Unicompartmental Osteoarthritis of the Knee

Diagnosis and Treatment of Malalignment

R.W. Brouwer

CIP-GEGEVENS KONINKLIJKE BIBLIOTHEEK, DEN HAAG

Brouwer, R.W.
Unicompartmental Osteoarthritis of the Knee. Diagnosis and Treatment of Malalignment.

Proefschrift Rotterdam. - Met lit. opg. - Met samenvatting in het Nederlands.

ISBN 90-75092-47-4

Cover: "Bridges of Rotterdam", E.Q. Bakker, Rotterdam NL
Layout: Kader Desktop Publishing, Zuidlaren NL
Printed by: Drukkerij Van Ark, Haren NL

Unicompartmental Osteoarthritis of the Knee

Diagnosis and treatment of malalignment

Unicompartimentele artrose van de knie

De diagnose en behandeling van de afwijkende stand

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
rector magnificus

Prof.dr. S.W.J. Lamberts

en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
woensdag 17 mei 2006 om 13.45 uur

door

Reinoud Willem Brouwer

geboren te Hoogeveen

Promotiecommissie

Promotor:	Prof.dr. J.A.N. Verhaar
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T.M. van Raaij

Revolving fund van het Erasmus MC Rotterdam, Anna Fonds te Leiden, Nederlandse Orthopaedische Vereniging, Reumafonds, Martini ziekenhuis Groningen, Biomet Nederland BV, Stryker Nederland BV, Zimmer Netherlands BV, Brink Orthopedie, GlaxoSmithKline BV, Smith & Nephew BV, Somas BV, Link Nederland, Albers Shuh-Orthopadie, Astra Tech BV, AstraZeneca BV, Bauerfeind Benulux BV, DePuy Johnson & Johnson, Heraues Medical, Janssen-Cilag BV, ID medical BV, Lohmann Rauscher BV, Mathys Orthopaedics BV, Oudshoorn chirurgische techniek BV, Plus Orthopedics BV, Pro-Motion Medical BV en Synthes BV hebben bijgedragen aan de totstandkoming van dit proefschrift.

Contents

Chapter 1

General Introduction

Osteoarthritis (OA) of the knee is a common medical condition that is often seen in general practice and causes considerable pain and immobility. In the United States, approximately 6% of the population aged 30 years and older and 12% of the population aged 65 years and older suffer from knee osteoarthritis.[1] In addition to the consequences for the patient, osteoarthritis forms a considerable burden for society because of its chronic course and the high costs of interventions.[2] In the Netherlands 1% of the total medical costs is spent on osteoarthritis.[3]

Osteoarthritis of the entire knee is distinguished from osteoarthritis of one compartment, which is generally caused by a mechanical problem.[4] The mechanical axis of a straight leg is defined as a line passing from the centre of the hip, through the centre of the knee to the centre of the ankle.[5] Patients with osteoarthritis of the medial compartment often have varus alignment, and the mechanical axis and load bearing pass through the medial compartment (=genu varum arthroticum). Patients with osteoarthritis of the lateral compartment often have a valgus alignment, and the mechanical axis and load bearing pass through the lateral compartment (genu valgum arthroticum). Axial malalignment (varus or valgus alignment) increases the risk for progression of knee osteoarthritis and predicts a decline in physical function.[6]

Besides the usual treatment for osteoarthritis, specific interventions for unicompartmental knee osteoarthritis include conservative interventions e.g. (knee braces and foot/ankle orthoses) as well as surgical treatments (e.g. a correction osteotomy to reduce load of the osteoarthritic compartment of the knee).[7-15]

The anterior-posterior whole leg radiograph (WLR) is considered the gold standard for determining axial alignment and serves as the basis for planning a knee osteotomy in patients with osteoarthritis. In many studies the WLR has been made in standing position, whereas others have preferred the supine position.[13,14,16,17]

In ***Chapter 2*** we study in the same group of patients the influence of standing or supine position on the alignment measured on an anteroposterior WLR.

Rotation of the lower extremity and flexion of the knee is supposed to affect the apparent alignment that is seen when a WLR is made. However, it is unknown how large the effect of rotation and flexion is on alignment of the leg. Therefore, in ***Chapter 3*** these effects are investigated in a cadaver study and subsequently confirmed by mathematical analysis.

The initial treatment for unicompartmental osteoarthritis of the knee is conservative.

Chapter 4 includes a systematic Cochrane review in which we summarize the current knowledge on the effectiveness of braces and foot/ankle orthoses for treatment of unicompartmental osteoarthritis of the knee.

Chapter 5 presents a prospective randomised trial in which we investigate the effect of a brace intended to reduce load applied in addition to usual conservative care for

unicompartmental osteoarthritis of the knee, with varus alignment as well as valgus alignment (genu varum and valgum arthroticum). If non-surgical therapy fails, these patients can be treated with a correction osteotomy, the aim of which is to transfer the load bearing to the normal compartment, which will reduce the symptoms and allow a total knee replacement to be postponed.

In ***Chapter 6*** we present an overview of osteotomy surgery for unicompartmental osteoarthritis of the knee. Indication, preoperative work-up, different operative techniques, results and complications are discussed.

Chapter 7 systematically summarizes (again in the form of a Cochrane review), the current knowledge on the effectiveness of a correction osteotomy for the unicompartmental osteoarthritic knee.

Chapter 8 presents the one-year results of a prospective randomised controlled trial comparing the closing with the opening wedge high tibial osteotomy (HTO) technique in patients with medial unicompartmental osteoarthritis of the knee. Outcome measures are accuracy of correction, pain and function scores.

In spite of a successful HTO, most of the patients will eventually undergo a total knee arthroplasty. It is suggested that a total knee replacement after HTO presents additional technical problems and complications because of scars, valgus alignment, descent of the patella (low position of the patella) and a change in tibial inclination.[18-20]

In ***Chapter 9*** we compare the severity of patellar descent and a change in the inclination angle of the tibial plateau after HTO using the first half of the study population included in the prospective randomised trial comparing the closing with the opening wedged HTO technique.

Chapter 10 of this thesis discusses the methods, results and implications of our studies, followed by recommendations for future research.

Chapter 11 presents an English and Dutch summary of the work in this thesis.

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Chapter 2

The Whole Leg Radiograph: Standing versus Supine for Determining Axial Alignment

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Acta Orthop Scand. 2003;74:565-8

Abstract

The whole leg radiograph (WLR) is the standard technique for determining axial alignment, is usually taken in a standing position, although some prefer the supine position.

To determine the difference between these two positions, we performed a standing as well as a supine WLR in 20 patients with a varus alignment. Measurement of the radiographs showed an average of two degrees more varus deviation in the standing position than in the supine position.

Introduction

The anteroposterior whole leg radiograph (WLR) is considered the gold standard for determining axial alignment and serves as the basis for planning a knee osteotomy in patients with arthrosis. Correct alignment after high tibial osteotomy and total knee arthroplasty is important.[1-6]

Assessment of the alignment, using the WLR in standing position has an interobserver variability of 1.3 degrees, which is regarded as sufficient for reliable calculation of the correction.[7]

In many studies the WLR has been made in a standing position, but others have preferred the supine position.[2,4,8-10]

We assessed the difference between the standing and supine WLR in the same group of patients, and the extent of rotation of the foot in very precise anteroposterior WLR in a standing position.

Patients and Methods

Between June and December 2001, we prospectively included 20 consecutive patients (11 women) with clinical and radiographic arthrosis of the medial compartment of the knee. Their mean age was 55 (range 49-67) years.

The exclusion criteria were a valgus alignment of the lower extremity on clinical examination, a history of a fracture of the lower extremity, and known congenital anomalies. Patients who were not able to stand on one leg were also excluded.

Six patients had previous surgery (1 high tibial valgus osteotomy, 2 open meniscectomy, and 3 arthroscopic meniscectomy).

We measured the clinical alignment of the lower extremity in a standing position and the range of motion in a supine position with a goniometer.

The collateral laxity was graded in supine position with 30 degree flexion and in full extension.[11]

The grade of arthrosis was measured on standard short posteroanterior radiographs in a standing position and the knee in full extension.[12]

Radiographic technique

First, the WLR in standing position was taken: the patient stood barefooted on the affected leg with the knee in full extension, while the contra-lateral flexed knee was supported by means of a small box. The X-ray beam was centered on the affected knee with the tube at a distance of 1.5 meters. The three-part 136/36 cm cassette with

graduated grid was immediately behind the patient. The 100% anteroposterior projection was ensured during lateral fluoroscopic control by superimposing the dorsal aspect of the femoral condyles. The tube was set perpendicular to this lateral view and was moved from the proximal end to the distal end so that a whole leg radiograph was obtained.

When the standing WLR was made, the extent of rotation of the foot (standing in a shoe box on a paper) was measured and recorded as the angle between the line of the second toe ray and the AP axis. Then, the WLR in supine position was made: the patient had to lie with the same leg on the cassette. The foot was held in the same amount of rotation as with the standing WLR. The tube was again at a distance of 1.5 meters.

After the radiographs were developed, they were taped together.

From both radiographs, the Hip-Knee-Ankle (HKA) angles were determined twice by an independent observer who did not know whether the radiographs were made in a standing or a supine position. Moreover, the HKA was determined by two independent observers. The intra- and interobserver variabilities are expressed as an intraclass correlation coefficient (ICC).

The HKA angle was defined as the lateral angle between two lines: one line from the center of the femur head using Mose circles to the middle of the distance between the tibial spines, and a second line from the center of the ankle to the center of the tibial spines. An angle of more than 180 degrees denoted a varus alignment.

For a 100% anteroposterior WLR, we also determined the difference (mean (SD))and the mean extent of rotation of the foot.

Differences between standing position and supine position were analyzed with the paired T-test. Pearson's test was used to analyze the correlation between the grade of arthrosis and the HKA angle, the extent of rotation and the grade of collateral laxity, as well as between the collateral laxity and the HKA angle. A p-value of 0.05 was considered significant.

We also assessed the difference between the two methods for determining the HKA angle, which had been plotted against the average of these two methods of Bland and Altman's method.[13]

Results

The lateral collateral laxity was graded as 1 (0-5 degrees) in 16 knees and 2 (5-15 degrees) in 4 knees. The severity of arthrosis (Ahlbäck) in the medial compartment was graded 1 in 13 knees, grade 2 in 6 and grade 3 in 1.[12]

The mean HKA angle of the standing WLR was 187 (182-196) degrees, but that of the supine WLR was 185 (180-194) degrees (Table 1).

Table. 1. HKA angle measured on whole leg radiograph, standing versus supine.

Case no.	Age (years)	Sex F/M	Ligament laxity	Grade of arthrosis (Ahlbäck)	HKA standing	HKA supine	Difference	External rotation
1	54	F	1	1	186	184	-2	34
2	63	F	1	2	188	186	-2	29
3	51	M	1	2	189	187	-2	19
4	67	M	1	2	187	185	-2	7
5	52	F	1	1	185	184	-1	28
6	50	M	1	1	187	185	-2	10
7	53	F	1	1	182	180	-2	21
8	60	M	2	2	187	186	-1	18
9	49	M	2	3	196	194	-2	16
10	58	M	1	1	188	186	-2	23
11	61	M	1	1	186	184	-2	18
12	53	F	1	1	182	180	-2	25
13	52	F	1	1	186	184	-2	9
14	54	M	1	2	188	186	-2	15
15	56	F	1	1	184	182	-2	10
16	60	M	1	2	196	193	-3	22
17	52	F	1	1	186	184	-2	7
18	51	F	1	1	184	182	-2	29
19	53	F	2	1	186	184	-2	32
20	52	F	2	1	188	187	-1	18

In men the mean HKA angle was 189 degrees standing and 187 degrees supine; in women, it was 185 degrees standing and 182 degrees supine.

In all patients, the mean difference between the HKA angles measured standing and supine was 2 (range 1-3; SD 0.45) degrees (Paired T-test; $p<0.001$), and more varus deviation was measured in the standing position than supine. We found no obvious relation between the methods and the average values. If we adjust for the consistent bias of two degrees by subtracting d (mean difference) from the alternative method, the difference will remain less than one degree. The intraobserver variability and the interobserver variability were low: ICC= 0.98; 95% CI= 0.94-0.99 and ICC= 0.97; 95% CI= 0.94-0.99 respectively.

The mean extent of rotation for a 100% anteroposterior WLR in standing position with lateral fluoroscopic control was 20 degrees external rotation (range 7- 34; SD 8.1); the mean extent of rotation in men was 16 degrees compared with 22 degrees in women.

We found a correlation between the grade of arthrosis and the HKA angle both standing (Pearson correlation 0.747; $p<0.001$) and supine (Pearson correlation 0.753; $p<0.001$).

The correlation between the grade of arthrosis and extent of rotation (Pearson correlation –0.15; $p=0.5$) and between the grade of collateral laxity (Pearson correlation 0.300; $p=0.2$).

There was also no correlation between the grade of collateral ligamentous laxity and the HKA angle either standing (Pearson correlation 0.31 p=0.2) or supine (Pearson correlation 0.38; p=0.1).

Discussion

We found an average of 2 degrees more varus deviation than in the supine WLR.

None of the patients had gross abnormal collateral laxity. In patients with an increase in ligamentous laxity, the difference between the standing and supine WLR may be even greater than that found in our patients. Edholm et al. in an ortho-radiographic study with healthy persons, found that knee instability affects the HKA angle.[14]

Sanfridsson et al. noted less varus alignment in the two-leg stance than in the one-leg stance WLR, because the one-leg stance forces the knee in varus against the lateral stabilizing structures.[15]

A WLR in supine position may be better in patients with abnormal laxity of the lateral collateral ligament, because lateral tibiofemoral separation increases the varus angulation on the WLR in the standing position which causes overcorrecting in case of a high tibial osteotomy.[2,16]

Ogata et al. recommended taking WLR in the supine position in all patients in order to evaluate the stretched ligamental structures and the condylar-plateau angle when planning high tibial osteotomy.[10]

In practice, it is not always possible to make a WLR in the standing position because of pain and/or instability of the affected knee.[17,18]

Moreover, the WLR in a standing position with 100% antero-posterior projection is time consuming, more costly, and exposure to radiographic radiation is greater because of the lateral fluoroscopic control. The exposure to radiographic can be reduced by modern techniques, but is less accurate if the patient has an extension lag of the knee.[15,19]

The intra- interobserver variabilities of the measurements of the HKA angle that we found were similar to those of Odenbring et al. and Sanfridsson et al.[9,15]

On the basis of the above-mentioned reports and our findings, we recommend a WLR in supine position. One should bear in mind that a WLR in the standing position will result in two degrees more varus deviation than in the supine position.

Secondly, if the anteroposterior WLR is not taken under lateral fluoroscopic control, we recommend that the radiograph should be taken in full extension and at 20 degrees of external rotation.

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Chapter 3

Pitfalls in Determining Knee Alignment
A Radiological Cadaver Study

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J. Knee Surg. in press

Abstract

Introduction The whole leg anteroposterior (WLR) radiograph provides the basis for evaluating leg alignment.
Methods A cadaver study was performed to determine the effect of flexion of the knee and rotation of the hip on projected angles on the anterior-posterior (AP) whole leg radiograph.
The outcomes were mathematically checked.
Results The results of the cadaver study were similar to the mathematical results:
Flexion of the knee without rotation of the lower extremity has very little effect on angles as projected on whole lower limb AP radiographs. Rotation of the lower extremity without flexion of the knee also has little effect.
Simultaneous flexion of the knee and rotation of the leg, however, cause large changes in projected angles.
Conclusion Whole leg radiographs can be made without fluoroscopic control as long as the knee can be fully extended. In the presence of a flexion contracture a 100% AP radiograph under lateral fluoroscopic control is necessary to obtain accurate determination of the mechanical axis.

Introduction

The best way to evaluate lower extremity alignment is to obtain a whole leg antero-posterior (AP) radiograph in supine or standing position.[2,3,6,10] This method is often used in the planning of correction osteotomy or knee arthroplasty. The degree of operative correction is based on the angles measured on the radiograph and this is probably the most critical and difficult part of a correction.[9]

Previous biomechanical and clinical studies have demonstrated that optimal operative correction is essential for clinical success of high tibial osteotomy and mechanical loosening of knee arthroplasty is related to postoperative alignment.[1,4,5,8,12]

Rotation of the lower extremity and flexion of the knee will affect the apparent alignment that is seen when a whole leg radiograph is made. It is unknown how large the effect of rotation and flexion is on alignment of the leg. Because varus alignment is more common than valgus alignment, we chose to use that clinical entity as the basis for our outcomes.

The results of the cadaver study were checked by mathematical analysis.

Materials and methods

Whole leg roentgenograms were made of a cadaver leg without soft tissue and a femur length of 46 cm and a tibia length of 37 cm.

The leg was laid flat on the three-part 136/36 cm radiographic cassette with graduated grid. The X-ray beam was centered on the knee with the tube at a distance of 150 cm.

The varus angle was expressed in the Hip-Knee-Ankle (HKA) angle and was defined as the angle between two lines: one line from the center of the femur head using Mose circles to the middle of the distance between the tibial spines, and a second line from the center of the ankle to the center of the tibial spines. An angle of more than 180° denoted a varus alignment. The HKA-angle of the cadaver leg was 190°.

First the influence of flexion was measured:
The radiographs were made with the leg flexed 0, 15, and 30 degrees. Flexion was achieved by placing radiolucent blocks under the knee.

Secondly, the leg was positioned in 15° and 30° of internal and external rotation. Rotation was controlled by a transcondylar rod perpendicular to the posterior aspects of the femoral condyles.

Finally, the leg was flexed 15° and 30° with simultaneous 15° and 30° internal and external rotation.

The HKA-angle was measured on the radiographs by a blinded observer.

The results of the cadaver study were checked by means of mathematical formulas, which are extensively explained in the appendix.

For the mathematical analysis we used the Mathcad Professional 7.0 soft ware.

Results

The cadaver and the mathematically outcomes are described in the tables.

The results of the cadaver study were similar to the mathematical results.

Table 1 shows that rotation without flexion causes minimal changes in projected angles on a whole lower limb radiograph. Table 1 shows that 30° of internal or external rotation changes the degree of varus less than 2°. The result were similar for flexion without rotation; even flexion of 30° changes the degree of varus less than one degree (Table 2). However, when a varus knee with a HKA-angle of 190° flexes and rotates

Table 1. Influence of rotation on a varus knee with a HKA angle of 190 degrees without flexion.

Rotation of the cadaver leg	Varus angle measured on radiograph	Varus angle calculated with formula
30° internal rotation	189°	188.7°
15° internal rotation	190°	189.7°
0° rotation	190°	190.0°
15° external rotation	190°	189.7°
30° external rotation	189°	188.7°

Table 2. Influence of flexion on a varus knee with a HKA angle of 190 degrees without rotation.

Flexion of the cadaver leg	Varus angle measured on radiograph	Varus angle calculated with formula
0°	190°	190.0°
15°	190°	190.1°
30°	190°	190.4°

simultaneously, large changes occur (Table 3); 15° of flexion and 15° of simultaneous external rotation produces 4° of varus.

Moreover in case of a varus alignment flexion in combination with external rotation causes more changes than flexion in combination with internal rotation.

Table 3. Influence of rotation and flexion on a varus knee with a HKA angle of 190 degrees.

Rotation of the cadaver leg	Flexion of the cadaver leg	Varus angle measured on radiograph	Varus angle calculated with formula
30° internal rotation	30°	175°	173.6°
30° internal rotation	15°	182°	181.2°
15° internal rotation	30°	183°	182.1°
15° internal rotation	15°	190°	189.9°
No rotation	0°	190°	190.0°
15° external rotation	15°	194°	193.6°
15° external rotation	30°	197°	197.9°
30° external rotation	15°	196°	196.2°
30° external rotation	30°	203°	204.1°

Discussion

From the cadaver study we can conclude that flexion of the knee in combination with rotation of the leg during the making of the whole leg radiograph results in false varus/valgus angles on the film.

Krackow and colleagues also performed a mathematical study, but did not check their formulas with a cadaver study. In our study the cadaver study validated their results.[7]

There are different methods of making a whole leg radiograph, but there are basically two main techniques: with and without fluoroscopic control.[2,10, 11,13]

In our hospital the whole leg radiograph is traditionally made with fluoroscopic control as described by Brouwer et al.[2] The patient is barefoot, stands on the affected leg with the knee in full extension, while the contra-lateral leg leans with a flexed knee on a small box. The X-ray beam is centered on the affected knee with the tube at a distance of 1.5 meters.

The three-part 136/36 cm cassette with graduated grid is immediately behind the patient. The 100% antero posterior projection is ensured under lateral fluoroscopic control by superimposing the posterior aspect of the femoral condyles.

The tube is set perpendicular to this lateral view and is moved from the proximal end to the distal end so that a whole leg radiograph was obtained.

In this way we try to avoid an inaccurate measurement caused by flexion-contracture in combination with a rotated position of the leg. This technique does, however, have some disadvantages: it is difficult for some patients to load on the painful knee despite the extra stability of the contra-lateral leg; slight motion of the leg will prevent the two parts of the radiograph fitting perfectly together; and there is increased exposure of the knee to radiographic radiation because of the lateral fluoroscopic control.

Odenbring et al. also used fluoroscopic control, although the radiograph is made with the knee 10 degrees flexed.[10] Without fluoroscopic control this method can cause false varus/ valgus angles.

Authors not using fluoroscopic control have described the whole leg radiograph with the patient standing on one leg with the patella forward.[13] This will not always lead to a perfect 100% antero posterior as for instance in a patient with a subluxated patella.

In an earlier study we reported that the mean extent of rotation for a 100% anteroposterior WLR in standing position with lateral fluoroscopic control in 20 patients with varus knee was 20 degrees external rotation.[2] Not using fluoroscopic control we advice as means of limiting the error to avoid more than 20 degrees of external rotation in varus knees and to avoid less than 20 degrees of external rotation in valgus knees.

Our study shows that the effect of some rotation is limited as long as there is no flexion contracture. However, in the presence of a flexion contracture, we advise performance of a 100% AP radiograph under lateral fluoroscopic control.

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Appendix

Figure 1 shows the definition of varus. The angles α_1 and α_2 are not the same since the lengths of the femur and the tibia are biologically different in size. The sum of the three angles will be 180 degrees. The heights h_1, h_2 and x can be derived by simple goniometry:

$$h_1 = L_f \sin \alpha_1$$

L_f= length of the femur

$$h_2 = L_t \sin \alpha_2$$

L_t= length of the tibia

$$x = L_f \cos \alpha_1 = L_t \cos \alpha_2$$

The femur and tibia we used in our study had lengths of 46 cm and 37 cm respectively. Thus the relative factor of the femur length in comparison with the tibia length is 1.243. Now alpha and beta can be determined by solving the relations:

$$\frac{\cos \alpha_2}{\cos \alpha_1} = 1.243$$

$$\text{var} = 180 - \alpha_1 - \alpha_2$$

Varus as a function of rotation

Figure 2 presents a 3D explanation of the situation during rotation. When a X-ray is made, there will be a 2D projection of this 3D situation in the 0YZ plane. In this projection x will differ from its original length, which will be defined by x'.

$$x'(\rho) = x \cos(\rho)$$

where ρ is defined as the rotation

Since the projection of x will give x', the lengths of the bones will be changed as well. The lengths can be derived using Pythagorean theorem.

$$L_f' = \sqrt{h_1^2 + x'^2}$$

$L_t' = \sqrt{h_2^2 + x'^2}$

By combining the functions, the measured varus' in the X-ray can be defined as a function of the rotation:

$$\text{var}'(\rho) = 180 - \arcsin\left(\frac{h_1}{L_f'}\right) - \arcsin\left(\frac{h_2}{L_t'}\right)$$

var'(ρ) in degrees

Varus as function of the flexion

During the X-ray, while flexion occurs, the projection of h_1 and h_2 will change in relation to the original heights.

Figure 3 is a projection from the side of the leg. A flexion φ of the leg can be divided in two angles τ_α and τ_h. To calculate both angles both equations have to be solved:

$$\frac{\sin \tau_\alpha}{\sin \tau_h} = 1.243$$

$$\varphi = \tau_\alpha + \tau_h$$

With these angles h_1' and h_2' can be calculated.

$$h_1' = h_1 \cos \tau_h$$

$$h_2' = h_2 \cos \tau_\alpha$$

Combining the goniometrical functions gives the varus' as a function of the flexion φ:

$$\text{var}'(\varphi) = 180 - \arctan\left(\frac{h_1'}{x}\right) - \arctan\left(\frac{h_2'}{x}\right)$$

Varus as a function of flexion and rotation

Figure 4 shows the 3D presentation of the femur during flexion. The projected heights of the bones are only dependent on the flexion similar to earlier relations (see varus as a function of flexion).

$$h_1 = L_f \sin \alpha_1$$

$$h_2 = L_t \sin \alpha_2$$

$h_1' = h_1 \cos \tau_h$

$h_2' = h_2 \cos \tau_\alpha$

Unlike the heights of the bones, the projected x lengths are dependent on both rotation and flexion. Figure 5 shows the triangle of the knee, Q and the hip from Figure 4. With this figure the length x' can be derived.

$$x'(\varphi) = L_f \cos\left(\arcsin\left(\frac{h_1'}{L_f}\right)\right)$$

where h_1' is defined above
Note: in this equation x' is not the same as in the former equation.

Figure 6 shows the projection of Figure 4 in the 0XY plane. In this figure δ is defined. This δ is an offset, which has to be added to the rotation ρ.

$$\delta = \arccos\left(\frac{x}{x'}\right)$$

γ is a virtual rotation angle added by δ.

$$\gamma(\rho,\varphi) = \arccos\left(\frac{x}{x'}\right) - \rho$$

Now a new function x" can be derived, which includes x' and a component for the virtual angle γ.

$x'' = x' \cos \gamma$

Since the projection of the height h' and the projection of the x-component x" are defined, finally the relation of varus as a function of flexion and rotation can be derived. The relations are presented for γ smaller and greater than 90 degrees.

$\gamma < 90$:

$$\text{var}' = 180 - \arctan\left(\frac{h_1'}{x''}\right) - \arctan\left(\frac{h_2'}{x''}\right)$$

$\gamma > 90$:

$$\text{var}' = 540 - \arctan\left(\frac{h_1'}{x''}\right) - \arctan\left(\frac{h_2'}{x''}\right)$$

Figure 1. A schematic varus leg seen from the frontal view.

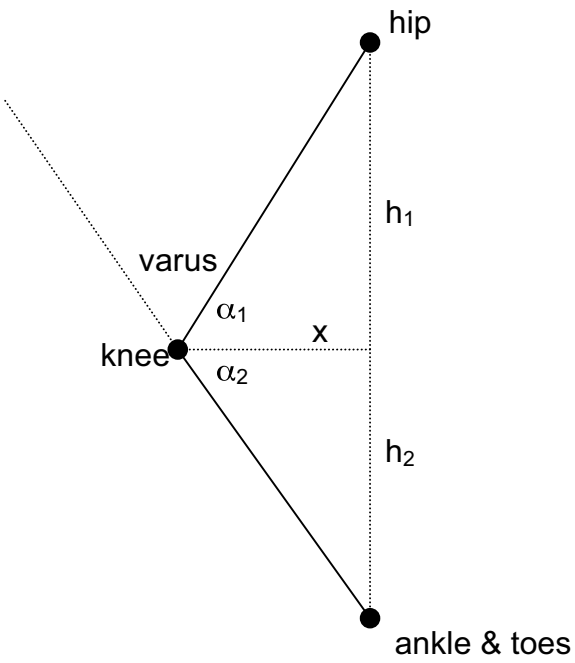


Figure 2. A schematic three-dimensional varus leg in neutral position and in endorotation.

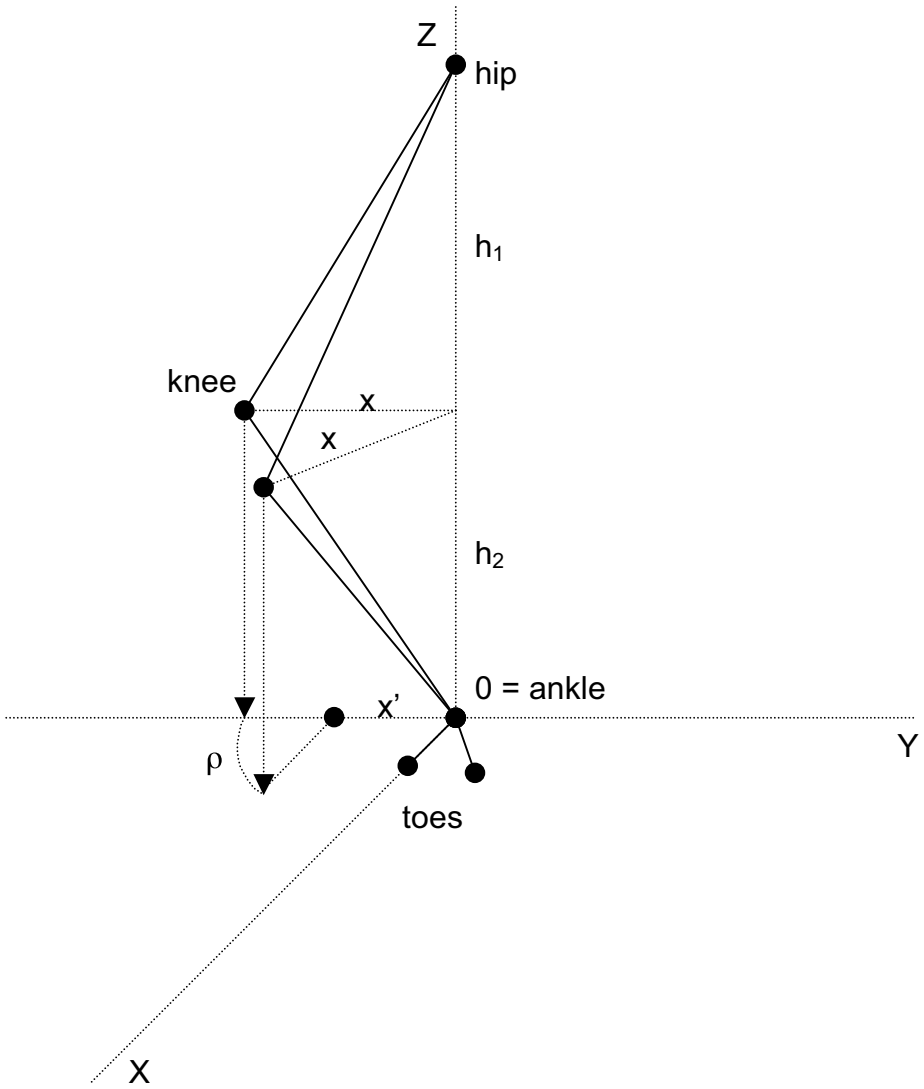


Figure 3. A schematic leg in flexed position seen from the lateral view.

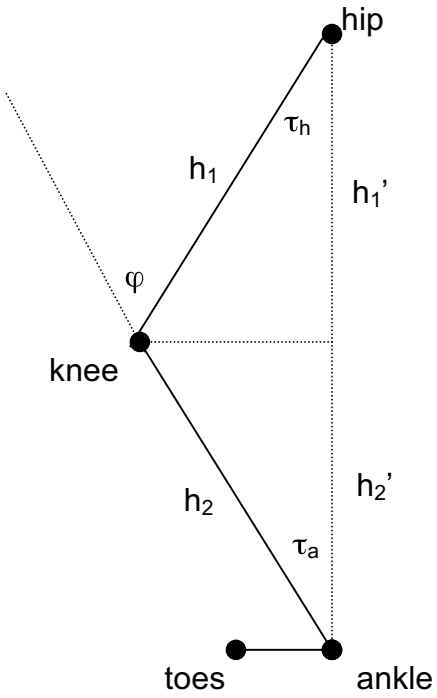


Figure 4. A schematic three-dimensional varus femur in extended and flexed position.

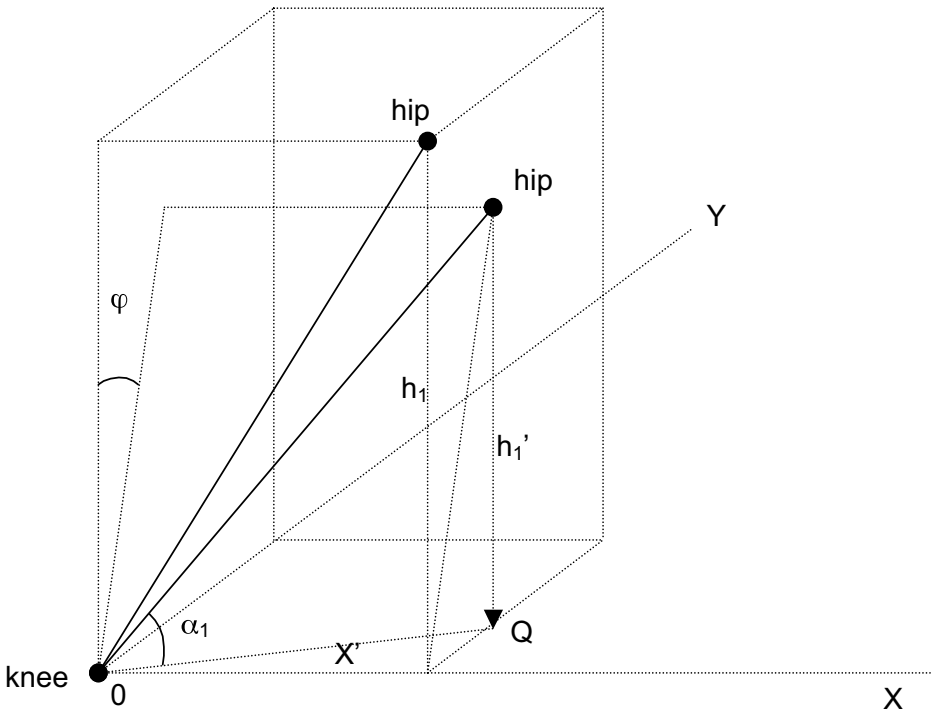


Figure 5. The triangle "knee-hip-Q" derived from Figure 4.

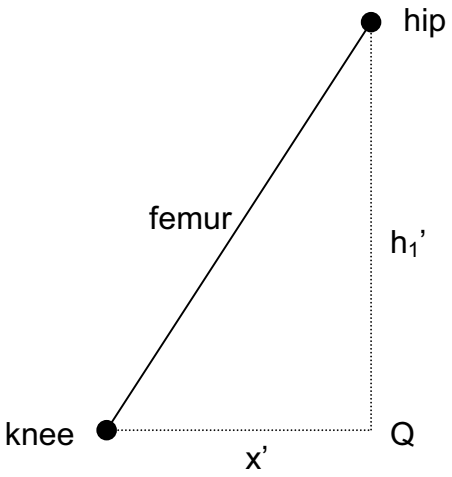
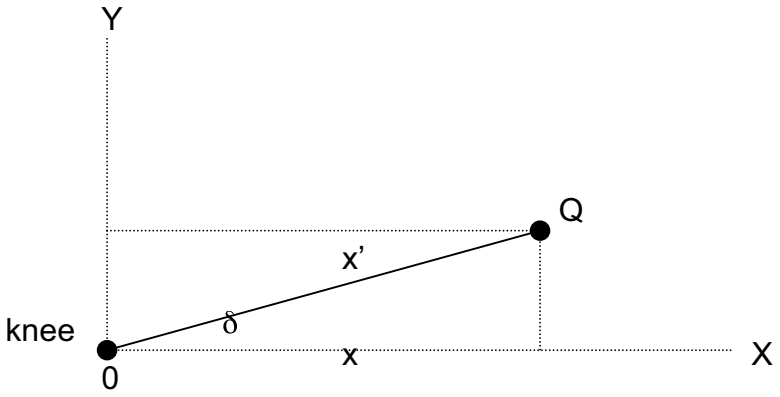


Figure 6. The projection of Figure 4 in the 0XY plane.



Chapter 4

Braces and Orthoses for Treating Osteoarthritis of the Knee

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Cochrane Database Syst Rev. 2005 Jan 25;(1):CD004020

Abstract

Background Patients with osteoarthritis of the knee can be treated with a brace or orthosis (shoe insole). The main purpose of these aids is to reduce pain, improve physical function and, possibly, to slow disease progression.

Objectives To assess the effectiveness of a brace or orthosis in the treatment of osteoarthritis of the knee.

Search Strategy We searched Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE (Current contents, Health STAR) up to October 2002. The reference lists of the publications in the identified trials were also screened.

Selection Criteria Extracted studies were included in the final analysis if they met the pre-defined inclusion criteria: 1) a randomised controlled clinical trial or a controlled clinical trial, 2) all patients had osteoarthritis of the knee, 3) the intervention in one of the studied groups was a brace or an orthosis.

Data collection and analysis Two reviewers independently selected the trials and assessed the methodological quality using the Delphi-list and one additional question about care programs. Three reviewers independently extracted the data on the intervention, type of outcome measures, follow-up, loss to follow-up, and results, using a pre-tested standardized form. Study authors were contacted for additional information.

Main Results Four trials involving a total of 444 people were included in this review. One study investigated a knee brace and three studies examined different types of ankle/foot orthoses for medial compartment osteoarthritis of the knee. Two studies were of high methodological quality while the other two studies were low. Notably, the randomisation and the blinding procedures were either insufficient or not described. The follow-up period (six weeks to six months) was too short to demonstrate long-term results. Pooling was difficult primarily due to the heterogeneity of the data and the way the information was presented.

The pain, stiffness and physical function (WOMAC and MACTAR) scores of a brace group showed greater improvement at six months compared with a neoprene sleeve group, which showed greater improvement compared with a control group.

The numbers of days of non-steroidal anti-inflammatory drug (NSAID) intake decreased significantly (relative percentage difference (RPD) 23.9%) compared with baseline in a group with laterally wedged insoles, and remained unchanged in the neutrally wedged group. Patient compliance with the laterally wedged insole was significantly better compared with the neutrally wedged insole. In one study, the Visual Analogue Pain (VAS) pain score was significantly decreased from baseline in a strapped insole

group (RPD - 24%), but not in the traditional laterally wedge group. However, this strapped insole showed more adverse effects (popliteal pain, low back pain, and foot sole pain) compared with the traditional laterally wedge insole. Pain during bed rest, after getting up, after getting up from seated position and walking distance was significantly improved in a subtalar strapped group compared with baseline, and no improvement was found in a sock type group. No studies were found that assessed the effectiveness of a brace or orthosis to treat lateral compartment osteoarthritis or general osteoarthritis of the knee, or that compared a knee brace with a wedge insole, or that compared a brace or orthosis with operative treatment.

Authors' conclusions Based on one brace study we conclude there is limited evidence that:

- a brace has additional beneficial effect (WOMAC, MACTAR, function tests) for knee osteoarthritis compared with medical treatment alone.(Silver)
- a sleeve has additional beneficial effect (WOMAC, function tests) for knee osteoarthritis compared with medical treatment alone.(Silver)
- a brace is more effective (WOMAC, function tests) than a neoprene sleeve.(Silver)

Based on 3 ankle/ foot orthoses studies, of which 2 were high quality, we conclude there is limited evidence that:

- a laterally wedged insole decreases NSAID intake compared with a neutral insole. (Silver)
- patient compliance is better in the laterally wedged insole compared with a neutral insole.(Silver)
- a strapped insole has more adverse effects than a laterally wedge insole.(Silver)

Background

Osteoarthritis of the knee is a common medical condition that is often seen in general practice and causes considerable pain and immobility. In the United States, approximately 6% of the population aged 30 years and older and 12% of the population aged 65 years and older suffer from knee osteoarthritis.[1] Risks for a poor function outcome are collateral and cruciate ligament laxity, age, Body Mass Index (BMI) and degree of pain.[2] In addition to the consequences for the patient, osteoarthritis forms a considerable burden for society because of its chronic course and the high costs of interventions.[3]

Osteoarthritis of the entire knee is distinguished from that of one compartment, which is generally caused by a mechanical problem.[4] Patients with osteoarthritis of the medial compartment often have a varus alignment, and the mechanical axis and load bearing pass through the medial compartment. Patients with osteoarthritis of the lateral compartment generally have a valgus alignment, and the mechanical axis and load bearing pass through the lateral compartment. Malalignment increases risk and progression of knee osteoarthritis and predicts decline in physical function.[5]

The initial treatment for osteoarthritis of the knee is conservative, consisting of restriction of activity, decrease of BMI, patient education, and physical therapy.[6-12] Pharmacological treatments tend to only modify symptoms (e.g. analgesics, anti-inflammatory drugs) but some are possibly curative (hyaluronic acids; chondroitin sulfate).[13-16] Electro-acupuncture, TENS (transcutaneous electrical stimulation) and leech therapy are not standard treatments, but can be effective in symptom reduction.[17,18] Braces and orthoses (shoe insoles) are defined as "any medical device added to a person's body to support, align, position, immobilize, prevent or correct deformity, assist weak muscles, or improve function.[19] The general purpose of braces and orthoses is to decrease pain and improve physical function and possibly slow disease progression. Proprioception and stability are hypothesised, but unproven, underlying explanatory factors only. Laterally wedge insoles and special valgisation braces are designed for reducing load of the medial compartment.[20-30]

Objectives

To assess the effectiveness (symptom reduction, improvement of knee function and quality of life) of braces and orthoses to treat osteoarthritis of the knee.

Criteria for considering studies for this review

Types of studies
Randomised controlled trials and controlled clinical trials investigating all types of braces and orthoses for osteoarthritis of the knee compared to no treatment and other treatment: such as restriction of activity/patient education, physiotherapy, pharmacological treatment, other types of braces and orthoses, and surgical treatment.

Types of participants
Adult patients with osteoarthritis of the knee confirmed by radiological investigation.

Types of intervention
All types of bracing and orthoses for patients with osteoarthritis of the knee.

Types of outcome measures
The primary measure of effectiveness is pain relief, as suggested by the third conference of Outcome Measures in Rheumatology (OMERACT)[31], and side effects.
The core OMERACT outcome measures for hip, knee and hand osteoarthritis include:
- Pain
- Physical function
- Patient global assessment
- Joint imaging (for studies of one year or longer)
- Health-related quality of life measure
- Physician global assessment

Side-effects:
The number of withdrawals in a study overall and the number of patients with side-effects were measured when possible.

Search strategy for identification of studies
See: Cochrane Musculoskeletal Group search strategy

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE (Current contents, Health STAR) up to October 2002 to identify all clinical trials investigating braces and orthoses for osteoarthritis of the knee. MEDLINE searches for clinical trials were based on the Cochrane Collaboration strategy. No language restriction was applied. In MEDLINE, the following search strategy was

combined with all phases of the optimal trial search strategy (Robinson[32]) and was modified for use in other databases:

1. osteoarthritis, knee
2. osteoarthritis/
3. (osteoarthritis or osteoarthrosis or degenerative joint disease).tw.
4. 2 or 3 (21816)
5. knee joint/ or knee .tw.
6. 4 and 5
7. 1 or 6
8. exp orthotic devices/
9. (brace$ or bracing).tw.
10. (orthotics$ or orthoses).tw.
11. or/ 8-10
12. 7 and 11

Methods of the review

Selecting trials for inclusion

Two reviewers (RB, TJ) independently selected the trials, initially based on title and abstract. The title, keywords and abstracts were assessed to establish whether the study met the inclusion criteria regarding diagnosis, design and intervention. For each selected study, the full article was retrieved for final assessment. Next, two reviewers (RB, TJ) independently performed a final selection of the trials to be included in the review, using a pre-tested standardized form. Disagreements on inclusion were resolved by discussion and, if required through arbitration by a third person (JV).

Methodological quality assessment

Two reviewers (RB, SB) independently assessed the methodological quality. They used the Delphi list, and one additional question adapted from the criteria list for Methodological Quality Assessment.[33,34] Disagreements were solved in a consensus meeting. In case of persisting disagreement a third reviewer (JV) would make the final decision. All items have a 'yes', 'no', 'don't know' answer option. Items rated as positive contribute to the quality assessment score by summing up.

The nine questions from the Delphi list and the additional question with (M) are:

D1. Was a method of randomisation performed?

D2. Was the treatment allocation concealed?
D3. Were the groups similar at baseline regarding the most important prognostic indicators?
D4. Were the eligibility criteria specified?
D5. Was the outcome assessor blinded?
D6. Was the care provider blinded?
D7. Was the patient blinded?
D8. Were point estimates and measures of variability presented for the primary outcome measures?
D9. Did the analysis include an intention-to-treat analysis?
M. Were care programs, other than the trial option identical?

The scores of the quality item of each study are presented in section additional tables. A score of 1 is given to each item with a 'yes' answer and a 0 score is given for a negative response. High quality is defined as presenting an adequate or concealed randomisation procedure and adequate blinding, or a positive score on 6 or more of the 10 quality assessment items.

Data extraction

Three reviewers (RB, TJ, AV) independently extracted the data on the intervention, type of outcome measures, follow-up, loss to follow-up, and outcomes, using a standardized form. The various outcome measures are presented separately.

Analysis

Methodology

The maximum score of the Overall Quality Score is 10 points (Delphi list is 9 points). The measure of agreement between the two reviewers (RB, SB) is presented as kappa.

Quantitative analysis

For dichotomous outcomes, relative risks were calculated. For continuous outcomes, weighted mean differences (WMD) were calculated using RevMan 4.2 software.[35] We had intended using a random effects model if the studies or subgroups of studies were clinically heterogeneous but in the actual analysis, we used a fixed effects model to pool the outcomes. Subgroup analysis was based on patient characteristics (gender, age, duration of symptoms, medial or lateral unicompartmental osteoarthritis, etc) or trial characteristics (duration of the trial period, etc).

Results are divided into a knee brace study and foot/ankle orthosis studies.

Qualitative analysis
Since the trial results were heterogeneous, the results were analysed according to 'best evidence analysis' using a rating system with levels of evidence based on the overall quality; the outcomes of the studies are also used (van Tulder [34]):

- strong evidence is defined as generally consistent findings in multiple high quality RCTs;
- moderate evidence is defined as generally consistent findings in one high quality RCT and one or more lower quality RCT;
- limited evidence is defined as only one RCT (either high or low quality) or generally consistent findings in CCTs;
- no evidence is defined as no CCTs or RCTs.

Secondly, an overall grading of evidence (Tugwell [36]) is used:
Platinum level
The Platinum ranking is given to evidence that meets the following criteria as reported: is a published systematic review that has at least two individual controlled trials each satisfying the following:

- Sample sizes of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome.
- Blinding of patients and assessors for outcomes.
- Handling of withdrawals >80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable).
- Concealment of treatment allocation.

Gold level
The Gold ranking is given to evidence if at least one randomised clinical trial meets all of the following criteria for the major outcome(s) as reported:

- Sample sizes of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome.
- Blinding of patients and assessors for outcomes.
- Handling of withdrawals > 80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable).
- Concealment of treatment allocation.

Silver level
The Silver ranking is given to evidence if a randomised trial does not meet the above

criteria. Silver ranking would also include evidence from at least one study of non-randomised cohorts who did and did not receive the therapy or evidence from at least one high quality case-control study. A randomised trial with a 'head-to-head' comparison of agents is considered Silver level ranking unless a reference is provided to a comparison of one of the agents to placebo showing at least a 20% relative difference.

Bronze level

The bronze ranking is given to evidence if there is at least one high quality case series without controls (including simple before/after studies in which the patient acts as their own control) or if it is derived from expert opinion based on clinical experience without reference to any of the foregoing (for example, argument from physiology, bench research or first principles).

Description of studies

From the results of the search strategy the reviewers (RB,TJ) selected 12 abstracts. After reading the full articles, eight trials were excluded because the design was not a CCT or RCT. We checked the reference lists of publications but no further studies were added. The four selected studies are described in detail in the Table 1. One study investigated knee braces and three studies examined foot/ankle orthoses (wedged shoe insole) for medial compartment osteoarthritis of the knee. No studies assessing the effectiveness of a brace or orthosis for treating lateral compartment or general osteoarthritis of the knee were found.

In all four studies the degree of osteoarthritis was scored according to Kellgren-Lawrence.[37] The mean number of participants in the four studies was 113 (range 88 to 156). The mean age was 64 (range 59 to 65 years). In two trials *(Toda (1); Toda (2))*, all the participants were females.[38,39] The interventions compared a valgus brace with a neoprene sleeve and medical treatment *(Kirkley)*, a laterally wedged insole with a neutral insole *(Maillefert)*, an elastic subtalar strapped insole versus a traditional laterally wedge insole *(Toda (1))*, and a subtalar strapped insole with a sock type ankle support *(Toda (2))*.[38-41]

Kirkley reported a RCT comparing a) a valgus brace with medical treatment (n=41), b) a neoprene sleeve with medical treatment (n=36), and c) a control group i.e. medical treatment only (n=33). The valgus brace was custom made and consisted of a polyethylene thigh shell connected to a polyethylene calf shell through a polyaxial hinge on the medial side, which allowed application of four degrees valgus. The randomisation procedure was a computer-generated blocked method using sealed envelopes. The follow-up was

Table 1. Characteristics of included studies Cochrane review " Braces and orthoses for treating osteoarthritis of the knee".

Study	Kirkley 1999
Methods	RCT; computer-generated blocked randomisation scheme with the use of sealed envelopes; blinding of the outcome assessment not described. Allocation concealment =A
Participants	Varus arthrosis; (n=119); Male/female: 79/31; Mean-age (yrs.): 59; Mean-varus (degrees): 9.
Interventions	I=Unloader brace (n=41) versus C1=neoprene brace (n=36) versus C2=medical treatment only (n=33). Follow-up 6 months.
Outcomes	WOMAC and MACTAR scores. Function assessing with the use of the 6-minute walking and 30-second stair climbing test.
Study	Maillefert 2001
Methods	RCT; randomisation procedure not described; outcome assessment partly blinded. Allocation concealment=B
Participants	Painfull medial knee osteoarthritis (n=156); Male/female: 41/108; Mean-age (yrs.): 65; Mean-BMI: 29. Grade of oa according to Kellgren- Lawrence: II= 69, III= 60, IV= 18.
Interventions	I= laterally wedged insole (n=78) versus C= neutrally wedged insole (n=69). Follow-up 1,3,6 months.
Outcomes	WOMAC, concomitant treatment, compliance.
Study	Toda (1) 2001
Methods	RCT; randomisation performed by date of bith. Blinded assessments of the level of pain according to the VAS, Lequesne index, the radiographic outcome. Allocation concealment= C
Participants	The American College of Rheumatology criteria for knee osteoarthritis (n=90); All female; Mean-age: 65; Mean-varus (FTA; degrees): 181. Degree of oa according to Kellgren-Lawrence: II=55, III=27, IV=8.
Interventions	I= strapped insole (n=46) versus C= laterally wedge insole (n=44). Follow-up 8 weeks.
Outcomes	VAS, Lequesne (pain) index score, radiographic changes.
Notes	In Table 3, the median value of the final VAS score in the strapped insole group is incorrect. No between-groups-analysis.
Study	Toda (2) 2002
Methods	RCT; randomisation performed by date of birth. Allocation concealment= C
Participants	The American College of Rheumatology criteria for knee oa (n=88); All female; Mean-age: 65; Mean-BMI: 25; Degree of varus (FTA; degrees): 181
Interventions	I= subtalar strapped support (n=44) versus C= sock type support (n=46). Follow-up 8 weeks.
Outcomes	Lequesne (pain) index, radiographic changes.
Notes	Scores in figures and no exact numbers were given. No between-groups-analysis.

six months. Nine patients were lost to follow-up (neoprene sleeve - two/ control - seven). The participants included 79 men and 31 women; the mean age was 59 years. The mean varus alignment was nine degrees. Degree of osteoarthritis of the knee was only described in the unloader brace group. The outcome data were presented as mean and p-value but without standard deviation, which made pooling impossible. Additional information was obtained from The Kirkley Research Group but this information was not sufficient to be analyzed.

Maillefert presented a RCT of 156 patients. Laterally wedged insoles (n=82) were compared with neutral insoles (n=74). Both insoles were made of Ledos material, which is made of pure rubber with cork powder. The laterally elevated insoles were individually modelled, with elevation depending on static pedometer evaluation. The randomisation procedure was not described. The participants included 41 men and 108 women; the mean age was 65 years. Mean Body Mass Index (BMI) was 29. Degree of varus alignment was not measured. The follow-up was six months and nine patients (four from the wedged insole group) were lost to follow-up.

Toda (1) published a prospective trial comparing an elastic subtalar strapped insole (n=46) versus a traditional laterally wedge insole (n=44). The wedge of the strapped insole was made from urethane with elevation of 6.35 mm strapped to an ankle sprain supporter. The traditional insole was a lateral rubber heel wedge with an elevation of 6.35 mm. The quasi-randomisation was according to birth date. All participants were female; the mean age was 65 and the mean BMI was 25. The follow-up was eight weeks and no patient was lost to follow-up. Standing radiographs of the participants with and without their respective insole was made before entering the eight week study. Degree of varus was 181 degrees (Femoral Tibial Angle-FTA). Results were presented in the original article as pre-post analysis and not as between group differences. However, the author was contacted for more information and he sent the missing information on the between group analysis of VAS and Lequesne index scores.

Toda (2) published a second trial comparing a subtalar strapped insole (n=42) with a sock type ankle support (n=46). The wedge of the strapped insole was made from urethane with elevation of 6.35 mm strapped to an ankle sprain supporter. The sock type ankle support extended from malleoli to metatarsals and consisted of a laterally wedged heel insole with elevation of 6.35 mm. The trial took place in the same year (2000) as the first study. The quasi-randomisation procedure was according to birth date. All participants were female; the mean age was 65 and the mean BMI was 25. Degree of varus was 181 degrees (FTA). The follow-up was eight weeks and no patient was lost to follow-up. The results were presented as pre-post analysis and not as between group difference. Secondly, the Lequesne index was presented graphically and no exact numbers were given. However, the author was contacted for more information again

and he provided the missing information of between group analysis of the Lequesne index.

Outcome measures were function scores, VAS (Visual Analog Scale), NSAID intake, Western Ontario-MacMaster (WOMAC) score, McMaster Toronto Arthritis (MACTAR) score, Lequesne index, Femoral Tibial Angle (FTA), compliance, and side effects.

Methodological quality

Two reviewers (RB, SB) assessed the methodological quality of the four studies independently from each other. As consensus was always reached between both reviewers (RB,SB) a third reviewer (JV) was unnecessary.

Methodological quality (Table 2)

The overall quality score ranged from 4 to 6 points (max = 10 points), and 2 studies scored more than 50% *(Maillefert*; *Toda (1))*.

The mean score was 5.25; the median score was 5 points corresponding with a 50% score. The measure of agreement (kappa) between the two reviewers (RB, SB) was 0.69. The Delphi quality score ranged from 4 to 6 (max = 9 points). Two studies scored more than 50% *(Maillefert; Toda (1))*.

In one study, the randomisation procedure was adequate or concealed *(Kirkley)*. In most of the trials the blinding procedures of the outcome assessors, treatment providers, and participants scored 'no'. No study had an adequate or concealed randomisation procedure and adequate blinding.

Table 2. Methodological quality of included studies Cochrane review " Braces and orthoses for treating osteoarthritis of the knee".

Study	D1	D2	D3	D4	D5	D6	D7	D8	D9	M	Delphi score	Total score
Kirkley	1	1	0	1	0	0	0	1	0	1	4	5
Maillefert	1	0	1	1	0	0	1	1	1	0	6	6
Toda (1)	1	0	1	1	0	0	0	1	1	1	5	6
Toda (2)	1	0	1	0	0	0	0	1	1	0	4	4

Results

All studies used different interventions or comparison treatments with a wide variety of outcome measures and follow-up periods. Due to the heterogeneity of the studies, the results could not be pooled. We described the different comparisons and performed a best evidence synthesis and an overall grading of evidence based on these studies. The results are also presented in clinical relevance tables. (Table 3)
Two main groups were identified:

A. Knee brace
One low-quality study described the effectiveness of a brace for medial compartment osteoarthritis of the knee *(Kirkley)*. It was impossible to extract data because the differences in scores were presented numerically and the baseline WOMAC, pain and MACTAR scores were presented graphically. Moreover, the graphs showed differences between the three groups at trial entry.

At the six-month assessment, the WOMAC score of the brace group showed greater improvement compared with the sleeve group, which showed greater improvement compared with the control group. The MACTAR score showed greater improvement in the brace group compared with the control group. Function tests (pain on the 6-minutes walk test, pain on the 30-seconds stair-climbing test) showed greater improvement in the brace group compared with the sleeve group, which showed greater improvement compared with the control group.

B. Foot/Ankle orthosis
Two high-quality studies *(Maillefert; Toda (1))* and one low-quality study *(Toda (2))* described the results of a foot/ankle orthosis for medial compartment osteoarthritis of the knee.

In *Maillefert*, the participant's overall assessment and WOMAC scores showed no significant differences between the laterally wedged group and the neutrally wedged group: the WOMAC-pain and WOMAC-stiffness were more decreased in the neutrally wedged group, but the WOMAC-function was more decreased in the laterally wedged group at the six-month assessment. The numbers of days with NSAIDs intake significantly decreased (relative percentage difference = 23.9%) compared with baseline in the laterally wedged group and remained unchanged in the neutrally wedged group. Patient compliance with the laterally wedged insole (87.8%) was significantly better compared with the neutrally wedged insole (74.3%).

From the standing radiographs (with and without insole) taken at the beginning of the Toda (1) study, there were no significant differences between the strapped insole

Table 3. Clinical relevance table Cochrane review " Braces and orthoses for treating osteoarthritis of the knee".

Study	Treatment groups	Outcome (scale)	No. of patients	Baseline mean	Mean (end-of-study)	Absolute benefit	Relative difference
Maillefert	laterally wedged insole neutrally wedged insole	WOMAC-pain (0-100)	78 69	53.5 52	52.8 (6 months) 46.6 (6 months)	4.9 (W)	9.4% (w)
Maillefert	laterally wedged insole neutrally wedged insole	WOMAC-stiffness (0-100)	78 69	51.8 50.3	51.4 (6 months) 47.1 (6 months)	2.8(W)	5.6% (W)
Maillefert	laterally wedged insole neutrally wedged insole	WOMAC-function (0-100)	78 69	48.8 50	53.3 (6 months) 47.3 (6 months)	7.2(I)	14.4% (I)
Maillefert	laterally wedged insole neutrally wedged insole	NSAID intake (days)	78 69	14.1 15.5	9.9 (6 months) 15 (6 months)	-3.7 (I)	23.9% (I)
Maillefert	laterally wedged insole neutrally wedged insole	Analgesic intake (days)	78 69	25.3 23.7	20.5 (6 months) 22.4 (6 months)	-3.5 (I)	15.4% (I)
Toda (1)	strapped insole inserted insole	Lequesne index (0-30)	46 44	11.1 10.1	8.2 (8 weeks) 8.8 (8 weeks)	-1.6 (I)	16% (I)
	strapped insole inserted insole	VAS (0-100)	46 44	43.4 42.3	34.6 (8 weeks) 43.8 (8 weeks)	-10.3 (I)	24% (I)
Toda (2)	subtalar strapped insole sock type insole	Lequesne index (0-30)	42 46	10.4 10.3	7.3 (8 weeks) 9.1 (8 weeks)	-1.9 (I)	18% (I)

group and the traditional laterally wedge insole group in the talocalcaneal, femorotibial (FTA), or talar tilt angles. However, in the elastically strapped insole group there was a significant decrease of the talar tilt and FTA angles compared to no insole. These significant differences were not found in the group with the traditonal laterally wedge insole. Both groups showed a significant change in the talocalcaneal angle.

The VAS pain score was significantly decreased from baseline (RPD=24%) in the strapped insole group, but not in the traditional laterally wedge group. The improved VAS score was not significant different in the between group analysis. The Lequesne index of severity for knee osteoarthritis was decreased in both groups compared with the baseline assessment. The strapped insole showed more adverse effects (n=6) compared with the laterally wedge insole (n=1). Adverse effects included popliteal pain, low back pain, and foot sole pain.

In *Toda (2)*, at baseline, the subtalar strapped insole demonstrated significantly decreased FTA compared with no insole, which showed no significant difference from the sock type group. Pain during bed rest, after getting up, after getting up from seated position and walking distance (Lequesne index) was significantly improved in the subtalar strapped group compared with baseline, and no improvement was found in the sock type group. In the between group analysis, the difference of the Lequesne index was almost significant (p=0.061).

Discussion

The purpose of this review was to assess the effectiveness of braces and orthoses for treating osteoarthritis of the knee.

The methodological quality was moderate; there were two *(Maillefert; Toda (1))* high quality and one *Toda (2)* low quality study. Except for the trial of *Kirkley*, the randomisation procedure was either not described or was inadequate. In the majority of trials, the inclusion/ exclusion criteria were only briefly presented. In most studies, the blinding procedures were insufficient and possibly influenced the results. In case of braces, blinding is not always possible, but for footwear inserts it is generally less difficult.

One trial investigated a knee brace and three studies examined foot/ankle orthoses for medial compartment osteoarthritis of the knee. It is important to note that there may be a lack of generalisability: in the studies of Toda *(Toda (1); Toda (2))* the participants were all female and mostly male in *Kirkley* trial. In all studies the age of the participants was relatively high (mean 64 years). In the *Kirkley* trial, the baseline characteristics differed between participants. It is important to present full data: *Kirkley* presented

change scores without baseline scores and without a standard deviation. *Toda (1); Toda (2)* presented pre and post analysis but did not report between-group differences.

Only braces and orthoses for medial compartment osteoarthritis were studied. Compared with lateral compartment osteoarthritis of the knee, medial compartment osteoarthritis has a much higher prevalence, because the lateral compartment is less frequently associated with trauma. This is probably why no RCTs or CCTs have examined the effect of a brace or orthosis for lateral compartment or general osteoarthritis of the knee. Furthermore, varisation bracing for lateral osteoarthritis is probably less effective; the adduction moment at the knee during stance phase of walking causes mainly medial loading.[42] In general osteoarthritis of the knee there is no compartment to unload and perhaps a sleeve or a neutral brace will benefit. None of the studies compared a brace or orthosis with no treatment or a knee brace with a foot/ankle orthosis. Also, no studies compared a brace or orthosis with operative treatment like high tibial osteotomy or unicompartmental knee arthroplasty.

Toda (1) suggested that there is correlation between joint realignment and clinical improvement (concordance of pain and Lequesne index). This suggestion confirms the conclusions of other studies.[4,5] Furthermore, Toda presented in both studies *(Toda (1); Toda (2))* that a laterally wedge insole with subtalar strapping demonstrated a significantly decreased FTA. These differences were not seen in the participants wearing a traditional laterally wedge insole *(Toda (1))* or the sock-type orthosis with lateral heel wedge insert *(Toda (2))*, which implicates that the subtalar strapping causes the joint realignment and reduces pain. *Toda (2)* concluded that further studies are necessary to address this mechanism. However in both studies *(Toda (1); Toda (2))* he used the FTA-angle, which is a surrogate measurement for determination of leg alignment. A whole leg radiograph with HKA (Hip-Knee-Ankle) angle measurement is considered the gold standard for determining leg alignment.[43]

There is limited evidence for the effectiveness of a brace for medial compartment osteoarthritis: only one controlled trial was published. *Kirkley* concluded that varus gonarthrosis benefits from the use of a knee brace, but the baseline characteristics between groups were different and the quality of the study was low.

There is limited evidence for the effectiveness of a foot/ ankle orthosis for medial compartment osteoarthritis: only three controlled trials were published. There was conflicting evidence, because *Maillefert* described a significant decrease of NSAID intake with a wedged insole compared with a neutral insole, but the WOMAC pain was more decreased in the neutral insole group. Moreover *Toda (1)* reported no significant VAS pain reduction with a traditional wedge insole.

In orthosis treatment, the number and degree of adverse effects in orthosis treatment were low *(Toda (1))* and the degree of compliance and tolerance were satisfactory *(Maille-*

fert). These factors were not reported in brace therapy. In addition, the costs of orthosis and brace therapy have not been investigated, which is important in treatment of chronic diseases.

Based on one brace study we conclude that there is limited evidence (Silver) that a brace or a neoprene sleeve has additional beneficial effect in terms of pain and function for knee osteoarthritis compared with medical treatment alone and a brace is more effective than a neoprene sleeve for improving pain and function.

Based on 3 orthoses studies, of which 2 were high quality, we conclude that there is limited evidence (Silver) that a laterally wedged insole decreases NSAID intake and has greater patient compliance compared with a neutral insole. There is also limited evidence (Silver) that a strapped insole has more adverse effects than a lateral wedge insole.

Authors' conclusions

Implications for practice

Based on the results of this review we conclude there is only limited evidence for the effectiveness of bracing or orthoses in treatment of medial compartment knee osteoarthritis. There is no available evidence for the effectiveness of bracing or orthoses in treating lateral or general compartment knee osteoarthritis.

The treatment with braces and orthoses have less side effects than surgical treatment, but the optimal choice remains unclear and long term implications are lacking.

Implications for research

The methodological quality of studies investigating the effectiveness of braces and orthoses has to be improved, particularly the randomisation procedure and the blinding measures.

The short-term benefit needs to be established first in order to justify the considerable resources required and ethical implications involved in a lengthy study. Subsequently, a follow-up period of at least five years is needed because osteoarthritis is a chronic disease. One general knee score would allow pooling of the results. We recommend using the WOMAC, because this has been shown to be a valid instrument to measure osteoarthritis.[32] Between groups analysis is necessary to show relevant differences. Future studies should provide complete data on outcome measures, including the mean and standard deviation or 95% confidence intervals.

It is important to score side effects, because these side effects influence the patient's acceptability of the intervention. This especially concerns braces, which can be obtrusive in many cases. New trials should investigate the long- term benefits of braces and orthoses compared with standard conservative care. If feasible, braces should be compared with

ankle/foot orthoses. If braces and orthoses are effective, they then need to be compared with operative treatment like high tibial osteotomy or knee arthroplasty for medial compartment osteoarthritis.

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Chapter 5

Brace Treatment for Osteoarthritis of the Knee: a Prospective Randomised Multicenter Trial

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Osteoarthritis Cartilage. in press

Abstract

Objective To evaluate the effect of a brace intended to reduce load in patients with medial or lateral compartmental osteoarthritis and concurrent varus or valgus alignment, respectively.

Design This multicenter randomised controlled trial (performed 2001-2003) studies the additive effect of a brace intended to reduce load in conservative treatment of unicompartmental osteoarthritis of the knee. Setting: Orthopedic department of a university medical center and of one general hospital. The follow-up was 12 months.

Patients: 117 patients with unicompartmental osteoarthritis of the knee.

Intervention group (n=60) comprising conservative treatment with additional brace treatment and a control group (n=57) comprising conservative treatment alone.

Primary outcome measures: Pain severity and knee function score.

Secondary outcome measures: Walking distance and quality of life.

Analysis: Multiple linear regression models according to the intention-to-treat-principle were used to assess outcome differences for the entire group of patients.

In addition, we performed explorative subgroup analyses on primary overall outcomes stratified for alignment, degree of osteoarthritis, origin of osteoarthritis, and age.

Results Although the primary outcome measures were improved in the intervention group in comparison with the controls at each assessment point, the differences reached only borderline significance.

The reported walking distances at 3 months and 12 months and overall were significantly longer in the brace group (p=0.03, p= 0.04 and p=0.02, respectively).

Subgroup analysis showed a better effect in the varus group, in patients with severe osteoarthritis, in patients with secondary osteoarthritis and in patients younger then 60 years.

In total 25 patients in the brace group and 14 in the control group changed their initial treatment, mostly (74%) because of a lack of beneficial effect.

Conclusions The results indicate that a brace intended to reduce load shows small effects in patients with unicompartmental osteoarthritis. However, many patients do not adhere in the long run to this kind of conservative treatment.

Introduction

Osteoarthritis of the knee is a common medical condition that is often seen in general practice and causes considerable pain and immobility. In the United States approximately 6% of the population aged 30 years and older and 12% of the population aged 65 years and older suffer from knee osteoarthritis.[1] In addition to the consequences for the patient, osteoarthritis forms a considerable burden for society because of its chronic course and the high costs of interventions.[2]

Osteoarthritis of the entire knee is distinguished from that of one compartment, which is generally caused by a mechanical problem.[3,4] Patients with osteoarthritis of the medial compartment often have a varus alignment and the mechanical axis and load bearing passes through the medial compartment. Patients with osteoarthritis of the lateral compartment generally have a valgus alignment and the mechanical axis and load bearing passes through the lateral compartment.

Malalignment increases the risk for progression of knee osteoarthritis and predicts decline in physical function.[5] Overall, more patients with osteoarthritis have varus alignment (76%-93%) than valgus alignment.[6]

The initial treatment for osteoarthritis of the knee is conservative, consisting of patient education (adaptation of activities and/or weight loss), and if needed physical therapy and medication.[7-13] The general purpose of a brace is to decrease pain and improve function; valgisation and varisation braces are available for unloading the medial and lateral compartment, respectively.[14-18]

A recently published Cochrane review concluded that there is very limited evidence for the effectiveness of brace treatment for knee osteoarthritis, mainly because of lack of studies on this issue.[19] Therefore, the present study investigated the additive effect of a brace intended to reduce load in conservative treatment of unicompartmental osteoarthritis with varus alignment or valgus alignment.

Material and Methods

Study design

A multicenter randomised controlled trial was designed to study the additive effect of a brace intended to reduce load in the conservative treatment of unicompartmental knee osteoarthritis.

The study was conducted at the orthopedic outpatient departments of a university medical center and of a general hospital. The medico-ethical committees of both hospitals approved the study protocol.

Inclusion/exclusion criteria

The inclusion criteria were symptomatic unicompartmental knee osteoarthritis and a malalignment in patients aged 18 years and over. We diagnosed the osteoarthritis as unicompartmental when the symptoms (pain and tenderness of the joint margins) were located over the medial or the lateral tibiofemoral compartment of the knee in combination with osteoarthritic signs according to the Ahlbäck score (Ahlbäck > 0) in the same medial or lateral tibiofemoral compartment of the knee as well as in combination with varus alignment (in combination with medial compartment OA) or valgus alignment (in combination with lateral compartment OA) respectively.[20] The degree of malalignment and mechanical axis was measured on a whole leg radiograph in standing position and determined according to one line (mechanical axis of the femur) from the center of the femur head using Mose circles to the middle of the distance between the tibial spines, and a second line (mechanical axis of the tibia) from the center of the ankle to the center of the tibial spines.

Patients with concurrent symptomatic osteoarthritis of medial and lateral compartment, symptomatic patellofemoral osteoarthritis (scored on the lateral radiograph of the knee), no malalignment, rheumatoid arthritis, previous high tibial osteotomy, symptomatic hip or ankle pathology, and an insufficient command of the Dutch language were excluded.

Procedures

After reading the patient information form informed consent was given and baseline measurements were made, patients were randomised according to a computer-generated procedure in blocks of 24; the allocation of treatment was concealed until after the patient was included and baseline measurements were executed; sealed envelopes contained the group assignment.

The follow-up assessments that took place at 3, 6 and 12 months included standardized questionnaires and physical examination by one investigator.

Treatment groups

Patients were randomly assigned to either an intervention group comprising conservative treatment with additional brace treatment, or to a control group comprising conservative treatment alone.

The conservative treatment was identical in both groups and consisted of standard care: i.e. patient education (adaptation of activities and/or weight loss), and (if needed) physical therapy and analgesics.

In the intervention group patients were fitted with a knee brace (OAsys brace, Innovation Sports, Irvine, CA, USA); this brace is commercially available for right/left

leg in four sizes (Figure 1). The brace is accepted and refunded by all Dutch health insurance companies. The brace consists of a thigh shell and a calf shell (both of carbon fiber) connected by titanium hinges on the medial and lateral side. The adjustable slide bar on the medial side of the brace provides valgisation (1-12.5 degrees) with medial unloading, or varisation (1-10 degrees) with lateral unloading. The degree of varisation or valgisation depends on the degree of malalignment and the acceptance of the patient (extensive correction will cause pressure ulcers). A specialized orthopedic technician applied the brace and gave instructions to the patients. During the follow-up this specialized orthopedic technician was present at the orthopedic outpatient department. If necessary the brace was adjusted during the follow-up visits.

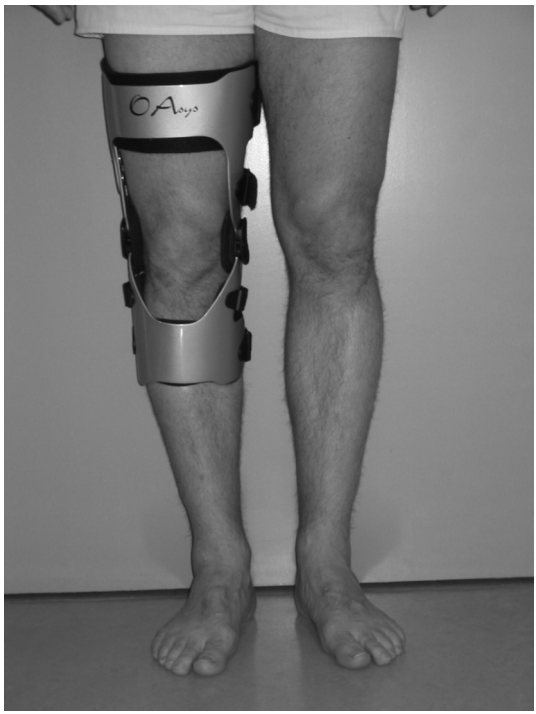

Figure 1. Photograph showing the fitted brace.

Baseline evaluation

Age, gender, Body Mass Index (BMI), duration of complaints, severity of osteoarthritis, varus alignment, pain severity, HSS score, walking distance, quality of life, and analgesic use were scored at baseline.

Outcome assessments at 3, 6 and 12 months

Primary outcome measures were pain severity measured with a visual analogue scale (VAS; range 0-10), and a knee function score using the hospital for special surgery score (HSS; range 0-100). The HSS is divided into 6 categories (pain, function, range of motion, muscle strength, flexion deformity, and instability), is often used in orthopedic interventions in knee osteoarthritis, and consists of a questionnaire and a physical examination.[21] In the present study physical examination for the HSS knee function score was determined by one un-blinded assessor.

Secondary outcome measures were walking distance (in kilometers), quality of life (measured with the EuroQol-5D).[22]

Sample size

The sample size calculation was based on the study of Magyar et al. who reported a standard deviation (SD) of 9 in the HSS knee score in their study population.[23] For the present study, with a difference between two groups of 5 points we would reach clinically relevant differences (effect size 0.55). To detect such a difference with two-sided testing (α= 0.05 and a power of 80%) we needed to include 51 patients in each study group. Over sizing by 15% allowed us to reach this power also in the largest subgroup of patients with unicompartmental osteoarthritis with varus alignment.

Statistical analyses

All data were analyzed according to an intention-to-treat principle, implying that all patients who were randomised were included in the analyses, and that they were analyzed according to the group to which they were allocated.

Outcome assessments at 3, 6 and 12 months (pain severity, HSS knee function score, walking distance and quality of life) were analyzed using multiple linear regression analysis. These analyzes were adjusted for the baseline value of the outcome measure. Further, those variables which changed the relationship (slope) between the independent variable (treatment group) and one of the dependent variables (outcomes) by more than 10% were considered as confounders and were included in the models. For patients who were lost to follow-up or were placed on the waiting list for surgical intervention (e.g. high tibial osteotomy, hemi/total knee prosthesis) during follow-up, the last available measurement or the last preoperative measurement was entered.

The overall outcomes during the 12 months were analyzed using linear regression for repeated measurements with the same adjustments as above. For these analyses, in case the patient was already lost to follow-up or underwent surgical intervention before the first 3-month follow-up, only baseline values were entered. Other measurements were not entered.

Standardized effect sizes (adjusted mean difference in outcome divided by the pooled SD) were calculated for all outcomes. Effect sizes between 0.2 and 0.5 represent small effects, between 0.5 and 0.8 moderate effects, and above 0.8 large effects.[24]

In addition, we performed explorative subgroup analyses on primary overall outcomes (using the methods stated above) stratified for alignment (varus vs. valgus), degree of osteoarthritis (mild: Ahlbäck 1 vs. severe: Ahlbäck 2 and 3), and origin of osteoarthritis (primary vs secondary: post meniscectomy or cruciate lesion), and age (younger than 60 years vs. 60 years and older).

The SPSS and SAS programs were used for the statistical analyses and a p-value of 0.05 was considered statistically significant.

Results

In the period January 2001 to January 2003, 118 patients were randomised. One patient withdrew immediately because of dissatisfaction with the randomisation outcome (no brace) and refused any further participation; this patient was excluded from analysis, resulting in a total sample of 117 patients.

Table 1 shows that the mean age of the total group was 59.2 (SD 13.7) years, 50% was male and mean BMI was 28.5 (SD 4.8). There were 60 patients in the intervention group and 57 in the control group; 4 patients in the control group were lost to follow-up. In total 95 patients had varus alignment and 22 had valgus alignment. At baseline, compared with controls, scores on pain severity, HSS knee function and walking distance were worse in the brace group.

Primary outcome measures (Table 2)

Compared with controls, pain severity (VAS) was less in the brace group at each of the three assessment points as well as overall during the 12 months follow-up; the largest difference was at 12 months (–0.81; 95%CI: –1.76; 0.14). At 12 months and overall the difference in VAS score was borderline significant ($p<0.1$). Effect sizes at the three assessment points ranged from 0.3 to 0.4.

Knee function (HSS) in the brace group was better at each assessment point; the largest difference was seen at 3 months follow-up (3.5 points; 95% CI: -0.24; 7.24). Borderline significance ($p<0.1$) was observed at 3 months ($p=0.07$), 6 months ($p= 0.10$), and overall ($p=0.09$). The effect size at the three assessment points was 0.3.

Secondary outcome measures (Table 2)

The reported walking distances at 3 months (1.21 km; 95% CI: 0.12; 2.28) and 12

Table 1. Baseline characteristics of the study population.

	Total group N = 117	Brace group N = 60	Control group N = 57
Male, n (%)	59 (50)	31 (52)	28 (49)
BMI (kg/m^2), mean (sd)	28.5 (4.8)	27.8 (4.3)	29.4 (5.2)
Duration of complaints (months), mean sd)	69.9 (90.2)	80.3 (101.1)	59.0 (76.6)
Severe OA, n (%)*			
- grade 1	74 (63)	41 (68)	33 (58)
- grade 2	43 (37)	19 (32)	24 (42)
Varus alignment, n	95	48	47
- HKA-angle, mean (sd)**	188.2 (4.1)	187.9 (3.4)	188.5 (4.4)
Valgus alignement, n	22	12	10
- HKA-angle, mean (sd) **	174.3 (3.7)	174.3 (3.9)	174.3 (3.6)
Pain severity, mean (sd)	6.0 (2.2)	6.6 (2.4)	5.5 (2.0)
HSS score, mean (sd)	66.9 (10.9)	64.9 (12.0)	69.0 (9.5)
Walking distance in km, mean (sd)	3.3 (3.7)	2.6 (3.1)	4.0 (4.0)
Quality of life, mean (sd)	0.53 (0.28)	0.50 (0.30)	0.56 (0.26)
Analgesic use			
- none, n (%)	47 (40.5)	28 (47)	19 (34)
- when needed, n (%)	18 (15.5)	9 (15)	9 (16)
- daily, n (%)	51 (44)	23 (38)	28 (50)

** osteoarthritis according to Ahlbäck*
*** Hip-Knee-Ankle angle: an angle of more than 180° denoted a varus alignment.*

months (1.34 km; 95% CI: 0.05-2.63) and overall (1.25 km; 95% CI: 0.15; 2.35) were significantly longer in the brace group (p=0.03, p= 0.04 and p=0.02, respectively). Effect sizes at the three assessment points ranged from 0.2 to 0.4. No significant differences in quality of life evaluations were found between the intervention and control group.

All our analyses were adjusted for baseline use of analgesics (daily, when needed, none). Also during the follow-up we scored the analgesic use: during follow-up there was increasingly lower medication use for each follow-up period in the brace group compared to the control group.

Subgroup analysis

Explorative subgroup analyses stratified for alignment showed a better and significant

Table 2. Differences between the intervention and control groups for primary and secondary outcomes at 3, 6 and 12 months.

	Analysis in total group(N=117)	
	Mean difference (95% CI)	Effect size
3 months follow-up		
Pain severity (VAS, 0-10)	-0.73 (-1.62;0.16)	0.3
Knee function (HSS, 0-100)	3.5 (-0.24;7.24)*	0.3
Walking distance (km)	1.21 (0.12;2.28)**	0.3
Quality of life (EQ-5D, 0-1)	0.03 (-0.05;0.12)	0.1
6 months follow-up		
Pain severity (VAS, 0-10)	-0.58 (-1.48;0.32)	0.3
Knee function (HSS, 0-100)	3.2 (-0.58;6,98)*	0.3
Walking distance (km)	0.79 (-0.40;1.98)	0.2
Quality of life (EQ-5D, 0-1)	0.01 (-0.08;0.10)	0.0
12 months follow-up		
Pain severity (VAS, 0-10)	-0.81 (-1.76;.0.14)*	0.4
Knee function (HSS, 0-100)	3.0 (-1.05;7.05)	0.3
Walking distance (km)	1.34 (0.05;2.63)**	0.4
Quality of life (EQ-5D, 0-1)	0.01 (-0.08;0.10)	0.0
Overall		
Pain severity (VAS, 0-10)	-0.63 (-1.38;0.12)*	0.3
Knee function (HSS, 0-100)	3.0 (-0.41;6.41)*	0.3
Walking distance (km)	1.25 (0.15;2.35)**	0.4
Quality of life (EQ-5D, 0-1)	0.02 (-0.05;0.09)	0.1

** $p < 0.1$, ** $p < 0.05$*
The mean difference is adjusted for baseline values for age, gender, BMI, duration of complaints, severity of knee osteoarthritis, (alignment), baseline pain severity, knee function, walking distance, medication, and quality of life

effect of the brace in the varus group (n=95) for the knee function score (estimate HSS 4.15; p=0.03) compared to the effect of the brace in the valgus group (n=22) (estimate HSS 0.20; p= 0.96). The effect for the pain severity showed a similar trend, but not as pronounced as for knee functions.

Explorative subgroup analyses stratified for degree of osteoarthritis showed a better effect of the brace in patients with severe osteoarthritis (n=43) for pain severity (estimate VAS -1.31; p= 0.10) compared to the effect of the brace in patients with mild osteoarthritis (n=73) (estimate VAS -0.21; p= 0.65). The effect for the knee functions showed a similar trend, but not as pronounced as for pain severity.

Explorative subgroup analyses stratified for origin of osteoarthritis showed a better effect of the brace in patients with secondary osteoarthritis (n=47) for knee function

(estimate HSS 4.87; p= 0.06) compared to the effect of the brace in patients with primary osteoarthritis (n= 70) (estimate HSS 1.59; p= 0.51). The effect for pain severity showed a similar trend, but not as pronounced as for knee function.

Explorative subgroup analyses stratified for age showed a slightly better effect of the brace in patients younger than 60 years (n= 60) for knee function (estimate HSS 3.38; p= 0.13) compared to the effect of the brace in patients 60 years and older (n= 57) (estimate HSS 2.48; p= 0.38). The effect for pain severity showed a similar trend, but not as pronounced as for knee function.

Discontinuation of treatment during follow-up

During the 12-month follow-up period, 25 patients in the brace group and 14 patients in the control group changed their initial treatment, mostly at around 3 months; in both groups the main reason for this was no effect of treatment (74%) (Table 3). Other reasons for stopping brace treatment were skin irritation and bad fit, and three patients stopped because the symptoms strongly reduced. Change in treatment during follow-up included surgery (e.g. high tibial osteotomy n=8; knee arthroplasty n= 16). Thirteen patients changed brace treatment for standard conservative treatment (Figure 2).

Table 3. Data on patients who stopped the treatment to which they were originally assigned.

	Brace group N= 60	Control group N=57
Stopped with treatment (total)	25	14
- within 3 months	16	6
- between 3 and 6 months	6	6
- between 6 and 12 months	3	2
Alternative treatment		
- High Tibial Osteotomy	5	3
- Unicompartment Knee Prosthesis	3	0
- Total Knee Prosthesis	3	10
- (other) brace	1	1
- only usual conservative care	13	0
Reason for stopping treatment		
- no effect	15	14
- skin irritation	2	-
- bad fit	2	-
- minimal symptoms	3	-
- several reasons	3	-

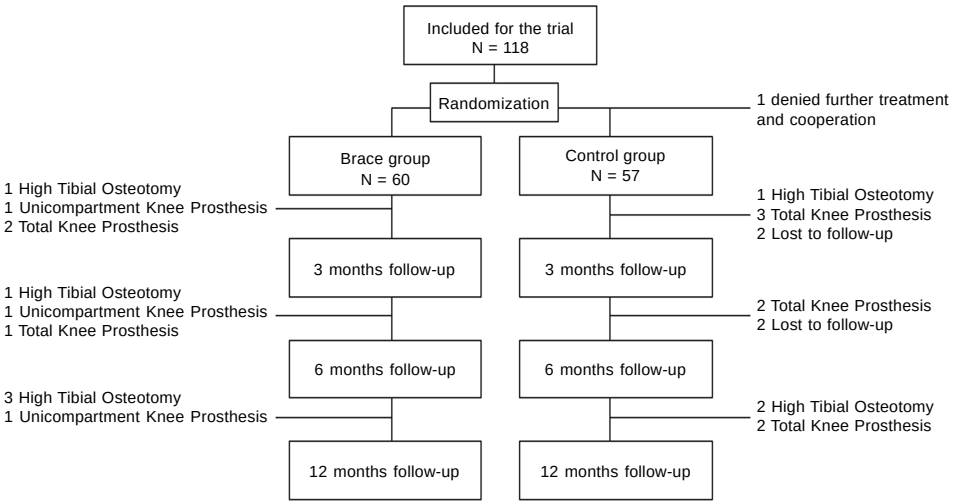

Figure 2. Flowchart showing the patients on the waiting list for surgical treatment, or who were lost to follow-up during the trial.

Discussion

The results of this study indicate that a brace intended to reduce load offers small additional beneficial effect in knee osteoarthritis compared with conservative treatment alone.

Many of the measured outcomes showed only a borderline significant difference. We decided in advance to perform two-sided testing. However looking at the comparison (standard care vs. standard care in combination with brace treatment), one-sided testing would have been allowed because one expects an additional beneficial effect of the additional treatment. Had we used one-sided testing, almost all of our primary outcomes would have been statistically significant.

Studies comparing the effectiveness of braces to treat osteoarthritis of the knee are scarce: only one randomised controlled trial has evaluated the effectiveness of braces for patients with unicompartmental osteoarthritis of the knee with varus alignment.[16] The results of the present study confirm those of the latter study, which included 119 patients who were followed for 6 months. In that study, a valgus brace was compared with a neoprene sleeve and with standard medical treatment (control group); the brace group showed greater improvement compared with the sleeve group, which showed greater improvement compared with the control group.

Also a cross-over study showed in 12 patients with osteoarthritis of the medial compartment and a varus alignment significant improvements gait with a valgus corrective brace compared with a neutral brace.[25]

In our study valgisation bracing in medial compartment osteoarthritis was more effective than varisation bracing in lateral compartment osteoarthritis. This might indicate that the unloading theory does not apply in patients with lateral compartment and a valgus alignment. Moreover, the knee adduction moment during the stance phase of walking causes mainly medial loading.[6,26] Possibly, a simple sleeve possibly will show the same or more effect in patients with lateral compartment osteoarthritis due to increased propioception.[27,28] This was also discussed by Kirkley et al. who reported an effect of a neoprene sleeve in unicompartmental osteoarthritis with varus alignment.[16] Therefore, in general osteoarthritis of the knee where there is no specific compartment to unload, a sleeve or a neutral brace may also be beneficial due to possible increased proprioception and stability.[27]

Study limitations

Firstly, the assessor was also the caregiver as well as the one who informed the patient about the aims of the study. Although the kind of intervention did not allow blinding of patients, methodological strength would have been gained by blinding the assessor for the functional outcome measurement (HSS knee score), e.g. by using an independent assessor. However, because the same effects were found for the self-evaluated functional outcome (i.e. walking distance), and because the caregiver had no definite opinion about the effectiveness of the brace, we assume that the assessments made by the caregiver had minimal or no bias.

Secondly, several patients stopped brace treatment during the 12-month follow-up, mainly due to non-effectiveness. Moreover, most of these patients stopped brace treatment before the first 3-month assessment point; this may be too short a period (in the absence of adverse side-effects) for a beneficial effect to emerge.

Thirdly, although we used the HSS knee function score (frequently used in orthopedic research), the WOMAC-function seems to have become the function score of choice.[21,29] Nevertheless, in view of the very high correlation between the WOMAC-pain and WOMAC-function, some have suggested that the WOMAC-function measures pain rather than function.[30]

Clinical implications

Although a brace intended to reduce load indicates a small additional beneficial effect in conservative treatment of knee osteoarthritis during a 12-month follow-up, many patients

do not adhere to the brace treatment in the long run, either because the positive effects are too small or because the adverse effects are too large.

Based on explorative subgroup analysis in the present study, a brace intended to reduce load seems to be a treatment option for younger patients with unicompartmental osteoarthritis with varus alignment, because few conservative alternatives have proven effective.[31,32] Correction osteotomy in relatively young patients with unicompartmental osteoarthritis has good results, but this surgery can present complications.[33,34] Knee arthoplasty for younger patients is not recommended because the degree of patient activity and life expectancy means that the arthroplasty may wear out and/or loosen.[35] For older (aged >60 years) less active patients, however, brace treatment seems less effective and therefore standard conservative treatment is recommended. If symptoms persist in this older group, a knee arthroplasty (nowadays a routine procedure with good long-term results) can be considered.[36,37]

Future research

Besides the above-mentioned practical considerations, a larger study is needed to identify predictive factors for the success of brace treatment. Particularly for the valgus group a larger study population is needed to identify what type of brace will benefit this group. In addition, brace treatment should be compared with using a neoprene sleeve with possibly better treatment adherence.

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Chapter 6

Osteotomie ter Hoogte van de Knie voor Jonge Patiënten met Gonartrose

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Ned Tijdschrift Geneeskd. 2004;148:1955-60

Abstract: Osteotomy at knee level for young patients with gonarthrosis

Young patients with gonarthrosis that does not respond adequately to conservative therapy can be treated with a correction osteotomy.

Osteoarthritis of one compartment more often has a mechanical aetiology than osteoarthritis of the entire knee.

Patients with osteoarthrits of the medial compartment often have a genu varum (bow-legs) while patients with osteoarthritis of the lateral compartment often have a genu valgum (knock-legs).

The goal of a correction osteotomy is to transfer the load bearing to the normal compartment, which will reduce the symptoms and permit arthroplasty to be postponed.

In retrospective studies, the procedure resulted in less pain, improved knee function or postponement of knee arthroplasty in 28-87% of the patients.

Possible complications include pseudarthrosis, thrombo-embolism, contracture of the patella tendon, paresis of the N. peroneus, compartment syndrome.

The outcome of osteotomy for gonarthrosis depends on careful patient selection, the stage of osteoarthritis and the achievement and maintenance of the load axis that was calculated before the operation.

Samenvatting

Jonge patiënten met gonartrose die onvoldoende baat hebben bij conservatieve therapie kunnen met een correctie osteotomie behandeld worden.

Artrose van één compartiment heeft waarschijnlijk vaker een mechanische oorzaak dan artrose van de gehele knie. Patiënten met artrose van het mediale compartiment hebben vaak een genu varum (O-been) en patiënten met artrose van het laterale compartiment hebben vaak een genu valgum (X-been).

Het doel van een correctie osteotomie is de belastingsas naar het goede compartiment te verplaatsen, waardoor de symptomatologie wordt gereduceerd en een artroplastiek uitgesteld kan worden.

In retrospectieve studies leidde de ingreep bij 28-87% van de patiënten tot minder pijn, een betere knie functie of tot uitstel van plaatsing van een knieprothese.

Mogelijke complicaties zijn pseudartrose, trombo-embolie, contractuur van de patellapees, N. peroneus uitval en compartiment syndroom.

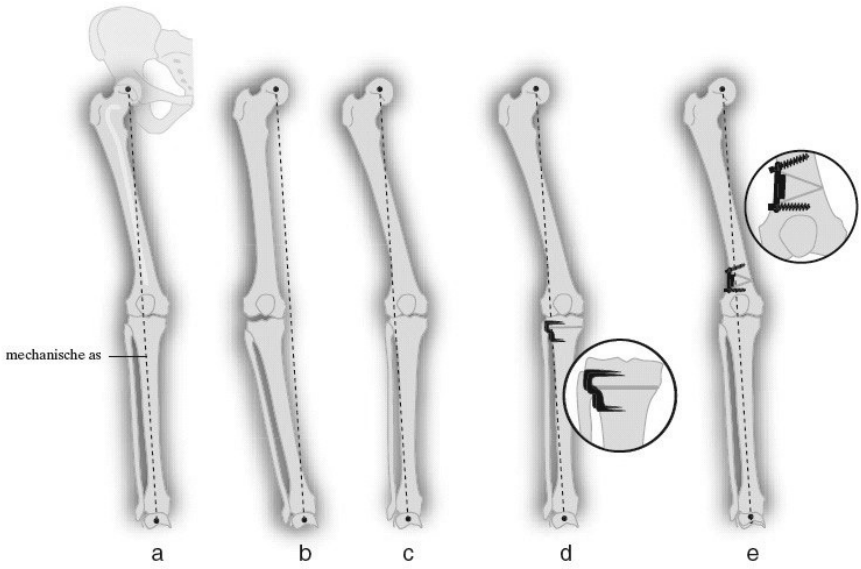
Het resultaat van een osteotomie bij gonartrose is afhankelijk van een nauwkeurige patiënten selectie, mate van artrose en het aanbrengen van de correctie van de belastingsas, die voor de operatie is berekend.

Inleiding

Gonartrose bij de jonge patiënt is een medisch probleem, omdat kraakbeenschade nauwelijks hersteld en kraakbeentransplantatie nog niet succesvol is.[1]

Bij artrose van de knie worden drie compartimenten onderscheiden: (a) het mediale compartiment bestaande uit de mediale femur condyl en het mediale tibiaplateau; (b) het laterale compartiment bestaande uit de laterale femur condyl en het laterale tibiaplateau; (c) het patellofemorale compartiment.

Er wordt onderscheid gemaakt tussen artrose van de gehele knie en artrose van één compartiment. Artrose van één compartiment heeft waarschijnlijk vaker een mechanische oorzaak en komt vooral op jonge leeftijd voor nadat eerder een mediale of laterale meniscectomie is verricht.[2,3] De normale mechanische (belastings) as van een recht been loopt van het centrum van het caput femoris door het midden van de knie naar het centrum van de enkel (Figuur 1a). Patiënten met artrose van het mediale compartiment



Figuur 1. (a) de mechanische(belastings)as van een been door het centrum van het caput femoris, door het centrum van de knie en naar het centrum van de enkel; (b) genu varum arthroticum, waarbij de as door het mediale compartiment loopt; (c) genu valgum arthroticum, waarbij de as door het laterale compartiment loopt; (d) toestand na een gesloten, valgiserende wigosteotomie van de tibiakop: de as is van het mediale naar het laterale compartiment verplaatst: (e) toestand na een open, variserende wigosteotomie van het distale femur: de as is van het laterale compartiment naar het centrum van de knie verplaatst.

hebben vaak een genu varum (O-been) en daarbij spreekt men van genu varum arthroticum; de mechanische as loopt door het mediale compartiment (Figuur 1b). Patiënten met artrose van het laterale compartiment hebben daarentegen veelal een genu valgum (X-been) en in deze situatie spreekt men van een genu valgum arthroticum; de mechanische as loopt door het laterale compartiment (Figuur 1c).

Een relatief jonge patiënt met invaliderende knieklachten en genu varum en valgum arthroticum wordt in eerste instantie conservatief behandeld. De conservatieve therapie bestaat uit aanpassen van de belasting, spierversterkende oefeningen, fysiotherapie, een brace en NSAID's.[4,5] Als deze conservatieve behandeling onvoldoende effect heeft, kan een operatieve therapie overwogen worden.[6]

Diagnostiek

De diagnose 'genu varum arthroticum' of 'genu valgum arthroticum' wordt gesteld na anamnese, lichamelijk onderzoek, en röntgendiagnostiek.

Anamnestisch is de pijn bij genu varum arthroticum aan de mediale zijde van de knie gelokaliseerd zijn en bij genu valgum arthroticum aan de laterale zijde. Er is sprake zijn van startpijn en stijfheid bij opstaan De loopafstand is beperkt en in ernstige gevallen is er sprake van nachtelijke pijn. Ten gevolge van de gonartrose wordt de patiënt beperkt in het dagelijks leven, zijn of haar werkzaamheden en sportactiviteiten.

Bij het algemeen lichamelijk onderzoek let men op het gewicht en de biologische leeftijd. Het gewicht is van belang omdat reductie daarvan de klachten kan verminderen. Daarnaast heeft overgewicht een negatieve invloed op het resultaat van een standscorrectie en 'de overleving' van een kunstgewricht. Ook is er bij overgewicht een grotere kans op complicaties bij een operatieve behandeling.[7,8]

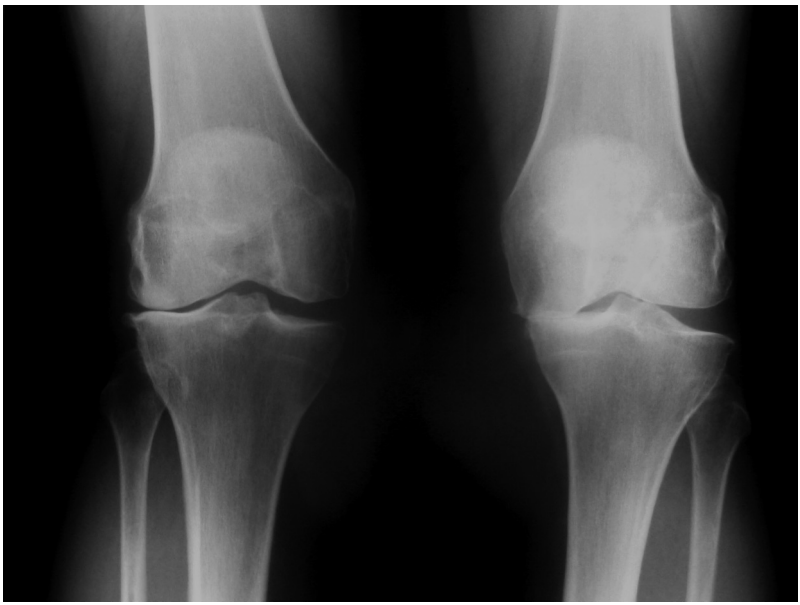
Bij het orthopedisch onderzoek let men op het looppatroon. De patiënt kan een antalgisch looppatroon hebben, waarbij de aangedane knie ontlast wordt. Tijdens de standfase kan de varus-stand van de knie toenemen hetgeen wijst op laterale knieband instabiliteit.

Terwijl de patiënt stilstaat, wordt de as van het been beoordeeld. Hydrops van de knie wijst op synovitis. De passieve bewegingsuitslagen van de knie (flexie en extensie) dienen vooraf bepaald te worden. De bewegingsuitslag neemt door de operatieve standscorrectie niet toe; hierover dient de patiënt geïnformeerd te zijn.

De collaterale stabiliteit en kruisbandstabiliteit moeten beoordeeld worden, omdat er in geval van instabiliteit naast de standscorrectie een collaterale reconstructie of kruisband reconstructie raadzaam kan zijn.[9] Bij palpatie is de mediale of laterale gewrichtsspleet pijnlijk.

De röntgendiagnostiek bestaat hoofdzakelijk uit een knie foto in twee richtingen terwijl de patiënt staat op beide benen en een anteroposterieure foto van het gehele been. Met deze röntgenfoto wordt met name aan de hand van gewrichtsspleet versmalling de mate en de locatie van de artrose bepaald (Figuur 2).[10] De foto van het gehele been is een betrouwbaar meetinstrument om de varus- dan wel de valgusmaat te bepalen (intra-waarnemervariabiliteit met een intraklassecorrelatiecoëfficiënt van 0.98; interwaarnemer-variabiliteit met een intraklassecorrelatiecoëfficiënt van 0.97).[11] Tevens wordt met behulp van deze röntgenfoto van het gehele been de noodzakelijke grootte van de correctie bepaald.

Bij twijfel over de mate en de locaties van artrose kan er aanvullende diagnostiek in de vorm van een MRI-scan plaatsvinden.



Figuur 2. Een patiënt met artrose van het mediale compartiment van de linker knie en artrose van het laterale compartiment van de rechter knie. De desbetreffende gewrichtsspleet is versmald door kraakbeen verlies.

De correctie osteotomie

In geval van artrose van één compartiment met een standsafwijking kan een stands-correctie (=correctie-osteotomie) de klachten in belangrijke mate reduceren.

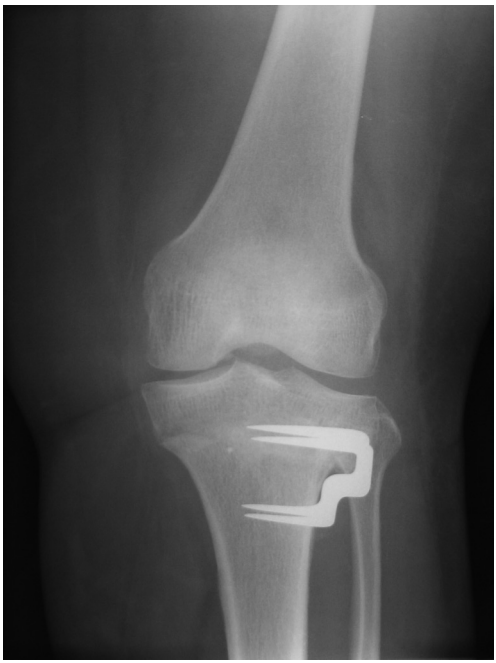
De 'ideale patiënt' is een actieve man of vrouw jonger dan 60 jaar zonder overgewicht met een beginnende artrose van één compartiment en een milde varus of valgus stand van de knie.

Het doel van een correctie-osteotomie is de belastingsas naar het goede compartiment te verplaatsen en de symptomen te verminderen, waardoor een arthroplastiek uitgesteld kan worden naar minder actieve levensfase.[12,13] Patiënten met artrose van het mediale compartiment kunnen met een valgiserende osteotomie behandeld worden en patiënten met artrose van het laterale compartiment met een variserende osteotomie.

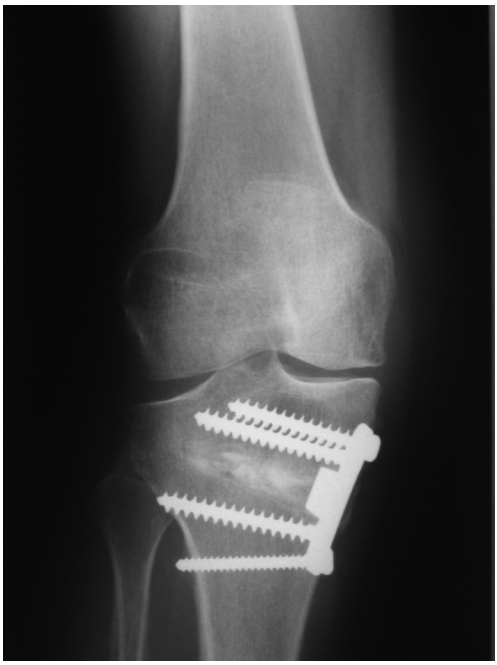
De standscorrectie kan op verschillende manieren worden bereikt.

- Bij een gesloten wigosteotomie wordt een botwig verwijderd; bij een variserende, supracondylaire osteotomie wordt de wig aan de mediale zijde verwijderd, en bij een valgiserende tiabiakop-osteotomie aan de laterale zijde verwijderd (Figuur 1d en 3).[13,14] Deze techniek heeft als voordeel dat de osteotomievlakken goed op elkaar aansluiten en de kans op consolidatie groot is.
- Bij een open wigosteotomie wordt een wig wordt gecreëerd met behulp van cristabot of biomateriaal; bij de variserende supracondylaire osteotomie wordt de wig aan de laterale zijde gecreëerd en bij de valgiserende tibiakop osteotomie aan de mediale zijde (Figuur 1e en 4).[17] Deze techniek is in opkomst. Er is geen botverlies en de correctie lijkt nauwkeurig te kunnen worden uitgevoerd.
- Bij een pendelosteotomie vindt een boogvormige osteotomie van de proximale tibia plaats. Hierna wordt in de meeste gevallen de osteotomie niet gefixeerd met osteosynthese-materiaal en vindt immobilisatie in een gewenste stand plaats met een bovenbeengips. De correctie is dan ook postoperatief bij te sturen.[16] De pendel-osteotomie wordt heden ten dage steeds minder toegepast, omdat de postoperatieve correctie onvoorspelbaar is en met name postoperatief verlies van correctie optreedt.
- Bij een osteotomie met behulp van een fixateur externe wordt postoperatief de correctie verkregen door de fixateur gedurende maanden bij te stellen in de gewenste stand.[17] Hierbij treedt evenmin botverlies op en de correctie is postoperatief nauwkeurig in te stellen. Het nadeel is echter dat de patiënt langdurig een fixateur heeft, evenals intensieve poliklinische contoles, en dat er bovendien een grotere kans is op infectie.[18]

Bij een correctie-osteotomie in valgusrichting is een lichte overcorrectie te prefereren, terwijl dit in varusrichting mindere mate het geval is.[13,15,19] De kans op een over- en ondercorrectie is ongeveer 20%.[20] Progressie van artrose van het contralaterale compartiment treedt met name op bij te grote overcorrectie.[21] De juiste correctie wordt in eerste instantie bepaald door het preoperatieve onderzoek, waarbij met name de röntgenfoto van het gehele been van belang is.[11]



Figuur 3. Toestand na gesloten, valgiserende wigosteotomie van de tibiakop. De osteotomie is na het verwijderen van de botwig gesloten en gefixeerd met twee krammen



Figuur 4. Toestand na open, valgiserende wigosteotomie van de tibiakop. Fixatie na osteotomie vond plaats met een plaat-osteosynthese. De wig is opgevuld met donorbot uit de crista iliaca.

De standscorrectie tijdens de operatie is afhankelijk van de operateur en het gebruikte instrumentarium. Het behoud van de correctie is afhankelijk van het gewicht van de patiënt, de mate van correctie, de botkwaliteit en de fixatie methode.[15,20] Voor fixatie wordt gebruik gemaakt van krammen, schroeffixatie en plaat fixatie.

De nabehandeling is afhankelijk van de fixatie van de osteotomie. In geval van een rigide fixatie is geen gipsbehandeling noodzakelijk.[22] Over het algemeen wordt de patiënt postoperatief onbelast of partieel belast gemobiliseerd. De consolidatie na de osteotomie vindt plaats in 6 tot 8 weken.

Complicaties. Als na de osteotomie geen consolidatie plaatsvindt ('pseudarthrose': 2-25% van de gevallen), is er een grotere kans op verlies van de correctie; in de meeste gevallen is na een langdurige gipsbehandeling opnieuw een standscorrectie met een bottransplantaat noodzakelijk.[18,20,23]

Thrombo-embolische processen (5-11%) kunnen verminderd worden door patiënten snel na de operatie te mobiliseren zonder een bovenbeengips.[22,24] Ten gevolge van de postoperatieve immobilisatie kan een contractuur van de patellapees (0-54%) optreden waardoor een laagstand van patella kan ontstaan.[22,25] Deze kan het implanteren van een kunstgewricht in de toekomst een lastige procedure maken. Om de correctie te bewerkstelligen wordt bij de gesloten wig en pendelosteotomie ter hoogte van de tibia tevens de fibula doorgenomen. Door de anatomische ligging van de N. peroneus ten opzichte van de fibula geeft deze fibula-osteotomie kans op N. peroneus uitval (2% van de gevallen).[26] Ter preventie van een compartiment syndroom, dat ontstaat door een verhoogde druk in een spierloge, wordt tijdens de operatie na de standscorrectie ook een fasciotomie verricht.

Alternatieve operatieve behandelingen

Een behandeling die veel wordt toegepast, is het arthroscopisch bijwerken van de degeneratieve meniscus en het artrotische kraakbeen. Vaak heeft deze behandeling echter alleen een kort termijn effect en blijkt niet beter te zijn dan een chirurgische placebo behandeling.[27,28]

Een eventuele kraakbeentransplantatie is alleen mogelijk als een lokaal deel van het compartiment is aangedaan en niet in geval van een diffuse artrose met een standafwijking.[29]

Omdat de lange termijn resultaten van een halve (unicompartimentele) en een totale knie prothese bij oudere patiënten goed zijn, is er een trend om ook bij jongere patiënten (< 60 jaar) met gonartrose een unicompartimentele of een totale knie vervanging uit te voeren.[8,30] Het voordeel van een unicompartimentele knieprothese is dat alleen het mediale of laterale compartiment vervangen wordt waardoor het goede compartiment behouden blijft.[31] In een gerandomiseerde studie naar de valgiserende proximale tibia-osteotomie versus de unicompartimentele knieprothese gaf de prothese geen significante betere

Tabel 1. Lange termijnresultaten van verschillende correctie-osteotomie technieken bij genu varum en valgum arthroticum.

Auteur	indicatie * femur/tibia	type osteotomie; (in jaren)	follow-up duur	aantal patiënten/ knieën	percentage met positief resultaat **
Choi [34]	O	gesloten wig; tibia	15	59/ 66	60
Aglietti [12]	O	gesloten wig; tibia	10	120/ 139	64
Coventry [13]	O	gesloten wig; tibia	10	73/ 87	75
Billings [22]	O	gesloten wig; tibia	10	61/ 64	53
Rudan [35]	O	gesloten wig; tibia	6	79/ 79	80
Hernigou [15]	O	open wig; tibia	12	66/ 93	45
Sundaram [16]	X	pendel; tibia	5	92/ 105	75
Edgerton [20]	X	gesloten wig; femur	8	23/ 24	71
Cameron [36]	X	gesloten wig; femur	7	49/ 49	87
Matthews [7]	O	gesloten wig; tibia	9	40/ 40	28
Terry [14]	X	gesloten wig; femur	5	34/ 36	65
Naudie [23]	X	gesloten wig/ pendel; tibia	10	85/ 106	51

O= artrose van het mediale compartiment met als gevolg een genu varum arthroticum;
X= artrose van het laterale compartiment met als gevolg een genu valgum arthroticum.
** *Positieve resultaten= afname pijn, verbeterde functie volgens de 'Hospital for Special Surgery score' (HSS) knie score, uitstel van knieprothese.*

resultaten qua pijnscore en functie.[32]

Bij intensief gebruik zal een kunstgewricht vroegtijdig slijtage en loslating vertonen, waardoor deze ingreep bij jonge, actieve patiënten met een lange levensverwachting niet als eerste keus behandeling geldt.[33]

In retrospectieve studies waren de lange termijnresultaten van de correctie-osteotomie bij gonartrose dusdanig dat een arthroplastiek 7-15 jaar kan uitstellen (zie Tabel 1). [7,12-16,20,22,34-36]

Conclusie

Een standscorrectie bij gonartrose die is beperkt tot het medial of laterale compartiment kan de klachten in belangrijke mate reduceren. Het resultaat is afhankelijk van een nauwkeurige patiënten selectie, de mate van artrose en de uiteindelijk bereikte correctie.

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Chapter 7

Osteotomy for Treating Knee Osteoarthritis

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Cochrane Database Syst Rev. 2005 Jan 25;(1):CD004019

Abstract

Background Patients with unicompartmental osteoarthritis of the knee can be treated with a correction osteotomy. The goal of the correction osteotomy is to transfer the load bearing from the pathologic to the normal compartment of the knee. A successful outcome of the osteotomy relies on proper patient selection, stage of osteoarthritis, achievement and maintenance of adequate operative correction.

Objectives To assess the effectiveness and safety of an osteotomy for treating osteoarthritis of the knee.

Search Strategy The Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE (Current contents, Health STAR) were searched up until October 2002 for controlled clinical trials. The reference lists of publications in the identified trials were also screened.

Selection Criteria Extracted studies were included in the final analysis if they met the pre-defined inclusion criteria: 1) a randomised controlled clinical trial or a controlled clinical trial 2) all patients had unicompartmental osteoarthritis of the medial or lateral compartment of the knee 3) the intervention in one of the studied groups was a high tibial osteotomy or a distal femoral osteotomy.

Data collection and analysis Two reviewers independently selected the trials, assessed the methodological quality using a validated tool and extracted the data. The planned analysis was to pool the results where appropriate, however, due the heterogeneity of the studies, pooling of the outcome measures was not possible. Results are described for each study and presented as a best evidence synthesis.

Main Results Following the search strategy and applications of selection criteria, eleven studies were included in this review. All the studies concerned a valgus high tibial osteotomy (HTO) for medial compartment osteoarthritis of the knee. Four studies compared two techniques of HTO. One study compared HTO alone versus HTO with additional treatment. Four studies compared within the same type of HTO, different per-operative conditions (two studies) or two different types of post-operative treatment (two studies). Two studies compared HTO with unicompartmental joint replacement. No study compared an osteotomy with conservative treatment. Most studies showed improvement of the patient (less pain and improvement of function scores) after osteotomy surgery, but in the majority of the studies there was no significant difference with other operative treatment (other technique of HTO/ unicompartmental joint replacement). Overall, the methodological quality was low.

Authors' conclusions Based on 11 studies, of which 6 were high quality, we conclude that there is silver level evidence that valgus HTO improves knee function and reduces

pain. There is no evidence whether an osteotomy is more effective than conservative treatment and the results so far do not justify a conclusion about effectiveness of specific surgical techniques.

Background

Osteoarthritis of the knee (gonarthrosis) is a common medical condition that is seen quite often in orthopaedics practice and causes pain and disability. The knee joint can be divided in three compartments: (1) the medial compartment consisting of the medial femur condyle and medial tibial plateau, (2) the lateral compartment consisting of the lateral femur condyle and lateral tibial plateau, (3) the patellofemoral compartment.

Osteoarthritis of the entire knee is distinguished from osteoarthritis of one compartment, which is generally caused by a mechanical problem.[1,2] The mechanical axis of a straight leg is a line passing from the center of the hip, through the center of the knee to the center of the ankle.[3] Patients with osteoarthritis of the medial compartment often have varus alignment, and the mechanical axis and load bearing pass through the medial compartment. Patients with osteoarthritis of the lateral compartment often have a valgus alignment, and the mechanical axis and load bearing pass through the lateral compartment. Malalignment increases risk for progression of knee osteoarthritis and predicts decline in physical function.[4]

Patients with osteoarthritis not reacting to non-surgical therapy can be treated with a correction osteotomy.[5-8] The goal of the correction osteotomy is to transfer the mechanical axis and load bearing from the pathologic to the normal compartment. Patients with osteoarthritis of the medial compartment can be treated with a proximal tibia valgus osteotomy and patients with osteoarthritis of the lateral compartment with a distal femoral varus osteotomy or a proximal tibia varus osteotomy.

Literature suggests that a correction osteotomy for gonarthrosis of one compartment has good results, but there are different operation techniques and alternatives.[9-11] A successful outcome of the osteotomy relies on a proper patient selection, stage of arthrosis, achievement and maintenance of adequate operative correction.[8,12-17] The osteotomy cannot stop the degenerative process and most of the patients will get a total knee arthroplasty. However the osteotomy seems to delay the progress of deterioration.

Objectives

To assess the effectiveness and safety of an osteotomy to treat osteoarthritis of the knee.

Criteria for considering studies for this review

Types of studies
Randomised controlled trials and controlled clinical trials investigating all types of osteotomy for treating osteoarthritis of the knee compared to other surgical and non-surgical treatment.

Types of participants
Adult patients with unicompartmental osteoarthritis of the medial or lateral compartment of the knee confirmed by radiographic or arthroscopic investigation.

Types of intervention
All types of high tibial osteotomy and distal femoral osteotomy for patients with unicompartmental gonarthrosis including osteotomy versus conservative treatment, different techniques of osteotomy, and osteotomy versus other surgery.

Types of outcome measures
The primary measure of effectiveness is pain relief, as suggested by the third conference of Outcome Measures in Rheumatology (OMERACT[18]):

The core OMERACT measure for hip, knee, and hand osteoarthritis include:
- pain
- physical function
- patient global assessment
- joint imaging (for studies of one year and longer)
- health related quality of life measure
- physician global assessment

Secondary outcomes include:
- inflammation
- stiffness
- performance-based measures, tenderness, time to revision surgery, difficulties at revision surgery, number of flares, and biologic markers.

Safety and side effects:
Number of people with side effects will be measured when possible.

Search strategy for identification of studies

See: Cochrane Musculoskeletal Group search strategy

We searched the Cochrane Central Register of Controlled Trials (CENTRAL). We also searched MEDLINE and EMBASE (Current contents, Health STAR) up until October 2002 to identify all clinical trials concerning an osteotomy for gonarthrosis. MEDLINE searches for clinical trials were based on the Cochrane Collaboration strategy. No language restriction was applied.

In MEDLINE, the following search strategy was combined with all phases of the optimal trial search strategy (Robinson [19]) and was modified for uses in other databases:

1. osteoarthritis, knee
2. osteoarthritis
3. (osteoarthritis or osteoarthrosis or degenerative joint disease).tw.
4. 2 or 3
5. knee joint/ or knee.t.w.
6. 4 and 5
7. 1 or 6
8. exp Osteotomy/
9. Osteotomy$.tw.
10. 8 or 9
11. 7 and 10
12. meta-analysis.pt,sh.
13. (meta-anal: or metaanal:).tw.
14. (quantitativ: review: or quantitativ: overview:).t.w.
15. (methodologic: review: or methodologic: overview:).tw.
16. (systematic: review: or systematic: overview) .tw.
17. review.pt. and medline.tw.
18. or/12-17
19. clinical trial.pt.
20. randomised controlled trial.pt.
21. tu.fs.
22. dt.fs.
23. random$.tw.
24. (double adj blind$).tw.
25. placebo$.tw.
26. or/ 19-25
27. 11 and 18
28. 11 and 26

Methods of the review

Selecting trials for inclusion

Two reviewers (RB, TJ) selected the trials, initially based on title and abstract. The title, keywords and abstract were assessed to establish whether the study met the inclusion criteria regarding diagnosis, design and intervention. For each selected study, the full article was retrieved for final assessment. Next, two reviewers (RB, TJ) independently performed a final selection of the trials to be included in the review, using a pre-tested standardized form. Disagreements on inclusion were resolved by discussion, and the final decision of a third reviewer (JV) was not necessary.

Methodological quality assessment

Two reviewers (RB, SB) assessed the methodological quality independently from each other. They used the Delphi list and one additional question adapted from the criteria list for Methodological Quality Assessment.[20,21] Disagreements were resolved in a consensus meeting. All items have 'yes', 'no', 'don't know' answer options. Items rated as positive contribute to the quality score by summing up.

The nine questions from the Delphi list and the additional question with M are:

D1. Was a method of randomisation performed?
D2. Was the treatment allocation concealed?
D3. Were the groups similar at baseline regarding the most important prognostic indicators?
D4. Were the eligibility criteria specified?
D5. Was the outcome assessor blinded?
D6. Was the care provider blinded?
D7. Was the patient blinded?
D8. Were points estimates and measures of variability presented for the primary outcomemeasures?
D9. Did the analysis include an intention-to-treat analysis?
M. Was the surveillance active and of clinically appropriate duration?

The scores of the quality items of each study are presented in Table 2. A score of 1 is given to each item with a 'yes' answer and a 0 score is given for a negative response. High quality is defined as presenting an adequate or concealed randomisation procedure and adequate blinding, or a positive score on 6 or more on the 10 quality items.

Data extraction

Three reviewers (RB, TJ, AV) independently extracted the data on the intervention, type of outcome measures, follow-up, loss to follow-up, and outcomes, using a pre-tested standardized form. The various outcome measures are presented separately.

Analysis

Methodology

The maximum score of the overall quality score is 10 points (Delphi list is 9 points). The measure of agreement between the two reviewers (RB, SB) is presented as kappa.

Quantitative analysis

For dichotomous outcomes, relative risks were calculated. For continuous outcomes, weighted mean differences (WMD) were calculated using RevMan 4.2 software.[22] A random effects model was used if the studies or subgroups of studies were considered clinically heterogeneous; otherwise where appropriate, a fixed effects model was used to pool the outcomes. Subgroups were based on patient characteristics (gender, age, duration of symptoms, medial or lateral unicompartmental osteoarthritis, etc) or trial characteristics (duration of the trial period, etc).

The analysis was set up to identify three study groups:

A. Operative versus conservative treatment
B. Different operative treatments:
    1. different high tibial osteotomy techniques
    2. high tibial osteotomy versus unicompartmental joint replacement
    3. differences in peroperative conditions
C. Different treatment post surgery

Qualitative analysis

Since the trial results are heterogeneous, the results are analysed according to 'best evidence analysis' (van Tulder [21]) using a rating system with levels of evidence based on the overall quality; the outcomes of the studies are also used:

- strong evidence - provided by generally consistent findings in multiple high quality RCT;
- moderate evidence - provided by generally consistent findings in one high quality RCT and one or more lower quality RCTs;
- limited evidence - provided by only one RCT (either high or low quality) or generally consistent findings in CCTs;
- no evidence - no CCTs or RCTs.

Secondly, an overall grading of evidence (Tugwell [23]) is used:

Platinum level

The Platinum ranking is given to evidence that meets the following criteria as reported:

Is a published systematic review that has at least two individual controlled trials each satisfying the following:

- Sample sizes of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome.
- Blinding of patients and assessors for outcomes.
- Handling of withdrawals >80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable).
- Concealment of treatment allocation.

Gold level

The Gold ranking is given to evidence if at least one randomised clinical trial meets all of the following criteria for the major outcome(s) as reported:

- Sample sizes of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome.
- Blinding of patients and assessors for outcomes.
- Handling of withdrawals > 80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable).
- Concealment of treatment allocation.

Silver level

The Silver ranking is given to evidence if a randomised trial does not meet the above criteria. Silver ranking would also include evidence from at least one study of non-randomised cohorts who did and did not receive the therapy or evidence from at least one high quality case-control study. A randomised trial with a 'head-to-head' comparison of agents is considered Silver level ranking unless a reference is provided to a comparison of one of the agents to placebo showing at least a 20% relative difference.

Bronze level

The bronze ranking is given to evidence if there is at least one high quality case series without controls (including simple before/after studies in which the patient acts as their own control) or if it is derived from expert opinion based on clinical experience without reference to any of the foregoing (for example, argument from physiology, bench research or first principles).

Table 1. Characteristics of included studies of Cochrane review "Osteotomy for treating knee osteoarthritis".

Study	**Adili 2002**
Methods	CCT; no randomisation; not blinded. Allocation concealment= D.
Participants	Varus alignment and symptomatic medial compartment osteoarthritis.
Interventions	I: high tibial osteotomy (HTO) using an Ilizarov apparatus (n=15) and C: closed wedge HTO (n=15). Follow-up: I=25,4 months and C=30,9 months.
Outcomes	WOMAC scores, FTA, patient satisfaction, complications.
Notes	The follow-up period was different. No drop-outs mentioned.
Study	**Akizuki 1997**
Methods	CCT; no randomisation: patients were assigned in both groups in turn; not blinded. Allocation concealment= D.
Participants	Medial compartment osteoarthritis.
Interventions	I: HTO with arthrscopic abrasion (n=45). C: HTO alone (n=34). Follow-up: I=4,8 years and C=3,5 years.
Outcomes	JOA knee score, FTA .
Notes	The follow-up period and the number of the patients were different. No drop-out.
Study	**Magyar (1) 1999**
Methods	RCT; randomisation procedure was not described; the follow-up examination was blinded. Allocation concealment= B.
Participants	Medial gonarthrosis and younger active patients.
Interventions	I: hemicallotasis open-wedge osteotomy (HCO/ n=24). C: closed wedge HTO (n=22). Follow-up: 2 years.
Outcomes	VAS score, ROM, HSS knee score, Lysholm score, Wallgren-Tegner activity score, NHP score, HKA-angle, hospital stay, complications.
Notes	Only pre- and post analysis. Only subgroup scores of the NHP were given. In our opinion the ROM of the HCO group on page 446 is not correct. Two drop-outs for the NHP assessment; one in each group.
Study	**Magyar (2) 1999**
Methods	RCT; randomisation using numbered closed enveloppes; not blinded. Allocation concealment= A.
Participants	Medial gonarthrosis grade I-III.
Interventions	I: HCO (n=18) and C: closed wedge HTO (n=15). Follow-up: 1 year.
Outcomes	Radiostereometry (RSA), HKA-angle.
Notes	RSA measurement is no outcome measurement in our protocol, but HTO was associated with more translation. No drop-out.
Study	**Mammi 1993**
Methods	CCT; randomisation according to order of admission to the hospital; double blind. Allocation concealment= C.
Participants	Maximum age of 80 years, good health, requiring tibial reduction osteotomy.
Interventions	I: HTO with electrical stimulation (n=18) and C: HTO without electrical stimulation (n=19). Follow-up: 60 days.
Outcomes	Rate of union (score 1t/m4).
Notes	I: 2 drop-outs; C: 1 drop-out.
Study	**Motycka 2000**
Methods	RCT; randomisation procedure was not described. Allocation concealment= B.
Participants	Varus osteoarthritis.

Interventions	I: HTO with a tourniquet (n=40) and C: HTO without a tourniquet (n=40). Follow-up: 9 weeks.
Outcomes	D-Dimer test and phlebography.
Notes	I: 3 drop-outs. C: 15 drop-outs.
Study	**Myrnerts 1980**
Methods	RCT; randomisation procedure was not clear. Not blinded. Allocation concealment= B.
Participants	Varus alignment.
Interventions	I: HTO without an overcorrection (n=40) and C: HTO with 5 degrees overcorrection (n=37). Follow-up: 1 year.
Outcomes	Pain on weightbearing, patient's opinion, HKA-angle, complications.
Notes	The study reports percentages and no numbers? No drop-out mentioned.
Study	**Nakamura 2001**
Methods	RCT; randomisation procedure was not described. Allocation concealment= B.
Participants	Medial osteoarthritis of the knee.
Interventions	I: HCO (n=23) and C:dome osteotomy (DMO; n=23).
Outcomes	FTA-angle, length of the patella tendon, slope of tibia-plateau, tibial condylar offset.
Notes	No drop-out.
Study	**Odenbring 1992**
Methods	RCT; "randomisation code was opened"; not blinded. Allocation concealment= B.
Participants	Stages I-III medial gonarthrosis.
Interventions	I: HTO with a hinged cast brace postoperative (n=14) and C: HTO with a cylinder plaster cast postoperative (n=17). Follow-up: 1 year.
Outcomes	ROM, pain free walking distance, pain at rest, degree of OA, HKA-angle, Lysholm-score, complications.
Notes	One patient with a complication was excluded.
Study	**Stukenborg 2001**
Methods	RCT; patients were computer randomised. Not blinded. Allocation concealment= A.
Participants	Medial unicompartmental OA, varus < 10 degrees, flexion contracture < 15 degrees, age > 60 years, ligament instability < grade II.
Interventions	I: HTO (n= 32) and C: unicompartmental knee arthroplasty (UKA; n= 28). Follow-up: 7,5 years.
Outcomes	Knee score, functional score, ROM, HKA-angle, survivorship, complications.
Notes	No drop-out.
Study	**Weidenhielm 1993**
Methods	RCT; randomisation procedure was not described. Not blinded. Allocation concealment= B.
Participants	Medial OA grade I-II, 55-70 years old.
Interventions	I: HTO (n=23) and C: UKA (n=36). Follow-up: 1 year.
Outcomes	ROM, Pain-Borg scale, BOA-kneescore, HKA-angle, survivorship, complications.
Notes	The cause of number-ineqality of both groups was not described. No drop-out.

Description of studies

From the search strategy the reviewers (RB, TJ) independently selected 11 abstracts. After reading the full article, one trial was excluded because the design was a post-hoc analysis.[24] After checking the reference lists of publications we added one study of *Myrnerts.*[25] The remaining eleven studies are described in detail in the Tabel 1. All studies concerned a valgus high tibial osteotomy (HTO) for medial compartment osteoarthritis of the knee, but were quite heterogenous. The mean number of the patients in the eleven studies was 52 (range 30 to 88). The interventions were different techniques of HTO, HTO versus unicompartmental joint replacement, different per-operative conditions, and different types of postoperative treatment. Outcome measures were range of motion (ROM), complications, VAS, Western Ontario-McMaster (WOMAC) osteoarthritis score, Hospital for Special Surgery (HSS) knee score, Lysholm score, Wallgren-Tegner score, Nottingham Health Profile (NHP) score , British Orthopaedic Association (BOA) knee score, Japanese Orthopaedic Association (JOA) knee score, gait analysis, joint imaging, degree of osteoarthritis, Hip Knee Ankle (HKA)-angle, and Femoral Tibial Angle (FTA).

Adili described a matched comparative analysis of two techniques: the osteotomy with the Ilizarov apparatus versus the Coventry-type closed wedge osteotomy.[26] Inclusion criteria were varus alignment and symptomatic medial compartment osteoarthritis. Both groups consisted of 15 participants, but they were not randomised. The study included 20 men and 10 women. The mean age was 52 and the body mass index was 32.8. The degree of varus was 185 degrees (FTA). The follow-up was different: 25.4 months in the Ilizarov group and 30.9 months in the Coventry group.

Magyar (1) presented a RCT of two techniques: the hemicallotasis open wedge osteotomy (HCO; 24 participants/ 25 knees) versus the closed wedge high tibial osteotomy (HTO; 22 participants/ 25 knees).[27] Inclusion criteria were medial gonarthrosis and younger, active patients. The study included 32 men and 14 women. The mean age was 55 years. The degree of varus was 171 degrees (HKA). The follow-up was two years. There were two drop outs (one in each group) for the NHP assessment.

Magyar (2) published a second RCT study with radiostereometry (RSA). RSA is a method that uses tantalum markers in the bone to determine 3-dimensional changes in the osseous correction.[28] This study is probably linked with the study *Magyar (1)*, because the participants and interventions (HCO versus HTO) are identical. The inclusion criterion was medial gonarthrosis grade I-III. Thirty-three patients (22 men and 11 women) were studied: HCO 18 participants/ 19 knees; HTO 15 participants/ 16 knees. The mean age was 54 years and the mean body mass index was 29.5. The degree of varus was 171 degrees (HKA). The follow-up was one year.

Nakamura presented a RCT where 46 participants were randomly allocated to either a hemicallotasis open wedge osteotomy (HCO; 23 participants/ 25 knees) or a dome osteotomy (DMO; 23 participants/ 25 knees).[29] The inclusion criterion was medial osteoarthritis of the knee. This study included 9 men and 37 women. The mean age was 63 years. The degree of varus was 181.5 degrees (FTA). They studied changes of FTA, patella tendon length, inclination angle of tibial plateau and condylar offset at one year post-operative. These measurements are factors which may cause difficulties in conversion to total knee arthroplasty and were scored as side effects. The follow-up was one year.

Stukenborg published a RCT of 60 participants. The study compared high tibial osteotomy (HTO; n= 32) with unicompartmental joint replacement (=unicompartmental knee arthroplasty UKA; n=28).[11] Inclusion criteria were medial unicompartmental OA, varus < 10 degrees, flexion contracture < 15 degrees, age > 60 years, ligament instability < grade II. This study included 25 men and 35 women. The mean age was 67 years. The degree of varus was 171 degrees (HKA). The follow-up was 7.5 (6.6-10) years.

Weidenhielm published a RCT of 59 participants and compared the HTO (n=23) with the UKA (n=36).[30] The reason for the difference in sample size in the two groups was not described. Inclusion criteria were medial OA grade I-II, 55-70 years old. This study included 28 men and 31 women. The mean age was 64 years. The mean body mass index was 28.5. The degree of varus was 171 degree (HKA). The follow-up was one year.

Akizuki described a RCT of 79 patients (88 knees). 45 patients (51 knees) were treated by osteotomy with arthroscopic abrasion arthroplasty and 34 participants (37 knees) were treated by osteotomy alone.[31] The inclusion criterion was medial compartment osteoarthritis. The study included 9 men and 70 women. The mean age was 64 years. The degree of varus was 185 degrees (FTA). The follow-up was 4.8 years in the osteotomy with abrasion group and 3.5 years the osteotomy group.

In the RCT of *Myrnerts*, the closed wedge HTO technique was the same, but the 77 participants were allocated at random to two groups: the normal correction group (n=40) and the 5 degree overcorrection group (n=37).[25] The inclusion criterion was varus alignment. The study included 32 men and 45 women. The mean age was 61 years. All the participants had a follow-up of one year and "most" were examined 24 months post-operatively.

Motycka published a RCT of 65 patients to look at the side effects of HTO.[32] He studied the incidence of thrombosis in HTO with (n=37) and without (n=28) the use of a tourniquet. A Dimer-test and phlebography were used to confirm the diagnosis. The inclusion criterion was varus osteoarthritis. The study included 30 men and 35 women. The mean age was 61 years. There was a follow-up 9 weeks. There was a dropout of 15 patients which caused the inequality in numbers in the groups.

Table 2. Methodological quality of included studies of *Cochrane review "Osteotomy for treating knee osteoarthritis"*

Study	D1	D2	D3	D4	D5	D6	D7	D8	D9	M	Total score	Delphi score
Adili	0	0	1	1	0	0	0	1	0	1	4	3
Akizuki	0	0	1	0	0	0	0	1	1	1	4	3
Magyar (1)	1	1	1	0	1	0	0	1	1	1	7	6
Magyar (2)	1	1	1	0	0	0	0	1	1	1	6	5
Mammi	1	0	0	1	1	1	1	1	0	1	7	6
Motycka	1	0	0	0	0	0	0	1	0	1	3	2
Mymerts	1	0	1	0	0	0	0	0	0	1	3	2
Nakamura	1	0	0	0	0	0	1	1	1	1	4	3
Odenbring	1	1	1	0	0	0	0	1	1	1	6	5
Sukenborg	1	0	1	1	0	0	0	1	1	1	6	5
Weidenhielm	1	0	1	1	0	0	0	1	1	1	6	5
% agreement	82	73	64	64	82	82	91	82	64	91		

Mammi described a double-blind study of 40 patients.[33] In this study, the HTO technique was the same but post-operatively patients were randomly assigned to the intervention group (long plaster cast with an electromagnetic field stimulation;n=20) or the control group (a long plaster cast with a dummy stimulator; n=20). The randomisation was according to their order of admission to the hospital. Incusion criteria were maximum age of 80 years, good health, and requiring tibial reduction osteotomy. The study included 9 men and 31 women. The mean age was 62 years. The follow-up was 60 days. There were two dropouts in the intervention group versus one dropout in the control group.

Odenbring published a RCT study with 32 participants randomised to either a cylinder plaster cast (n=17) or a hinged cast-brace (n=14) after HTO.[34] Because of a complication, one patient in the brace group was excluded and not included in analysis. Inclusion criteria were stages I-III medial gonarthrosis. The follow-up was one year.

Methodoligical quality

Methodological quality (Table 2)

The overall methodological quality score ranged from 3 to 7 (max = 10 points), and six studies scored more than 50% *(Magyar (1); Magyar (2); Mammi; Odenbring; Stukenborg; Weidenhielm)*. The mean score was 5.6 and the median score was 6 points and corresponded with a 60% score. In three studies, the randomisation procedure was adequate or concealed *(Magyar (1); Magyar (2); Odenbring).* In most of the trials the blinding procedures of the outcome assessors, treatment providers, and participants frequently scored 'no'. Only one study presented adequate or concealed randomisation procedure and adequate blinding *(Magyar (1)).*

The measure of agreement (kappa) between the two reviewers (RB, SB) was 0.54. Disagreement occurred mainly because of reading errors and differences in interpretation of the methodological criteria list.

The Delphi list quality score ranged from 2 to 6 (max = 9). Six studies score more than 50%. These six studies were the same as in the overall quality assessment.

Results

All studies used different interventions or comparison treatments with a wide variety of outcome measures. Pooling of the results was not possible due to the heterogeneity of the studies. We have described the different comparisons and performed a best evidence

Table 3. Clinical relevance table
Cochrane review "Osteotomy for treating knee osteoarthritis"

Study	Treatment groups	Outcome (scale)	No. of patients	Baseline mean	Mean (end-of-study)	Absolute benefit	Relative difference
Adili	HTO (Ilizarov) HTO (Coventry)	WOMAC pain	15 15	12.3 12.8	5.5 (25.4 months) 9.1 (30.9 months)	-3.1 (I)	24.2% (I)
Adili	HTO (Ilizarov) HTO (Coventry)	WOMAC stiffness	15 15	4.5 4.3	2.6 (25.4 months) 3.8 (30.9 months)	-1.4 (I)	32.6% (I)
Adili	HTO (Ilizarov) HTO (Coventry)	WOMAC function	15 15	39.0 36.3	19.0 (25.4 months) 28.4 (30.9 months)	-12.1 (I)	33.3% (I)
Akizuki	HTO with abrasion HTO	JOA-score (0-100)	45 34	52.4 49.8	86.0 (4.8 years) 86.5 (3.5 years)	-3.1 (W)	6.2% (W)
Magyar (1)	HCO HTO	ROM (degrees)	24 22	130 125	125 (2 years) 120 (2 years)	0	0%
Magyar (1)	HCO HTO	HSS knee score (0-100)	24 22	69 67	94 (2 years) 89 (2 years)	3(I)	4.5% (I)
Magyar (1)	HCO HTO	Lysholm score (0-100)	24 22	55 56	91 (2 years) 86 (2 years)	6 (I)	10.7% (I)
Magyar (1)	HCO HTO	Wallgren-Tegner score (0-15)	24 22	7 8	10 (2 years) 9 (2 years)	2 (I)	25% (I)
Magyar (1)	HCO HTO	NHP pain (0-100)	24 22	63 43	8 (2 years) 8 (2 years)	-20 (I)	47% (I)
Myrnerts	HTO overcorected HTO	pain on weight bearing (%)	37 40	100 100	31 (1 year) 45 (1 year)	-14	14%
Nakamura	HCO HTO	lenght of the patellar tendon (ratio)	23 23	0.94 0.92	0.93 (1 year) 0.80 (1 year)	0.11 (I)	11.9% (I)

Nakamura	HCO HTO	Inclination angle tibial plateau (degrees)	23 23	10.9 10.6	10.1 (1 year) 4.7 (1 year)	5.4 (I)	50.9% (I)
Nakamura	HCO HTO	Tibial condylar offset (ratio)	23 23	0.50 0.50	0.56 (1 year) 0.61 (1 year)	-0.05 (I)	10% (I)
Odenbring	HTO with brace HTO with plaster	ROM (degrees)	14 17	128 135	135 (1 year) 125 (1 year)	17 (I)	12.6% (I)
Odenbring	HTO with brace HTO with plaster	Pain free walking (Lysholm; score 1-7)	14 17	5.9 6.1	2.1 (1 year) 1.9 (1 year)	0.4 (W)	6.6% (W)
Odenbring	HTO with brace HTO with plaster	Pain at rest (Lysholm; score 1-3)	14 17	1.7 2.1	1.1 (1 year) 1.1 (1 year)	0.4 (W)	19% (W)
Stukenborg	HTO UKA	Knee score (0-100)	32 28	32 32	76 (7.5 years) 74 (7.5 years)	2 (I)	6.3% (I)
Stukenborg	HTO UKA	Function score (0-100)	32 28	46 49	71 (7.5 years) 59 (7.5 years)	15 (I)	30.6% (I)
Weidenhielm	HTO UKA	ROM (degrees)	23 36	116 118	121 (1 year) 119 (1 year)	4 (I)	3.4% (I)
Weidenhielm	HTO UKA	BOA knee score (0-39)	23 36	30 30	38 (1 year) 37 (1 year)	1 (I)	3.3% (I)
Weidenhielm	HTO UKA	Pain during walking (Borg; 0-10)	23 36	3.5 3.3	1.0 (1 year) 0.5 (1 year)	0.3 (W)	9.1% (W)

synthesis and an overall grading of evidence based on these studies. The results are also presented in the Clinical Relevance Table 3.

A. Osteotomy versus conservative treatment:
No studies found.

B1. Different techniques of a high tibial osteotomy:
Four trials compared two techniques of high tibial osteotomy *(Adili; Magyar (1); Magyar (2) ; Nakamura)* of which two were high quality studies *(Magyar (1); Magyar (2))*.

In *Adili* the Ilizarov group showed significantly less (WOMAC) pain with a relative percentage difference (RPD) of 24.2% improvement. Ilizarov also showed better WOMAC stiffness (RPD=32.6%) and function (RPD=33.3%) as well as more patient satisfaction (see Clinical relevance Table 3). The Ilizarov group had significantly more complications; especially pin-track infections.

In *Magyar (1)*, there was a significant improvement in HSS, Lysholm, Wallgren-Tegner, NHP scores in both groups, but no significant difference between both groups. The HCO group had significantly more complications, especially pin-track infections. The hospital stay of the HCO group was significantly shorter. After one year follow-up, the HTO-group showed significantly more loss of correction. The HCO-group had significantly more patients with optimal postoperative correction (HKA = 182 to 186 degrees) after one year follow-up; the two year follow-up results showed the same tendency, but the difference was not significant.

In *Magyar (2)* the HKA-angle was not significantly different one year postoperatively. The HCO group showed significantly less translation, which means a more stable fixation of the osteotomy.

In *Nakamura*, factors which may cause difficulties in conversion to total knee arthroplasty were measured and scored as side effects. The HCO group had significantly less change in patella length, less change in inclination angle of the tibial plateau and less increase of the tibial offset. The FTA was not significantly different.

B2. High tibial osteotomy versus the unicompartmental joint replacement:
Two studies were found, both of high quality *(Stukenborg; Weidenhielm)*. The HTO in *Stukenborg* showed better knee and function scores, but the differences were not significant. The range of motion (ROM) was 103 degrees (HTO) versus 117 degrees (UKA). The HTO group had more complications (nine versus two). The Kaplan-Meier survivorship after 5 and 10 years was not significantly different.

In *Weidenhielm*, the BOA-score, pain during walking and knee flexion, improved after surgery in both groups (HTO and UKA), but there was no significant difference

between the groups. Some gait analysis tests showed greater improvement after unicompartmental joint replacement, but there were no significant differences between the two groups.

B3. Differences in per-operative conditions:
Three studies were found, all of low quality *(Akizuki; Myrnerts; Motycka)*.

Akizuki found there was no difference of the mean JOA knee score at final follow-up between the osteotomy with abrasion group and the osteotomy alone group. The one year post-operative FTA angle did not differ.

After 12 months in the *Myrnerts* RCT, there was no significant difference in pain reduction between the normal and an overcorrection group. However, the overcorrection group was significantly more satisfied with the results of the operation and reported significantly better walking ability. The ROM and complications were described for the whole group with percentages and no numbers. This prevented any form of statistical analysis.

Motycka found that the average incidence of thrombosis was 10.8% and occurred five times with the use of a tourniquet and one time without the use of a tourniquet, but the difference was not significant.

C. One technique of high tibial osteotomy with different types of post-operative treatment:
Two high quality studies were found *(Mammi; Odenbring*).

In *Mammi*, the intervention group with a long plaster cast with an electromagnetic field stimulation had significantly positive effect on the rate of union of the HTOs compared to the control group with a dummy stimulator.

After one year follow-up in the *Odenbring* trial, there was significantly better range of motion in the hinged cast-brace group compared to the cylinder plaster cast group. There were no significant differences in the other clinical results (degree of pain, Lysholm knee score) nor changes in knee alignment or progression of osteoarthritis.

Discussion

The purpose of this systematic review analysis was to assess the effectiveness and safety of an osteotomy for osteoarthritis of the knee. All the studies concerned valgus HTO for medial compartment osteoarthritis of the knee. Only eleven studies were included in this review and no study compared an osteotomy with conservative treatment and no RCTs or CCTs examined the effect of a varus osteotomy for lateral compartment osteoarthritis of the knee.

Unfortunately the methodological quality of the included studies was generally low: the randomisation procedure was frequently not described or insufficient. In the majority of the trials, the inclusion and exclusion criteria were briefly presented. The number of the patients in most of the studies was too low to show significant differences. In most studies the blinding procedures were insufficient, although we realize that blinding is not always possible. Except for the study of *Stukenborg* the follow-up of the trials was relatively short. Some studies did not provide full data on outcome measures, measures of variability (such as the standard deviation) were especially lacking *(Magyar (2); Nakamura; Myrnerts)*, which makes quantitative analysis impossible. Because of the heterogeneity of the studies pooling of the results was not possible.

Although in most studies patients improved in knee function and had pain reduction after HTO, there were no studies which compared these results with conservative treatment. There was only one study which showed a significant difference (WOMAC pain and fuction) between different techniques *(Adili)*. The safety of an osteotomy is in question: the HTO technique with the external fixator *(Adili; Magyar (1))* had a significantly higher infection rate (pin-track), but showed less side effects for revision to total knee arthroplasty in the future *(Nakamura)*. Early mobilisation of the knee joint postoperative seems of imminent importance: the postoperative treatment with a cylinder plaster showed significantly less reduction of range of motion *(Odenbring)*.

Conclusions for each group

A. Osteotomy versus conservative treatment

No studies were found; there is no evidence of whether an HTO is more effective than conservative treatment.

B1. Different techniques of a high tibial osteotomy

According to the 4 studies, 2 of which are high quality, we conclude:

- There is limited evidence for significantly less pain and a better function on WOMAC scale after a HTO with Ilizarov compared with a closed wedge HTO. (Silver)
- There is limited evidence for no difference of FTA after HCO or dome osteotomy HTO. (Silver)
- There is limited evidence for more optimal 1-year postoperative correction after HCO compared with closed wedge HTO. (Silver)
- There is limited evidence for less side-effects influencing total knee arthroplasty in the future with HCO technique compared with the DMO. (Silver)

- There is moderate evidence for more short term complications after HTO with an external fixator compared with a closed wedge HTO. (Silver)

B2. High tibial osteotomy versus the unicompartmental joint replacement

According to these two high quality studies we conclude:

- There is moderate evidence for no significant difference in pain and function after HTO compared to UKA. (Silver)
- There is limited evidence that HTO causes more complications compared with UKA. (Silver)
- There is limited of evidence for no difference in gait analysis between UKA and closed wedge HTO. (Silver)

B3. Differences in per-operative conditions:

According to these three low quality studies we conclude:

- There is limited evidence for no differences of JOA knee score and FTA after HTO without and HTO with abrasion arthroplasty. (Silver)
- There is limited evidence that there is no significant difference in incidence of thrombosis during HTO with or without a tourniquet. (Silver)
- There is limited evidence that HTO with 5 degrees overcorrection has better walking ability and more patient satisfaction compared with HTO with normal correction. (Silver)

C. One technique of high tibial osteotomy with different types of post-operative treatment

According to these two high quality study we conclude:

- There is limited evidence that electromagnetic field stimulation stimulates HTO healing. (Silver)
- There is limited evidence that a hinged cast-brace after HTO results in a better range of motion compared with a post-operative plaster cast. (Silver)

Therefore, based on 11 studies, of which 6 were high quality, we conclude that on the results of this review there is no evidence of whether an osteotomy is more effective than conservative treatment and the results so far do not justify a conclusion about effectiveness of specific surgical techniques.

Authors' conclusions

Implications for practice

Based on the results of this review we conclude that valgus HTO improves knee function

and reduces pain, but there are no significant differences between different techniques. There is limited evidence for the effectiveness of an osteotomy for treating medial compartment osteoarthritis when compared with unicompartmental joint replacement. It is unclear which technique of osteotomy we have to use, quite a number of complications were reported, and there is no evidence of whether an osteotomy is more effective than conservative therapy.

Implications for research

1. The methodological quality of future studies will be improved by a concealed randomisation.
2. New research should use outcome measures relevant to the patients, and adequate and responsive to the treatment under study. One general knee score makes pooling of the results possible. Follow-up should be of sufficient length to assess long-term effects.
3. New research should provide full data on outcome measures, including the mean and standard deviation or 95% confidence intervals.
4. Therefore, large, high quality research is needed, focusing on appropriate allocation concealment, blinding and an adequate data presentation and analysis. The design and reporting of future trials should conform to the CONSORT-statement.[35]
5. Future research should examine the effect of treatments not only in pragmatic trials comparing various interventions with each other, but also in more explanatory trials comparing the intervention with conservative or no treatment control group.
6. Future research should focus on treating unicompartmental knee osteoarthritis because there are a broad variety of treatments available and most treatments are costly, and data on effectiveness are not available.

We conclude that performing randomised studies with high methodological quality concerning the effectiveness of osteotomy compared to other frequently performed treatments is both possible and necessary to provide strong evidence on the effectiveness of treatments in knee osteoarthritis.

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Chapter 8

High Tibial Osteotomy for Osteoarthritis of the Knee a Randomised Trial

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J Bone Joint Surg Br. in revision

Abstract

Objective Patients with osteoarthritis of the medial compartment of the knee can be treated with a valgus high tibial osteotomy (HTO).
Design This prospective randomised study compared two different techniques of HTO, a medial opening wedge and a lateral closing wedge osteotomy, regarding achievement and maintenance of adequate operative correction. Setting: Orthopedic department of a university medical center. Primary outcome measure at 1-year follow-up was achievement of an overcorrection of 4 degrees valgus. Secondary outcome measures were pain severity (VAS; range 0-10), the knee function score (HSS; range 0-100), and walking distance (in kilometers).
Results During the inclusion period (Jan. 2001-Apr. 2004) 92 patients were randomised. At 1-year follow-up the postoperative Hip-Knee-Ankle (HKA) angle was 1.3 degrees valgus (SD 4.7) after the opening wedge HTO and 3.4 degrees valgus (SD 3.6) after the closing wedge HTO; the adjusted mean difference of 2.12 (95% CI 0.38; 3.86) was significant (p=0.02). The deviation from 4 degrees valgus alignment was 4.0 degrees (SD 3.6) in the opening wedge HTO group and 2.7 degrees (SD 2.4) in the closing wedge group; the adjusted mean difference of 1.67 degrees (95% CI 0.42; 2.92) was also significant (p=0.01).
The VAS score was decreased in both groups: 2.7 points after the opening wedge HTO and 2.3 after the closing wedge HTO; this difference was not significant (p=0.93).
The HSS knee score and the walking distance were increased in both groups: 9.4 points and 2.3 km after the opening wedge HTO and 8.5 points and 1.5 km after the closing wedge HTO; these differences were also not significant (p=0.78 and p=0.65, respectively).
Because of pain, the osteosynthesis material was removed in 27 (60%) patients in the opening wedge HTO group and in 11 (23%) patients in the closing wedge group; this difference was significant (p< 0.001) (OR= 0.15; CI 0.06; 0.41).
Conclusion Based on this study we conclude that the closing wedge HTO achieves a more accurate correction and that both techniques (opening and closing wedge HTO) reduce pain and improve function.

Introduction

Osteoarthritis of the entire knee is distinguished from osteoarthritis of one compartment, which is generally caused by a mechanical problem.[1,2] Malalignment increases the risk of progression of knee osteoarthritis and predicts deterioration in physical function.[3]

Young patients with unicompartmental osteoarthritis not reacting to non-surgical therapy can be treated with a correction osteotomy. The goal of the correction osteotomy is to transfer the mechanical axis and load bearing from the pathologic to the relatively normal compartment. Patients with osteoarthritis of the medial compartment can be treated with a valgus high tibial osteotomy (HTO).

Correction osteotomy in relatively young patients with osteoarthritis of one compartment and a varus alignment has good results, but different techniques are used to achieve this.[4-8] However, very few randomised controlled trials (RCT) have investigated which of these techniques are most successful.[9]

A successful outcome of the osteotomy relies on proper patient selection, and achievement and maintenance of adequate operative correction.[6,10-12]

The goal of this prospective randomised study was to compare two different techniques of HTO, a medial opening wedge and a lateral closing wedge osteotomy, regarding achievement and maintenance of adequate operative correction.

Material and Methods

Design

A randomised controlled trial.

Patients

This study was conducted at the Orthopedic Department of the Erasmus University Medical Center after approval of its Ethics Committee.

Criteria for inclusion (from Jan. 2001 to April 2004) were radiological medial compartment osteoarthritis with medial joint pain and a varus malalignment. The grade of radiological osteoarthritis was scored according to Ahlbäck and measured on standard short posteroanterior radiographs in standing position.[13] The degree of malalignment and mechanical axis was measured on a whole leg radiograph (WLR) in standing position. We used lateral fluoroscopic control by superimposing the dorsal aspect of the femoral condyles to ensure a 100% anteroposterior WLR.[14]

Criteria for exclusion were symptomatic osteoarthritis of the lateral compartment, rheumatoid arthritis, range of motion less than 100 degrees, grade 3 collateral laxity

(Insall [15]), history of fracture or previous open operation of the lower extremity, flexion contracture more than 10 degrees, and a HTO on the opposite knee.

Procedures

After obtaining informed consent and baseline measurements, patients were randomised according to a computer-generated procedure in blocks of 16; sealed envelopes contained the group assignment. These sealed envelopes were opened by an independent assistant after enrolment of the patients by the orthopedic surgeon.

Treatment groups

Randomisation involved the following procedures:

1. closing wedge HTO and a cylinder plaster cast for six weeks postoperatively (Figure 1).
2. opening wedge HTO (Figure 2).

In the opening wedge group there was a second randomisation (in blocks of 8) for treatment after the osteotomy; namely, with or without a plaster to determine whether a plaster influenced the postoperative results.

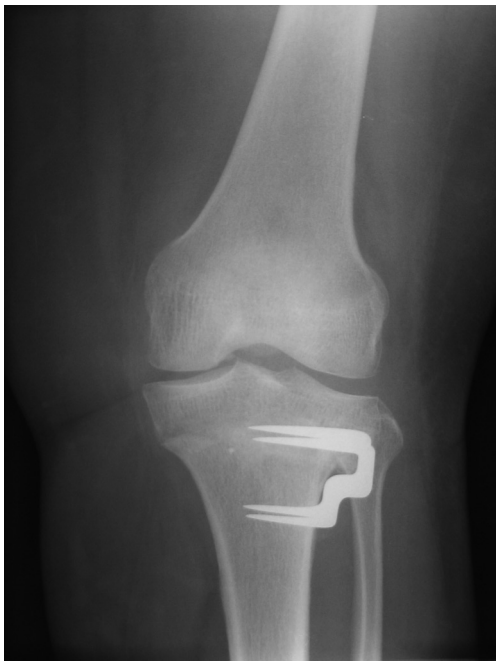

Figure 1. Closing wedge high tibial osteotomy (an example of a closing wedge high tibial osteotomy; the osteotomy is fixated with two staples)

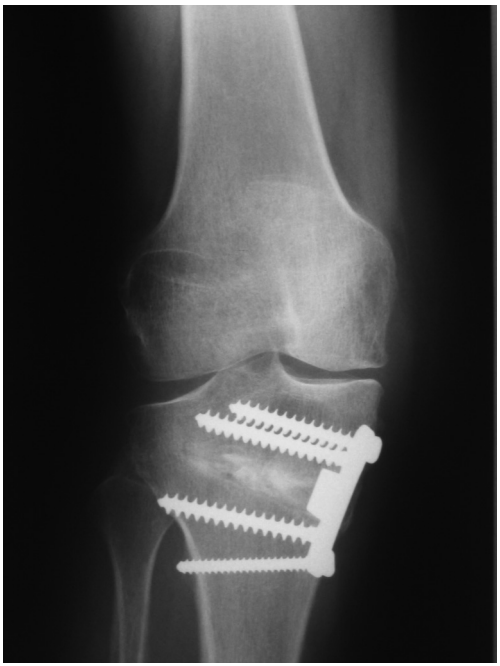

Figure 2. Opening wedge high tibial osteotomy (an example of an opening high tibial osteotomy; the osteotomy is fixated with a Puddu plate and the open wedge is filled with bone from the ipsilateral iliac crest)

For the closing wedge HTO we used the instrumentation of Allopro (Zimmer; Winterthur, Switzerland). The common peroneal nerve was exposed and snared with a nerve band. Subsequently the anterior part of the proximal fibular head (anterior part of the proximal tibia-fibula syndesmosis) was resected. The osteotomy was fixated with two staples. At the end of the procedure a fasciotomy of the anterior compartment was performed to prevent a compartment syndrome.

The opening wedge HTO was created with the Puddu HTO (Arthrex; Naples, Florida, USA) instrumentation; the osteotomy was fixated with the Puddu plate. If the open wedge was more than 7.5 millimeters, the open wedge was filled with bone from the ipsilateral iliac crest. In both techniques the goal was to achieve a correction of 4 degrees in excess of physiological valgus.

Baseline evaluation

Age, gender, severity of medial and lateral osteoarthritis (Ahlbäck score, 0-3), varus alignment / Hip-Knee-Ankle angle (HKA, degrees), pain severity measured with a visual analogue scale (VAS, 0-10), knee function using the hospital for special surgery score (HSS score, 0-100), and walking distance (km) were scored at baseline.

Outcome assessments at 1 year

Primary outcome measure was achievement of an overcorrection of 4 degrees valgus. The continuous differences in achievement of a valgus overcorrection and the deviation from 4 degrees valgus were determined. In addition a dichotomous outcome was as an achievement of a valgus alignment within zero and six degrees.

Secondary outcome measures were pain severity (VAS; range 0-10), walking distance (in kilometers), and the knee function score (HSS; range 0-100). The HSS is divided into 6 categories (pain, function, range of motion, muscle strength, flexion deformity, and instability) and consists of a questionnaire and a physical examination. In the present study physical examination for the HSS knee function score was determined by one un-blinded assessor.

Furthermore, adverse events like complications, re-operations including hardware removal, and morbidity of the iliac crest were scored.

Sample size

The sample size was calculated based on an expected increase of the success rate from 60% in the closed wedge HTO to 85% in the open wedge HTO. A successful operative result was defined as achievement of circa 4 degrees of valgus alignment. To detect such a difference with one-sided testing (α= 0.05 and a power of 80%) we needed to include 46 patients in each study group.

Statistical Methods

A multivariable linear regression method was used to analyze the impact of closing versus opening wedge HTO on postoperative alignment, VAS and HSS knee scores, walking distance, and patients with adverse events at 1-year follow-up. A multivariable logistic regression method was used for the dichotomous outcome measures.

All data were analyzed according to an intention-to-treat principle, implying that all patients who were randomised were included in the analyses, and that they were analyzed according to the group to which they were allocated.

Gender, age and baseline values for HKA angle, VAS knee, HSS knee, walking distance, medial osteoarthritis more than joint space loss alone, and concurrent OA of the lateral compartment were considered as possible confounders and were included in the regression models only if they changed the relationship between dependent variable and type of HTO by at least 10%. The same was done for the relationship between the above-mentioned dependent variables and type of postoperative treatment (plaster versus no plaster) in the group with the opening wedge HTO.

For patients who were lost to follow-up or were re-operated during follow-up, the last available measurement or the last measurement was forwarded.

The SPSS program was used for the statistical analyses and a p-value of 0.05 was considered statistically significant.

Results

During the inclusion period 92 patients were randomised. One patient (closing wedge HTO group) was lost to follow-up. In one patient (opening wedge HTO group) we had a 1-year postoperative VAS and HSS knee score, a standard short posteroanterior radiograph in standing position available, but not a WLR; because of an aorta dissection this patient was urgently admitted to the hospital, thus precluding a WLR.

Table 1 presents baseline characteristics of the total study population: the mean age was 50.2 years (SD 8.5), there were 33 women and 59 men. The mean HKA angle was 6.3 varus (SD 2.8) degrees and differed significantly ($p<0.05$) between the two groups:

Table 1. Baseline characteristics for the total study population and separately for both intervention groups

	Total group	Opening wedge HTO	Closing wedge HTO
	N= 92	N= 45	N= 47
Female gender, n (%)	33 (36)	13 (29)	20 (43)
Age [years], mean (SD)	50.2 (8.5)	49.6 (9.4)	50.8 (7.7)
VAS knee pain [0-10], mean (SD)	6.1 (1.8)	6.3 (1.6)	5.9 (2.0)
HSS knee score [0-100], mean (SD)	71.2 (9.8)	71.5 (9.9)	70.9 (9.8)
Walking distance [km], mean (SD)	3.0 (2.8)	3.1 (2.9)	2.9 (2.8)
HKA angle# [degrees], mean (SD)	6.3 (2.8)	5.7 (2.7)*	6.8 (2.8)
Medial OA more than joint space loss alone, n (%)	12 (13)	7 (16)	5 (11)
Concurrent lateral compartment OA, n (%)	8 (9)	3 (7)	5 (11)
Concurrent patellofemoral OA, n (%)	22 (24)	8 (18)	14 (30)

 # positive angle represents varus alignment, negative angle represents valgus alignment
** P < 0.05 for difference two groups*

the opening wedge group 5.7 varus (SD 2.7) and the closing wedge group 6.8 varus (SD 2.8).

Preoperatively the mean VAS score was 6.1 (SD 1.8) and mean HSS knee score was 71.2 (SD 9.8). A total of 47 patients had a closing wedge HTO and 45 patients had an opening wedge HTO; 22 patients of the opening wedge HTO were postoperatively treated with a plaster and 23 with no plaster.

Primary outcome measures (Table 2)

The power calculation was based on one-sided testing, because we expected a higher success rate in the opening wedge group. However, because raw data showed better results for the closing wedge HTO, it was decided to test two-sided with 0.05 significance level.

At 1-year follow-up the postoperative HKA was 1.3 degrees valgus (SD 4.7) in the opening wedge HTO group and 3.4 degrees valgus (SD 3.6) in the closing wedge HTO group; the adjusted mean difference of 2.12 (95% CI 0.38; 3.86) was significant (p=0.02).

The deviation from 4 degrees valgus alignment was 4.0 degrees (SD 3.6) in the opening wedge HTO group and 2.7 degrees (SD 2.4) in the closing wedge group; the adjusted mean difference of 1.67 degrees (95% CI 0.42; 2.92) was also significant (p=0.01).

Table 2. Continuous outcomes for opening wedge HTO versus closing wedge HTO after one-year follow-up

	Opening wedge HTO Mean (SD)	Closing wedge HTO Mean (SD)	Mean difference*	95% CI mean difference*	p-value
Primary outcome HKA angle [degrees]	-1.3 (4.7)	-3.4 (3.6)	-2.12	0.38;3.86	0.019
Deviation from 4 degrees valgus	4.0 (3.6)	2.7 (2.4)	-1.67	0.42;2.92	0.011
Secondary outcomes VAS knee pain [0-10]	3.6 (2.9)	3.6 (2.2)	0.05	-0.97;1.07	0.93
HSS knee score [0-100]	80.9 (13.5)	79.4 (12.0)	-0.68	-5.88;4.52	0.78
Walking distance [km]	5.3 (4.4)	4.6 (3.6)	-0.33	-1.74;1.1	0.65

** adjusted for confounders (possible confounders tested: gender, age, and baseline values for HKA angle, VAS knee, HSS knee, walking distance, medial OA more than joint space loss alone, concurrent OA lateral compartment)*

The dichotomous outcome measure (achievement of a valgus alignment within zero and six degrees) was achieved in 25 patients (57%) in the opening wedge HTO group and in 37 patients (79%) in the closing wedge HTO group resulting in an odds ratio (OR) for successful overcorrection of 3.44 (95% CI 1.29; 9.16) in the closing HTO group compared to the opening wedge group; this difference was significant (p=0.01).

Secondary outcome measures (Table 2)

The VAS score was decreased in both groups: 2.7 points after the opening wedge HTO and 2.3 after the closing wedge HTO; this difference was not significant (p=0.93).

The HSS knee score and the walking distance were increased in both groups: 9.4 points and 2.3 km after the opening wedge HTO and 8.5 points and 1.5 after the closing wedge HTO; these differences were also not significant (p=0.78, p=0.65 respectively).

Plaster versus non plaster in the open wedge HTO group

The baseline characteristics in this subgroup were almost the same for the plaster group and the non-plaster group, without any significant differences (data not shown).

In the opening wedge HTO group there were no significant differences in primary outcome or the secondary outcome measures between the plaster and the non-plaster subgroup (Table 3).

Table 3. Continuous outcomes for no plaster versus plaster in the opening wedge HTO after one-year follow-up

	Opening wedge HTO, no plaster Mean (SD)	Opening wedge HTO, plaster Mean (SD)	Mean difference*	95% CI mean difference*	p-value
Primary outcome					
HKA angle [degrees]	-1.6 (4.0)	-1.0 (5.3)	0.7	-2.1;3.5	0.64
Secondary outcomes					
VAS knee pain [0-10]	3.1 (3.0)	4.0 (2.8)	0.6	-1;2.2	0.46
HSS knee score [0-100]	84.1 (12.7)	78.0 (13.9)	-3.4	-11.4;4.7	0.41
Walking distance [km]	6.8 (4.9)	3.8 (3.3)	-2.3	-4.6;0.1	0.07

** adjusted for confounders (possible confounders tested: gender, age, and baseline values for HKA angle, VAS knee, HSS knee, walking distance, medial OA more than joint space loss alone, concurrent OA lateral compartment)*

Adverse events during follow-up

One patient in the closing wedge HTO group was re-operated because of overcorrection (varus HTO), another patient in the closing wedge HTO group was re-operated because of progression of symptoms (total knee arthroplasty), and three patients in the opening wedge HTO group were re-operated because of recurrent varus alignment (re-valgus HTO).

Because of pain the osteosynthesis material was removed in 27 (60%) patients in the opening wedge HTO group and in 11 (23%) patients in the closing wedge group; this difference was significant (p< 0.001) (OR= 0.15; CI 0.06; 0.41).

In the opening wedge group 8 patients had persisting iliac crest pain: VAS 0.8 (SD=2.1); one of these patient was re-operated because of a symptomatic exostosis at the donor site. Another patient had a lesion of the lateral femoral cutaneous nerve.

The remaining adverse events are described in Table 4.

Table 4. Adverse events after opening and closing wedge HTO

Adverse events, n	Open wedge HTO	Closed wedge HTO
	N=45	N=47
Wound infection	1	0
Non-union	2	0
Peroneus neuropathy	0	1
Pain proximal tibia- fibula joint	0	1
Iliac crest morbidity	9	0
Fracture of the tibial plateau	2	1
Re-surgery (re-valgisation)	3	0
Re-surgery (re-varisation)	0	1
UKP/TKP surgery	0	1
Removal of osteosynthesis material	27	11

Discussion

In the present study the closing wedge HTO achieves significantly more accurate correction with less deviation after 1-year follow-up. An important reason for inadequate correction after one-year follow-up is the Puddu plate, which is not strong enough to sustain the per-operative correction.[16] A new design, in which the screw head locks into a more rigid plate, might provide more stability and might yield better results in the opening wedge HTO. Moreover, Lobenhoffer et al. used a medial plate fixator in 92 opening wedge HTOs and reported no correction loss in these patients.[7]

Although the VAS and HSS knee scores were improved in both groups, they differed not between the groups. The 1-year follow-up is perhaps too short to show the benefits of the slight overcorrection or the 4 degrees valgus, or the theorem of the optimal overcorrection or circa 4 degrees valgus after HTO is not correct.[17] At least for the most important outcome, whether one type of osteotomy delays the need for total knee replacement more than the other, a much longer follow-up period is required.

A plaster after opening wedge HTO seems not to prevent loss of correction, because our subgroup analysis showed no difference at the one-year follow-up in HKA angles between the plaster and non-plaster group. However, the sample size in our study was calculated to detect difference between the opening wedge and the closing wedge HTO, and not between the plaster and no plaster groups. Therefore this study is not powerful enough to make a strong statement about plaster or no plaster.

An advantage of the opening wedge is the medial approach, which is easier than the lateral approach used in the closing HTO. On the other hand, a plate on the medial side of the proximal tibia causes significantly more pain and early removal.

In the closing HTO technique the peroneal nerve is exposed and the anterior part of the proximal fibular head is resected. Using this technique, only one of our patients had pain at the proximal tibia-fibular joint and in one case there was transient peroneal neuropathy. A fasciotomy of the anterior compartment was used in order to prevent a compartment syndrome in the closing wedge HTO and in this trial no compartment syndrome occurred.

For the open wedge more than 7.5 millimeters we used bone from the ipsilateral iliac crest. Two patients in the opening wedge HTO group had a non-union with autologic bone grafting and the number of patients with morbidity of the iliac crest was relatively high (18%). There are alternatives with less-side effects, but up to now we have chosen to use for the gold standard for bone grafting so far. Future studies need to compare bone substitutes with the autologic bone grafts in the opening wedge HTO; moreover this will reduce the duration of the procedure.[18]

Study limitations

Again, the follow-up period (1 year) was relatively short for a chronic disease, so that important longer-term effects (e.g. delayed knee arthroplasty) could not be explored.

Another limitation might be that we did not make a WLR the first day postoperatively because the patient could not stand on his operated leg; therefore we are not 100% sure if there was insufficient correction or correction loss during the 1-year follow-up. Although we performed the opening wedge osteotomy under fluoroscopic control (and controlled the correction during the surgical procedure).

Computer- assisted surgery may have provided the surgeon with more information during surgery thus resulting in a more accurate alignment post-HTO.[19]

Roentgen stereophotogrammetric analysis (RSA) studies will provide more information on the postoperative course of the correction.[20,21]

Finally, the outcome assessor was not blinded for physical examination of the HSS score and postoperative HKA angle. Because the prior hypothesis was a better outcome after the opening wedge HTO, bias due to a non-blinded assessor would be in favor of the opening wedge HTO resulting in a better HSS score in this group than in reality and possibly the reason that we did not detect any difference between the groups for the HSS score. We have however no reason to think this bias occurred because the patients' assessed outcomes like pain and walking distance did neither show any difference between the groups.

Clinical implications and future research

In this study we compared two different HTO techniques, which is important to better choose the most successful technique. However, the degree of delay and the operative results of total knee arthroplasty after HTO techniques in general need further study, because the literature is inconsistent on this issue.[22-24] Besides comparing different HTO techniques prospectively, we need to compare the HTO with other operative treatments for medial compartment osteoarthritis such as the propagated hemi-knee arthroplasty.[25] RCTs comparing HTO with unicompartmental knee arthroplasty are limited: Stukenborg et al. reported non-significant differences in knee and function scores and difference in survival after 5 and 10 years was also non significant.[26]

Non-surgical treatment with braces and ortheses may also be effective in medial compartment knee osteoarthritis; however the comparison of the operative and conservative treatment is still lacking.[27] A positive aspect of conservative treatment is that there are no adverse effects of HTO that will influence the results of a total knee arthroplasty.[28-30] However, in retrospective studies HTO has been proven effective to delay a total knee arthroplasty for 5-10 years and the long-term effects of conservative treatment in medial compartment osteoarthritis are still unknown.[10,11]

Based on this study we conclude that the closing wedge HTO achieves a more accurate correction and that both techniques (opening and closing wedge HTO) reduce pain and improve function.

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Chapter 9

Patellar Height and Inclination of Tibial Plateau after High Tibial Osteotomy

The opening versus the closing wedge technique

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J Bone Joint Surg Br. 2005;87:1227-31

Abstract

Our aim was to compare the degree of patellar descent and alteration in inclination angle of the tibial plateau in lateral closing wedge and medial opening wedge high tibial osteotomy (HTO) in 51 consecutive patients with medial compartment osteoarthritis and varus malalignment. Patellar height was measured by the Insall-Salvati (IS) and the Blackburne-Peel (BP) ratios. The tibial inclination was determined with the Moore-Harvey (MH) method. Multivariate linear regression analysis was used to determine the influence of type of HTO (closing versus opening wedge) on postoperative patellar height or tibial inclination. The intra- and interobserver variability of these methods was determined preoperatively and at follow up at 1 year.

After an opening wedge HTO the patellar height was significantly more decreased (mean postoperative difference: IS= 0.15; 95% confidence interval (CI) 0.06 to 0.23; BP=0.11; 95% CI: 0.05 to 0.18) compared with a closing wedge HTO.

The angle of tibial inclination differed significantly (mean postoperative difference MH= -6.40 degrees; 95% CI:-8.74 to-4.02) between the two HTO techniques, increasing after opening wedge HTO and decreasing after closing wedge HTO.

There was no clinical- relevant difference in the intra- and interobserver variability of measurements of patellar height either before or after HTO.

Introduction

High tibial osteotomy (HTO) for the treatment of medial compartment osteoarthritis of the knee delays the need for an arthroplasty.[1-3] However, total knee replacement after HTO presents more technical problems and complications because of scars, valgus alignment, patella baja and the change in tibial inclination.[4-6]

Our aim in this prospective, randomised study was to compare the severity of patellar descent and alteration in the inclination angle of the tibial plateau in two different techniques of HTO: a medial opening wedge and a lateral closing wedge osteotomy.

In addition, in the opening wedge group we compared the use of plaster and non plaster. We also determined the intra- and interobserver variability of two methods of measurement of patellar height; the Insall-Salvati (IS) and the Blackburne-Peel (BP) ratios, and of one method of tibial inclination measurement: the Moore-Harvey (MH) method.[7-9]

Material and Methods

Approval of the Ethics Committee of the university medical centre was obtained for the trial and the patients gave their informed consent.

The criteria for inclusion included osteoarthritis of the medial compartment with medial pain and varus malalignment of the mechanical axis measured on long- standing radiographs. The criteria for exclusion were symptomatic osteoarthritis of the lateral compartment, rheumatoid arthritis, a range of motion less than 100 degrees, lateral collateral ligament laxity of grade 3, a history of fracture or previous open operation of the lower extremity, and flexion contracture.

Between January 2001 and January 2003, 51 consecutive patients were randomised according to a computer-generated procedure using sealed envelopes.

Randomisation involved the following procedures: 1) closing wedge HTO and a cylinder plaster cast for six weeks postoperatively; 2) opening wedge HTO and no plaster postoperatively and 3) opening wedge HTO and a cylinder plaster cast for six weeks postoperatively.

The primary randomisation was between the closing and opening wedge techniques, with the intention to create two groups of equal size. In the opening wedge group there was a second randomisation for treatment after the osteotomy, namely with or without a plaster cast to determine if a plaster influenced the post-operative results.

The goal was to achieve a correction of 4 degrees in excess of physiological valgus.

For the closing wedge HTO we used the instrumentation of Allopro (Centerpulse, Winterthur/ Switzerland). The anterior part of the proximal fibula head (anterior part of the proximal tibiofibular syndesmosis) was resected and the tibial osteotomy was secured with two staples.

The open wedge HTO was created by the Puddu HTO (Arthrex, Naples, USA) instrumentation. The osteotomy was fixated with the Puddu plate. If the opening wedge was more than 7.5 millimetres the void was filled with bone harvested from the ipsilateral iliac crest.

The patients were mobilised on the first post-operative day and partial weight- bearing was allowed in all three groups. After 6 weeks any plaster used was removed.

Standardised radiography was performed pre-operatively, and on the first day and 12 months after the operation. Patients who were re-operated for various reasons during the 1-year follow-up also received standardised radiography before re-operation. In these patients the measurements just before the re-operation were considered as measurements at the follow-up at 1-year.

Measurements

Radiography of the knee included a standing posteroanterior view and a true lateral radiograph in at least 30 degrees of flexion.

From all the lateral radiographs the length of the patella tendon was measured according to IS and BP ratios (Figure 1 and 2) and the inclination angle of the tibial plateau according to MH method (Figure 3).

Two observers (RB and AK) measured the patellar height and the inclination angle of the tibial plateau pre-operatively and at follow-up at 1-year.

Statistical analysis

A multivariate linear regression method was used to analyse the impact of closing versus opening wedge HTO on changes in patellar height or tibial inclination between measurements made pre-operatively and at follow-up at 1-year.

Two multivariable regression analyses were performed. In one the dependent variable was the post-operative patellar height and the independent variables the wedge HTO (opening vs closing) and pre-operative patellar height. In the second, the dependent variable was the post-operative tibial inclination and the independent variables the wedge HTO (opening vs closing) and pre-operative tibial inclination.

Age, gender, pre-operative hip-knee-ankle angle and the pre-operative degree of osteoarthritis were considered as possible confounders and were included in the model only if they changed the relationship between dependent variable and type of HTO by at least 10%. The same was done for the relationship between the above-mentioned

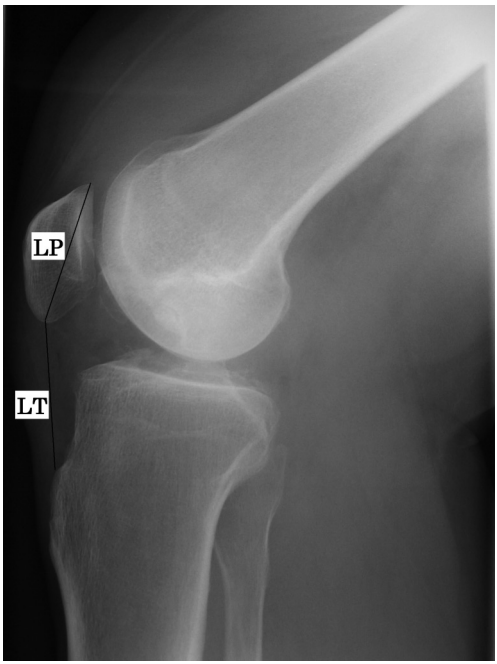

Figure 1. Radiograph showing determination of the patellar height according to Insall-Salvati ratio. The length of the patella tendon (LT) is divided by the longest length of the patella (LP).

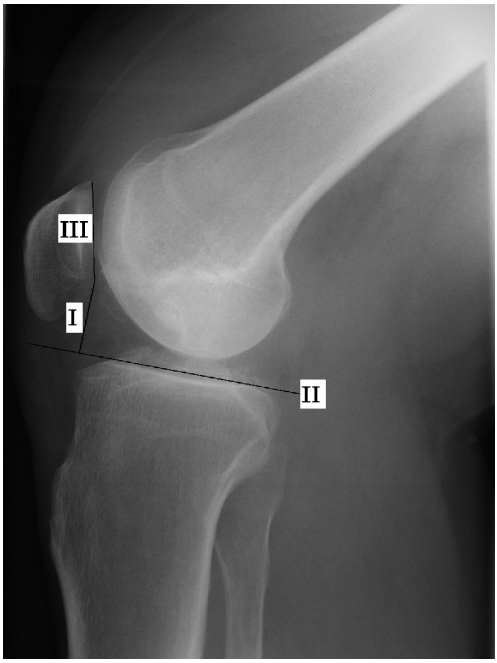

Figure 2. Radiograph showing determination of the patellar height according to Blackburne-Peel. The distance (I) from the distal pole of the articular surface of the patella to a perpendicular at the level of the tibia plateau (II) divided by the length of the patellar articular surface (III).

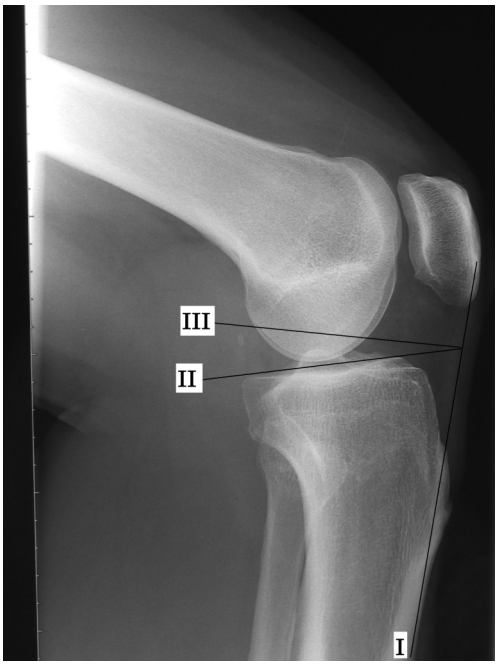

Figure 3. Radiograph showing the angle of inclination of the tibial plateau according to the Moore-Harvey method using three lines. The first (I) line tangential to the tibial crest, the second (II) line tangential to the proximal tibial articular articular surface and the third (III) line is perpendicular to line of the tibial crest. The angle formed by the second and the third lines is equivalent to the posteroinferior slope of the plateau.

dependent variables and type of post-operative treatment (cast versus no cast) in the group with opening wedge HTO.

The Pearson correlation between the difference in patellar height and (pre-operative minus post-operative) and that of the angle of inclination angle (pre-operative minus post-operative) was assessed in order to estimate dependency between the outcome measures.

The intra- and interobeserver variability are expressed as intraclass correlation coefficients (ICC) which vary from zero (no agreement at all) to 1 (total agreement).

Additionally, the Bland-Altman approach was used to determine the limits of agreement and to ensure that the repeatability was constant.[10]

A p-value of 0.05 was considered to be statistically significant.

Results

One patient was lost to follow-up leaving 18 women and 32 men in the study. Their mean age was 50.1 (SD 8.2) years. The mean pre-operative HKA-angle was 186.6 degrees (SD 2.9) (Table 1). In all patients the cruciate ligaments were intact.

Table 1. Details of the patients

	Closing wedge HTO (n = 24)	Opening wedge HTO (n = 26)	Total (n = 50)
Male: Female	12: 12	20: 6	32: 18
Age, mean (SD) years	52.6 (8.5)	47.7 (7.4)	50.1 (8.2)
HKA angle, mean (SD)	187.8 (2.6)	185.4 (2.7)	186.6 (2.9)
Ahlbäck[18] score medial compartment:			
- no osteoarthritis	1	0	1
- joint space narrowing	22	21	43
- obliteration	1	5	6
- no osteoarthritis	22	23	45
- joint space narrowing	2	3	5
- obliteration	0	0	0

Pre-operatively, the mean IS and mean BP ratios were 0.90 (SD 0.17) and 0.76 (SD 0.11), respectively. The mean inclination angle of the tibial plateau was 9.6 degrees (SD 3.1).

A total of 24 patients had a closing wedge HTO and 26 patients had an opening wedge HTO; 12 patients of the opening wedge group had a plaster cast and the remainder not.

Four patients required operation during the 1-year follow-up period. In one patient in the closing wedge HTO group this was because of overcorrection (varus HTO) and in another for progression of symptoms (total knee arthroplasty). In the opening wedge two patients required re-operation because of recurrent varus alignment (re-valgus HTO).

Postoperatively, the patella height according to the IS was 0.92 (SD 0.17) in the closing wedge HTO group and 0.81 (SD 0.20) in the opening wedge HTO group. The mean patella height according to the BP ratio was 0.77 (SD 0.12) in the closing wedge group and 0.70 (SD 0.16) in the opening wedge group (Table 2; Figure 4).

The z-residuals plotted against the predicted residuals gave a normal distributed scatterplot for all models presented, meaning that these values were independent of each other, and that this specific condition for executing linear regression is satisfied.

Testing for possible confounding between type of HTO and post-operative patellar height or post-operative angle of inclination showed that the pre-operative hip-knee-ankle angle was a confounder. Adjustment for this value in multivariate linear regression (type of HTO and pre-operative hip-knee-ankle angle and pre-operative patellar height as independent variables; post-operative patellar height as dependent variable) showed that the post-operative mean difference in patellar height due to type of HTO was 0.15

Table 2. Mean (SD) patellar height according to Insall-Salvati (IS) and Blackburne-Peel (BP) ratios and the mean (SD) inclination of the tibial plateau according to Moore-Harvey (MH) method after closing and opening wedge high tibial osteotomy (HTO).

	Closening wedge HTO n = 24 Mean (SD)	Opening wedge HTO n = 26 Mean (SD)	Adjusted* postoperative difference, β (95% CI)	P-value for adjusted postoperative difference
Patellar height IS ratio				
- preoperative	0.91 (0.18)	0.90 (0.17)		
- postoperative	0.92 (0.17)	0.81 (0.20)	0.15 (0.06;0.23)	0.001
Patellar height BP ratio				
- preoperative	0.75 (0.10)	0.78 (0.11)		
- postoperative	0.77 (0.12)	0.70 (0.16)	0.11 (0.05;0.18)	0.001
Tibial slope MH, degrees				
- preoperative	9.79 (2.70)	9.50 (3.50)		
- postoperative	6.02 (3.87)	11.87 (4.89)	-6.40 (-8.74;-4.02)	< 0.001

** This table reflects the post-operative difference between the closing and opening wedge HTO, adjusted for baseline measurement of patellar height or tibial slope, and hip-knee-ankle angle at baseline, estimated in linear regression analysis. The closing wedge HTO is compared with the opening wedge HTO meaning that a positive value indicates more patellar height or more slope for the closing wedge HTO, while a negative value indicates the opposite.*

(p= 0.001; 95% CI: 0.06 to 0.23) for the IS and 0.11 (p=0.001; 95% CI: 0.05 to 0.18) for the BP ratio.

The mean angle of inclination of the tibial plateau was 11.9 degrees (SD 4.9) in the opening wedge HTO group and 6.0 degrees (SD 3.9) in the closing wedge HTO group (Table 2). The adjusted mean post-operative difference was -6.40 degrees (p< 0.001; 95% CI: –8.74 to -4.02; Figure 5)

In the opening wedge HTO group, subgroup without a plaster (n=14) had mean postoperative IS and BP ratios of 0.79 (SD 0.18) and 0.66 (SD 0.12), respectively, compared with 0.83 (SD 0.24) and 0.75 (SD 0.20), respectively, in the subgroup with plaster (n=12). Multivariate linear regression analysis (plaster vs no plaster, pre-operative hip-knee-ankle angle, and pre-operative patella height as independent variables; post-operative patella height as dependent variable) showed no statistically significant difference between groups with and without plaster. The mean postoperative difference due to type of post-operative treatment was 0.012 (p=0.83 ; 95% CI: –0.10 to 0.13) for the IS and 0.07 for the BP ratios (p=0.15; 95% CI: -0.03 to 0.16).

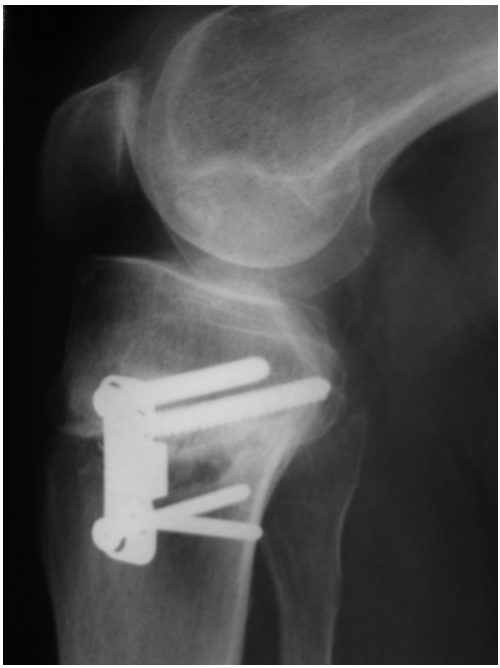

Figure 4. Radiograph showing patella baja after an opening wedge high tibial osteotomy.

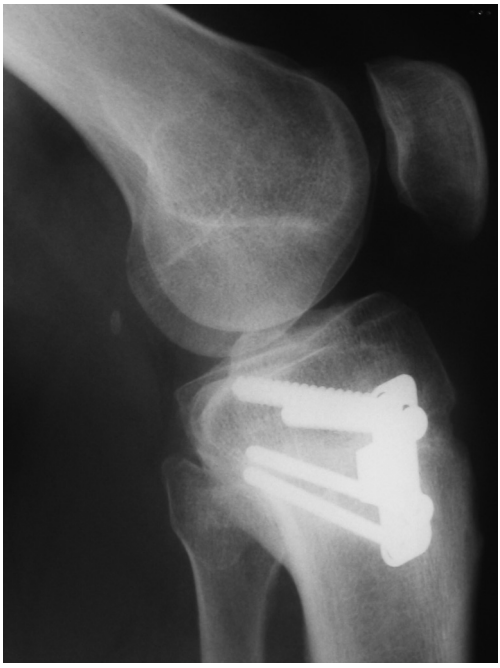

Figure 5a. Radiograph showing the increase of the inclination of the angle of the tibial plateau after an opening- wedge high tibial osteotomy.

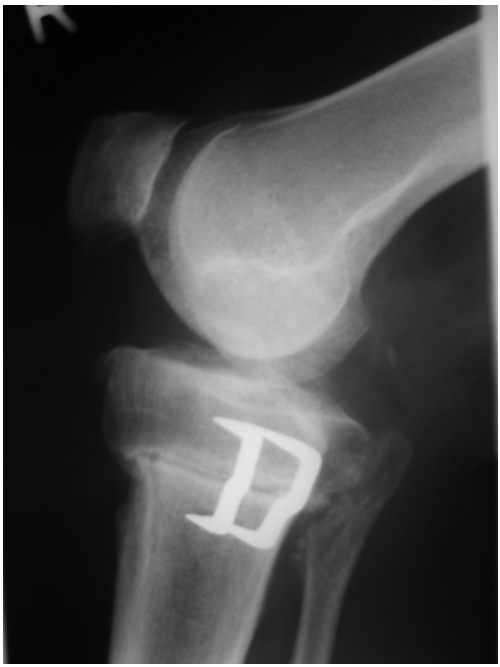

Figure 5b. Radiograph showing the decrease of the inclination angle of the tibial plateau after an closing wedge high tibial osteotomy.

After HTO there was a significant correlation between differences in patellar height and differences in inclination angle of the tibial plateau, for the patellar height measured with the IS (r=0.398; p=0.005) and BP (r= 0.453; p=0.001) methods.

The ICCs of the IS and BP ratios together with the MH slope estimations are presented in Table 3. In all measurements the ICCs were reasonable. For the two ratios the intraobserver agreement was superior to the interobserver agreement in every situation. For the MH assessments intra- and interobserver agreement was similar throughout.

For measurements of patellar height the Bland-Altman approach showed that the plot of the difference in the measurements recorded by the two observers for each patient against their mean indicated that the differences were not related to the size of the measurement. However, for the measurements of the angle of inclination angle of the tibial plateau the Bland-Altman plot showed that the differences increased when the size of the measurements became larger.

The post-operative mean differences between the two observers and the limits for agreement were as follows: IS: -0.20 (-0.56 to 0.17), BP: -0.02 (-0.32 to 0.30), MH 1.80 degrees (-4.69 to 8.29).

These limits of agreement were comparable with pre-operative limits of agreement.

Table 3. Intraclass correlation coefficients (ICC) of the Insall-Salvati and Blackburne-Peel ratios.

	Insall-Salvati ratio Observer variability (ICC)		Blackburne-Peel ratio Observer variability (ICC)		Moore-Harvey tibial slope Observer variability (ICC)	
	Intra	Inter	Intra	Inter	Intra	Inter
Preoperative	0.83	0.45	0.81	0.42	0.65	0.73
Postoperative	0.86	0.63	0.79	0.56	0.82	0.82
Closing wedge HTO	0.87	0.56	0.79	0.79	0.71	0.77
Opening wedge HTO	0.85	0.66	0.78	0.45	0.78	0.82

Discussion

Patella baja, the change in tibial slope and valgus alignment after HTO can cause technical difficulties during total knee replacement particularly in relation of eversion of the patella, exposure of the lateral compartment, and placing the tibial component in the correct position, both for rotation and slope.

In our study more patella baja was created after opening wedge HTO, and the angle of inclination increased. After a closing wedge HTO the angle of inclination decreased.

Pre-operatively, the hip-knee-ankle angles differed between the closing and opening wedge HTO groups. This angle proved to be a confounder for the relationship between post-operative patellar height or post-operative angle of inclination of the tibial plateau and type of HTO. Correction for this confounder resulted in an even stronger difference in outcome between the opening and closing wedge HTO groups.

For measurement of patellar height we chose the IS method because it is most frequently used. Secondly, we applied the BP method in accordance of Seil et al following their comparison of different methods of measurements of patellar height.[11] In their study on 22 non-operated knees the BP method showed the lowest interobserver variability and best discrimination of patella alta, norma and baja.[11]

In our study there was no clinically relevant difference in the intra- and interobserver variability of patellar height measurements either before or after operation.

According to both the IS and the BP method, there was significantly more patellal descent after opening wedge HTO. However, we agree with Kaper et al that the BP ratio is not a valid measurement for patellar height after HTO, because a change in the angle of the inclination of the tibial plateau adversely affects the reproducibility of this

measurement.[5] In the retrospective trial of Tagiana et al more patellal descent occurred after opening wedge compared with closing wedge HTO.[12] However, they used the Caton-Dechamps method which is thought to be insufficient for measurements of the patellar height after HTO or total knee arthroplasty because this ratio is adversely affected by the joint line.[13]

According to Kaper et al loss of tibial slope after closing wedge HTO was significantly associated with patella baja.[5] Our results showed that an increase of tibial slope was also significantly associated with patella baja according to the IS and BP ratios. Patellar descent was caused by several factors such as scarring in and around the patellar ligament because of immobilisation, the formation of new bone at the site of the osteotomy, the alteration of tibial inclination and the elevation of the tibial plateau after opening wedge osteotomy.[5, 12, 14-16]

In a prospective randomised trial, Nakamura et al showed that the opening wedge osteotomy hemicallotasis technique caused little change in length of patellar tendon or angle of inclination of the tibial plateau while both decreased in a group which received a dome osteotomy.[17] Hemicallotasis caused less change in patellar length and angle of inclination of the tibial slope because the osteotomy was below the insertion of the patellar tendon and the external fixator could be adjusted after osteotomy.

HTO with rigid fixation and early motion is advised to avoid patella baja.[14,15] However, in spite of immobilisation, we did not have significant patellar descent after a closing wedge HTO. After an opening wedge HTO, the degree of patellar descent did not differ significantly between the plaster and non-plaster subgroups.

A change in inclination after HTO can have several causes. The first is the precision of the osteotomy of both opening and closing wedge HTOs, which should be parallel to the angle of inclination of the tibial plateau. Secondly, in opening wedge HTO, if the plate is placed too anteriorly more inclination will be created.

Caution with regard to the neurovascular bundle can cause incomplete bony resection posteriorly during removal of the wedge and can cause loss of inclination after closing wedge HTO. Retained posterolateral support from the proximal tibiofibular syndesmosis is another possible reason for loss of inclination of tibial slope after closing wedge HTO.[5]

Loss of inclination after closing wedge HTO produces a relative elevation of the posterior cruciate ligament.[5]

When planning a total knee arthroplasty after HTO it should be borne in mind that the patellar height and angle of inclination of the tibial plateau have been altered.

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Chapter 10

General Discussion

Unicompartmental osteoarthritis of the knee occurs often in relatively young patients with a high demand for work and sports.[1] It is therefore a disabling condition for the patients with high costs for society. Our literature reviews showed that, despite this frequent occurrence, limited evidence is available to assist the treating physician in selecting the most optimal treatment. Our studies aimed to clarify some aspects of radiological diagnoses, conservative and operative treatment. The most important question, however, remains unanswered, i.e. what is the optimal treatment: conservative or operative? And at what moment in the course of the disease may the patient benefit more from operative than from non-operative treatment? Only studies using randomisation to either an operative or conservative treatment can answer these questions, but such studies are still lacking. However, many surgeons and their patients are reluctant to participate in such a study: orthopedic surgeons obviously believe in their surgical treatments and many patients consulting these specialists expect a surgical treatment for their problem. Moreover, most patients have already received conservative treatment from their general practitioner before being referred to the orthopedic surgeon. Even if a randomised trial could be conducted with operative versus non-operative treatment, the participants could not be blinded which would lead to a significant bias.

Radiological diagnosis of the malaligned osteoarthritic knee

Axial malalignment the increases risk of progression of knee osteoarthritis and predicts a decline in physical function.[2] The anteroposterior whole leg radiograph (WLR) is considered the gold standard for determining axial alignment and serves as the basis for planning a knee osteotomy in patients with osteoarthritis.

Although the WLR is often made in a standing position, some prefer the supine position. A WLR in supine position may be preferred in patients with abnormal laxity of the lateral collateral ligament. Moreover, in practice, it is not always possible to make a WLR in the standing position because of pain and/or instability of the affected knee.[1,3] In this thesis we have reported that a WLR made in standing position will result in two degrees more varus deviation in a patient with a varus knee than in supine position.[4]

The WLR can be made with or without fluoroscopic control.[4-7] Lateral fluoroscopic control ensures a 100% anteroposterior projection by superimposing the dorsal aspect of the femoral condyles. Based on our studies, especially in the presence of a flexion contracture of the knee, our advice is to use fluoroscopy, because simultaneous flexion of the knee and rotation of the leg affect the apparent alignment that is seen when a WLR is made.

Additional trials are needed to study the additive value of modern techniques in determining lower extremity alignment, such as reconstruction computed tomography (CT), which will probably provide the surgeon with more preoperative information. Computer-assisted high tibial osteotomy (HTO) will provide more information during surgery and may result in a more accurate correction.[8] Furthermore, radiostereometric analysis (RSA) will provide more information concerning the maintenance of adequate operative correction post HTO.[9,10] It is important to include a cost-benefit analysis, because additional radiological support as well as computer assisted surgery will increase costs. These techniques may, however, not be required in all patients. Moreover, in randomised controlled trials the optimal correction after HTO has not yet been demonstrated so far. Although, the general advice in retrospective studies is to over-correct the alignment by 4 degrees, the methodological qualities of these studies is rather low.

Conservative treatment of the osteoarthritic malaligned knee

The initial treatment for osteoarthritis of the knee is conservative, consisting of adaptation of loading, decrease of body mass index (BMI), patient education, and physical therapy.[11-17] Pharmacological treatment aims primarily to decrease symptoms (e.g. use of analgesics, anti-inflammatory drugs) but some of these substances may be considered as disease-modifying (hyaluronic acids, glucosamine, chondroitin sulfate).[18-21] Laterally wedge insoles and special valgisation braces are designed to reduce the load of the medial compartment.[22-29]

Reviews of the literature on the effectiveness of braces and orthoses to treat osteoarthritis of the knee are scarce. For example, the Cochrane review included only four, mostly small controlled clinical studies.[30] All included studies were conducted amongst patients suffering from medial-femoral compartment disease, one study evaluated valgus knee bracing, and three studies evaluated orthoses (laterally wedged shoe inserts).[24,27-29] More well-designed studies are needed to evaluate the effectiveness of these treatment modalities. New trials should investigate the long-term benefits of braces and orthoses because osteoarthritis is a chronic disease. If feasible, braces should be compared with other conservative treatments such as pharmacological curative or disease-modifying treatments, or ankle/foot orthoses.[18-21,27-29] If braces prove to be effective in the longer term, they then need to be compared with operative treatments such as a correction osteotomy or knee arthroplasty for unicompartmental osteoarthritis.

Based on the results of our own trial, a brace intended to reduce load seems to be a reasonable additional treatment option for patients with unicompartmental osteoarthritis

of the knee. Although, the effect sizes were not large, similar or even higher effect sizes have been reported for standard treatments with exercise regimes and use of NSAIDs.[14,18]

In our study valgisation bracing in medial compartment osteoarthritis was more effective than varisation bracing in lateral compartment osteoarthritis. [31] This might indicate that the unloading theory does not apply in patients with lateral compartment and a valgus alignment. Moreover, the knee adduction moment during the stance phase of walking causes mainly medial loading. For the patients with lateral compartment osteoarthritis and a valgus alignment a larger study population is needed to identify what type of brace will benefit this particular group.

In our trial many patients stopped brace treatment, either because the positive effects were too small or because the adverse side-effects (e.g. skin irritation, bad fit) were unacceptable.

We need to establish why a brace intended to reduce load shows a beneficial effect. Is the aspect of unloading essential, or are stability and proprioception the most important factors?

If unloading of a brace is proven effective, the manufacturer of these braces needs to address this problem of undesired side-effects, in order to increase compliance of the patient. If the unloading aspect is not the issue, a sleeve which is more comfortable and less bulky may increase treatment adherence.

Surgical treatment of the osteoarthritic malaligned knee

Patients with osteoarthritis not reacting to non-surgical therapy can be treated with a correction osteotomy.[32-35] The goal of the correction osteotomy is to transfer the mechanical axis and load bearing from the pathologic to the normal compartment. Patients with osteoarthritis of the medial compartment can be treated with a proximal tibial valgus osteotomy. Although, in the long term the osteotomy cannot stop the degenerative process and most patients will eventually undergo a total knee arthroplasty, the osteotomy seems to delay the progress of deterioration. These techniques include the closing wedge osteotomy, the opening wedge osteotomy, the dome osteotomy and the hemicallotasis technique with the external fixator.[33,36-39] Each technique has its own advantages and complications.[40,41] The choice of technique depends on the degree and location of malalignment and the personal experience of the surgeon with one or more of these techniques. The most important message emerging from the retrospective studies is that a successful outcome of the osteotomy correlates with proper patient selection, stage of osteoarthritis, achievement and maintenance of adequate operative correction.

Loss of correction correlates with type of fixation, the degree of correction, the duration of consolidation, and the BMI of the patient.[35,37,42,43]

The Cochrane review focusing on osteotomy in treating knee osteoarthritis included eleven controlled studies. All the studies concerned a valgus high tibial osteotomy (HTO) for medial compartment osteoarthritis of the knee.[44] Four studies compared two techniques of HTO [45-48]; one study compared HTO alone versus HTO with additional treatment [49]; four studies compared within one type of HTO different peroperative conditions (two studies) [50,51] or two different types of postoperative treatment (two studies) [52,53]; two studies compared HTO with unicompartmental joint replacement.[54,55] Most of the studies reported patient improvement after osteotomy surgery, but in the majority of the studies there was no significant difference compared with another operative treatment (i.e. another technique of HTO/ unicompartmental joint replacement UKA).

The opening wedge technique has become very popular recent years. Advantages (theoretical) of this method, compared to other techniques, are no bone loss, one osteotomy cut, no peroneal nerve problem, no fibula osteotomy, and accurate correction. However, in our trial comparing the opening wedge with the closing wedge technique, we found more loss of correction postoperatively. The HSS knee score and VAS score, however, improved in both groups and showed no significant difference after one-year follow-up. One important reason for the undercorrection with the opening wedge technique may be that we used the Puddu plate as fixation device. This construction was apparently not strong enough to maintain the correction obtained during the operation, until bony union of the osteotomy occurred.[56] A newly designed plate, in which the screw head locks into a more rigid plate, may be more stable and may eventually provide better results. Based on our own studies we prefer the closing wedge osteotomy because the results are better.

It is remarkable, however, that the designer of this plate has never addressed this problem, even though independent users have, in the meantime, reported the same problems as reported earlier by our group. Lobenhoffer et al used a medial plate fixator in 262 opening wedge HTOs and no correction loss occurred.[38]

Our group used bone from the iliac crest to fill the open wedge. Until now, autologous bone is the gold standard for grafting, but new trials are needed to compare our results with alternatives for bone substitution in combination with bone growth factors.[57]

The timing of the HTO remains an important question. More studies are required to establish at what stage of osteoarthritis we need to operate the patient with genu varum arthroticum: i.e. the younger patient with arthroscopic cartilage lesions, or the older patient with radiological osteoarthritis?

Further research should also focus on alternative surgical treatments of unicompart-

mental knee osteoarthritis because a broad range of treatment is available. Different HTO techniques need to be compared, and the HTO technique has to be compared with the unicompartmental knee prosthesis. It must be stressed that all new treatment modalities should be compared with the traditional treatment modalities. There has been a large increase in the use of unicompartmental kee prosthesis in young patients who recently were treated with a correction osteotomy. However, in the absence of good scientific evidence, this remains a risky approach. So far randomised controlled trials comparing HTO with unicompartmental knee arthroplasty are limited: Stukenborg et al showed no significant knee and function scores and the Kaplan-Meier survivorship after 5 and 10 years was also not significantly different.[55] Most importantly, as stated earlier, HTO has to be compared with conservative treatments using a randomised trial design.

Although the goal of a HTO is to decrease pain and functional limitation in patients with medial compartmental osteoarthritis of the knee, many patients will get a total knee arthroplasty.[32,58-60] Total knee replacement after HTO has presented more technical problems and complications because of scars, valgus alignment, patella baja (low position of the patella) and a change of tibial inclination. We therefore studied the position of the patella in the closing and opening wedge osteotomy.[61] After opening wedge HTO the patellar height was significantly more decreased compared to the closing wedge HTO. There was a significant difference in the tibial inclination angle between the two HTO techniques, increasing after opening wedge HTO and decreasing after closing wedge HTO. Future studies will confirm whether these side-effects of the osteotomy technique influence the conversion to a total knee arthroplasty, including the long-term results of such subsequent arthroplasty.

Cartilage repair probably may prove to be a useful treatment for knee osteoarthritis, but no conclusive long-term data are currently available.[62-64] Moreover, in the presence of a malalignment, cartilage repair may have to be combined with a correction osteotomy in order to prevent overloading of the biologically repaired joint surface.

Finally, the work presented in this thesis has some limitations.

Firstly, the methodological quality of the brace and osteotomy trials could have been increased if we had used a blinded outcome assessor to get the HSS score, which is partly based on the measurements of an outcome assessor. In both trials the outcome assessor was unblinded, even though they could easily have been blinded, especially for the brace trial. For all other outcomes the patient himself/ herself was the outcome assessor.

Secondly, in both trials we used the HSS knee function score, while the WOMAC seems to have become the function score of choice.[65] Although the WOMAC score has

been criticized recently, use of this score would have enabled easier comparability with similar trials.[66]

Thirdly, the follow-up period of both trials was one year, which is relatively short for a chronic disease such as osteoarthritis of the knee.

Fourthly, in the osteotomy trial the primary outcome was achievement of 4 degrees of valgus correction. We made a standing WLR one year after the operation and not immediately postoperatively because, at that time, the patient could not stand on the operated leg. Therefore we are not 100% certain whether there was insufficient correction or correction loss during the one-year follow-up. In retrospect, in our osteotomy trial it would have been better to use additional WLRs in supine position directly after the surgery, especially now this thesis have shown that the difference between the standing and supine position is 2 degrees.

Fifthly, the optimal overcorrection after HTO remains questionable, because the pain and function scores were improved after both osteotomy techniques, whereas the valgus alignment after opening wedge HTO was 1 degree and after closing wedge HTO was 3 degrees. Evaluation of the groups after a longer follow-up period will establish whether the recurrence of symptoms or progression of disease is dependent on the size of correction.

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Chapter 11

Summary

Chapter 1: Osteoarthritis of the entire knee is distinguished from osteoarthritis of one compartment (medial or lateral), which is generally caused by a mechanical problem. Moreover, malalignment increases the risk for progression of knee osteoarthritis and predicts a decline in physical function.
Chapter 2: The whole leg radiograph, which is the standard technique for determining axial alignment, is usually taken in a standing position. However, some prefer the supine position. To determine the difference between these two positions, we performed a standing as well as a supine whole leg radiograph in the same 20 patients with a varus alignment. Measurement of the radiographs showed an average of two degrees more varus deviation in a patient with a varus knee in the standing position than in the supine position.
Chapter 3: Subsequently, a cadaver study was performed to determine the effect of flexion of the knee and rotation of the hip on projected angles on the anterior-posterior (AP) whole leg radiograph. The outcomes were mathematically checked. The results of the cadaver study were similar to those of the mathematical analysis: i.e. flexion of the knee without rotation of the lower extremity has very little effect on angles as projected on whole lower limb AP radiographs. Rotation of the lower extremity without flexion of the knee also has little effect. Simultaneous flexion of the knee and rotation of the leg, however, cause large changes in projected angles. Whole leg radiographs can be made without fluoroscopic control as long as the knee can be fully extended. In the presence of a flexion contracture a 100% AP radiograph under lateral fluoroscopic control is necessary to obtain accurate determination of the mechanical axis.
Chapter 4: Braces and foot/ankle orthoses may fix or correct the alignment, as well as provide support and help weak muscles. It is thought that by providing support, braces and foot/ ankle orthoses may also decrease pain, improve physical function, and slow the progress of osteoarthritis of the knee.

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE (Current contents, Health STAR) up to October 2002 for randomised controlled clinical or controlled clinical trials concerning patients with unicompartmental osteoarthritis of the knee and with the intervention of a brace or a foot/ ankle orthosis in one of the studied groups. Four studies were included and analyzed, which together tested over 440 people suffering from osteoarthritis of the knee. One study compared a brace with a neoprene sleeve and standard conservative treatment. Three studies compared different foot/ankle orthoses. The follow-up was at the most 6 months. Although the studies were small and ranged from high to low quality, this review provides the best evidence available. In the included brace trial the pain, stiffness and physical function (WOMAC and MACTAR) scores of the brace group showed greater improvement at six months compared with a neoprene sleeve group, which showed

greater improvement compared with the control group. In a foot orthosis trial the number of days of NSAID intake decreased significantly compared with baseline in a group with laterally wedged insoles, and remained unchanged in the neutrally wedged group. Patient compliance with the laterally wedged insole was significantly better compared with the neutrally wedged insole. In another foot/ankle orthosis study, the VAS pain score was significantly decreased from baseline in a strapped insole group, but not in the traditional laterally wedge group. Nevertheless, this strapped insole resulted in more adverse effects (e.g. popliteal pain, low back pain, and foot sole pain) compared with the traditional laterally wedge insole. In the third foot/ankle orthosis study pain during bed rest and after getting up from seated position as well as walking distance were significantly improved in a subtalar strapped group compared with baseline, and no improvement was found in a sock type group. The four studies had a follow-up period up to 6 months only. Since osteoarthritis is a chronic disease, longer studies are needed to more effectively test braces and orthoses.

Chapter 5: A multicenter randomised controlled trial was conducted to study the additive effect of a brace intended to reduce load in conservative treatment of unicompartmental osteoarthritis of the knee. The follow-up period was 12 months. A total of 117 patients with unicompartmental osteoarthritis of the knee (95 with varus alignment and 22 with valgus alignment) were included. The intervention group (n=60) received conservative treatment with additional brace treatment, and the control group (n=57) received conservative treatment only.

The primary outcome measures were pain severity and knee function score.

The secondary outcome measures were walking distance and quality of life.

Multiple linear regression models according to the intention-to-treat-principle were used to assess outcome differences for the entire group of patients. In addition, we performed explorative subgroup analyses on primary overall outcomes stratified for alignment, degree of osteoarthritis, origin of osteoarthritis, and age.

The primary outcome measures were slightly improved in the intervention group compared with the controls at each assessment point, although the differences reached only borderline significance ($p< 0.1$). The reported walking distances at 3 months and 12 months and overall were significantly longer in the brace group ($p=0.03$, $p= 0.04$ and $p=0.02$, respectively).

No significant differences in quality of life evaluations were found between the intervention and control group.

Subgroup analysis showed a better effect in the varus group, in patients with severe osteoarthritis, in patients with secondary osteoarthritis and in patients younger then 60 years.

In total 25 patients in the brace group and 14 in the control group changed their

initial treatment, most of them (74%) because of a lack of beneficial effect. The results indicate that a brace intended to reduce load provides small beneficial effects in patients with unicompartmental osteoarthritis. However, many patients do not adhere to this kind of conservative treatment in the long run.

Chapter 6: Patients with osteoarthritis not reacting to non-surgical therapy can be treated with a correction osteotomy. The goal of a correction osteotomy is to transfer the load bearing to the normal compartment, which will reduce the symptoms and allow arthroplasty to be postponed. In retrospective studies, this procedure resulted in less pain, improved knee function or postponement of knee arthroplasty 7-15 years. Possible complications include non-union, thrombo-embolism, contracture of the patellar tendon, paresis of the peroneal nerve, and compartment syndrome. The outcome of osteotomy for osteoarthritis of the knee depends on careful patient selection, the stage of osteoarthritis, and the achievement and maintenance of adequate operative correction.

Chapter 7: We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE (Current contents, Health STAR) up to October 2002 for randomised controlled clinical or controlled clinical trials concerning patients with unicompartmental osteoarthritis of the medial or lateral compartment of the knee and with the intervention of a high tibial osteotomy (HTO) or a distal femoral osteotomy in one of the studied groups. Eleven studies were included and analyzed, all of which concerned a valgus HTO for medial compartment osteoarthritis of the knee. Four studies compared different surgical techniques used in a HTO. Three studies compared HTO to HTO with another procedure such as using a tourniquet, abrasion and overcorrection. One study compared HTO to HTO plus electromagnetic stimulation, and another study compared plaster cast to a hinged-cast brace after surgery. There were no differences between the different techniques and procedures regarding improvement in pain and function. However, HTO with the electromagnetic stimulation increased healing, and patients with the brace achieved a better range of motion in the knee. Two studies compared HTO with unicompartmental knee replacement surgery, but no differences were found regarding improvements. Based on these 11 studies (of which 6 were of high quality), we conclude that an osteotomy results in a significant reduction of pain and improvement of the knee function. However, it has not yet been demonstrated that an osteotomy is better than no surgery at all, and it remains unclear which technique provides the best results.

Chapter 8: A prospective randomised controlled trial was conducted to study and compare two different techniques of HTO, a medial opening wedge HTO and a lateral closing wedge HTO, regarding achievement and maintenance of adequate operative correction (the goal was achievement of an overcorrection of 4 degrees valgus), pain severity (VAS;

range 0-10), the knee function score (HSS; range 0-100), and walking distance (in kilometers). During the inclusion period 92 patients were randomised. At one-year follow-up the postoperative hip-knee-ankle angle was 1.3 degrees valgus after the opening wedge HTO, and 3.4 degrees valgus after the closing wedge HTO; the adjusted mean difference of 2.12 was significant ($p< 0.05$).

The deviation from 4 degrees valgus alignment was 4.0 degrees (SD 3.6) in the opening wedge HTO group and 2.7 degrees (SD 2.4) in the closing wedge group; the adjusted mean difference of 1.67 degrees was also significant ($p=0.01$).

The VAS score was decreased in both groups: 2.7 points after the opening wedge HTO and 2.3 after the closing wedge HTO; this difference was not significant. The HSS knee score and the walking distance were increased in both groups: respectively 9.4 points and 2.3 km after the opening wedge HTO and 8.5 points and 1.5 km after the closing wedge HTO; these differences were also not significant. Because of pain, the osteosynthesis material was removed in 27 (60%) patients in the opening wedge HTO group and in 11 (23%) patients in the closing wedge group; this difference was significant ($p< 0.001$). Based on this study we conclude that the closing wedge HTO achieves a more accurate correction and that reduction of pain and improvement of function can be expected after both techniques.

Chapter 9: It seems that a total knee replacement after HTO presents more technical problems and complications because of scars, valgus alignment, patella baja (low position of the patella) and a change in the tibial inclination angle. A prospective randomised controlled trial was conducted to study the degree of patellar descent and alteration in inclination angle of the tibial plateau in lateral closing wedge and medial opening wedge HTO in 51 consecutive patients with medial compartment osteoarthritis and varus malalignment. Patellar height was measured by the Insall-Salvati (IS) and the Blackburne-Peel (BP) ratios. The tibial inclination was determined with the Moore-Harvey method. Multivariate linear regression analysis was used to determine the influence of type of HTO (closing versus opening wedge) on postoperative patellar height or tibial inclination. The intra- and interobserver variability of these methods was determined preoperatively and at one-year follow up. After an opening wedge HTO the patellar height was significantly ($p< 0.05$) more decreased compared with a closing wedge HTO (IS ratio= 0.15; BP ratio= 0.11). The angle of tibial inclination differed significantly by 6.4 degrees between the two HTO techniques, increasing after opening wedge HTO and decreasing after closing wedge HTO. There were no clinically relevant differences in the intra- and interobserver variability of measurements of patellar height either before or after HTO. When planning a total knee arthroplasty after HTO it should be borne in mind that the patellar height and angle of inclination of the tibial plateau may have been altered.

Chapter 10: The thesis concludes with a review of the methods, results and implications of our studies, and makes some recommendations for future research.

Chapter 12

Nederlandse Samenvatting

Hoofdstuk 1: Er wordt onderscheid gemaakt tussen artrose van de gehele knie en artrose van één compartiment (mediaal of lateraal). Artrose van één compartiment heeft waarschijnlijk vaker een mechanische oorzaak. Patiënten met artrose van het mediale compartiment hebben vaak een genu varum (O-been) en patiënten met artrose van het laterale compartiment hebben vaak een genu valgum (X-been). Deze afwijking van de stand vergroot daarbij de kans op voortgang van artrose met als gevolg een afname van de kniefunctie.
Hoofdstuk 2: De lange been foto in voor-achterwaartse richting is de standaard techniek om afwijkingen in de stand van een been te bepalen. Deze foto wordt over het algemeen in staande positie gemaakt. Er zijn echter een aantal orthopedische chirurgen die de voorkeur hebben voor een foto in een liggende positie. Wij hebben onderzocht of een foto in liggende en staande houding van de patiënt een verschil in varus-afwijking oplevert. Daartoe werden bij 20 patiënten met een genu varum zowel een foto in staande als in liggende houding gemaakt.

Het bleek dat in staande houding de foto gemiddeld twee graden meer varus-afwijking liet zien dan de foto in liggende houding.
Hoofdstuk 3: In een studie bij kadavers werd nagegaan of flexie van de knie en rotatie van de heup invloed hadden op de varus-hoek op een afgedrukte lange beenfoto in voor-achterwaartse richting.

De resultaten van deze studie werden met een theoretisch wiskundig model vergeleken. De uitkomsten van het kadaveronderzoek en het wiskundig model waren gelijk: flexie van de knie zonder rotatie van de heup had weinig invloed op de geprojecteerde varus-hoek op een lange been foto. Hetzelfde gold voor alleen rotatie van de heup zonder flexie van de knie. Echter tegelijkertijd flexie van de knie en rotatie van de heup veroorzaakt grote afwijkingen in de geprojecteerde varus hoek op een lange been foto.

Wij adviseren dan ook om bij een knie met een strekbeperking een 100% voor-achterwaartse lange been foto te maken met behulp van laterale röntgendoorlichting waarbij er op wordt gelet dat de achterzijde van de femurcondylen over elkaar heen projecteren (= 100% laterale knie foto). De voor– achterwaartse lange been foto wordt vervolgens loodrecht op deze laterale röntgendoorlichting genomen.
Hoofdstuk 4: Men veronderstelt dat in geval van artrose van de knie een knie brace of een corrigerende steunzool met of zonder enkelband de pijn verlicht, de functie verbetert en het slijtage proces vertraagt. Een knie brace of een corrigerende steunzool met of zonder enkelbanden zou een afwijking in de stand kunnen corrigeren. Bovendien geeft een brace stabiliteit en ondersteunt verzwakte spieren. Aangezien het nut van deze behandelmogelijkheden voornamelijk berust op retrospectief onderzoek werd door ons een systematische literatuurstudie verricht voor de Cochrane library naar de conserva-

tieve behandeling met behulp van een brace of een steunzool bij artrose van de knie. Daartoe werd in MEDLINE en EMBASE gezocht (tot oktober 2002) naar gerandomiseerde en klinische gecontroleerde prospectieve studies op het gebied van een brace en een steunzool bij de behandeling bij artrose van de knie. Vier studies met totaal 440 patiënten werden geïncludeerd en geanalyseerd. Eén studie vergeleek een brace met een neopreen knie band en met een controle groep die de standaard conservatieve therapie kreeg (= aanpassen van de belasting en indien nodig ontsteking remmende medicijnen). Drie studies vergeleken verschillende corrigerende steunzolen met of zonder enkelbanden. Ondanks het feit dat slechts vier studies met verschillend kwaliteit niveaus geïncludeerd werden, geeft deze review de huidige stand van zaken op het gebied van conservatieve behandeling met behulp van een brace of een steunzool bij artrose van de knie het beste weer. Pijn, stijfheid en functie (WOMAC en MACTAR) scores na 6 maanden waren meer verbeterd in de brace groep dan in de neopreen knieband groep waarbij de scores in deze laatste groep weer beter waren dan in een controle groep. In een gerandomiseerd steunzool onderzoek was in de groep met een steunzool met een laterale wig het aantal dagen met NSAID gebruik significant meer gedaald dan in de groep met een neutrale steunzool waarbij het NSAID gebruik onveranderd bleef. Bovendien was de therapietrouw in de groep met een steunzool met een laterale wig significant hoger dan in de groep met de neutrale steunzool. In een tweede gerandomiseerde steunzool onderzoek was de mate van pijn volgens de VAS score significant meer afgenomen in een groep met een steunzool met een laterale wig en met bovendien enkelbanden. In deze studie was de mate van pijn in de groep met een steunzool met een laterale wig zonder enkelbanden onveranderd. De steunzool met enkelbanden vertoonde echter wel meer bijwerkingen zoals pijn in knieholte, pijn laag in de rug en pijn ter hoogte van de voetzool. In een derde steunzool studie werd een steunzool met een laterale wig en enkelbanden vergeleken met een sok-type steunzool met laterale wig. Pijn liggend op bed, pijn bij het opstaan vanuit zitpositie en loopafstand waren significant meer verbeterd in de groep met een steunzool met een laterale wig en enkelbanden in vergelijking met een groep met een sok-type steunzool met laterale wig. De follow-up van de vier geincludeerde studies was slechts maximaal 6 maanden. Aangezien artrose een chronische ziekte is, zijn studies met een langere follow-up nodig om de effectiviteit van een brace en een corrigerende steunzool aan te tonen.

Hoofdstuk 5: Er werd een prospectief gerandomiseerde vergelijkende multi-center studie uitgevoerd om het aanvullende effect te toetsen van een ontlastende brace bij de conservatieve behandeling (aanpassen van de belasting, zonodig fysiotherapie en NSAIDs) van gonarthrosis van één compartiment (mediaal of lateraal). De follow-up hierbij was 12 maanden en 117 patiënten werden geincludeerd. Daarvan hadden 95 patiënten artrose van het mediale

compartiment en een genu varum en 22 patiënten hadden artrose van het laterale compartiment en een genu valgum. De interventie groep (n=60) kreeg naast de standaard conservatieve therapie een ontlastende brace en de controle groep (n=57) kreeg alleen de standaard conservatieve therapie. De primaire uitkomstmaten waren de mate van pijn en de kniefunctie en de secundaire uitkomstmaten waren loopafstand en kwaliteit van leven.

Multipele regressie analyse met intention to treat principe werd toegepast om verschillen aan te tonen. Aanvullend werd er nog een subgroep analyse verricht gestratificeerd voor de afwijking van de stand (varus versus valgus), mate van gonarthrosis (mild versus ernstig), oorzaak van gonarthrosis (primair versus secundair) en leeftijd (jonger versus ouder dan 60 jaar).

In de gehele groep (n=117) waren de primaire uitkomstmaten (mate van pijn en functie van de knie) tijdens elke follow-up beter in the interventie groep. Echter het verschil met de controle groep was slechts borderline (p< 0.l) significant. De gemelde loopafstanden na 3 maanden, na 12 maanden en de totale loopafstanden na 3,6 en 12 maanden waren significant groter in the brace groep (respectievelijk p=0.03, p=0.04 and p=0.02). Er waren geen verschillen in kwaliteit van leven tussen beide groepen.

De subgroep analyse toonde een beter effect van de brace bij genu varum, ernstige gonarthrosis, secundaire gonarthrosis en bij patiënten jonger dan 60 jaar.

Van belang is dat vooral vanwege onvoldoende effect 25 patiënten in de brace groep en 14 patiënten in de controle groep tijdens de 12 maanden follow-up de hun toegewezen behandeling op eigen initiatief beëindigden.

De resultaten van deze studie impliceren dat een ontlastende brace bij gonarthrosis van één compartiment en een afwijking in de stand wel enig additief effect heeft, maar dat een groot aantal patiënten deze vorm van behandeling op de lange termijn niet accepteren.

Als de conservatieve behandeling onvoldoende effect heeft, kan een operatieve behandeling in de vorm van een correctie-osteotomie (= standverandering) overwogen worden. Het doel van een correctie-osteotomie is de as van de belasting naar het goede compartiment te verplaatsen en daardoor de symptomen te verminderen. Hierdoor kan een arthroplastiek uitgesteld worden tot de patiënt in een minder actieve levensfase verkeert.

Hoofdstuk 6: In dit hoofdstuk wordt een overzicht gegeven van retrospectieve studies naar de lange termijn resultaten van de correctie-osteotomie bij gonartrosis. Deze resultaten van een correctie-osteotomie zijn zodanig dat een eventuele arthroplastiek 7-15 jaar uitgesteld kan worden. Als mogelijke complicaties van een correctie osteotomie worden genoemd: pseudartrose, thrombo-embolie, verkorting van de patella pees, uitval van nervus peroneus

en een compartiment syndroom. Het resultaat van een correctie osteotomie bij gonartrosis is uiteraard afhankelijk van een nauwkeurige patiëntenselectie, mate van artrose en het aanbrengen van de juiste correctie in de as van de belasting die voor de operatie is berekend.

Hoofdstuk 7: Er werd een systematische literatuurstudie verricht voor de Cochrane library naar de behandelingsresultaten van een correctie osteotomie. Daartoe werd in MEDLINE en EMBASE (tot oktober 2002) gezocht naar gerandomiseerde en klinisch gecontroleerde prospectieve studies op het gebied van een correctie osteotomie ter hoogte van de knie bij gonarthosis van één compartiment (mediaal of lateraal). Elf studies voldeden aan de gestelde voorwaarden en konden worden geïncludeerd en geanalyseerd. De interventie was in alle gevallen een valgiserende osteotomie ter hoogte van de proximale tibia bij patiënten met artrose van het mediale compartiment. Vier studies vergeleken twee verschillende osteotomie technieken. Drie studies vergeleken één osteotomie techniek met of zonder bloedleegte, met of zonder een aanvullende abrasion (schaven van het kraakbeen) en met of zonder overcorrectie. Twee studies vergeleken verschillende behandelingen na een correctie osteotomie: met of zonder elektromagnetische stimulatie en een brace versus een gipskoker. Er waren geen verschillen tussen de diverse correctie osteotomie technieken met betrekking tot pijnverlichting en verbetering van de kniefunctie. Wel bleek dat postoperatieve electromagnetische stimulatie de consolidatieduur van de osteotomie verkort. Patiënten met een brace in plaats van een gipskoker hadden postoperatief een betere functie van de knie.

Twee studies vergeleken een correctie osteotomie met een unicompartimentele knie prothese; in deze 2 studies werden geen significante verschillen in functiescores gevonden.

Gebaseerd op de 11 geïncludeerde studies (waarvan 6 een hoge kwaliteit hadden) concluderen wij dat een correctie osteotomie een significante pijnverlichting en een significante verbetering van de functie van de knie geeft. Echter op dit moment is niet aangetoond dat een correctie osteotomie betere resultaten geeft dan een conservatieve behandeling. Bovendien is nog steeds onduidelijk welke correctie osteotomie techniek we moeten gebruiken.

Hoofdstuk 8: Er werd een prospectieve gerandomiseerde vergelijkende studie uitgevoerd van twee verschillende valgiserende osteotomie technieken ter hoogte van de proximale tibia: de mediale open wig en de laterale gesloten wig. Bij een open wig osteotomie wordt een wig gecreëerd aan de mediale zijde van de tibia met behulp van cristabot. Bij een gesloten wig techniek wordt, nadat een botwig verwijderd is aan de laterale zijde, de osteotomie gesloten. De uitkomstmaten waren de nauwkeurigheid van de correctie (het doel was een 4 graden valgus stand), de mate van pijn (VAS 0-10), de functie van de knie (HSS 0-100) en de loopafstand (km). 92 patiënten werden geïncludeerd. Na één

jaar follow-up was de postoperatieve heup-knie–enkel hoek 1.3 graden valgus na de open wig osteotomie en 3.4 graden valgus na de gesloten wig osteotomie. Het gecorrigeerde gemiddelde verschil van 2.12 was significant ($p< 0.05$). De afwijking van de geplande 4 graden valgus was 4.0 graden (SD 3.6) bij de open wig osteotomie en 2.7 graden (SD 2.7) na de gesloten wig osteotomie. Ook dit gecorrigeerde gemiddelde verschil tussen beide technieken van 1.67 was ook significant ($p=0.01$).

De VAS pijn score was in beide groepen gedaald: 2.7 punten na de open wig osteotomie en 2.3 na de gesloten wig osteotomie; dit verschil was niet significant. De HSS kniefunctie score en loopafstand waren in beide groepen toegenomen: respectievelijk 9.4 punten en 2.3 kilometer na de open wig osteotomie en 8.5 punten en 1.5 kilometer na de gesloten wig osteotomie; deze verschillen waren niet significant.

Bij 27 (60%) patiënten na de open wig osteotomie en bij 11 (23%) patiënten na de gesloten wig osteotomie werd vanwege pijn het osteosynthese materiaal verwijderd; het verschil was significant ($p< 0.001$).

Aan de hand van de resultaten van deze studie concluderen wij dat een laterale gesloten wig osteotomie een nauwkeuriger correctie geeft dan een mediale open wig osteotomie en dat na beide technieken de pijn vermindert en de kniefunctie verbetert.
Hoofdstuk 9: Het blijkt dat het plaatsen van een knie prothese na een valgiserende tibia osteotomie technisch lastiger kan zijn vanwege littekens, een valgus as, laagstand van de patella door verkorting van de patella pees en verandering van de helling van het tibiaplateau.

Om na te gaan of de operatietechniek hier van invloed op is werd nog een gerandomiseerde vergelijkende studie verricht naar de patella hoogte en veranderingen van de helling van het tibiaplateau na een mediale open wig en een laterale gesloten wig tibia osteotomie.

51 patiënten met gonarthrosis van het mediale compartiment en een varus as werden geïncludeerd. De patella hoogte werd bepaald volgens de Insall-Salvati (IS) en de Blackburne-Peel (BP) ratios. De helling van het tibiaplateau werd gemeten volgens de Moore-Harvey methode. Met behulp van multivariabele lineaire regressie analyse werd de invloed bepaald van het type osteotomie op de postoperatieve patella hoogte en de helling van het tibiaplateau. De intra- and interobserver variabiliteit van deze methoden werd preoperatief en één jaar postoperatief bepaald.

Na de open wig osteotomie was de patella hoogte significant ($p< 0.05$) meer afgenomen dan bij de gesloten wig osteotomie (IS ratio= 0.15; BP ratio= 0.11). De helling van het tibiaplateau nam toe na de open wig osteotomie en nam af na de gesloten wig osteotomie. Het verschil van 6.4 graden was significant verschillend. De intra- and interobserver variabiliteit van beide methoden om de patella hoogte te bepalen was klinisch niet relevant verschillend.

Aan de hand van de resultaten van deze studie concluderen wij dat als men een totale knie plaatst na een valgiserende tibia osteotomie moet men in gedachte houden dat de hoogte van de patella en de helling van het tibiaplateau veranderd kunnen zijn.
Hoofdstuk 10: Het proefschrift wordt afgesloten met een terugblik op de methoden, resultaten en implicaties van onze studies. Bovendien worden aanbevelingen voor toekomstige studies gegeven.

Dankwoord

De volgende personen wil ik bedanken voor de bijdrage aan mijn promotie en opleiding tot orthopedisch chirurg.

Prof. dr. J.A.N. Verhaar, beste Jan:

Opleider en promotor. Ten eerste hartelijk dank dat je me destijds zonder klinische ervaring hebt aangenomen voor de opleiding tot orthopedisch chirurg. Op dag 1 van de orthopedie opleiding begon je al over een promotie onderzoek. Je hebt me gestimuleerd en ruimte gegeven om tijdens mijn opleiding wetenschappelijk onderzoek te verrichten. Ook toen ik naar Groningen vertrok, bleef je begeleiding strak, de communicatie goed en reageerde je altijd vlot op mijn vragen.

Dr. S.M.A.Bierma-Zeinstra, beste Sita:

Co-promotor. Zonder jouw goede begeleiding was ik nu waarschijnlijk halverwege met dit proefschrift. Jij, een export Friezin, en ik, een import Fries, konden het meteen goed vinden. Je wetenschappelijke kwaliteiten en mijn klinische werkzaamheden hebben geresulteerd in een mooi promotieboekje met 8 artikelen. Ik ben je veel dank verschuldigd voor de vele extra werkzaamheden die je voor mij hebt verricht. Ik hoop dat de orthopedie de samenwerking met jou en de huisartsgeneeskunde voorzet.

Drs. T.M. van Raay, beste Tom:

Amice collega, medeonderzoeker en paranimf. Na mijn vertrek naar het Noorden heb jij de laatste gegevens van mijn gerandomiseerde onderzoeken verzameld en vervolgens het stokje van de onderzoekslijn "diagnostiek en behandeling van unicompartimentele gonarthrosis" overgenomen. We zullen de samenwerking voortzetten, hetgeen moet resulteren in een tweede boekje. Het voelt overigens goed dat er iemand naast je staat tijdens de verdediging die goed op de hoogte is van het verrichte promotie onderzoek.

Drs. T.S.C. Jakma, beste Tijs:

Amice collega en medeonderzoeker. De radiologische studies en Cochrane reviews hebben we samen verricht resulterend in vier publicaties. Voor jou heeft dat een opleidingsplek tot orthopedisch chirurg opgeleverd. Je vooropleiding is bijna afgerond zodat we op korte termijn de mogelijkheid hebben om samen met Tom van Raaij diverse onderzoeksactiviteiten weer op te pakken.

Dr. A.P. Verhagen, beste Arianne:

Medeonderzoekster. Met jouw ervaring op het gebied van systematische review studies had ik geen betere medeonderzoekster en begeleidster kunnen treffen voor dit onderdeel van mijn promotie. Mede dankzij jou inbreng heeft dit geresulteerd in twee Cochrane reviews.

Ir. K.H. Brouwer, beste Kees:

Paranimf en broertje. Jij als technisch natuurkundige beschouwt de geneeskunde als een pseudo-wetenschap, en je hebt gelijk. Gelukkig hebben we met jouw wiskundige inbreng

in hoofdstuk 3 enige exactheid kunnen toevoegen. Diverse redacties van internationale orthopedische tijdschriften vonden de materie te ingewikkeld om te publiceren. Uiteindelijk is het toch gelukt en heb jij je eerste publicatie. Vanzelfsprekend ben jij een van mijn paramimfen en moet je me ondersteunen bij vragen over de geometrische materie.

Dr. H.F. Veen, beste Herman:

Opleider chirurgie en één van de laatste algemeen chirurgen. Aan de promotie heb je niet veel bijgedragen maar aan de opleiding tot orthopedisch chirurg des te meer. Ik wil je nogmaals hartelijk bedanken dat je me destijds hebt opgenomen in jullie warme chirurgische kliniek. Ik denk nog regelmatig terug aan die twee goede jaren in het Ikazia ziekenhuis. Dankzij jou, Boel, Cees en Wibo kon ik mijn vervolgopleiding orthopedie starten met een goede basis algemene chirurgie.

De orthopedisch chirurgen van het Dijkzigt en Sophia kinderziekenhuis (nu Erasmus MC) in Rotterdam:

Gert Bessems, Frans van Biezen, Ad Diepstraten, Peter Fontijne, Rien Heijboer, Bram van Koeveringe, Luuk de Klerk en Bart Swierstra. Dank voor de academische opleiding waar alle aspecten van de orthopedie de revue passeren. Verder dank voor het ondersteunen van mijn promotie activiteiten.

De orthopedisch chirurgen van het Leyenburg ziekenhuis in Den Haag:

Jon Bruijn, Napoleon Coene, Frank Faber en Dolf Sauter. Hartelijk dank voor het perifere jaar van mijn orthopedische opleiding en de mogelijkheid om een prospectief gerandomiseerd onderzoek op te zetten naar brace behandeling bij unicompartimenele gonartrose.

De dames van het secretariaat van de afdeling orthopedie van het Erasmus MC:

Simone Bleeker, Viviane van Gent, Patricia Hil en Esther van der Vlies. Uitvoeren van wetenschappelijk onderzoek lukt niet zonder jullie. Ik wil jullie bedanken voor de gezelligheid en het regelen van diverse zaken.

Maatschap orthopedie Martini ziekenhuis in Groningen:

Carina Gerritsma-Bleeker, Jan Bolscher, Jos van Raaij, Maurits Sietsma en Remmelt Veen. Hartelijk dank voor de dagelijkse samenwerking en de stimulans om mijn promotie af te ronden. We zijn een goed team met ieder zijn eigen kwaliteiten. Helaas zal Remmelt Veen ons verlaten, maar gelukkig hebben we een goede wisselspeler gevonden in de persoon van Bas ten Have.

Dr. R. Deutman:

Beste Robbie, jij hebt me destijds enthousiast gemaakt om orthopedisch chirurg te worden. Een keuze co-assistentschap onder jouw begeleiding vonden ze destijds in de regio Zuid-Holland voldoende om mij voor de opleiding aan te nemen. Met veel plezier heb ik je praktijk in 2003 overgenomen.

Dr. W.K. Brouwer:
Lieve papa, jij hebt me altijd gemotiveerd om te promoveren. Je hebt de samenvatting leesbaar gemaakt voor een niet medicus. Verder heb je kritisch commentaar gegeven op mijn stellingen. Ik bewonder je werkdrive: tot en met 65e ga je vol gas door als opleider gynaecologie met de volledige dienstbelasting. Daarnaast heb je ook nog energie voor het voorzitterschap van het consilium en wetenschap. Om te relaxen ga je een rondje skeeleren of fietsen. Ik hoop dat ik op dezelfde wijze mijn carrière in de verre toekomst zal afsluiten.
Mw. T.A.E. Brouwer-Zijlstra:
Lieve mama, ik ben me ervan bewust dat door jouw ondersteuning papa zoveel activiteiten kan verrichten. Ook al ben je niet meer actief als specialist, je blijft geïnteresseerd in de geneeskunde. Ook jij hebt mijn samenvatting en stellingen kritisch doorgelezen zodat het zelfs voor anesthesiologen te volgen is. Dank hiervoor maar nog meer voor het feit dat je gewoon mijn moeder bent.
Als allerlaatste mijn basisgeluk lieve Margot, Jelle en Saar(tje):
Ik wil jullie bedanken voor de ondersteuning van mijn promotie, maar nog veel meer voor het feit dat ik elke dag en soms ook s'nachts van jullie mag genieten.

Curriculum Vitae

Reinoud Brouwer was born on May 31, 1969 in Hoogeveen, the Netherlands.
After graduating from the Stedelijk Gymnasium in Leeuwarden in 1988, he started his study of Medicine at the University of Groningen. In 1995 he registered as Doctor of Medicine.
In 1996 he worked as a resident at the thoracic surgery department of the University hospital in Groningen. In 1997 he started his training in general surgery at the Ikazia hospital in Rotterdam (Head: dr. H.F. Veen). In 1999 to 2003 his training in orthopaedic surgery was fulfilled: 3 years in the University Medical Centre Rotterdam (former Dijkzigt hospital; Head: prof. dr. J.A.N. Verhaar) and 1 year in the Haga hospital (former Leyenburg hospital; Head: dr. L.N.J.E.M Coene). Since 2003, he works as an orthopaedic surgeon at the Martini hospital in Groningen together with drs. J.D.H. Bolscher, dr. C.L.E. Gerritsma-Bleeker, dr. J.J.A.M. van Raaij, drs. M.S. Sietsma, dr. M.R. Veen (followed by drs. B.L.E.F. ten Have).
The author is married to Margot Brouwer-Bergsma, with whom he shares two children: Jelle and Saar(tje).