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ORIGINAL STUDY

Is there a difference in outcome between two types of valgus unloading braces? A randomized controlled trial

N. van Egmond, S. van Grinsven, C.J.M. van Loon

From the Rijnstate Hospital Arnhem, The Netherlands

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

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

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

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

Keywords : valgus unloading brace ; osteoarthritis ; knee ; RCT

Trial registration number: ID-number 2010/200, ABR nr.: NL32412.091.10, 27-09-2010

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INTRODUCTION

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

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

■ N. van Egmond, MD.
■ S. van Grinsven, MSc, PhD.
■ C.J.M. van Loon, MD, PhD.
Department of Orthopaedics, Rijnstate Hospital Arnhem
Correspondence : Nienke Van Egmond, MD, Department of Orthopaedics, Rijnstate Hospital Arnhem, Wagnerlaan 55, 6800 TA Arnhem, The Netherlands.
E-mail : nienkevanegmond@hotmail.com.
Tel: +3188-0058888, Fax: +3188-0057878
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suggests that these unloader braces decrease disease progression which could delay the need for operative treatment, which is desirable in young patients *(1,3)*. Operative treatment is not suitable for every patient, because of medical comorbidity, old age or other circumstances. In several patient studies, OA related symptom-relief and functional improvement were found after treatment with valgus bracing *(1,4,9,11,15,18-20,26,32)*. A recent Cochrane review, however, concluded that there is only little low-quality evidence for the effectiveness of bracing in the treatment of medial compartment knee OA*(6)*.

Another problem is, that the compliance to use the brace is poor *(6,31,33)*. As most unloading braces are expensive it is important to know what the reason is of non-compliance, and if there is a difference in non-compliance between different kinds of braces. To our knowledge no other study has compared the effectiveness, complications and compliance of two different kinds of valgus unloading braces in a RCT. Therefore, the objective of this study was to compare the effectiveness of two different kinds of valgus unloading braces (the Bledsoe Thruster brace (B&Co Inc. N.V., Sint-Antelinks, Belgium) and the SofTec OA Brace (Bauerfeind AG, Zeulenroda-Triebes, Germany)) in the management of patients with medial knee OA and varus leg alignment after 2 and 12 weeks follow-up. The Bledsoe Thruster brace has a dual-hinged strut and a larger moment than the SofTec OA brace and on that account it is expected to be a mechanical stronger brace. The SofTec OA brace has airchambers for valgus force and on that account it is expected to be a more comfortable brace. Because of the differences in brace design we therefore hypothesised that the Bledsoe group would show a significant lower VAS pain (primary outcome) compared to the SofTec OA group at 2 and 12 weeks. As to our secondary outcomes we hypothesised that the Bledsoe group would have superior scores considering the Dutch Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), SF-12, 6-Minutes Walking Test, hip-knee-ankle alignment and analgesic use. On the other hand, we hypothesised that the SofTec OA group would over class the Bledsoe group in VAS satisfaction, number of complication and compliance.

PATIENTS AND METHODS

Study design and patients

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

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

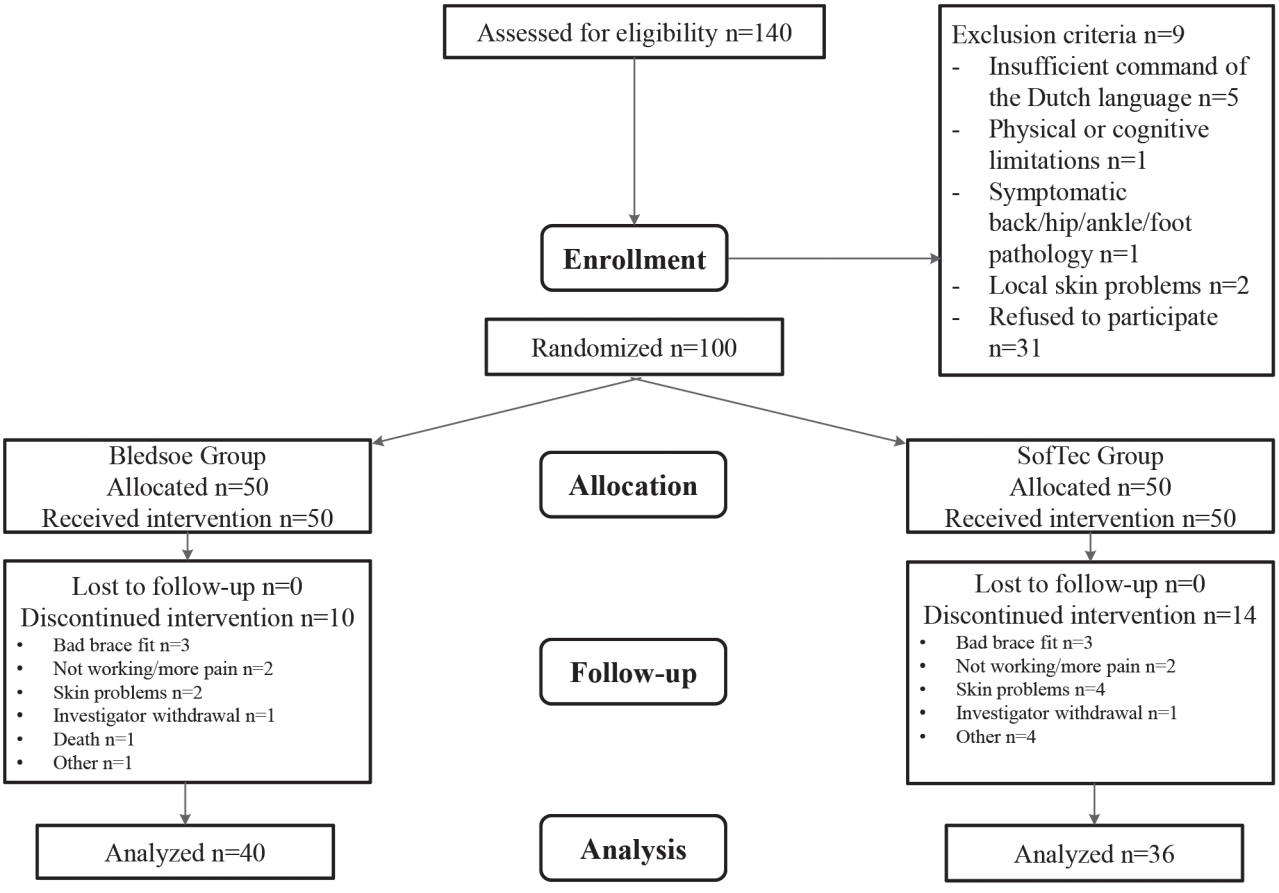

Fig.1. — Flowchart
Randomization and blinding

Braces

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

Clinical outcomes

The primary outcome was VAS pain (range 0-10) at 2 and 12 weeks. Secondary outcomes were VAS satisfaction (range 0-10), WOMAC (0-96 scale, with zero as optimum score) (25), the SF-12® (Quality Metric, Lincoln, RI, mental component summary (MCS) and a physical component summary (PCS), range 0-100, mean score 50, SD 10) and the 6-Minutes Walking Test (6MWT) (distance in meters) at 2 and 12 weeks. During the 12 weeks follow-up period, patients kept a diary in which they recorded analgesic use, complications and compliance (the mean number of hours per week they used the brace).

Fig. 2. — Bledsoe Thruster Brace

Radiographic outcomes

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

Statistics

At baseline, 2 and 12 weeks total test scores (mean or median, standard deviation (SD) or range, frequencies or percentages) were calculated for continuous and categorical variables for each of the 2 treatment groups. To assess normality, we used the Kolmogorov–Smirnov and Shapiro–Wilk tests. The Levene test was used to check the assumption of equal group variance.

The Student's t-test or Mann–Whitney U test was used to analyse differences in continuous data at 2 and 12 weeks follow-up between treatment groups. The Fisher's exact test or Chi-squared test was used in case of categorical variables. The paired t test or Wilcoxon signed rank test was used to analyse differences in numerical data between baseline and 12 weeks follow-up per treatment group. A $P < 0.05$ was considered significant. All data were analysed with SPSS version 20.0 (SPSS Benelux BV, IBM Company Nieuwegein, The Netherlands).

The sample size calculation was based on a baseline mean score for pain (VAS, 0-10) of 6.0 and a standard deviation SD of 2.2 (2). We estimated that a 1.5-point difference in VAS between both groups would represent a clinical relevant difference. To detect such a difference with two-sided testing (α=0.05 and power of 80%) 34 patients in each

Fig. 3. — SofTec OA brace

Table I. — Demographics

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

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

Table II . — Baseline parameters

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

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

group would be needed. With the assumption of 15% rate of loss to follow-up 80 patients should be included. After almost 2 years of study execution, the actual loss to follow-up was 30% and higher than anticipated. Approval of the Medical Ethics Committee (Radboud University Medical Centre Nijmegen, ID-number 2010/200, ABR nr. : NL32412.091.10) was obtained to include 100 instead of 80 patients to generate the necessary power for this study.

RESULTS

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

Complications and compliance

Analgesic use, compliance and complications at 2 and 12 weeks follow-up are shown in Table V. Patients reported complications mainly at 2 weeks (Bledsoe group 78.0%), SofTec OA group

Table III. — Results at 2 and 12 weeks follow-up (between group differences)

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

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

Table IV. — Results at 12 weeks follow-up (within group differences)

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

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

Table V.— Analgesic use, compliance and complications at 2 and 12 weeks follow-up

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

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

73.0%), but this reduced at 12 weeks (Bledsoe group 40.5%), SofTec OA group 46.9%). Only minor complications were reported. There were no significant differences between the Bledsoe and the SofTec OA group. 24% of the patients discontinued using their brace for several reasons.

DISCUSSION

The most important finding of our study is that there was no difference in clinical and radiographic outcomes between the Bledsoe Thruster brace and the SofTec OA brace after 2 and 12 weeks follow-up. Both groups showed improvement in the clinical outcomes after 12 weeks follow-up compared to baseline, thereby proving their short-term effectiveness.

No differences in clinical outcomes between two types of valgus unloading braces was shown in this study. No study compared two different kinds of valgus unloading braces before, but Dessery et al.*(4)* conducted a crossover trial in 24 patients, with three different types of braces, of which one was a valgus unloading brace : an ACL brace (ACL Orthoconcepts Inc.), a valgus unloading brace (V3P Orthoconcepts Inc.) and an unloader brace with valgus and external rotation (VER Orthoconcepts Inc.). They found that the three braces provide similar pain relief and improvement in function and gait. The VER brace seemed to offer a slight comfort advantage.

Although no differences in clinical outcomes between the two valgus unloading braces was found, their effectiveness at 12 weeks was proven. Our results are confirmed in previous literature *(1,2,12,15,32)*. Brouwer et al. *(2)* performed a RCT comparing an intervention group of 60 patients (conservative treatment with additional brace (OAsys valgus unloader brace) treatment) with a control group of 57 patients (conservative treatment alone) and found significant better results in VAS pain, functional outcome, walking distance and quality of life in the intervention group after a follow-up of 3, 6 and 12 months. Hunter et al. *(12)* compared an active treatment (DonJoy OAdjuster valgus unloader knee brace with customised neutral foot orthoses and motion control shoes) with a control treatment (a neutral knee brace with unsupportive foot orthoses and shoes with a flexible mid-sole) in 80 patients with symptomatic medial knee OA. They concluded that a multi-modal realignment treatment (i.e. the active treatment) is the most effective treatment in patients with medial knee OA.

The mean HKA in both groups did not significant change from baseline to 12 weeks, and there was no significant difference between both groups. These results were also found in studies of van Raaij et al.(32) (MOS genu valgus unloader brace) and Horlick et al. *(8)* (GII valgus unloader brace). Although valgus unloader braces seem to fail in changing malalignment on whole leg radiographs, this is only a static measurement. Dynamic gait studies showed reduction in adduction moment of the knee in patients wearing a valgus unloading brace *(18,19,21,30)*. So the improvement of our

clinical results could therefore be explained by unloading the medial compartment during gait and not by changing the HKA on whole leg radiographs.

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

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

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

Also the high percentage of minor complications (e.g. bad fit, skin irritation, blisters) could have contributed to non-compliance in both braces. Main reasons for discontinue using the braces were mostly these minor complications (bad brace fit (n=6), more pain (n=4) and skin problems (n=6), (Fig. 1). Squyer et al. *(31)* suggested that some patients may be easier to fit than others and that bad brace fitting leads to non-compliance and complications. The type and number of complications in our study are in line with those reported in previous literature, were a complication rate of approximately 42% is reported *(2,19,20,31,32)*.

This study had some limitations. First, 24% of the patients discontinued using their brace, which could have introduced selection bias. This percentage is however not higher when compared to previous literature *(2,8,19,31,33)*. Second, some information bias could have been introduced, because blinding of the patient and investigator was not possible due to the type of intervention. The investigator who analysed the intervention effect was however blinded, reducing information bias to its minimum. Third, we did not to use a control group (or a placebo treatment) to establish the changes in outcome that are entirely due to the intervention. However, the main purpose of this study was to determine the difference in effectiveness between

to different kinds of valgus unloading brace types. Fourth, the follow-up was only 12 weeks. The long-term differences between the two brace types have still to be determined.

CONCLUSIONS

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

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