical testing

The reconstructions were subjected to a loading regime representing the forces occurring during the toe-off phase of normal walking [19] (Table 3), which is the most frequent activity of daily living, and is therefore representative of one of the most frequent loading configurations that were applied to the reconstruction. During this phase, the axial force acting on the tibia is at its peak, but also substantial moments of force are acting, forcing abduction and external rotation of the tibia. The load applicator attached to the proximal tibia was specifically designed to apply this complex loading condition. It allowed loading at an offset of 8.7mm. For this purpose, the proximal tibia was placed in the applicator with the intercondylar eminence aligned with the center of the load applicator. The compressive force was applied through the linear actuator of the mechanical testing system (MTS Systems, Eden Prairie, MN, USA). An abduction moment was accounted for by applying the force medially from the center of the tibia. External torque was applied through a separate air power driven actuator, attached to a lever arm of the load applicator (Fig. 3). This actuator was synchronized with the linear actuator of the mechanical testing system, and cyclically activated in an alternating fashion. To simulate partial weight bearing of a patient immediately after surgery, the applied forces were scaled down to 50% [9] of the values as reported by Bergmann et al. [19]. The resulting loading configuration applied to the constructs is given in Table 3.

Table 3 Applied loading configuration

Loading profile	Standard (Bergmann et al. [4])	Partial weight bearing[b]
Compressive force ($-F_z$)	1950N	975N
Abduction moment ($-M_y$)	17Nm[a]	8.5Nm[a]
External torque ($-M_z$)	6.2Nm	3.1Nm

[a] Achieved by applying the compressive force 8.7mm medially from the centre of the tibial plateau
[b] Applied forces; 50% of the values as reported by Bergmann et al. [19]

The loading regime was applied for 50,000 cycles, at a frequency of 2 Hz (ca. 7 hours of testing), representing approximately 2-3 weeks of normal functioning after surgery [20]. A frequency of 2 Hz was chosen to prevent the formation of fatigue damage in the bone tissue [9].

After completion of this loading history, a displacement-controlled crush test was performed, at a speed of 5.0 mm/min [21]. The maximum load measured during this test served as a measure for the strength of the reconstruction.

The stability of the reconstruction was evaluated using roentgen stereophotogrammetry analysis (RSA). Six tantalum markers were attached to the proximal part of the osteotomy using plastic tracers, to ensure they were not obscured by the load applicator and osteotomy material (Fig. 4). Five additional markers were glued to the distal tibia, with a larger marker glued to the tibial tuberosity, which was taken as the reference of the RSA coordinate system. Hence, all translations and rotations were calculated with respect to this marker (Fig. 4). The initial stability of the osteotomy was measured by calculating the difference in migration between the proximal and distal tibia. RSA measurements were performed at the beginning of the experiment, and after 1,000, 10,000, 25,000 and 50,000 loading cycles. Considerable variation was seen in the results of the RSA measurements, expressing different modes of motions occurring in the reconstructions. These variations in motions complicated a straightforward quantitative comparison between the two osteotomy implants. In order to condense the data, we focused on a comparison of the total translations and principal rotations after 50,000 loading cycles, functioning as an indication of the final stability of the two systems. The total translation after 50,000 loading cycles was calculated as the root of the sum of the squared translations in the three orthogonal directions (Pythagorean theorem). Similarly, the resultant of the three rotations was based on Euler's rotation theorem. In accordance with this theorem, a resulting axis of rotation was determined, representing the complex 3D rotation as a unit vector and a single angle, representing the total amount of rotation occurring in the system.

Statistical analysis

The aim of our analysis was to show that the FlexitSystem was 'not unacceptably worse' (i.e. non-inferior) than the TomoFix. The sample size calculation was based on a mean failure force of 2900N with a standard deviation (SD) of 300N, based on a study of Stoffel et al. [11]. We estimated the non-inferior limit to be 300N. To show non-inferiority of the FlexitSystem versus the TomoFix with an α of 0.05 and a power of 80%, 6 cadaveric tibiae in each group were needed. To account for possible experimental failures, in each group 1 tibia was added to the sample size, resulting in 7 cadaveric tibiae per group.

Translations, rotations and compressive strength of the two systems were compared using paired t-tests. In cases the data were not normally distributed Wilcoxon Signed Rank tests were performed. P-values $p<0.05$ were considered statistically significant.

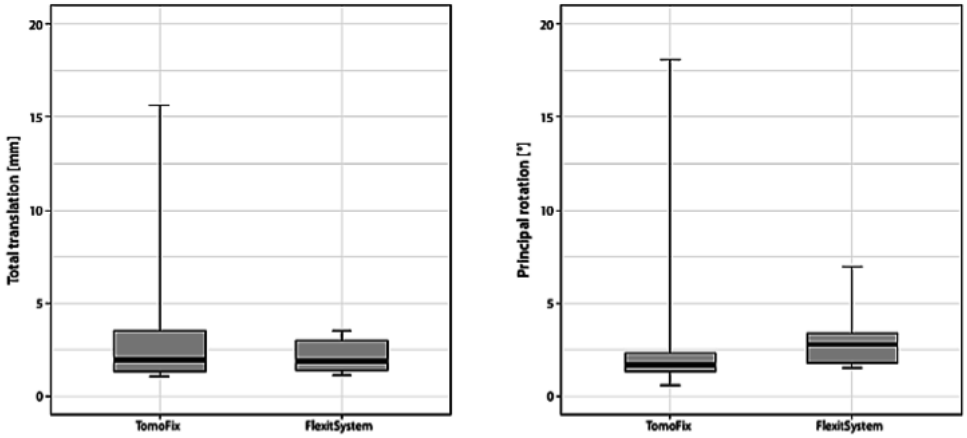
Results

During preparation of the osteotomies, a fracture occurred in one tibia (female, 83 years) while preparing for the TomoFix implant. Although it was possible to implant the FlexitSystem plate in the contralateral tibia, this pair of tibiae was excluded from further analyses, except for BMD analysis, leaving six paired tibiae for mechanical testing.

RSA measurements

The overall stability (e.g. the total translations and principal rotations) after 50,000 loading cycles, of the two systems are shown in Fig. 5. Statistical evaluation indicated that translations and rotations were not normally distributed. The FlexitSystem implant displayed a similar stability compared to the TomoFix implant, with median translations of 1.89 mm (range 1.10 to 3.53 mm) vs. 1.95 mm (range 1.07 to 15.65 mm) and rotations 2.77 ° (range 1.50 to 7.00 °) vs. 1.69 ° (range 0.61 to 18.09 °). Wilcoxon Signed Rank tests demonstrated no significant differences between the total translations and principal rotations ($p=1.0$ and $p=0.44$, respectively).

Figure 5 Average of the total translation and principal rotation

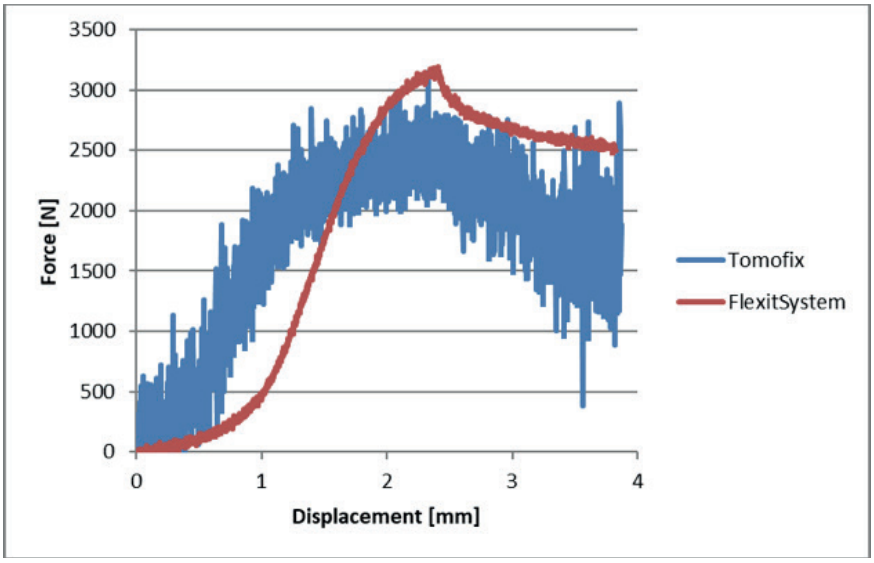


Average of the total translation (left) and principal rotation (right) after 50,000 loading cycles

Compressive test to failure

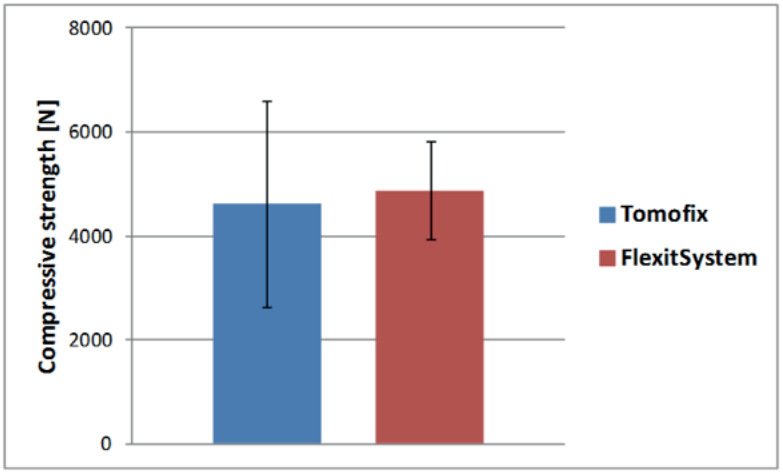
During the compressive test to failure, either a sharp change in the force was seen, or the force gradually reduced after reaching a maximum value (Fig. 6). The strength values had a normal distribution; no significant differences were found between the FlexitSystem and TomoFix reconstructions (mean 4,867±944N vs. 4,628±1,987N; (p=0.71)). The variation in strength was lower for the FlexitSystem reconstructions than for the TomoFix reconstructions (Fig. 7). No correlation (r=0.53, p=0.08) was found between compressive strength and BMD, with compressive strength increasing with increasing BMD.

Figure 6 Example results of a compressive failure test (specimen 5)



Both systems had reconstructions that caused a reaction force displaying a sharp peak (TomoFix in this particular case), and specimens that displayed a gradual decrease in reaction force after reaching a maximum (FlexitSystem in this particular case).

Figure 7 Compressive strength of the reconstructions with the TomoFix and FlexitSystem implants

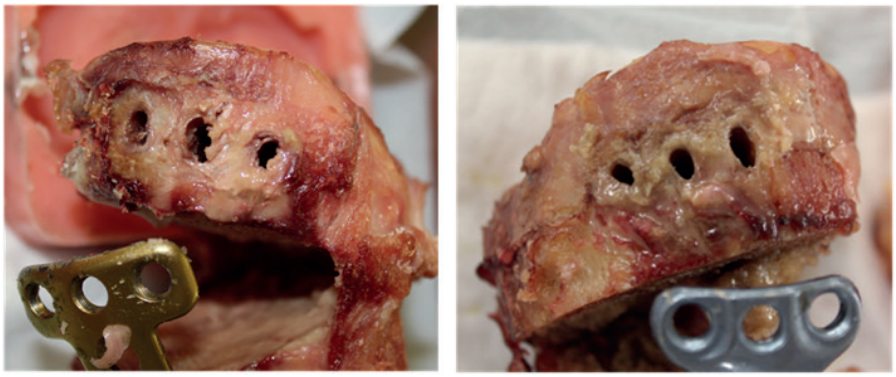


The FlexitSystem implants had a slightly higher compressive strength, which was not significant.

Post-failure analyses

Radiographs of the reconstructions after the destructive test indicated that for both systems no damage occurred to the implants or screws. After removal of the plates, the screw holes in the proximal tibia appeared to be oval-shaped, suggesting a collapse of the proximal tibial bone, possibly due to fracturing of the lateral cortex, as the origin of failure of the reconstructions (Fig. 8).

Figure 8 Post-failure analyses, after removal of the proximal screws



Removal of the proximal screws revealed oval-shaped screw holes in the proximal tibiae, both for the TomoFix (left) and FlexitSystem (right) reconstructions, suggesting collapse of the proximal tibiae as a mode of failure during the destructive tests.

Discussion

The results of the experiments showed that the FlexitSystem implant has a stability comparable to the TomoFix implant, which has a well-reported clinical and biomechanical track record. Open wedge high tibial osteotomy has been associated with high non-union rates and loss of correction due to unstable fixation [6,7]. Therefore sufficient strength of the implants is very important. The FlexitSystem implant displayed translations lower than 5 mm and rotations lower than 5°. The strength of the FlexitSystem reconstructions was slightly higher compared to the TomoFix reconstructions, although this difference was not statistically significant.

As this is a novel implant, no previous studies comparing the FlexitSystem to other implants have been performed. The strength of the reconstructions as found in the current study in general is slightly higher than published in the literature. Agneskirchner et al. [9] reported a strength of 3,069N for a reconstruction with a TomoFix implant in Sawbones. Stoffel et al. [11] compared the Puddu plate (modified Arthrex Osteotomy Plate) to the TomoFix plate, also in synthetic tibiae. Failure occurred after axial compression loading at a mean load of 2,537N (Puddu plate) and 2,904N (TomoFix plate). The TomoFix plate was also compared to the Aescular Plate and Puddu Plate by Kim et al. [10]. The maximal loads at failure were 6,793.8±499.8N, 6,055.1±1184.7N and 6,798.2±988.7N, respectively. They used porcine bone and considered only axial loading, both could explain the higher maximal loads compared to our study. Evidently, there are differences between all these studies in terms of the type of bone used (synthetic or cadaveric, human or porcine), surgical approach (single- or bi-planar cuts), loading history and brand and type of implants.

We found no differences in the magnitude of the failure load and failure mechanism between the two implants. Post-failure analysis showed oval-shaped screw holes, due to a collapse of the proximal tibial bone. This suggests compressive failure of the lateral tibia and fracturing of the trabecular bone surrounding the screws as the origin of failure of the reconstructions. Fracturing of the lateral cortex as construct's failure is also seen in the literature [9, 11, 22]. An intact lateral cortex is important for the stability of the osteotomy [23]. Our results suggest that with an intact lateral cortex, partial axial loading postoperative in both implants, could be tolerated.

When evaluating the biomechanical functionality of implants for OWO, obviously, the choice of the base material affects the outcome of the investigation. The main advantage of using synthetic tibiae is that it minimizes the inter-specimen variability, making the results more reproducible [24, 25]. Synthetic bones are designed such that they reproduce the structural biomechanical response of the bone, such as the global stiffness of the bone. A drawback

of using such a material is that, although the global biomechanics are well-represented, the local interaction between the screw and the bone is not. Hence, testing with actual human cadaveric tissue therefore may provide additional insights into the actual failure mechanisms that otherwise would have been missed. Moreover it provides more information about the relation between strength of the reconstruction and bone quality. In the current experiments, the strength of the reconstructions with both implants decreased with BMD, suggesting that patient selection is important for the procedure, with a preference for younger, active patients with an adequate bone stock, in line with previous reports [4].

Some limitations of our study should be discussed. First, the use of cadaveric tissue over synthetic tibiae could reduce the reproducibility [24, 25]. To minimize the effect of inter-specimen variation on the comparison between the implants, a paired study was performed comparing the left and right tibiae. Nonetheless, a significant amount of variation in translations and rotations was seen, of which the patterns could not be explained easily based on the local CT-based BMD measurements. Second, in the current study the fourth proximal screw for the TomoFix system was not used, as it lines up with the osteotomy gap. In the current study, supra-tuberosity osteotomies with a single cut were created using both systems. The biplanar cut technique allows for the use of the fourth screw. The biplanar cut and the additional screw for the TomoFix system may increase the initial stability of the osteotomy. From that point of view, one can consider the current experiments to represent a worst case scenario for the Tomofix implant. One could argue that, as the FlexitSystem implant does not facilitate a fourth proximal screw, the approach adopted in the current study provided a fairer comparison of the two systems. Moreover, as the post-failure analyses of the failure mechanisms indicated that the trabecular bone was crushed through the screws, rather than damage occurring to the screws or the connection between screws and implants, it is debatable whether the addition of the fourth screw would have provided a significant increase to the strength of the reconstruction. Third, the loading condition reported by Bergmann et al. [19], which evaluated the simulated loads during daily activities in patients with TKA, were used. Obviously, there still are substantial differences between an intact and a TKA reconstructed knee joint, but we tried to incorporate out-of-plane loads to apply a more rigorous loading regime, which may be more demanding on the osteotomy reconstruction compared with other experiments described in the literature [9-11]. Due to the pre-operative condition of the osteotomy patients the medial compartment will be off-loaded after the osteotomy, restoring a more natural alignment. We aimed at representing loads occurring during such an alignment by adopting loads of reconstructed patients. Moreover, by increasing the wedge in an OWO the loads may indeed be shifted further to the lateral compartment, which may be different from the loading configuration adopted here.

In conclusion, from a biomechanical point of view, the FlexitSystem implant behaves similarly to the TomoFix implant. Both systems can be used to fixate a high tibial open wedge osteotomy.

Compliance with ethical standards

Conflict of Interest

The authors declare that they have no competing interests.

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CHAPTER 6

Clinical study of the novel FlexitSystem implant for high tibial open wedge osteotomy

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Abstract

Purpose The FlexitSystem implant is a novel implant used in open wedge high tibial osteotomy.
Methods A clinical safety study was performed. Retrospectively 50 patients were analyzed who were treated with an open wedge high tibial osteotomy and the new FlexitSystem implant, with a minimal follow-up of one year. Complication rate, radiographic outcomes and implant removal were investigated.
Results One patient underwent a revision surgery because of loss of correction and non-union. The complication rate was 10.0%. No other radiographic complications (screw breakage, implant failure) were found. In 24 patients (48%) the FlexitSystem implant was removed at a mean follow-up of 12.6 months (range 2.6 till 24.0 months). The mean reason was irritation of the implant.
Conclusions The FlexitSystem implant is a clinical safe and stable implant for an open wedge high tibial osteotomy, with a low complication rate. The rate of implant irritation requiring removal remained high.

Level of Evidence III

Keywords Open wedge high tibial osteotomy, FlexitSystem implant

Introduction

Patients with knee osteoarthritis (OA) of the medial compartment often present with varus leg alignment which causes an overload of the medial compartment. Malalignment increases the risk for progression of knee OA and is associated with a decline in physical function and progression of pain (2,29). In order to unload the medial compartment, a valgus high tibial osteotomy is the treatment of choice for the young and active patient (5,14,16,24).
The most commonly used techniques include closed-wedge osteotomy (CWO) and open-wedge osteotomy (OWO) (4,19,36). The disadvantages of a CWO are the need for a fibular osteotomy, the high rate of tibial neuropathies, bone stock loss, and a potentially more demanding subsequent total knee arthroplasty (4,19,21). On the other hand, OWO has been associated with high non-union rates and loss of correction due to unstable fixation (19,21). Therefore, fixation strength and maintenance of stability until osseous consolidation is obtained are a prerequisite of the implants used in OWO (20). Several implants have been designed for OWO (1,17,20,34). The TomoFix implant (DePuy Synthes Trauma, West Chester, USA) is widely used because of a well-reported clinical (4,9,15) and biomechanical (1,27,33) track record. The TomoFix implant is a long and rigid titanium plate with locking screws, functioning as an internal fixator (20). Due to its size, the disadvantages of this implant have been reported to be local irritation and wound healing issues (24,25,35,39). Therefore, implant removal after surgery is often needed (39). The FlexitSystem implant (Neosteo, Nantes, France (Fig. 1)) is a novel implant to be used in case of an OWO. The FlexitSystem implant is shorter and thinner compared to the TomoFix implant. To compensate for the smaller dimensions, a different grade titanium alloy (stiffer and stronger) is used for the FlexitSystem. The potential benefit of the implant is that, due to its smaller dimensions, patients may experience less discomfort from the plate, which may eliminate the necessity of implant removal after surgery. A potential concern is that the smaller dimensions of the implant may affect the primary stability of the reconstruction.

Figure 1 FlexitSystem implant

A FlexitSystem implant
B 3 plate sizes; 4-, 6,- and 7-holes plate

Recently an experimental test was performed to evaluate the initial stability of the FlexitSystem implant. The tests were performed in cadaveric tibiae, with the TomoFix implant serving as a base for comparison (37). The current results in this experimental study showed that there were no differences between the two implants and from a biomechanical point of view, the FlexitSystem implant is a suitable alternative to the TomoFix implant for OWO. In this study the clinical outcomes of this new implant, the FlexitSystem implant, were analyzed. Our primary objective was to investigate the complication rate, union outcomes and incidence of implant removal with a minimal one year follow-up in 50 patients who were treated with an OWO and the new FlexitSystem implant. Our hypothesis was that this is a safe and stable implant to be used in patients who underwent an OWO.

Material and methods

Study design

This retrospective follow-up study was performed between June 2016 and October 2016. Fifty patients with medial knee OA and a varus leg alignment, who were treated between March 2013 and October 2015 with an OWO and FlexitSystem implant in Hospital Gelderse Vallei Ede, the Netherlands were included in this study. Informed consent was obtained. There were no exclusion criteria. Approval of the Medical Ethics Committee (Hospital Gelderse Vallei Ede, the Netherlands, ID-number BC/1603-157) was obtained.

Surgical technique

All operations were performed in a standardized manner. There are three different sizes of the standard FlexitSystem implant (4,- 6,- and 7-holes) (Fig. 1B). In most of the patients a 6-holes plate (80.0%) was used. A 4-holes plate was used in 4 patients (8.0%) and a 7-holes plate in 5 patients (10.0%). A 10-holes plate (5 screws proximal and 5 screws distal) was used in one patient (2.0%), because of stock problems (standard plate was not available). In 48 (96.0%) patients a wedge (Tricalcium phosphate or hydroxy apatite) was used and in 2 (4.0%) patients no wedge was used. A wedge was standard used in this hospital and independent of the amount of correction. The mean degrees of correction was 7.9 (range 5.0-12.0) All patients received antibiotic prophylaxis preoperatively (Cefazoline 2 gram intravenous), except for three patients. Postoperative antithrombotic therapy for 6 weeks (Nadropin 0.3 milliliters) was given. All patients received physiotherapy. Mobilization started on the first postoperative day with partial weight bearing (touch toe weight bearing) with crutches and full range of motion exercises for six weeks.

Outcome measurements

Baseline patient parameters (age, gender, height, length, BMI, side of the operation, smoking, general prehistory, previous operations at the same leg) were obtained. Clinical outcomes were evaluated by analyzing medical files. The complications registered were wound complications, infection, non-union, loss of obtained correction and other complications. Hardware removal and reason for removal were also analyzed. Radiographic evaluation parameters were implant failure and loss of correction.

Results

Baseline patient parameters are shown in Table 1.

Table 1 Baseline Parameters

Parameters	Total group (50 patients)
Gender (m/v)[1]	28/22 (56.0/44.0)
Age (yr)[2]	57.4 (37.2-73.7)
Height (cm)[2]	175 (155.0-196.0)
Weight (kg)[2]	91.3 (58.0-159.0)
BMI (kg/m^2)[2]	29.7 (21.8-41.8)
Side (L/R)[1,a]	26/24 (52.0/48.0)
Prehistory (N)	
- **Hypertension**	22
- **Diabetes Mellitus**	5
- **Cardial history**	6
- **DVT**	1
- **Astma/COPD**	2
- **THA**	2
- **HTO (controlateral)**	2
- **Spine problems**	11
- **Proximal Tibial Fracture (ipsilateral)**	2
- **Other**	2
Previos surgery ipsilateral leg (N)	
- **Arthroscopy ± partial lateral or medial**	30
meniscectomy	1
- **Arthroscopy + ACL repair**	1
- **Open (partial) meniscectomy**	1
- **Other**	
Smoking (N)	8

Yr years, *cm* centimeter, *kg* kilograms, *L/R* Left/Right, *N* Number, *DVT* Deep venous thrombosis, *COPD* Chronic Obstructive Pulmonary Disease, *THA* Total Hip Arthroplasty, *HTO* High Tibial Osteotomy, *ACL* Anterior Cruciate Ligament

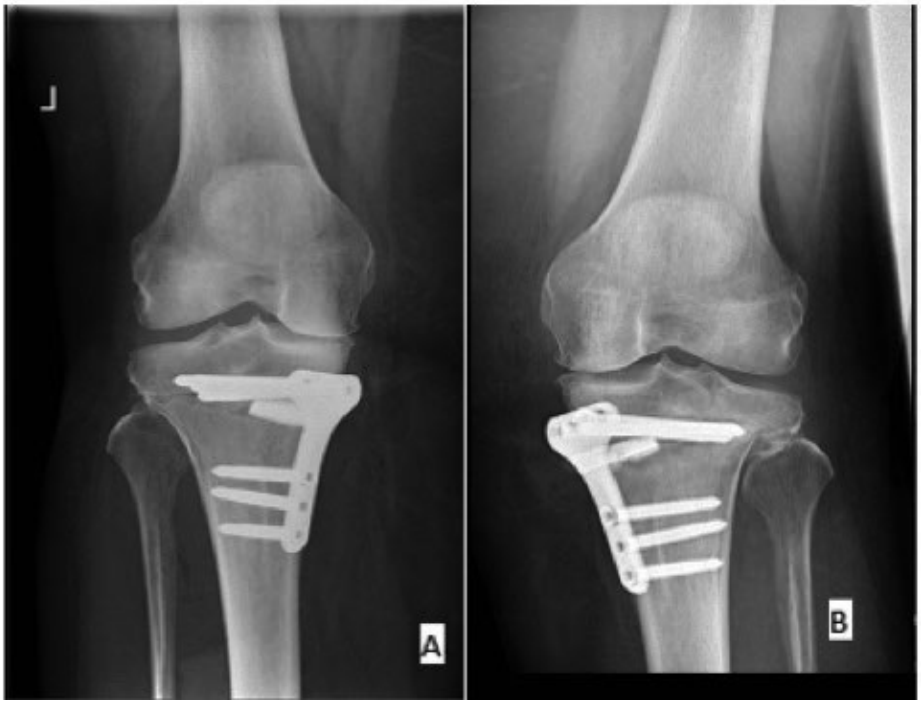
[1] Number (%)

[2] Mean (range)

[a] 5 bilateral

Mean follow-up was 28.4 months (range 12.3 till 39.8 months). Mean correction angle was 8.0° (range 5° till 12°). There was one revision (2.0%), due to loss of correction and non-union. This was treated with a bone graft and a new FlexitSystem implant after 2.6 months (Figure 2). No other radiographic complications (screw breakage, implant failure) were found. All complications are shown in Table 2. In 23 patients (46.0%) the FlexitSystem implant was removed at a mean follow-up of 12.6 months (range 2.6 till 24.0 months) (Table 3). No patient needed conversion to a total knee arthroplasty.

Figure 2 Revision case



A Direct postoperative Xray. Notice the position of the screws and the lateral cortex fracture
B 2.6 months postoperative Xray. Loss of correction

Table 2 Complications and treatment

Complications	Treatment	Outcomes (Number of patients (%))
Infection		
***Deep (late, posttraumatic)**	Removal FlexitSystem implant, debridement and oral antibiotics	1 (2.0)
***Superficial**	Oral antibiotics	2 (4.0)
Lateral Cortex Fracture	Expectative	1 (2.0)
	Revision[1]	1 (2.0)
Loss of correction	Revision[1]	1 (2.0)
Woundhealing disorder	Expectative	1 (2.0)
Haematoma	Operative debridement	1 (2.0)

[1] Same patient

Table 3 Osteosynthesis removal

Reason of osteosynthesis removal	Number of patients (%)
Irritation	19 (38.0)
Deep late posttraumatic infection	1 (2.0)
Revision	1 (2.0)
No reason known	3 (6.0)

Discussion

The most important finding of our study is that the novel FlexitSystem implant is a safe implant to be used in an open wedge osteotomy.
In our study, only one revision (2.0%) was needed due to loss of correction and non-union. This is comparable to the TomoFix implant (3.6 to 5.4%) (22,39). Non-union rates requiring revision for other implants are between 0.0 to 4.3% (3,10,13). In a previous experimental study the initial stability of the FlexitSystem implant was investigated, compared to the TomoFix implant (37). In that study it was concluded, that from a biomechanical point of view, the FlexitSystem implant is a suitable alternative to the TomoFix implant for OWO (37). The clinical results found in the current study confirmed this conclusion. Also, no screw breakage and plate breakage were found. This is comparable to the TomoFix implant (0.0-0.5%) (22,39) and superior to other implants (2.2 to 22.9%) (6,18,32). If this revision case was looked in further detail, a peroperative unnoticed lateral cortex fracture was noticed. Also the location of the screws was partial in the osteotomy gap. This suboptimal surgical technique contributed to the failure mechanism.
Two (4.0%) lateral cortex fractures were found postoperative. In the literature lateral cortex fractures were reported with frequencies between 0.3 to 34.0% (3,7,12,26,31,34,38). In lateral cortex fractures, sufficient fixation is needed to maintain alignment and union of the osteotomy. The TomoFix implant creates immediate stability in case of a lateral cortex fracture (7,33). Although one revision was needed in a patient with a lateral cortex fracture, the position of the screws was suboptimal, which is more likely to contribute to the failure mechanism. In the other patient with a lateral cortex fracture no non-union was found, nor was a revision required.
A postoperative complication rate of only 10.0% (excluding revision and osteosynthesis removal) was noted. The complications registered, were two superficial infections (4.0%), one woundhealing disorder (2.0%) and one large haematoma (2.0%). The infection rate is comparable to the TomoFix implant (0.5 to 10.8%) (22,34,39) and other implants (0.0-10%) (3,6,8,10,11,13,18,31,32). The superficial infections were successfully treated with oral antibiotics, and did not require in-hospital treatment.
No deep venous thrombosis, deep postoperative infection or other more severe complications (e.g. compartment syndrome, vascular injury) were found in our study. Severe complications after an OWO are rare, being less than 2% in the literature (39).
In our study, the FlexitSystem implant was removed in 48% of the patients, mostly due to irritation (79%). In the literature percentages between 0 to 23% implant irritation requiring plate removal are reported (3,8,10,23,28,30,34,38,39). These outcomes are superior compared

to ours. Implant removal due to irritation in 38% of the patients was found. No clear explanation for the high percentage could be found. This study was a single centre study and in this hospital the indication for implant removal was knocking pain over the plate. It could be that the indication for implant removal was more surgeon driven then patient driven. Another option could be that the FlexitSystem implant caused more irritation compared to other implants. This is however not obvious, as the FlexitSystem implant is thinner (2.8 mm plate thickness) compared to the TomoFix implant.

Some limitations of this study should be discussed. First, this study is a single centre retrospective study. A randomized clinical trial comparing the TomoFix implant with the FlexitSystem implant would be ideal. Second, 6 different surgeons performed the operations. This could contribute to heterogeneity of the results, although the different surgeons performed the OWO in a standardized manner. Third, the patient related outcomes measurements (PROMS) were not investigated. This study focused on the clinical outcomes of the implant and not on the outcomes of a OWO, which is already proven in the literature (4,14,16,19,21,36).

Conclusions

The FlexitSystem implant is a safe and stable implant for an open wedge high tibial osteotomy. The complication rate was low. The rate of implant irritation requiring removal remained high.

Competing interest

Conflict of Interest

The authors declare that they have no competing interests.

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CHAPTER 7

Better clinical results after closed,- compared to open- wedge high tibial osteotomy in patients with medial knee osteoarthritis and varus leg alignment

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Abstract

Purpose Studies comparing mid- or long-term outcomes of open- and closed-wedge high tibial osteotomy are limited. Here, the midterm survival rate and clinical and radiographic outcomes were compared for these two techniques. The study hypothesis, based on short-term follow-up, was that after midterm follow-up, the two techniques would not differ.

Methods A prospective follow-up study was conducted for a previously reported randomized controlled trial of an original 50 patients (25 open-wedge osteotomy and 25 closed-wedge osteotomy) with medial knee osteoarthritis and a varus leg alignment. We analyzed patients without knee arthroplasty (mean age 48.7 years, SD 8.0) for clinical and radiographic follow-up.

Results Five patients in each group had undergone conversion to a total knee arthroplasty or unicompartmental knee arthroplasty, leaving 19 patients for analysis in each group. At 7.9 years of follow-up (range 7–9 years), survival did not differ significantly between groups (open-wedge group 81.3 % [95 % confidence interval (CI) 75.2–100], closed-wedge group 82.0 % [95 % CI 66.7–100]). At final follow-up, total Dutch Western Ontario and McMaster Universities Arthritis (WOMAC), Knee Society Score, and visual analog scale (VAS) pain did not differ between groups. However, the results were significantly better in the closed-wedge group for VAS satisfaction and WOMAC pain and stiffness compared to the open-wedge group. Radiographic evaluation did not differ between groups for any outcome at final follow-up.

Conclusions After a mean follow-up of 7.9 years, patients undergoing a closed-wedge osteotomy had favorable clinical results compared to those who underwent an open wedge osteotomy.

Level of evidence II

Keywords Open-wedge high tibial osteotomy, Closed-wedge high tibial osteotomy, Osteoarthritis, Knee, RCT

Introduction

High tibial osteotomy is performed to stop or inhibit progression of osteoarthritis (OA) of the knee joint and to avoid or postpone placement of a knee arthroplasty in patients with medial knee OA. In several studies, different techniques have been evaluated, each with their own advantages, disadvantages, and complications [8, 19, 21, 29]. The techniques most commonly used include closed-wedge osteotomy (CWO) and open-wedge osteotomy (OWO), stabilized by a locking plate [19, 21]. Long-term (10–20 years) survival of CWO is well documented in the literature, varying between 74 and 97.6 % after 10 years [1, 9, 16, 30, 32], 56–93.2 % at 15 years [1, 9, 16, 30, 32], and 66.9–85.1 % at 20 years [9, 32]. The survival rates of OWO are not as well documented, but are reported to be between 88.9 and 97 % at 5 years [3, 26, 31] and 74–89 % at 10 years [5, 26]. For both techniques, good clinical and radiographic results are described [5, 12, 13, 16, 23, 26, 32]. Disadvantages of CWO include the need for a fibular osteotomy, the high rate of tibial neuropathies, bone stock loss, and a more demanding subsequent total knee arthroplasty [19, 21]. OWO has been associated with high nonunion rates, donor site morbidity (if an autograft is used), loss of correction due to unstable fixation, and increased posterior tibial slope [19, 21].

OWO has gained popularity in recent years, but direct comparisons of the two techniques are rare, and mid- and long-term comparisons are almost completely lacking [11, 27]. Because a valgus osteotomy is still an important treatment option for patients with medial knee OA and a varus leg alignment, knowing which technique is superior is relevant. To address these gaps in the literature, this study was conducted as an update of a previous report after a mean follow-up of 7.9 years (range 7–9 years). The current work involved analysis of differences in survival and clinical and radiographic outcomes between patients with medial knee OA and a varus leg alignment who were treated with an open- or a closed-wedge high tibial osteotomy. The study hypothesis, based on short-term follow-up findings, was that after midterm follow-up, the outcomes for the two techniques would not differ.

Materials and Methods

This prospective follow-up study was carried out between March 2012 and January 2013. All patients without a knee arthroplasty who participated in the previous randomized controlled trial [11] (2002/181) were invited to visit one of two orthopedic outpatient clinics (Rijnstate Hospital in Arnhem and Radboud University Medical Centre in Nijmegen, the Netherlands) once for questionnaires, physical examination, and radiographs of the knee and of the whole leg. Informed consent was obtained.

The initial inclusion criteria were radiological evidence of medial gonarthrosis, age 18–70 years, and having a hip–knee–ankle varus alignment. Exclusion criteria were rheumatoid arthritis and previous osteotomy of the same knee. Initially, 50 patients (50 knees) were included, between January 2003 and March 2005, and allocated to the medial OWO group (25 patients) or the lateral CWO group (25 patients) using a randomization procedure with sealed opaque envelopes. A four-hole angle stable plate (Numelock II System, Stryker, Switzerland) and screws were used as fixation devices. In the OWO group, an appropriate tricalcium-phosphate (TCP) wedge (Otis, Lourdes, France) was used as a defect filler. In keeping with a standardized operation technique, a TCP wedge was used in all OWO. The preoperative goal of correction was an overcorrection of 4° of the mechanical femur–tibial axis. The surgical techniques have been described in a previous report of Gaasbeek et al. [11].

The survival rate at mean final follow-up was determined based on conversion or not to total knee arthroplasty (TKA) or unicompartmental knee arthroplasty (UKA). The clinical evaluation consisted of the Knee Society Score (KSS) [14], visual analog scale (VAS) for pain and satisfaction, and the Dutch Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) [24]. The KSS [14] assesses pain, range of movement, stability, and ability to walk and climb stairs, with 200 points representing the best possible function. A VAS for pain and satisfaction is a 0–10-point scale to assess pain and satisfaction. In VAS pain, 0 indicates no pain, and 10 is the worst pain the patient can imagine. A VAS satisfaction score of 0 is the lowest score (unsatisfied), and 10 is the highest score (very satisfied). The WOMAC [24] is a disease-specific questionnaire, divided into five questions about pain, two about stiffness, and 17 about function. Scores from 0 to 96 are possible. The optimum score is zero.

In the preoperative period, at 1 year of follow-up, and at final follow-up, radiographs were made of the whole leg (double-limb stance, hip-to-ankle) and the knee (weight-bearing anteroposterior and true lateral views at 30° of flexion). One investigator (NvE) performed the measurements. The radiographic evaluation consisted of grading the severity of OA of the knee, using the Kellgren and Lawrence system [15]. The patellar height was measured according to Caton Deschamps index (CI) [4]. The tibial slope was calculated as the angle

determined between the tibial anatomical axis and the tangent to the medial plate [18]. Furthermore, the mechanical axis was measured following the method described by Dugdale et al. [6], in which the angle is calculated between the weight-bearing line (drawn from the center of the femoral head to the center of the tibiotalar joint) and a line drawn from the center of the knee to the center of the ankle.
Approval of the Medical Ethics Committee (Radboud University Medical Centre Nijmegen, ID-number 2011/531) was obtained.

Statistical analysis

Total test scores for continuous and categorical variables (hip–knee angle, WOMAC, KSS, VAS pain, VAS satisfaction, CI, tibial slope, OA severity) at baseline and after 1 year of follow-up from the study by Gaasbeek et al. [11] were used in the current analyses. Total test scores [mean or median, standard deviation (SD) or range, frequencies or percentages] for the same continuous and categorical variables were calculated for both groups at mean final follow-up. To assess normality, we used the Kolmogorov–Smirnov and Shapiro–Wilk tests. The Levene test was used to check the assumption of equal group variance.
The Student's t test or Mann–Whitney U test was used to analyze differences in continuous data at final follow-up between treatment groups. The Fisher's exact test or chi-squared test was used in case of categorical variables. A $P < 0.05$ was considered significant. Survivorship analysis was performed using the Kaplan–Meier method with conversion to TKA or UKA as the end point at 5 years and at final follow-up [percentage and 95 % confidence interval (95 % CI)]. Differences between the two treatment groups were calculated with a log-rank test. All data were analyzed with SPSS version 18.0 (SPSS Benelux BV, IBM Company Nieuwegein, The Netherlands).
In the initial report [11], a sample size was calculated based on an expected 30 % difference in the ratio of lateral ligament instability between the two groups. To detect such a difference with $\alpha = 0.05$ and a power of 80 %, 25 patients were required in each group.

Results

Demographic and baseline parameters of the 50 included patients (25 CWO and 25 OWO) are shown in Tables 1 and 2. The results at 1 year of follow-up are shown in Table 3 [11].

Table 1 Demographic parameters

Parameter	Open wedge osteotomy (n=25)	Closed wedge osteotomy (n=25)	Total group (n=50)	*P* value
Male/female (n)	15/10	16/9	31/19	n.s.[c]
Age (y)[a]	47.1 (8.5)	50.3 (7.4)	48.7 (8.0)	n.s.[b]
Side L/R (n)	16/9	8/17	24/26	n.s.[c]
Location Rijnstate/ Radboud (n)	17/8	19/6	36/14	p=0.022
BMI (kg/m2)[a]	29.7 (4.2)	28.4 (3.0)	29.0 (3.7)	n.s.[b]

BMI body mass index, *n* number, *n.s.* non significant
[a] Values given as mean (standard deviation)
[b] Student's t-test
[c] Chi-Squared test
Gaasbeek et al [11]

Table 2 Baseline parameters

Parameter	Open wedge osteotomy (n=25)	Closed wedge osteotomy (n=25)	Total group (n=50)	*P* value
HKA (°)[a]	4.3 (2.2)	4.1 (2.2)	4.2 (2.2)	n.s.[b]
WOMAC (0–96)[a]	52.0 (18.6)	46.5 (14.9)	49.2 (16.9)	n.s.[b]
KSS (0–200)[a]	111.7 (24.1)	113.6 (15.9)	112.6 (20.2)	n.s.[b]
VAS pain (0–10)[a]	6.6 (1.7)	6.4 (1.3)	6.5 (1.5)	n.s.[b]
VAS satisfaction (0–10)[a]	2.3 (1.8)	2.8 (1.8)	2.6 (1.8)	n.s.[b]
OA classification (n)	I: 8 II: 9 III: 7 IV: 1	I: 11 II: 12 III: 1 IV: 1	I: 19 II: 21 III: 8 IV: 2	n.s.[c]
CI[a]	1.0 (0.2)	1.0 (0.2)	1.0 (0.2)	n.s.[b]
Tibial Slope (^{0})[a]	16.2 (2.7)	14.6 (3.6)	15.4 (3.2)	n.s.[b]

HKA Hip-knee-ankle, *WOMAC* Western Ontario and McMaster University osteoarthritis index, *KSS* Knee Society Score, *VAS* Visual Analogue Scale, *OA* Osteoarthritis Classification Kellgren and Lawrence, *CI* Caton index, *n* number, *n.s.* non significant
[a] Values given as mean (standard deviation)
[b] Student's t-test
[c] Fischer's exact test
Gaasbeek et al [11]

Table 3 Results at one year follow-up

Parameter	Open wedge osteotomy (n=25)	Closed wedge osteotomy (n=25)	Total group (n=50)	Mean Difference (95% CI)	*P* value
HKA (°)	3.6 (1.6)[a]	3.9 (2.0)[a]	3.8 (0.6-7.4)[b]	0.4 (-1.4; 0.7)	n.s.[c]
Correction angle HKA preop and 1yr (°)	7.8 (2.6)[a]	8.0 (2.7)[a]	7.9 (2.6)[a]	0.2 (-1.7; 1.3)	n.s.[c]
WOMAC (0-96)	20.0 (19.4)[a]	14.0 (0-48)[b]	13.5 (0-70)[b]	4.0 (-5.9; 13.9)	n.s.[c]
KSS (0-200)	182 (140-200)[b]	185 (130-200)[b]	185 (130-200)[b]	3.6 (-16.6; 9.4)	n.s.[d]
VAS pain (0-10)	2.5 (1.9)[a]	1.8 (1.5)[a]	2 (0-7)[b]	0.6 (-0.4; 1.6)	n.s.[c]
VAS satisfaction (0-10)	8.5 (3-10)[b]	9.1 (6-10)[b]	8.8 (3-10)[b]	0.9 (-1.8; 0.1)	n.s.[d]
CI	0.9 (0.6-1.3)[b]	1.0 (0.2)[a]	0.9 (0.6-1.3)[b]	0.2 (-0.3;-0.1)	<0.001[c]
Tibial slope	16.3 (2.6)[a]	13.7 (3.9)[a]	15.0 (3.5)[a]	2.6 (0.7; 4.5)	0.009[c]

HKA Hip-knee-ankle, *WOMAC* Western Ontario and McMaster University osteoarthritis index
KSS Knee Society Score, *VAS* Visual Analogue Scale, *CI* Caton index, *yr* year, *n* number, *preop* preoperative, *n.s.* non significant, *CI* confindence interval
[a] Values given as mean (standard deviation)
[b] Values given as median (range)
[c] Student's t-test
[d] Mann-Whitney U test
Gaasbeek et al [11]

Two patients were lost to follow-up because of emigration. A total of nine patients (five OWO, four CWO) were converted to a TKA, and one patient received a UKA (one CWO) before final follow-up, leaving 19 patients in each group for clinical and radiographic analysis. Four patients refused to travel to the outpatient clinics because of distance, and their physical examination (knee score of the KSS) could not be analyzed at final follow-up for this reason. All other questionnaires were sent to these four patients and returned completed. One other patient was not able to complete the WOMAC at final follow-up because of dementia. The median time to follow-up was 8.0 years (range 7–9 years).

Clinical outcomes

At final follow-up, the total WOMAC, KSS, and VAS pain scores were better in the CWO group compared to the OWO group, although the differences were not significant. Patients in the CWO group, however, reported significantly less WOMAC pain and WOMAC stiffness compared with the OWO group at the last follow-up (P = 0.025 and P = 0.036, respectively). Furthermore, patients in the CWO group were significantly more satisfied than in the OWO group (VAS satisfaction, mean 8.1 vs. 6.1, P = 0.017) at the final follow-up. Also, at the final follow-up, a total of nine (18 %) patients had said that they would not go forward with this operation if they had the opportunity to choose again; among these, significantly fewer patients were in the CWO group [one patient (4 %) in CWO vs. eight (32 %) in OWO; P =

0.018]. The clinical outcomes at 7.9 years are shown in Table 4.

Table 4 Clinical Results at 7.9 years follow-up

Parameter	Open wedge osteotomy (n=19)	Closed wedge osteotomy (n=19)	Total group (n=38)	Mean Difference (95% CI)	*P* value
KSS	155.5 (34.9)[a]	181.5 (102-200)[b]	170.0 (89-200)[b]	-13.1 (-36.9; 10.7)	n.s.[c]
VAS pain	4.1 (2.6)[a]	2.8 (2.7)[a]	3.4 (2.7)[a]	1.3 (-0.5; 3.0)	n.s.[c]
VAS satisfaction	6.1 (2.9)[a]	8.0 (3-10)[b]	8.0 (0-10)[b]	-1.95 (-3.5; -0.4)	0.017[c]
WOMAC	36.2 (26.8)[a]	21.1 (22.3)[a]	28.9 (25.5)[a]	15.2 (-1.4; 31.6)	n.s.[c]
WOMAC pain	7.3 (5.4)[a]	2.5 (0-12)[b]	5.0 (0-16)[b]	3.7 (0.5; 6.8)	0.025[c]
WOMAC Stiffness	3.3 (2.5)[a]	1.0 (0-6)[b]	2.0 (0-8)[b]	1.6 (0.1; 3.1)	0.036[c]
WOMAC ADL	25.7 (20.1)[a]	15.8 (17)[a]	20.9 (19.1)[a]	9.9 (-2.6; 22.3)	n.s.[c]
Removal OSM	12	10	22		n.s.[d]
Re-operation other reasons (n) **- Debridement tuberositas tibiae** **- Infection** **- Arthroscopy persisting complaints**	1 1 0 0	3 1 1 1	4 2 1 1		n.s.[d]

KSS Knee Society Score, *VAS* Visual Analogue Scale, *WOMAC* Western Ontario and McMaster University osteoarthritis index, *ADL* Activities of Daily Living, *yr* year, *n* number, *preop* preoperative, *OSM* osteosynthesis material, *n.s.* non significant, *CI* confindence interval

[a] Values given as mean (standard deviation)

[b] Values given as median (range)

[c] Student's t-test

[d] Chi-Squared test

Radiographic outcomes

Compared to preoperative scores, the grade of OA was progressive in the CWO and total groups, with significantly more patients in classes 3 and 4 together at 7.9 years of follow-up (P = 0.008 and P = 0.001, respectively). There were no significant differences in mean correction angle, tibial slope, or CI between groups at mean final follow-up and between 1 year and the final follow-up. At the final follow-up, there was a nonsignificant decrease in the CI in the OWO group compared to the preoperative CI (0.9 and 1.0, respectively), but in the CWO group, there was no change (CI 1.0 at both time points). In both techniques, there was no loss of correction angle. The radiographic results at 7.9 years are shown in Table 5.

Table 5 Radiographic results at 7.9 years follow-up

Parameter	Open wedge osteotomy (n=18)	Closed wedge osteotomy (n=18)	Total group (n=36)	Mean Difference (95% CI)	*P* value
OA classification (n)	I: 2 II: 8 III: 5 IV: 3	I: 3 II: 6 III: 7 IV: 2	I: 5 II: 14 III: 12 IV: 5		n.s.[c]
HKA (°)	3.1 (2.4)[a]	3.6 (2.3)[a]	3.3 (2.3)[a]	-0.5 (-2.1; 1.0)	n.s.[b]
Correction angle HKA preop and 7.9yr (°)	7.3 (2.3)[a]	7.6 (3.2)[a]	7.5 (2.8)[a]	-0.3 (-2.2; 1.6)	n.s.[b]
CI	0.9 (0.2)[a]	1.0 (0.2)[a]	1.0 (0.2)[a]	-0.1 (-0.2; 0.0)	n.s.[b]
Tibial Slope (°)	17.0 (4.5)[a]	15.5 (3.9)[a]	16.2 (4.2)[a]	1.6 (-1.3; 4.4)	n.s.[b]

OA Osteoarthritis Classification Kellgren and Lawrence, *HKA* Hip-knee-ankle, *CI* Caton index, *yr* year, *n* number, *preop* preoperative, *n.s.* non significant, *CI* confindence interval

[a] Values given as mean (standard deviation)

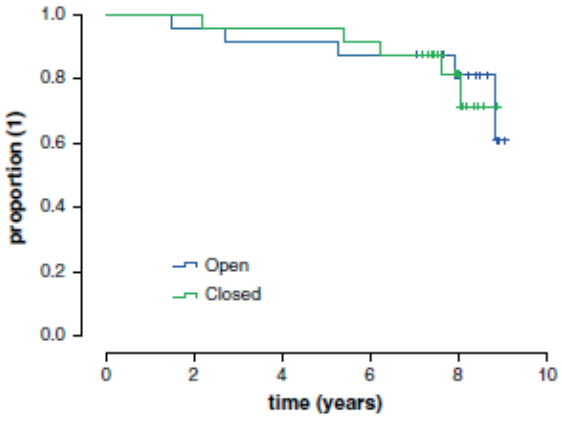
[b] Student's t-test

[c] Chi-Squared test

Survivorship

The number of and reasons for re-operations are described in Table 4. The survival after 5 years of follow-up for the total group was 93.7 % (95 % CI 87.1–100); after 7.9 years of follow-up, it was 81.6 % (95 % CI 74.7–95.9). For the OWO group, survival after 5 years was 91.7 % (95 % CI 81.3–100); after 7.9 years, it was 81.3 % (95 % CI 75.2–100). For the CWO group, survival at 5 years was 95.8 % (95 % CI 88.2–100) and was 82.0 % (95 % CI 66.7–100) at 7.9 years (Fig. 1). The two groups did not differ significantly in survival.

Figure 1 Survivorship analysis



Discussion

The most important finding of this study was the favorable clinical result for the CWO technique compared with the OWO technique after 7.9 years of follow-up, in contrast to the results after 1 year of follow-up. The clinical outcomes (WOMAC, KSS, VAS pain) suggest a trend toward superior results (approximately 15 %) for patients treated with CWO compared to patients treated with OWO (Table 4). In addition, the other clinical results (VAS satisfaction, WOMAC pain, and stiffness) were significantly better in the CWO group. Also, significantly fewer patients from the CWO group expressed that they would elect not to go forward with this operation if they had the opportunity to choose again ($P = 0.018$). A possible explanation could be that there was a patella baja after OWO, which could lead to patellofemoral complaints and a negative influence on clinical results. At the final follow-up, there was a decrease in the CI in the OWO group compared to the preoperative CI values (0.9 vs. 1.0), which is comparable to the literature [7, 28]. The CI remained unchanged from preoperative to final follow-up in the CWO group (both 1.0). Increases and decreases in this index following CWO have been described [7, 28]. In a biomechanical study, Gaasbeek et al. [10] investigated the differences in dynamic patellar tracking after open- and closed-wedge high tibial osteotomy with the same operative techniques used here. They concluded that patellar height significantly decreased with OWO and increased with CWO. Unfortunately, a patellofemoral questionnaire such as the Kujala score was not used in the current study [17]. Future research is needed to confirm the results and to evaluate the hypothesis that patella baja after an OWO causes patellofemoral complaints and therefore may negatively influence clinical results.

The current study did not involve standard MRIs to evaluate a greater degeneration of the cartilage of the patellofemoral joint after OWO compared with CWO. On the radiographs, in fact, the results were more the reverse: There was a greater progression of total OA in the knee in the CWO group compared with the OWO group. No indications were observed for some of the other potential disadvantages of OWO (e.g., high nonunion rates) [19, 21]. One possible disadvantage of the OWO technique is the use of a TCP wedge. At the time of the initial 1-year report, a TCP wedge had been used in all patients who underwent OWO, which could become a serious problem in revision surgeries in the future. Concerns persist about their resistance to compressive loads and biological degradability [2], and the use of a TCP wedge in a correction <10° is not advised [2]. The reason the TCP wedge was used in these procedures was to follow a standardized operative technique intended to promote perioperative maintenance of the precise correction made.

The favorable results for CWO reported here have not been previously described. A few short-term—and therefore not fully comparable—randomized controlled trials found no significant

difference in clinical outcomes comparing OWO and CWO after 1 year of follow-up [11, 33]. Song et al. [29] performed a retrospective comparison of 50 patients who underwent OWO or CWO. After a minimum follow-up of 3 years, the mean Hospital for Special Surgery Knee scores were similar in the two groups. Schallberger et al. [27] found no significant differences between OWO and CWO for Knee injury and Osteoarthritis Outcome Score or WOMAC after a median of 16.5 years (range 13–21). A possible explanation for the divergent results is that other groups did not use the same fixation technique applied here of a rigid plate fixation and locking screws, complicating comparisons.

Survival in the present study with conversion to UKA or TKA was comparable to values reported in the literature [1, 3, 5, 9, 16, 26, 30–32]. In Schallberger et al. [27], survival after 10 years was 92 % (95 % CI 86–99), and it was 71 % (95 % CI 58–85) after 15 years, with TKA as an end point. These authors concluded that there was no significant difference between OWO and CWO in survival and functional outcome, but that their results must be approached with caution because the number of included patients with OWO was small (16) compared to those with CWO (56).

Today, it is recognized that changes in the tibial slope may have a profound influence on the biomechanics and kinetics of the knee joint. OWO is suggested to increase the tibial slope, while CWO decreases it [7, 29], but these assertions are debated [20]. In the current study, both groups had a slight but nonsignificant increase in the tibial slope at the last follow-up compared to the preoperative values. The tibial slope at the final follow-up was also not significantly different between the two groups, suggesting that a correct osteotomy was performed also in the lateral plane in both groups.

The best correction angle is a matter of debate. Rudan et al. [25] found that a correction to a femorotibial angle between 6° and 14° of femorotibial valgus is associated with an optimal clinical result. Hernigou et al. [13] concluded that an overcorrection of more than 6° femorotibial valgus is associated with progressive degeneration of the lateral compartment and that an undercorrection of <3° femorotibial valgus is associated with a poorer result and reappearance of the medial compartment OA. Odenbring et al. [22] found that overcorrected (>7° femorotibial valgus) knees had clinically and radiographically better results than normal-corrected (1°–7° femorotibial valgus) and undercorrected (<1° femorotibial valgus) knees. In the current study, both techniques resulted in a stable correction with locked plate fixation and good clinical results. The mean postoperative femorotibial angle at 1 year for the osteotomies that were converted to a TKA or a UKA was 3.3° valgus; for the osteotomies that survived, it was 3.9° valgus. Thus, no association was found between femorotibial angle and failure rate at follow-up. Also, there appeared to be no association between severe correction (>6°) and worse clinical results, but the number of patients (three) with such a correction was very small.

This study had some limitations. At final follow-up, the data were not complete: Two patients were lost, and the data for five patients at last follow-up were incomplete. At almost 8 years after the surgery, however, this level of loss seems reasonable. Also, no new power analysis was performed, and a small number of patients were evaluated (38 in total). If more patients were included, the trend to better clinical results and a difference in CI for the CWO group compared to the OWO group might become significant. The surgeries were performed in two hospitals. Because of the standardized operation technique (the use of a TCP wedge in all patients who underwent an OWO), use of the same instruments, and the same standardized postoperative management, the use of two separate institutions should not have had an influence on the outcomes.

This study was the first prospective study to investigate the midterm results (7.9 years) of OWO compared to CWO. The favorable clinical results for the CWO technique have not been described previously. Results from the 1-year follow-up report led to the conclusion that the OWO technique was preferable. The current midterm findings, however, suggest the need to reconsider these conclusions or to recalibrate the surgical technique so that a patella baja does not occur, for example, by using an undercutting technique in case of an OWO.

Conclusion

In summary, patients who underwent a closed-wedge osteotomy had favorable clinical results compared with patients who underwent an open-wedge osteotomy after a mean follow-up of 7.9 years. The survival rates and radiographic results were similar for both techniques. A possible explanation could be the development of a patella baja after OWO, which can lead to patellofemoral complaints and worse results.

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CHAPTER 8

Summary and general discussion

Summary

The objective of this thesis was to evaluate aspects of non-arthroplasty treatment options for patients with unicompartmental knee osteoarthritis (OA) and a malalignment. We evaluated conservative treatment with valgus unloading braces and different aspects of correction osteotomies, biomechanical and clinical. In **Chapter 1**, the topic, objectives, and eight research goals were specified.
Conservative treatment with a valgus unloading brace appears to be effective in selected patients with medial knee OA and a varus malalignment [1-9], however the preferred type of brace remains unknown. An important issue is that compliance when using the unloading brace is poor [10-12]. It is obviously important to gain a better understanding of the clinical outcomes of different types of braces, and whether there are differences in non-compliance.

1. *Determine the differences in outcome between two different types of valgus unloading braces in a randomized controlled trial*

In **Chapter 2**, we describe the short-term clinical and radiographic outcomes of a randomized controlled trial (RCT) in which two different types of valgus unloading braces were compared in patients with medial knee osteoarthritis (OA) and a varus leg alignment. Fifty patients treated with a Bledsoe Thruster brace (B&Co Inc. N.V., Sint-Antelinks, Belgium) were compared with 50 patients treated with a SofTec OA brace (Bauerfeind AG, Zeulenroda-Triebes, Germany). The Bledsoe Thruster brace has a dual-hinged strut and a larger moment (torque) than the SofTec OA brace and is therefore expected to be a mechanically stronger brace with better correction and clinical outcomes. The SofTec OA brace has air chambers for valgus force, and is therefore expected to be a more comfortable brace. Outcomes were the visual analogue scale (VAS) pain and satisfaction, Dutch Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), SF-12, 6-Minutes Walking Test, hip-knee-ankle alignment, analgesic use, complications and compliance after a follow-up of 2 and 12 weeks. We found no significant clinical differences in clinical and radiographic outcomes between the two groups. Almost all clinical outcomes improved in both groups at follow-up compared to baseline. Of all patients, 24% discontinued using the brace. Most of the complications were reported at week 2 (Bledsoe group 78.0%, SofTec OA group 73.0%), but this had declined by week 12 (Bledsoe group 40.5%, SofTec OA group 46.9%). Only minor complications were reported. In conclusion, we found no significant differences in clinical and radiographic outcomes between both groups after 2 and 12-week follow-up. Both braces were effective in the treatment of varus medial knee OA. The number of minor complications and compliance

remain a problem.

In **Chapter 3 - 7**, we describe different aspects of a correction osteotomy of the knee. Operative treatment with a correction osteotomy is a preferred treatment option in young and active patients with unicompartmental knee OA and a leg malalignment [13]. A high tibial open wedge osteotomy (OWO) is one of the most commonly used techniques in the treatment of patients with a medial knee OA and varus leg alignment. There is an ongoing debate in the literature whether the medial collateral ligament (MCL) in an OWO should be released [14, 15]. For exposure and unloading the medial compartment of the knee, release of the superficial MCL is advised [14-16]. However, a release may influence the stability of the knee [15].

In **Chapter 3**, we present the results of a biomechanical study of the three research goals (2 - 4) about the effect of an OWO and the release of the superficial MCL on the tibiofemoral contact pressure, the MCL tension and the valgus laxity. Seven fresh-frozen, human cadaveric knees were used. Medial and lateral contact pressure (CP), peak contact pressure (peakCP), and contact area (CA) were measured using a pressure-sensitive film (I-Scan; Tekscan, Boston, MA). The MCL tension was measured continuously for five minutes after an OWO of 10° using a custom-made device. After the osteotomy, the valgus laxity was measured with a hand-held Newtonmeter. For one knee, the measurements were continued for 24 hours. Finally, a complete release of the superficial MCL was performed, and the measurements were repeated at 10°.

2. *Determine the effect of MCL relaxation after an OWO on the CP, peakCP and CA, in the medial and lateral compartment of the knee*

In this study, we noted relaxation of the MCL after the osteotomy; the tension dropped in five minutes by 10.7% (mean difference 20.5N (95%CI 16.1-24.9)), and in 24 hours, the tension decreased by 24.2% (absolute difference 38.8N) (one knee). After the osteotomy, the mean CP, peakCP and CA increased in the medial compartment (absolute difference 0.17MPa (95%CI 0.14-0.20), 0.27MPa (95%CI 0.24-0.30), 132.9mm2 (95%CI 67.7-198.2), respectively), and decreased in the lateral compartment (absolute difference 0.02MPa (95%CI 0.03- 0.01), 0.08MPa (95%CI 0.11- 0.04), 47.0mm2 (95%CI -105.8-11.8), respectively). Within the first five minutes of opening the osteotomy gap to 10°, the mean CP in the medial and lateral compartment decreased slightly (1.7% (SD1.7) and 1.6% (SD3.3), respectively). In the knee which was continuously monitored for 24 hours, the CP decreased within 24 hours by 11.3%

in the medial and by 10.5% in the lateral compartment.

3. *Determine the effect of a complete release of the superficial MCL after an OWO on the CP, peakCP and CA in the medial and lateral compartment of the knee*

We report in **Chapter 3** that only after a release of the superficial MCL after an OWO, did the mean CP, peakCP and CA decrease significantly in the medial compartment (absolute difference 0.17MPa, 0.27MPa, 119.8mm2, respectively), and increase in the lateral compartment (absolute difference 0.02MPa, 0.11MPa, 52.4mm2, respectively).

4. *Determine the effect of a complete release of the superficial MCL after an OWO on the valgus laxity of the knee*

In this study, also described in **Chapter 3**, we concluded that valgus laxity was unaffected by the osteotomy (mean difference -0.1° (95%CI -1.9-1.6; p=N.S.)) alone. However, after the release of the superficial MCL, the laxity significantly increased (mean difference 7.9° (95%CI 6.1- 9.6; p<0.001)) compared to the situation without OWO.

Many studies have been conducted on kinetics and kinematics of gait of a varus medial osteoarthritic knee and the effect of a valgus osteotomy on these gait characteristics [17-24]. Results convincingly show that a valgus producing osteotomy improves the kinetics and kinematics of gait, causing improvements in clinical results and quality of life [19, 23, 25, 26]. In contrast, no studies have been conducted on the detailed kinetic and kinematic aspects of gait of a valgus lateral osteoarthritic knee and the effect of a varus osteotomy on these gait characteristics.

5. *Evaluate the changes in gait and clinical outcomes after a varus producing osteotomy in patients with lateral OA of the knee and a valgus leg alignment and compare these to a normal control group*

Chapter 4 describes the results of a prospective study to answer research goal 5, in which we investigated the changes in kinetics and kinematics of gait and clinical outcomes after a varus osteotomy (tibial, femoral or double osteotomy) in patients with lateral knee OA and a valgus leg alignment. Twelve patients and ten healthy controls were included. Both kinetics and kinematics of gait and clinical and radiographic outcomes were evaluated. The knee adduction moment increased significantly postoperatively (p<0.05); this was related to the

degree of correction. Postoperatively, the patients showed kinetics and kinematics of gait similar to those of a healthy control group. Patients showed less preoperative and postoperative knee and hip flexion/extension motion and moment during gait compared to the controls. The radiographic measurements showed a mean Hip Knee Ankle (HKA) angle correction of 10.4° (95%CI 6.4°-14.4°). The correction of the HKA angle to zero degrees caused a medial shift in the dynamic knee loading. The medial shift restores cartilage loading forces and knee ligament balance, and reduces progression of OA or the risk of OA. A significant improvement was found in WOMAC (80.8 (SD16.1), p=0.000), KOS (74.9 (SD14.7), p=0.018), OKS (21.2 (SD7.5), p=0.000) and VAS-pain (32.9 (SD20.9), p=0.003) in all patients, irrespective of the osteotomy technique used.

Many implants are designed for an OWO and new implants are regularly introduced. This continuous innovation in implants for correction osteotomy is valuable, as many existing implants have a poor track record, and patients experience discomfort from the plate. Fixation strength and maintenance of its stability untill the osseous consolidation and low complication rates are a prerequisite for implants used in an OWO [27]. The TomoFix (TomoFix Osteotomy system, DePuy Synthes, West Chester, PA, USA) implant is widely used because of its well-reported clinical [28-30] and biomechanical track record [31-33]. The FlexitSystem implant (Neosteo, Nantes, France) is a novel implant for OWO and is shorter and thinner than the TomoFix implant. To compensate for the smaller dimensions, a stiffer and stronger grade of titanium alloy has been used for the FlexitSystem. Due to its smaller dimensions, patients may experience less discomfort from the plate, which may eliminate the necessity of implant removal after surgery. A potential concern is that the smaller dimensions of the implant may affect the primary stability of the reconstruction.

6. Compare the biomechanical properties of an OWO fixated with the novel FlexitSystem implant to an OWO fixated with the well recorded TomoFix implant

In **Chapter 5**, we present the results of a biomechanical study comparing the mechanical stability of an OWO fixated with the novel FlexitSystem implant to that of the TomoFix implant. Seven freshly frozen paired human cadaveric tibiae were used. The OWO in the left tibiae were fixated with the FlexitSystem implant and in the right tibiae with the TomoFix implant. The tibias were CT-scanned to determine the bone mineral density (BMD). One pair (with the lowest BMD) failed during the preparation of the osteotomy. Axial loading was applied in a cyclic fashion for 50,000 cycles. Throughout the loading history, the relative motions between the proximal and distal tibia were compared using roentgen

stereophotogrammetry analysis (RSA) at set intervals. The FlexitSystem implant displayed a similar stability to the TomoFix implant, with low translations (FlexitSystem implant mean 2.16±1.02mm vs. TomoFix implant 4.29±5.66mm) and rotations (FlexitSystem implant mean 3.17±2.04° vs. TomoFix implant 4.30±6.78°); results were not significantly different. We also compared the strength of the reconstructions using a displacement-controlled compressive test until failure. Although the FlexitSystem reconstructions were, on average, slightly stronger than the TomoFix reconstructions (mean 4867±944N vs. 4628±1987N), no significant (p=0.71) differences between the two implants were found. We concluded that, from a biomechanical point of view, the FlexitSystem implant is a suitable alternative to the TomoFix implant for an OWO.

7. *Report the clinical and radiographic safety (loss of correction, revision rate, complication rate) of the novel FlexitSystem implant*

In **Chapter 6**, we describe the results of a retrospective study set up to answer research goal 7, in which the clinical and radiographic safety of the novel FlexitSystem implant is recorded. Retrospectively, we analysed 50 patients treated with an OWO and the FlexitSystem implant, with a minimal follow-up of one year, recording complication rate, radiographic outcomes, and implant removal. One patient underwent a revision surgery because of loss of correction and non-union. The complication rate was 10.0%; no other radiographic complications (screw breakage, implant failure) were found. In 24 patients (48%), the FlexitSystem implant was removed at a mean follow-up of 12.6 months (range 2.6 till 24.0 months), mainly due to irritation caused by the implant. We conclude that the FlexitSystem implant is a clinically safe and stable implant for an OWO, with a low complication rate. We note that the rate of implant irritation requiring removal of the implant remains high.

In recent years, an OWO has gained popularity compared to a closed wedge osteotomy (CWO). Direct comparison of these two commonly used techniques is rare, and mid and long-term comparisons are almost completely lacking. As a valgus osteotomy is still an important treatment option for patients with medial knee OA and a varus leg alignment, it is relevant to investigate which technique is superior.

8. *Report the mid-term follow-up clinical and radiographic results of an OWO compared to a CWO in the treatment of patients with a medial knee OA and a varus leg alignment*

Chapter 7 presents the results of a prospective study in which we compared the midterm survival rate, clinical and radiographic outcomes of an OWO and CWO. We based this follow-up study on a previously reported RCT [34] with 50 patients (25 OWO and 25 CWO) with medial knee OA and a varus leg alignment. Patients without knee arthroplasty (mean age, 48.7 years; SD 8.0) were analysed for clinical and radiographic follow-up. Five patients in each group had undergone conversion to a total knee arthroplasty or a unicompartmental knee arthroplasty, one patient in each group was lost to follow-up, leaving 19 patients for analysis in each group. At 7.9 years of follow-up (range, 7–9 years), survival did not differ significantly between groups (OWO group, 81.3% (95% confidence interval (CI) 75.2–100)); CWO group, 82.0% [95%CI 66.7–100]). At final follow-up, total WOMAC, Knee Society Score, and VAS pain did not differ between the groups. However, the results were significantly better in the CWO group for VAS satisfaction and WOMAC pain and stiffness compared to the OWO group. Radiographic evaluation did not differ between groups for any outcome at final follow-up. In conclusion, after a mean follow-up of 7.9 years, patients who underwent a CWO showed favourable clinical results compared to those who underwent an OWO.

General discussion

The prevalence and incidence of OA continue to increase. The general aging of the population and increasing level of obesity contribute to OA in the knee joint, and in younger populations, this is mainly sport-related [35-38]. OA of the knee can be treated conservatively and surgically (joint preserving surgery or with a unicompartmental or total knee arthroplasty (UKA or TKA)). The treatment goals are reducing pain, improving function, and improving leg alignment. It is important that patients receive the correct treatment, reducing unnecessary interventions and costs.

An unloading knee brace is a conservative treatment option, although the literature notes a debate on whether these braces are effective in the treatment of patients with unicompartmental knee OA in combination with a leg malalignment [10]. In our study (**Chapter 2**), we showed that unloading braces improved clinical outcomes after a 3-month follow-up. Unfortunately, 24% of the patients discontinued their use of the brace, so non-compliance remains an issue. It is important to investigate which factors influence compliance and to detect which patient-type is most likely to benefit from a brace. Factors which may influence compliance are BMI, shape of the leg, age, grade of knee OA, as well as a range of patient-related factors that currently have not been assessed. We recommend investigating whether the brace-related factors such as design and use of other materials for unloading braces will reduce non-compliance.

We investigated different aspects of correction osteotomies in the treatment of patients with unicompartmental knee OA and a malalignment. Although a correction osteotomy is a valuable treatment option in young and active patients with unicompartmental knee OA and a leg malalignment [13, **Chapter 4, Chapter 7**], worldwide, including the Netherlands, the use of correction osteotomies of the knee is steadily decreasing [39]. In 2010 in the US, only 1,040 high tibial osteotomies were performed [40]; it appears that correction osteotomies of the knee have fallen from favour, which we believe is a concerning development. Instead, knee arthroplasties, especially UKA are being used [40]. However, the indication for knee arthroplasty is completely different than that of a correction osteotomy of the knee. Correction osteotomy is indicated for young and active patients with moderate-severe knee OA, and knee arthroplasty is indicated for older patients with bone-on-bone knee OA (grade IV following the Kellgren and Lawrence classification of Xrays). Furthermore, a knee arthroplasty does not preserve the joint. In 2010 in the Netherlands, 20,569 primary knee arthroplasties were performed; by 2015 this had increased to 27,082 [41], and this included increasing numbers of younger patients; in 2010, 19% of patients were aged under 60, in 2015 this had increased to 23% [41].

In the media and on the internet, patients are overloaded with success-stories of knee arthroplasty. In general, patients believe knee arthroplasty to be a relatively easy surgical intervention leading to the perception that they will obtain 'a new knee' as a solution for their pain. This treatment is often advised by their orthopaedic surgeon. However, the expectations of getting 'a new knee' are often overrated. Despite the increasing number of patients treated with a knee arthroplasty, several studies have reported that about 20% of patients undergoing a TKA are dissatisfied with the results of their surgery [42]; there is a clear mismatch between patient expectations versus actual clinical outcomes following TKA, as 85% of patients expect to be completely pain-free after surgery when in fact only 43% report complete absence of pain [43].

If a knee arthroplasty fails, in most cases the only treatment option is a revision knee arthroplasty. Unfortunately, multiple revisions cannot be performed, and some patients have to undergo an amputation. The facts described above of increasing numbers of revision knee arthroplasties, is mainly due to the fact that younger patients are undergoing this treatment. It is important to note that their life expectancy will usually exceed implant survival. The rise of the number of patients aged under 60 is thus a concern, as joint registries reveal that 10-year revision rates in this group are higher than for older age groups [44]. Younger patients with a knee arthroplasty have a risk of a second or even third revision surgery during their life time. In 2015, 2,667 revision operations were performed in the Netherlands, compared to 1,617 in 2010 [41]. In the US, over 55,000 revision surgeries were performed in 2010, with 48% of these revisions in patients under 65 years [45]. By 2030, nearly 2 in 3 TKA revision patients will be younger than 65 [46]. The most common reasons for revision following TKA are infection (40%), instability (20%), pain (19%), aseptic loosening (13%), and arthrofibrosis (11%) [40]. A revision knee arthroplasty is associated with considerable expense, morbidity, and inferior clinical outcomes compared to primary knee arthroplasty, thus the burden for both patient and society is enormous [40]. Preoperative and postoperative problems reported with revision knee arthroplasties are bone stock loss, ligamentous insufficiency, soft tissue problems, extensor mechanism failures, and increased risk of infection; all can lead to a loose, instable, painful knee. The costs of treating a periprosthetic joint infection are between 50,000-100,000 EUR per patient [47]; these patients require multiple and longer hospital admissions, multiple revision operations, long-term use of medication and other care factors. In the US, each revision knee arthroplasty is associated with a total cost of $49,360 [48]; the current annual economic burden of revision knee arthroplasties is estimated at $2.7 billion for hospital charges alone. By 2030, assuming a 5-fold increase in the number of revision procedures [49], the annual economic burden will exceed $13 billion.

We believe that correction osteotomy is a valuable alternative treatment option, especially

in young and active patients with unicompartmental knee OA and a leg malalignment. Osteotomy is an operation, which restores the alignment and biomechanics of the knee joint; it is a joint preservation procedure which preserves the normal anatomy and restores the kinematics of the knee. A correction osteotomy is performed to stop or reduce the progression of OA of the knee joint, and to avoid or postpone placement of a TKA. As previously mentioned, the use of correction osteotomies is unfortunately decreasing steadily, and knee arthroplasties are being used more frequently. Possible explanations are: 1) orthopaedic surgeons are unfamiliar with the beneficial results that can be obtained by correction osteotomy, and 2) orthopaedic surgeons are less familiar with (the technique of) knee correction osteotomy procedures. We review both explanations in more detail in the following sections.

Orthopaedic surgeons are unfamiliar with the beneficial results that can be obtained by correction osteotomy.
In the past, the more demanding CWO procedure was commonly used. Most available long-term data reports concern the CWO technique; only recently long-term data of the OWO have been published [50-52]. The OWO is easier to perform and is a more accurate technique than the CWO [53, 54]. In **Chapter 7** we report favourable results of the CWO compared to the OWO. This may be due to patellofemoral complaints caused by the postoperative patella baja in the OWO technique. By using undercutting techniques (biplanar osteotomy) this problem can be prevented. A biplanar osteotomy preserves the tibial tubercle and thus preserves patellar height (Figure 6, p11) [55].

In contrast, in Asian countries, an increase has been reported in the use of correction osteotomies. For example, over the past 5 years in South Korea, the number of knee osteotomies increased by 210% and TKAs by only 18%. The reason for these differences, compared to the worldwide trend, is not clear, but the fact that kneeling and squatting after a correction osteotomy is often possible without any pain could be an explanation; these activities are mostly not possible after a TKA. To be able to kneel and squat is important in the Asian culture. Another explanation could be the arthroplasty regulation policy in South Korea, whereby knee arthroplasties are reimbursed for patients aged between 60-64 years only when they have a grade IV OA (following the Kellgren Lawrence classification) on Xrays. Therefore, orthopaedic surgeons prefer to perform a correction osteotomy or delay the timing of knee arthroplasty until patients are older than 65, in cases where the patient does not have severe radiographic knee OA [39].
Performing correction osteotomies leads to postponing the TKA treatment. The 10-year survival rates of tibial osteotomies range from 51% to 98% [56]. The literature reports that results of conversion to a TKA following previous high tibial osteotomy are less satisfactory or similar. Surgeons need to consider the factors affecting technical difficulties during conversion

to achieve similar results reported when performing primary TKA [56]. These surmountable disadvantages of conversion to a TKA should not be used as reasons for not performing a correction osteotomy in patients with knee OA. In our opinion, the advantages of joint preservation, restoration of normal biomechanics, postpone the placement of a TKA and prevent expensive revision surgery: these benefits greatly outweigh the disadvantages.
In addition to the perceived complexity of a correction osteotomy, orthopaedic surgeons argue that the long revalidation process is a problem. In the past, it was normal to accept a non-weight-bearing period of 6 weeks. With the use of the new angle stable implants in an OWO, this is usually not necessary; patients can fully bear weight (almost) immediately after surgery [57].
Another problem of the use of a correction osteotomy of the knee is that many patients experience discomfort from the implant, thus implant removal is often necessary. The literature reports percentages between 0 to 23% implant irritation requiring plate removal [34, 58-65]. Novel implants with different alloys and smaller dimensions may eliminate this problem. In **Chapter 5 and 6** we present the results of our study of the novel FlexitSystem implant. Although we found that the FlexitSystem implant is a stable and safe implant for use in an OWO, unfortunately, it was removed in almost half of the patients, mostly due to irritation (38%) recorded by the surgeon. This study was a retrospective single centre study and in this hospital, the indication for implant removal was knocking pain over the plate, a very low-threshold; whether patients experienced discomfort from the implant on a regular basis remained unclear. Another explanation could be that the FlexitSystem implant caused more irritation then we expected. Further research of novel implants with different alloys and plate thickness needs to be conducted.
To improve knowledge and reinstate the popularity of correction osteotomy of the knee, available and comparable results are required. National registries have been set up that provide valuable insights into operative techniques; quality of implants, patients' reported outcomes, and the quality of hospitals and surgeons. In the United Kingdom and Sweden, correction osteotomies have been included in their national registries [66, 67]. We propose that the Dutch national register (LROI) [41] also includes correction osteotomies. In this way, it will be possible to more easily compare surgical techniques and types of implants, as well as evaluate the benefits of correction osteotomy with those of knee arthroplasties.

Orthopaedic surgeons are less familiar with (the technique of) knee correction osteotomy procedures.
Due to the declining popularity of a correction osteotomy in the treatment of patients with unicompartmental knee OA and a malalignment, less orthopaedic surgeons are familiar with the correct osteotomy technique or do not feel competent to perform this kind of operation.

If this trend continues, young orthopaedic surgeons will no longer be able to perform a knee correction osteotomy. It is therefore important to educate residents and recently qualified orthopaedic surgeons in these procedures, as they will have to deal with the expected increase in revision rates and complications of knee arthroplasties used in young patients. They need to be trained in joint preserving treatment options for young patients with knee OA, e.g. correction osteotomies of the knee and knee joint distraction treatment. The findings reported in this thesis should contribute to increasing the correct use and improving the popularity of knee correction osteotomy.

An additional option to enhance the familiarity of the surgeons with the correction osteotomy procedures would be to make an osteotomy course during residency mandatory, and to ensure that knee correction osteotomy is a basic surgical technique for any qualified (knee) orthopaedic surgeon.

In the near future a new protocol produced by the Dutch Orthopaedic Association "Hip and Knee OA" will be released in the Netherlands; we would urge giving knee correction osteotomy a prominent place in this protocol for treating young and active patients with unicompartmental knee OA and a malalignment.

To continuously improve clinical outcomes, osteotomy techniques also need to improve.

In this thesis, we have contributed to the literature and knowledge of correct osteotomy techniques. For example, in **Chapter 3**, we studied the release of the superficial MCL in an OWO, thereby contributing to the discussion on developing the correct osteotomy technique in an OWO. A release of the superficial MCL is needed to unload the medial compartment. However, after the release of the superficial MCL, we report that the laxity significantly increased compared to the situation without OWO. Whether the release of the superficial MCL leads to any clinically relevant instability requires further investigation.

Currently, the OWO is the preferred technique, leading to the fact that surgeons' expertise and familiarity with the CWO technique is disappearing. In **Chapter 7**, we note that this is a regrettable loss, as the CWO technique also produces excellent results when used correctly.

Other future technical developments which will contribute to improving osteotomy techniques are: better imaging techniques (e.g. 3D techniques), better cutting techniques (e.g. thinner saw blades), pre-operative use of navigation or real-time intra-operative feedback (e.g. monitoring intra-articular pressure for the correct amount of release of the superficial MCL), and patient specific instruments. These new techniques will lead to advantages that are expected to further improve the clinical outcomes of the correction osteotomy technique.

In this thesis, we show that correction osteotomy in the treatment of young and active patients with unicompartmental knee OA and a malalignment is a valuable technique. 'Young' patients have until recently been defined as those aged under 60, however this is based on old

literature [13]. These days, a 'young' patient may be someone aged 70 or older, as the person is considered 'biologically' young. It is more relevant to look at this 'biological' age when reviewing the results of a knee correction osteotomy, instead of the calendar age. Whether a correction osteotomy of the knee is also successful in this age group needs further investigation, but based on the results reported in this thesis and from the literature, we are convinced that it is worthwhile investigating whether more patients can be treated with correction osteotomies.

Recommendations for future research and developments

Based on the studies reported in this thesis, we have formulated a number of recommendations for future research and development in the joint preserving treatment of unicompartmental knee OA and a malalignment:

1. Investigate which factors (patient-specific and brace-specific) influence the compliance of unloader braces.
2. Investigate new technical developments which can contribute to improving knee correction osteotomy techniques, for example better imaging techniques (like 3D techniques), navigation and patient specific instruments.
3. Investigate whether the release of superficial MCL leads to clinically important instability in patients treated with an OWO.
4. Investigate novel implants (type of alloy; thickness) used in correction osteotomies of the knee, in order to reduce removal of the implants due to irritation.
5. Educate residents and young orthopaedic surgeons in the correct osteotomy techniques of the knee in the treatment of patients with unicompartmental knee OA and a malalignment.
6. Give the correction osteotomy of the knee a more prominent position in national protocols as treatment of choice for patients with unicompartmental knee OA and a malalignment.
7. Include correction osteotomy of the knee in the national registries to record patient reported outcomes, complication rates, and survival rates.
8. Investigate whether a correction osteotomy of the knee is as successful in older but 'biologically young', active patients with unicompartmental knee OA and a malalignment.

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CHAPTER 9

Summery and general discussion in Dutch/ Samenvatting en discussie

Samenvatting

Het doel van dit proefschrift is om de verschillende behandelopties voor patiënten met unicompartimentele gonartrose en een standsafwijking van het been te onderzoeken. Er is onderzoek gedaan naar een conservatieve behandeling (valgiserende knie braces) en verschillende aspecten (biomechanisch en klinisch) van stand correcties van het been door middel van een osteotomie. **Hoofdstuk 1** geeft een algemene introductie over de onderwerpen van dit proefschrift. Er zijn 8 onderzoeksvragen geformuleerd en de antwoorden hierop worden in dit hoofdstuk samengevat en bediscussieerd.

Bij geselecteerde patiënten met mediale gonartrose en een varusbeenas lijkt een behandeling met een valgiserende knie brace een effectieve behandeling te zijn, echter het is nog steeds niet duidelijk wat voor type brace de voorkeur heeft. Een belangrijk probleem is de slechte therapietrouw van patiënten. Het is belangrijk om meer inzicht te krijgen in de klinische uitkomsten van verschillende types valgiserende braces en of er verschil is in therapietrouw bij verschillende types valgiserende braces.

1. *Bepaal de verschillen in uitkomst tussen twee verschillende types valgiserende knie braces in een gerandomiseerde gecontroleerde studie*

Hoofdstuk 2 beschrijft de klinische en radiologische resultaten op korte termijn van een gerandomiseerde gecontroleerde studie waarin twee verschillende types valgiserende knie braces worden vergeleken bij patiënten met een mediale gonartrose en een varus beenas. Er werden 50 patiënten behandeld met de Bledsoe Thruster brace (B&Co Inc. N.V., Sint-Antelinks, Belgium) en deze patiënten werden vergeleken met 50 patiënten die behandeld zijn met de SofTec OA brace (Bauerfeind AG, Zeulenroda-Triebes, Germany). De Bledsoe Thruster brace heeft een dubbel scharnier en een groter momentarm dan de SofTec OA brace en de verwachting is dan ook dat dit een mechanisch sterkere brace is. De SofTec OA brace heeft luchtkamers voor de valgiserende kracht en de verwachting is dan ook dat dit een meer comfortabele brace is. Na een follow-up van 2 en 12 weken werden de volgende uitkomsten geregistreerd: visual analogue scale (VAS) pijn en tevredenheid, Dutch Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), SF-12, 6-Minutes Walking Test, heup-knie-enkel alignement, gebruik van pijnstillers, complicaties en de therapietrouw van de patiënten. Uit de studie kwam dat deze klinische en radiologische resultaten niet significant verschillend waren tussen beide groepen. Wel verbeterden bijna alle klinische uitkomsten in beide groepen gedurende de follow-up. 24% van de patiënten stopten met het

dragen van de brace. De meeste complicaties werden door de patiënten binnen de eerste 2 weken gerapporteerd (Bledsoe group 78.0%, SofTec OA group 73.0%), maar dit werd na 12 weken minder (Bledsoe group 40.5%, SofTec OA group 46.9%). Alleen kleine complicaties werden beschreven. Concluderend is er geen verschil gevonden in klinische en radiologische uitkomsten tussen de twee verschillende valgiserende kniebraces na 2 en 12 weken. Het aantal kleine complicaties en gebrek aan therapietrouw blijven een probleem.

In **Hoofdstuk 3 – 7** worden verschillende aspecten van de correctie osteotomie van de knie beschreven. Een standscorrectie door middel van een osteotomie is een goede operatieve behandelopties voor jonge en actieve patiënten met unicompartimentele gonartrose en een standsafwijking. Bij patiënten met een mediale gonartrose en een varusbeenas is een open wig osteotomie (OWO) één van de meest gebruikte technieken. In de literatuur is er discussie of de mediale collaterale band (MCL) gereleased moet worden of niet. Een release van de oppervlakkige MCL tijdens een OWO wordt geadviseerd voor een goede exposure en het ontlasten van het mediale compartiment van de knie. Aan de andere kant kan een release invloed hebben op de stabiliteit van de knie.

Drie onderzoeksvragen (2 tot 4) gaan over het effect van een OWO en de release van de oppervlakkige MCL op de druk van het tibiofemorale kraakbeen, de spanning van de MCL en de valgus laxiteit van de knie. Deze aspecten zijn onderzocht in een biomechanische studie, welke beschreven is in **Hoofdstuk 3**. Hiervoor zijn 7 vers ingevroren humane kadaverknieën gebruikt. Door middel van een drukgevoelig film (I-Scan; Tekscan, Boston, MA) werd de contact drukken (CP), piek contact drukken (peakCP) en contact oppervlak (CA) van het mediale en laterale compartiment gemeten. De spanning van de MCL werd gemeten met een op maat gemaakt apparaat. Na een OWO van 10° werden deze metingen vijf minuten continue gemonitord. Na de osteotomie werd de valgus laxiteit met de hand gemeten met een Newtonmeter. Bij één knie werden alle metingen gedurende 24 uur geregistreerd. Aan het eind van de metingen werd een volledige release van de oppervlakkige MCL verricht en alle metingen werden herhaald bij een OWO van 10°.

2. *Bepaal het effect van relaxatie van de MCL na een OWO op de CP, peakCP en CA in het mediale en laterale compartiment van de knie*

In de bovengenoemde studie, beschreven in **Hoofdstuk 3**, werd een relaxatie van de MCL na een OWO gevonden: de spanning van de MCL daalde in 5 minuten met 10.7% (gemiddeld verschil 20.5N (95%CI 16.1-24.9)), en in 24 uur was dit 24.2% (absoluut verschil 38.8N)

(één knie). Na de osteotomie nam de gemiddelde CP, peakCP en CA toe in het mediale compartiment (absoluut verschil 0.17MPa (95%CI 0.14-0.20), 0.27MPa (95%CI 0.24-0.30), 132.9mm2 (95%CI 67.7-198.2), respectievelijk), en nam het af in het laterale compartiment (absoluut verschil 0.02MPa (95%CI 0.03- 0.01), 0.08MPa (95%CI 0.11- 0.04), 47.0mm2 (95%CI -105.8-11.8), respectievelijk). Wel daalde de gemiddelde CP in het mediale en laterale compartiment (1.7% (SD1.7) en 1.6% (SD3.3), respectievelijk) licht de eerste vijf minuten na het openen van de osteotomie tot 10°. In de knie, die voor 24 uur continue werd gemonitord, daalde de CP in die 24 uur met 11.3% en 10.5% in respectievelijk het mediale en laterale compartiment.

3. *Bepaal het effect van een volledige release van de oppervlakkige MCL na een OWO op de CP, peakCP en CA in het mediale en laterale compartiment van de knie*

In de bovengenoemde studie, beschreven in **Hoofdstuk 3**, werd gevonden dat alleen na een release van de oppervlakkige MCL na een OWO, de gemiddelde CP, peakCP en CA significant afnamen in het mediale compartiment (absoluut verschil respectievelijk 0.17MPa, 0.27MPa en 119.8mm2), en toenamen in het laterale compartiment (absoluut verschil respectievelijk 0.02MPa, 0.11MPa en 52.4mm2).

4. *Bepaal het effect van een volledige release van de oppervlakkige MCL na een OWO op de valgus laxiteit van de knie*

In de bovengenoemde studie, beschreven in **Hoofdstuk 3**, werd gevonden dat de valgus laxiteit niet beïnvloed wordt door de osteotomie (gemiddeld verschil -0.1° (95%CI -1.9-1.6; p=N.S.)). Echter na een release van de oppervlakkige MCL nam de laxiteit van significant toe (gemiddeld verschil 7.9° (95%CI 6.1- 9.6; p<0.001)) vergeleken met de situatie zonder OWO.

De kinetica en kinematica van het looppatroon van een knie met mediale varus gonartrose en het effect van een valgiserende osteotomie op deze looppatroon-karakteristieken zijn goed beschreven in de literatuur. Het is bewezen dat een valgiserende osteotomie de kinetica en kinematica van het lopen kan verbeteren, wat weer zorgt voor verbetering in de klinische resultaten en de kwaliteit van leven van de patiënt. Echter, de kinetica en kinematica van het lopen van een laterale valgus gonartrose en het effect van een variserende osteotomie op deze looppatroon-karakteristieken zijn niet in detail beschreven in de literatuur.

5. *Evalueer de veranderingen in het looppatroon en de klinische uitkomsten na een variserende osteotomie bij patiënten met een laterale gonartrose en een valgus beenas en vergelijk dit met een gezonde controle groep*

Hoofdstuk 4 beschrijft de resultaten van een prospectieve studie, waarin de veranderingen in de kinetica en kinematica van het looppatroon en de klinische uitkomsten na een variserende osteotomie (tibiale, femorale of dubbel osteotomie) in patiënten met gonartrose en een valgus beenas worden beschreven. Er werden twaalf patiënten en 10 gezonde controle proefpersonen geïncludeerd. De kinetica en kinematica van het lopen en de klinische en radiologische uitkomsten werden geëvalueerd. Postoperatief verbeterde het knie adductie moment significant ($p<0.005$) en dit was gerelateerd aan de mate van correctie. Over het algemeen zag de kinetica en kinematica van het looppatroon van de patiënten er postoperatief vergelijkbaar uit met die van de gezonde controle groep. Echter de patiënten hadden een verminderde knie,- en heup flexie/extensie beweging en moment gedurende het lopen, pre,- en postoperatief, in vergelijking met de gezonde controle groep. Radiologisch werd een correctie van de Heup Knie Enkel (HKA) hoek van 10.4° (95%CI 6.4°-14.4°) gemeten. De correctie van de HKA hoek richting de 0° zorgt voor een mediale verschuiving in de dynamische belasting van de knie. Deze mediale verschuiving herstelt de krachten die op het kraakbeen komen en de ligamentaire balans van de knie en daardoor zal de progressie van de gonartrose of het risico op gonartrose afnemen. Postoperatief werd een significante verbetering gevonden in de WOMAC (80.8 (SD16.1), p=0.000), KOS (74.9 (SD14.7), p=0.018), OKS (21.2 (SD7.5), p=0.000) en VAS-pijn (32.9 (SD20.9), p=0.003) scores van alle patiënten onafhankelijk van welke osteotomie techniek er werd gebruikt.

Er zijn veel verschillende implantaten ontworpen welke gebruikt kunnen worden voor een OWO. Regelmatig worden nieuwe implantaten geïntroduceerd. Het is belangrijk om te innoveren en het beste implantaat te vinden voor een correctie osteotomie, aangezien er veel implantaten met slechte resultaten op de markt zijn en veel patienten klachten ervaren van het implantaat. Belangrijke eigenschappen van een implantaat welke gebruikt wordt voor een OWO zijn fixatie sterkte, en stabiliteit totdat er een ossale consolidatie is gevormd en een laag risico op complicaties. Het TomoFix (TomoFix Osteotomy system, DePuy Synthes, West Chester, PA, USA) implantaat is wereldwijd veel gebruikt vanwege zijn goed gedocumenteerde klinische en biomechanische resultaten. Het FlexitSystem implantaat (Neosteo, Nantes, Frankrijk) is een nieuw implantaat welke gebruikt wordt voor een OWO. Het FlexitSystem implantaat is een korter en dunner implantaat vergeleken met het TomoFix implantaat. Om deze dunnere kenmerken te compenseren is een ander soort titanium legering (stijver en

sterker) gebruikt voor het FlexitSystem implantaat. Een mogelijk voordeel van dit implantaat is, vanwege het dunnere uiterlijk, dat patiënten minder klachten ervaren van de plaat, wat ervoor kan zorgen dat er minder implantaten postoperatief verwijderd hoeven te worden. Een mogelijk nadeel hiervan is dat de dunnere uitvoeringen van het implantaat invloed kan hebben op de primaire stabiliteit van de reconstructie.

6. *Vergelijk de biomechanische eigenschappen van een OWO gefikseerd met het nieuwe FlexitSystem implantaat en vergelijk dit met een OWO gefikseerd met het, goed gedocumenteerde, TomoFix implantaat*

In **Hoofdstuk 5** worden de resultaten beschreven van een biomechanische studie waarin de mechanische stabiliteit en OWO gefixeerd met het nieuwe FlexitSystem implantaat wordt vergeleken met een OWO gefikseerd met het, goed gedocumenteerde, TomoFix implantaat. Er werden zeven vers ingevroren gepaarde humane kadaver tibiae gebruikt. De OWO in de linker tibiae werd gefikseerd met het FlexitSystem implantaat en in de rechter tibiae met het TomoFix implantaat. Vooraf werden van alle tibiae middels een CT scan de botdichtheid (BMD) bepaald. Er faalde één paar tibiae (met de laagste BMD) tijdens de preparatie van de osteotomie. Axiale kracht werd cyclisch toegediend met 50.000 cycli. Door middel van röntgen stereofotogrammetrie analyse (RSA) werd op vaste momenten, gedurende de gehele belastingsgeschiedenis de relatieve bewegingen vergeleken tussen de proximale en distale tibia. Er werd een vergelijkbare stabiliteit tussen het FlexitSystem implantaat en het TomoFix implantaat gevonden, met weinig translaties (gemiddeld 2.16±1.02mm vs. 4.29±5.66mm) en rotaties (gemiddeld 3.17±2.04° vs. 4.30±6.78°), dit was niet significant verschillend. Ook werd de sterkte van de reconstructies vergeleken door middel van een verplaatsinggecontroleerde druk test tot aan falen. Gemiddeld genomen waren de reconstructies met de FlexitSystem implantaten iets sterker dan de reconstructies met de TomoFix implantaten (gemiddeld 4867±944N vs. 4628±1987N), echter dit was niet significant (p=0.71). Concluderend, vanuit een biomechanisch oogpunt bekeken, is voor een OWO het FlexitSystem implantaat een goed alternatief voor het TomoFix implantaat.

7. *Rapporteer de klinische en radiologische veiligheid (correctieverlies, revisies, complicaties) van het nieuwe FlexitSystem implantaat*

Hoofdstuk 6 beschrijft de resultaten van een retrospectieve studie, waarin de klinische en radiologische veiligheid van het nieuwe FlexitSystem implantaat wordt bekeken. Retrospectief zijn er 50 patiënten geanalyseerd, welke behandeld zijn met een OWO en een FlexitSystem

implantaat, met een minimale follow-up van 1 jaar. Het aantal complicaties, de radiologische uitkomsten en het verwijderen van het osteosynthese materiaal zijn geanalyseerd. Eén patiënt moest een revisie operatie ondergaan, vanwege correctie verlies en een non-union. Het complicatie percentage was 10.0%. Er werden geen andere radiologische complicaties (schroefbreuk, implantaat falen) gevonden. In 24 patiënten (48%) werd het FlexitSystem implantaat verwijderd na een gemiddelde follow-up van 12.6 maanden (range 2.6 tot 24.0 maanden). De belangrijkste reden om het osteosynthese materiaal te verwijderen was irritatie van de plaat. Concluderend, het FlexitSystem implantaat is een klinisch veilig en stabiel implantaat te gebruiken bij een OWO, met een lage kans op complicaties. Wel werd een relatief hoog percentage gevonden waarin de plaat, vanwege irritatie, verwijderd werd.

Een OWO is de laatste jaren steeds populairder geworden in vergelijking tot een gesloten tibia osteotomie (CWO). Dit ondanks dat een directe vergelijking tussen deze twee technieken weinig is onderzocht, en er nauwelijks middellange en lange termijnresultaten hiervan bekend zijn. Aangezien een valgiserende osteotomie een belangrijke behandeloptie is voor patiënten met een mediale gonartrose en een varusbeenas, is het van belang om te weten welke operatie techniek het beste is.

8. Rapporteer de middellange klinische en radiologische resultaten van een OWO in vergelijking met een CWO in de behandeling van patiënten met een mediale gonartrose en een varus beenas

Hoofdstuk 7 beschrijft de resultaten van een prospectieve studie waarin de middellange overlevingspercentages, klinische en radiologische uitkomsten zijn vergeleken tussen een OWO en CWO. Dit betrof een vervolgstudie, van een eerder uitgevoerde gerandomiseerde gecontroleerde studie, met resultaten na 1 jaar follow-up. In de originele studie werden er 50 patiënten geïncludeerd (25 patiënten ondergingen een OWO en 25 patiënten een CWO) met mediale gonartrose en een varus beenas. Patiënten die nog geen totale knieprothese (TKP) hadden gekregen (gemiddelde leeftijd 48.7 jaar; SD 8.0) werden geanalyseerd voor klinische en radiologische follow-up. Vijf patiënten in elke groep hadden een TKP of uni knieprothese (UKP) gekregen, en 2 patiënten waren 'lost to follow-up', waardoor er 19 patiënten in elke groep overbleven voor analyse. Na 7.9 jaar follow-up (range 7 tot 9 jaar), was er geen significant verschil in overleving tussen beide groepen (survivalrate OWO groep, 81.3% [95% betrouwbaarheidsinterval (CI) 75.2–100]; survival rate CWO groep, 82.0% (95%CI 66.7–100)). Aan het eind van de follow-up verschilden de totale WOMAC, KSS, VAS pijn niet tussen beide groepen. Wel waren de VAS tevredenheid en WOMAC pijn en

stijfheid significant beter in de CWO dan in de OWO. Radiologische uitkomsten verschilden niet tussen beide groepen bij de laatste follow-up. Concluderend, na een gemiddelde follow-up van 7.9 jaar, hadden patiënten die een CWO hadden ondergaan betere klinische resultaten in vergelijking met patiënten die een OWO hadden ondergaan.

Algemene discussie

De prevalentie en incidentie van artrose neemt toe. In de knie komt dit specifiek door het stijgen van de gemiddelde leeftijd van de populatie, progressieve groei van mensen met obesitas, en de toename van het aantal sportletsels van de knie in de jonge populatie. Gonartrose kan conservatief en operatief (gewrichtssparend of met een UKP dan wel TKP) behandeld worden. Behandeldoelen zijn het verminderen van pijn, het verbeteren van de functie van de knie en het verbeteren van het alignement van het been. Het is belangrijk om de patiënt de juiste behandeling te geven, om zo onnodige interventies te minimaliseren en kosten te reduceren.

Een ontlastende kniebrace is een conservatieve behandeloptie, echter in de literatuur is er discussie of deze kniebraces effectief zijn in de behandeling van unicompartimentele gonartrose in combinatie met een standsafwijking van het been. In onze studie (**Hoofdstuk 2**) laten we zien dat, na een follow-up van 3 maanden, deze ontlastende valgiserende braces de klinische uitkomsten verbeteren bij patiënten met unicompartimentele gonartrose en een standsafwijking van het been. Helaas is het wel zo dat 24% van de patiënten stopten met het dragen van de brace. Het gebrek aan therapietrouw is een groot probleem. Het is dan ook belangrijk om te onderzoeken welke factoren invloed hebben op de therapietrouw en welke type patiënt het meeste baat heeft bij het dragen van zo'n kniebrace. Factoren die van invloed kunnen zijn op de therapietrouw zijn BMI, vorm van het been, leeftijd, mate van gonartrose, en waarschijnlijk nog veel meer andere patiënt gerelateerde factoren waar we nu nog geen weet van hebben. Het is ook interessant om te onderzoeken of brace-gerelateerde factoren, zoals het ontwerp en het gebruik van andere materialen, de therapietrouw kunnen verbeteren.

In dit proefschrift worden verschillende aspecten van een correctie osteotomie onderzocht in de behandeling van patiënten met unicompartimentele gonartrose en een standsafwijking van het been. Hoewel een correctie osteotomie een goede behandeling is voor jonge en actieve patiënten met unicompartimentele gonartrose en een standsafwijking (**Hoofdstuk 4 en 7**), daalt wereldwijd, inclusief in Nederland, de toepassing hiervan. In Amerika werden in 2010 maar 1.040 osteotomiën van de tibia verricht voor unicompartimentele gonartrose. Het is een zorgerlijke trent dat er tegenwoordig nauwelijks meer correctie osteotomiën van de knie worden verricht. Daarvoor in de plaats krijgen patiënten een knieprothese, en dan met name een UKP. Echter de indicatie voor een knieprothese is niet hetzelfde als de indicatie voor een correctie osteotomie van de knie. De indicatie voor een correctie osteotomie is de jonge en actieve patiënt met matig ernstige gonartrose en de indicatie voor een knieprothese is de oudere patiënt met bot-op-bot gonartrose (graad IV volgens de Kellgren en Lawrence classificatie op röntgenfoto's). Een andere probleem is dat een knieprothese geen

gewrichtssparende operatie is. Er is dus een toenemend aantal patiënten die worden behandeld met een UKP of TKP. In 2010, werden in Nederland 20.569 primaire knieprotheses geplaatst en in 2015 nam dit aantal toe tot 27.082. Steeds jongere patiënten worden behandeld met een knieprothese. In 2010 was in Nederland 19% van de patiënten die een knieprothese kregen onder de 60 jaar en in 2015 was dit al 23%.

Patiënten horen vanuit de media en via internet over de succesverhalen van een knieprothese. Over het algemeen geloven patiënten dat het plaatsen van een knieprothese een relatief kleine en makkelijke operatie is. Patiënten eisen 'een nieuwe knie' als oplossing voor hun kniepijn. Het is niet in de laatste plaats dat deze behandeling wordt geadviseerd door hun behandelend orthopedisch chirurg. De verwachtingen van zo'n 'nieuwe knie' zijn vaak te hoog. Ondanks de toename van het aantal patiënten die worden behandeld met een knieprothese, hebben meerdere studies aangetoond dat 1 op de 5 patiënten die een knieprothese hebben gekregen niet tevreden zijn na de operatie. Er is een duidelijke mismatch tussen de verwachtingen van de patiënt en de klinische uitkomsten na een knieprothese. Zo verwacht 85% van de patiënten volledig pijnvrij te zijn na de operatie, terwijl dit uiteindelijk maar bij 43% van de patiënten het geval is.

Als een knieprothese faalt, is een revisie operatie in de vorm van een revisie knieprothese vaak de enige oplossing. Helaas is het niet mogelijk om een knieprothese eindeloos te reviseren, en sommige patiënten eindigen zelfs met een amputatie. De toename van het aantal revisie knieprotheses wordt veroorzaakt door de jongere leeftijd waarop patiënten een knieprothese krijgen (de levensverwachting van deze patiënten is hoger dan de overlevingsduur van de prothese) en door de absolute toename van het aantal knieprotheses. De toename van patiënten onder de 60 jaar die een knieprothese krijgen is zorgelijk, aangezien nationale registers laten zien dat de 10-jaar revisie aantallen in deze groep veel hoger liggen in vergelijking met de aantallen in de oudere groep patiënten. Ook heeft de jonge patiënt een risico op een tweede of zelfs derde revisie operatie ergens gedurende zijn leven. In 2015 werden in Nederland 2.667 revisie operaties uitgevoerd in vergelijking met 1.167 revisie operaties in 2010. In Amerika werden in 2010 meer dan 55.000 revisie operaties uitgevoerd, waarbij 48% van deze patiënten jonger was dan 65 jaar. De verwachting is dat omstreeks 2030, bijna twee van de drie patiënten die een revisie knieprothese krijgen onder de 65 jaar is. De meest voorkomende redenen voor een revisie na een TKP zijn infectie (40%), instabiliteit (20%), pijn (19%), aseptische loslating (13%), en arthrofibrose (11%). Een revisie knieprothese is een operatie welke geassocieerd is met aanzienlijke kosten, morbiditeit en inferieure klinische uitkomsten in vergelijking met een primaire knieprothese en de belasting voor patiënt en samenleving is dan ook enorm. Per,- en postoperatieve problemen met revisie knieprotheses zijn botverlies, ligamentaire insufficiëntie, weke delen problemen, extensor apparaat falen en

een verhoogd infectierisico wat allemaal kan leiden tot een situatie met een losse, instabiele en pijnlijke knieprothese. De kosten van de behandeling van een periprosthetische infectie zijn tussen de €50.000 - €100.000 per patiënt. Patiënten hebben vaak meerdere en langdurige ziekenhuisopnames nodig, meerdere operaties, langdurig gebruik van medicatie, etc. In Amerika zijn de totale kosten van elke revisie knieprothese $49.360. De huidige jaarlijkse kosten voor alleen al de ziekenhuisrekeningen voor revisie knieprotheses zijn $2.7 biljoen. In 2030, uitgaand van een vijfvoudige toename in het aantal revsies operaties, worden deze jaarlijkse kosten geschat op meer dan $13 biljoen.
Wij geloven dat een correctie osteotomie een goede alternatieve behandeloptie is in plaats van een knieprothese, met name voor de jonge en actieve patiënt met unicompartimentele gonartrose en een standsafwijking van het been. Een osteotomie is een operatie wat het alignement en de biomechanica van het kniegewricht hersteld. Het is een gewrichtssparende operatie; het bewaart de normale anatomie en herstelt de kinematica van de knie. Een correctie osteotomie wordt gedaan om de progressie van gonartrose te stoppen of af te remmen. Verder voorkomt of stelt een correctie osteotomie de plaatsing van een knieprothese uit in patiënten met gonartrose. Helaas, zoals eerder beschreven, daalt het gebruik van correctieosteotomiën wereldwijd en worden er steeds meer knieprotheses geplaatst. Mogelijke verklaringen zijn: 1) orthopedische chirurgen zijn niet bekend met de goede resultaten die kunnen worden behaald met een correctie osteotomie, en 2) orthopedische chirurgen zijn onvoldoende vertrouwd met (de operatie techniek van) een correctie osteotomie van de knie. Beide verklaringen zullen hieronder beargumenteerd worden.

Orthopedische chirurgen zijn niet bekend met de goede resultaten die kunnen worden behaald met een correctie osteotomie.

In het verleden werd de technisch meer ingewikkelde CWO procedure vaker gebruikt. Meest beschikbare langetermijn resultaten zijn van de CWO techniek en het is pas tot recentelijk dat de zeer goede resultaten van een OWO gepubliceerd worden. De OWO is een makkelijker en meer accurate techniek in vergelijking met de CWO. Hoewel we in **Hoofdstuk 7** betere klinische resultaten aantoonden voor de CWO in vergelijking met de OWO, komt dit waarschijnlijk door patellofemorale klachten vanwege het ontstaan van een patella baja in de OWO techniek. Het gebruik van de undercutting techniek (biplanaire osteotomie) kan dit probleem voorkomen. Een biplanaire osteotomie bespaart de tuberositas tibiae en daardoor verandert de patellahoogte niet (Figure 6, p11).
In Aziatische landen is er juist een toename van het aantal correctie osteotomiën van de knie. Bijvoorbeeld in Zuid-Korea, is het aantal correctie osteotomiën de laatste 5 jaar met 210% toegenomen en het aantal TKPs met 18%. De reden voor deze verschillen, vergeleken met de

wereldwijde trent, is niet helemaal duidelijk, maar de postoperatieve mogelijkheid tot pijnvrij knielen en hurken kan een verklaring zijn; deze activiteiten zijn vaak niet mogelijk na een knieprothese. Knielen en hurken zijn belangrijke bewegingen in de Aziatische cultuur. Een andere verklaring kan het prothese regulatie beleid in Zuid-Korea zijn, waarin alleen maar knieprotheses worden vergoed bij patiënten ouder dan 60-64 jaar in combinatie met een graad IV gonartrose (volgens de Kellgren en Lawrence classificatie op röntgenfoto's). Daarom geven orthopedische chirurgen de voorkeur aan een correctie osteotomie om zo het plaatsen van een knieprothese uit te stellen tot boven de 65 jaar, mits de patiënt dan ook ernstige radiologische gonartrose heeft.
Met een correctie osteotomie wordt de behandeling met een knieprothese uitgesteld. De 10-jaars overlevingspercentages van tibiale osteotomiën zitten tussen de 51% tot 98%. Er zijn studies die laten zien dat de resultaten van het plaatsen van een TKP na een osteotomie vergelijkbaar of zelfs minder goed zijn. Het is belangrijk dat chirurgen de technische moeilijkheden die bij het plaatsen van een knieprothese na een osteotomie komen kijken, goed kennen, om zo vergelijkbare resultaten als bij een primaire knieprothese te kunnen halen. Deze overkomelijke nadelen van een conversie naar een knieprothese, is geen argument om dan maar geen correctie osteotomiën meer te verrichten bij patiënten met gonartrose. Wij zijn van mening dat de voordelen van een gewrichtssparende operatie, herstel van de normale biomechanica, uitstel van het plaatsen van een knieprothese en voorkomen van dure revisie operaties verweg opwegen tegen de nadelen.
Naast de mogelijke complexe uitvoering van een correctie osteotomie van de knie, beargumenteren veel orthopedische chirurgen dat de lange revalidatie een probleem is. In het verleden was het normaal om patiënten postoperatief 6 weken niet of gedeeltelijk te laten belasten. Met het gebruik van de nieuwe hoekstabiele implantaten in een OWO is dit meestal niet nodig. Patiënten kunnen (vrijwel) direct postoperatief volledig belasten.
Een ander probleem wat de toepassing van de correctie osteotomie beperkt, is dat veel patiënten klachten ondervinden van het implantaat en dat meestal het implantaat verwijderd moet worden vanwege deze klachten. In de literatuur worden percentages tussen de 0 tot 23% genoemd dat vanwege klachten het implantaat verwijderd moet worden. Nieuwe implantaten met verschillende legeringen en dunnere contouren kunnen dit probleem verminderen. In **Hoofdstuk 5 en 6** hebben we een dergelijk nieuw implantaat onderzocht (FlexitSystem implant). Hoewel we vonden dat dit implantaat stabiel en veilig was in het gebruik bij een OWO, moest helaas toch bij 38% van de patiënten het implantaat verwijderd worden vanwege irritatie (geregistreerd door de chirurg). Echter deze studie was een retrospectieve single centrum studie en in dit deelnemende ziekenhuis was de reden om een implantaat te verwijderen kloppijn over het implantaat. Het verwijderen van het implantaat werd dus

laagdrempelig gedaan en het was dan ook niet duidelijk hoeveel klachten patiënten op dagelijkse basis ervaarden van het implantaat. Een andere reden voor het hoge percentage verwijderde implantaten vanwege klachten kan zijn dat het FlexitSystem implantaat meer irritatie geeft dan dat we verwacht hadden. Het is in ieder geval zo dat onderzoek naar nieuwe implantaten met verschillende legeringen en plaat diktes nodig is.
Om de kennis over en populariteit van de correctie osteotomie van de knie te verbeteren, zijn goede klinische resultaten nodig, maar ook dat deze resultaten makkelijk gevonden en vergeleken kunnen worden. Heel belangrijk zijn de nationale registratiesystemen om inzage te geven in operatietechnieken, kwaliteit van implantaten, patiënt gerapporteerde uitkomsten, kwaliteit van ziekenhuizen en chirurgen. In de nationale registers van het Verenigd Koninkrijk en Zweden wordt de correctie osteotomie al geregistreerd. We stellen voor aan de Landelijke Registratie Orthopedische Implantaten (LROI) om de resultaten van de osteotomiën ook in Nederland te registreren. Dan kan men in de toekomst een vergelijking maken tussen operatietechnieken en type implantaten, maar ook kunnen de resultaten vergelijken worden met knie protheses.

Orthopedische chirurgen zijn onvoldoende vertrouwd met (de operatie techniek van) een correctie osteotomie van de knie.
Door de afgenomen populariteit van de correctie osteotomie in patiënten met unicompartimentele gonartrose en een standsafwijking, zijn er steeds minder orthopedisch chirurgen bekend met de juiste operatie techniek van een osteotomie of ze voelen zich niet bekwaam genoeg om dit soort operaties te verrichten. Als deze trent voortgezet wordt, zijn de jonge orthopedische chirurgen in de toekomst zeker niet bevoegd om een correctie osteotomie van de knie te verrichten. Het is belangrijk dat de orthopedisch chirurgen in opleiding en jonge orthopedische chirurgen getraind worden in de osteotomie technieken. Aangezien het deze jonge orthopedische chirurgen zijn die in de toekomst moeten dealen met de verwachte toename in revisie operaties en complicaties van knieprotheses welke geplaatst zijn bij jonge patiënten. Zij moeten zichzelf trainen in gewrichtssparende behandelopties voor de jonge patiënt met gonartrose, zoals correctie osteotomiën en knie distractiebehandelingen. Hopelijk draagt dit proefschrift bij aan de populariteit van de correctie osteotomie van de knie.
Een andere mogelijke bijdrage om orthopedische chirurgen meer vertrouwd te maken met een correctie osteotomie is een verplichte osteotomie cursus gedurende de opleiding, en het verplicht stellen van een correctie osteotomie als één van de basis chirurgische technieken van een gespecialiseerde (knie) orthopedische chirurg.
In Nederland komt binnenkort het nieuwe protocol “Heup en Knie Artrose” uit en we adviseren de Nederlandse Orthopaedische Vereniging (NOV) om de correctie osteotomie van

de knie een prominente plaats te geven in dit protocol als behandeling van de jonge en actieve patiënt met unicompartimentele gonartrose en een standsafwijking.
Om continu de klinische resultaten van een correctie osteotomie te verbeteren, moet de juiste operatie techniek ook verbeterd worden. Dit proefschrift draagt bij aan de kennis over de juiste operatie techniek van een correctie osteotomie. Zo werd in de studie over de release van de oppervlakkige MCL in een OWO (**Hoofdstuk 3**) bijgedragen aan de discussie over wat nou de juiste osteotomie techniek in een OWO is. Een release van de oppervlakkige MCL is nodig, om zo het mediale compartiment te ontlasten. Echter, na de release van de oppervlakkige MCL nam de laxiteit significant toe in vergelijking met de situatie zonder OWO. Of de release van de oppervlakkige MCL nou leidt tot instabiliteit van klinische relevantie moet verder onderzocht worden.
Tegenwoordig heeft de OWO techniek de voorkeur, wat ervoor zorgt dat de expertise van de CWO techniek afneemt. Dit zou spijtig zijn, aangezien de CWO techniek, mits correct uitgevoerd, ook uitstekende klinische uitkomsten laat zien (**Hoofdstuk 7**).
Andere toekomstige technische ontwikkelingen welke kunnen bijdragen aan het verbeteren van de osteotomie techniek zijn bijvoorbeeld betere beeldvormingtechnieken (zoals 3D technieken), betere zaag technieken (bijvoorbeeld een dunner zaagblad), peroperatief gebruik van navigatie of realtime terugkoppeling (bijvoorbeeld directe monitoring van de intra-articulaire druk om zo de exacte mate van release van de oppervlakkige MCL te kunnen bepalen) en patiëntspecifieke instrumenten. Het is zeer waarschijnlijk dat deze ontwikkelingen voor nog betere resultaten van de correctie osteotomie kunnen leiden.
Dit proefschrift bewijst dat er nog steeds plaats is voor de correctie osteotomie in de behandeling van de jonge en actieve patiënt met unicompartimentele gonartrose en een standsafwijking. Tot nu toe wordt de jonge patiënt gedefinieerd als onder de 60 jaar, maar ook dit is gebaseerd op oudere literatuur. De 'jonge' patiënt kan tegenwoordig wel 70 jaar of ouder zijn, mits biologisch jong. Het is meer relevant om te kijken naar de biologisch jonge patienten als kandidaat voor een correctie osteotomie van de knie dan naar de kalenderleeftijd. De invloed van biologische leeftijd in plaats van kalenderleeftijd op de resultaten van een correctie osteotomie van de knie moet verder worden onderzocht, echter op basis van de resultaten uit dit proefschrift en de literatuur, is het zinvol om te onderzoeken of er meer patiënten behandeld kunnen worden.

CHAPTER 10

Acknowledgements / Dankwoord
List of publications and presentations
Curriculum Vitae

Acknowledgements / Dankwoord

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Presentations

1. EFORT Congress, Geneva, Switzerland June 2016
   Is there a difference in outcome between two types of valgus unloading braces for varus medial knee osteoarthritis? A randomized controlled trial
2. ISAKOS Congress, Lyon, France June 2015
   The effect of a valgus opening wedge high tibial osteotomy and release of the medial collateral ligament on the cartilage pressure, tension over the medial collateral ligament and valgus stability of the knee
3. ESSKA Congress, Amsterdam, the Netherlands May 2014
   Superior clinical results after closed wedge high tibial osteotomy comparing to open wedge high tibial osteotomy in patients with medial knee osteoarthritis and varus leg alignment. 7.9 years follow-up of a randomized controlled trial
4. EFORT Congress, Vienna, Austria June 2009
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Curriculum Vitae

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