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Valgus bracing in symptomatic varus malalignment for testing the expectable "unloading effect" following valgus high tibial osteotomy

Philipp Minzlaff · Tim Saier · Peter U. Brucker · Bernhard Haller · Andreas B. Imhoff · Stefan Hinterwimmer

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Abstract
Purpose The purpose of this study was to evaluate whether the expectable postoperative pain relief following valgus high tibial osteotomy (HTO) is reliably predictable with the temporary use of an unloading knee brace preoperatively.
Methods Fifty-seven patients with symptomatic varus malalignment were treated with a valgus producing unloading knee brace for 6–8 weeks. The pain intensity in the respective knee compartment was monitored using the visual analogue scale (VAS) before and following this treatment. A "positive" Brace-Test was defined as a pain relief medially without initiated symptoms laterally. In these cases, a valgus HTO was suggested as a promising surgical option. Patients who were subsequently operated were clinically re-evaluated 1 year postoperatively to compare the postoperative outcome with the result of the Brace-Test.
Results The mean VAS score decreased from 6.7 [standard deviation (SD) 1.6] to 2.5 points (SD 1.7) ($p < 0.001$) following the Brace-Test. Overall, 48 patients had a positive test. A valgus HTO was performed in 29 of them. The mean postoperative VAS score was 1.9 (SD 1.7) points with no difference to the result of the test (n.s.). Nineteen patients with a positive test initially decided for a conservative treatment. In three of nine patients with a negative test, a total knee replacement was performed.
Conclusion This study shows that the temporary use of an unloading valgus producing knee brace may well predict future outcome of HTO surgery in terms of expectable postoperative pain relief. The Brace-Test gives both the patient and the orthopaedic surgeon more detailed preoperative information, especially in critical or borderline indications. Thus, it is a useful tool to test the unloading effect before indicating an HTO.
Level of evidence III.

Keywords High tibial osteotomy · Malalignment · Osteoarthritis · Unloading brace · Brace-Test

Introduction

Osteoarthritis of the knee is one of the most common joint disorders and represents a major public health problem [11, 13]. Usually, in early stages of osteoarthritis, not the entire knee joint is degenerated. Particularly in case of varus malalignment, only the medial compartment is mainly affected and symptomatic [6, 8]. In these cases, unloading the affected compartment is an accepted and successful treatment option to relieve the symptoms [6, 33, 34]. This can be achieved non-invasively using malalignment adjusting braces [5, 7, 29]. A three-point force system with an adjustable constant abduction (valgus) moment is applied directly at the knee and leads to slight but measureable unilateral separation of the femorotibial joint

P. Minzlaff · T. Saier · P. U. Brucker · A. B. Imhoff · S. Hinterwimmer
Department for Orthopaedic Sportsmedicine, Technische Universitaet Muenchen, Munich, Germany

B. Haller
Institute of Medical Statistics and Epidemiology, Technische Universitaet Muechnen, Munich, Germany

A. B. Imhoff (✉)
Orthopaedic Surgery and Traumatology, Department of Orthopaedic Sports Medicine, Klinikum Rechts der Isar, Technische Universität Muenchen, Ismaningerstr. 22, 81675 Munich, Germany
e-mail: a.imhoff@lrz.tum.de; imhoff@tum.de; a.imhoff@sportortho.de

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space and consecutive pain relief in the affected compartment [9, 29].

Among all surgical options, a valgus high tibial osteotomy (HTO) is the most established option to unload the medial compartment by mechanically shifting the weight-bearing axis to the asymptomatic compartment with good-to-excellent results in mid- and long-term studies [1, 2, 5, 12, 18, 23, 34].

The International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine have formulated criteria for the ideal HTO patient in 2004 [5]. In detail, these patients are active, between 40 and 60 years of age with a body mass index (BMI) <30 kg/m^2 and isolated medial joint-line pain [5]. However, sometimes not all of these criteria are met or patients additionally present with clinical findings like tenderness to palpation or low-grade cartilage defects in the non-affected compartment. These combinations may lead to reasonable doubts in indicating and performing an osteotomy promptly. Furthermore, even if the indication of an osteotomy is clear from a physician's perspective, the patient may still be sceptic due to the invasiveness of the surgery.

Therefore, the hypothesis of this study was that unloading of the medial compartment in patients with symptomatic varus malalignment leads to significant knee pain reduction and can be achieved either by using a valgus producing knee brace or by performing a valgus HTO with comparable results. Aim was to evaluate whether the postoperative pain status following valgus HTO can be reliably predicted doing a temporarily unloading knee bracing preoperatively in order to establish a test (Brace-Test) to identify appropriate candidates or verify the indication.

Materials and methods

From 2008 to 2011, 57 patients with symptomatic varus malalignment were prospectively enrolled. Inclusion criteria were femorotibial varus deformity (>2° on full-leg weight-bearing radiographs) in combination with high-grade chondral lesions in the affected compartment as grade III/IV according to the Outerbridge classification system in the MRI and medial knee osteoarthritis seen on radiographs with a minimum of grade I according to the radiographic classification of Kellgren and Lawrence [19, 27]. The original Outerbridge classification was not based on MRI but is widely accepted by the "orthopaedic community" to be used with MRI [4, 25]. All of these patients were non-responder for conservative treatment (analgetic therapy, physiotherapy, and weight reduction) within the corresponding compartment. They did not want to decide for a correcting osteotomy but were subjectively sceptic for an expectable pain relieving unloading effect at the time of consultation or had tenderness at the non-symptomatic compartment or small and low-grade cartilage defects in the non-symptomatic contralateral compartment [27].

Exclusion criteria were high-grade chondral lesions in the lateral compartment seen on MRI (>3 according to Outerbridge), insufficiency of the anterior or posterior cruciate ligament, skin lesions around the knee or previous valgus bracing, or a flexion contracture of >25°.

The mean age was 49.9 years [range 25–73; standard deviation (SD) 9.1], and the mean BMI was 27.0 kg/m^2 (range 20–37; SD 3.6). Four patients were younger than 40 years and six patients older than 60 years. Overall, there were 19 (33.3 %) females and 38 (66.6 %) males with 23 (40.4 %) right and 34 (59.6 %) left knees affected.

Clinical and radiological examination

The history of all patients included previous knee surgeries as well as knee pain intensity and localization (medial/lateral) during activities of daily life. For quantification of the pain intensity at the symptomatic compartment, the visual analogue scale (VAS) was used [15]. A standardized clinical examination of the knee was performed by a resident who was not mainly involved in patient's treatment under the supervision of an orthopaedic surgeon specialized in knee surgery (P.U.B., A.B.I., S.H.). In addition to the clinical findings in the symptomatic compartment, tenderness to palpation in the non-symptomatic compartment was further tested and documented. Overall, 14 patients (24.6 %) presented tenderness to palpation in the non-symptomatic compartment. Moreover, 47 patients (82.5 %) were sceptic for a valgus HTO at the primary consultation.

The deviation of the leg axis was measured on a full-leg weight-bearing radiography, and the degree of joint degeneration was classified according to the grading scale of Kellgren and Lawrence on radiographs (anterior–posterior, lateral, and patella axial) [19].

The cartilage lesions of the symptomatic knee were graduated on MRI according to the Outerbridge classification [27]. The data of the varus malalignment as well as the osteoarthritic and cartilage lesion grading are listed in Table 1. In addition, small chondral lesions in the non-symptomatic compartment were found in 30 knees (52.6 %) (grade I/II $n = 26$; grade III $n = 2$; small osteochondral lesions $n = 2$).

Overall, a valgus HTO to unload the symptomatic medial compartment was suggested as the adequate therapeutic option in all cases.

Brace-Test

A valgus force applying knee brace (M4 OA^{TM} varus; Medi$^{®}$ GmbH, Bayreuth, Germany) was provided for

Table 1 Malalignment, cartilage lesion, and osteoarthritis grade of the study population

	Mean	Standard deviation	Minimum	Maximum
Varus malalignment (°)	4.5	2.6	2.0	12.0
			n	%
Osteoarthritis (Kellgren and Lawrence)				
Grade 1			9	15.8
Grade 2			25	43.8
Grade 3			16	28.1
Grade 4			7	12.3
Cartilage defect medical compartment (Outerbridge)				
Grade 1			0	0.0
Grade 2			2	3.5
Grade 3			16	28.1
Grade 4			39	68.4
Cartilage defect patella (Outerbridge)				
No defect			16	28.1
Grade 1			8	14.0
Grade 2			7	12.3
Grade 3			16	28.1
Grade 4			10	17.5
Cartilage defect lateral compartment (Outerbridge)				
No defect			27	47.4
Grade 1/2			26	45.6
Grade 3			2	3.5
Grade 4			0	0.0
Small osteochondral lesion			2	3.5

permanent daily use (from getting up in the morning until going to bed at night) including full weight bearing for 6–8 weeks to simulate the effect of a correcting osteotomy. After this time frame, a beneficial brace effect has been shown before [20]. The applied valgus moment depended on the individual patients' tolerance. An orthopaedic technician adjusted the primary setting, and patients were instructed to readjust the brace during the treatment period. The VAS score was subsequently re-evaluated, and patients were re-examined with special focus on the decrease in pain within the symptomatic medial compartment as well as newly initiated symptoms in the previously non-symptomatic lateral compartment during activities of daily life. Furthermore, it was documented whether wearing the brace was uncomfortable.

The Brace-Test was stated "positive" in case of pain relief medially without pain generation laterally. In these cases, the beneficial unloading effect was confirmed and an osteotomy was suggested as a promising surgical treatment option with respect to the overall pain relief postoperatively.

The Brace-Test was rated "negative" in case of insufficient pain relief or newly initiated symptoms in the previously non-symptomatic lateral compartment. In these cases, unloading the compartment with an osteotomy was therefore not recommended and other surgical options were proposed (partial or total knee replacement).

In case of a subsequently performed valgus HTO following a positive Brace-Test, patients were re-evaluated 1 year postoperatively. The postoperative VAS score at this time was compared to the result of the Brace-Test.

Surgical procedure

In supine position, the cartilage status in the patellofemoral and medial and lateral femorotibial compartments was evaluated by arthroscopy. The correction target was determined depending on the difference of chondromalacia between the medial and lateral compartments according to Mueller and Strecker, and a valgus open-wedge HTO was performed in the technique previously described by Hinterwimmer et al. [16, 26]. The osteotomy was gradually opened by preserving a lateral bony bridge and fixed with a self-locking plate (Tomofix™, DePuy-Synthes®, Solothurn/Switzerland, or Peek Power Plate™, Arthrex®, Naples, FL).

The Ethics Committee of the medical school of the "Technische Universität München" approved the study from an ethical and legal point of view (IRB Nr. 5562/12). All patients agreed to participate in this study.

Statistical analysis

The Statistical Package for Social Sciences (SPSS, version 20, SPSS Inc. Chicago, IL, USA) was used for analysis. Absolute and relative frequencies are shown for categorical data. For quantitative data means, minima, maxima, and standard deviations are presented. To compare the VAS scores (before and following the Brace-Test; following the Brace-Test and 1 year postoperative after valgus HTO), the *t* test for dependent samples was used.

The Brace-Test was defined to be predictable for the final outcome, if the VAS score 1 year postoperatively following valgus HTO was not worse than one point compared to the VAS score following the Brace-Test.

Number and proportion of patients with a predictable Brace-Test are presented. An exact 95 % confidence interval (CI) was used for the proportion of predictable Brace-Test.

To assess the association between the amount of varus malalignment, BMI, age, and the reduction in the VAS score following the Brace-Test, the Pearson's correlation coefficient was calculated.

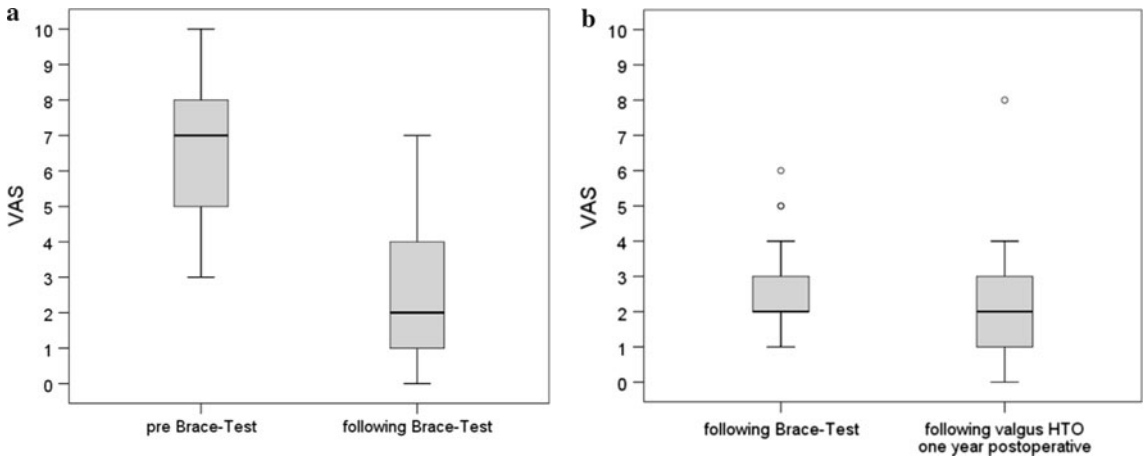

Fig. 1 *Box-plot* graphs showing the pain level using the VAS score before and after the Brace-Test of all included patients (**a**) and the VAS result of the Brace-Test and the VAS score of all operated patients 1 year after valgus HTO (**b**). These diagrams include the median (*line* across the *box*), the quartiles (inferior and superior boarder of the *box*), and the extreme values. The *box* represents 50 % of the range, the whiskers extend to the highest and lowest values, and *circles* represent outliers

All statistical tests were performed two-sided, and p value <0.05 was considered to indicate statistical significance.

Results

All patients of the study population had pain in the affected compartment during activities of daily life with a mean VAS score of 6.7 (range 3–10; SD 1.6). After the Brace-Test, the mean VAS score decreased significantly ($p < 0.001$) to 2.5 (range 0–7; SD 1.7; Fig. 1a) with pain relief in the medial compartment in 53 (93.0 %) patients. Five of these 53 (9.4 %) patients developed additional symptoms laterally during activities of daily life. Four of 57 (7.0 %) patients were non-responder to the Brace-Test. These patients not present a pain relief within the affected compartment, and one of them developed additional pain in the initially non-symptomatic lateral compartment (Fig. 2). All patients completed the temporary brace treatment, but 31 (54.4 %) patients stated the wearing of the brace as impractical and reported about discomfort due to the valgus applying force resulting in skin irritations in some cases.

A valgus producing medial open-wedge HTO was performed in 29 of 48 (60.4 %) patients with a "positive" Brace-Test. The amount of correction was based on the recommendations published by Mueller and Strecker [26] and targeted at 50 % of the medio-lateral tibia plateau in one, at 55 % in 17, at 58 % in one, and at 62 % in ten patients depending on the difference of chondromalacia between the compartment to be unloaded (medial) and the compartment to be loaded (lateral) found arthroscopically prior to osteotomy.

One year postoperatively, the mean VAS score was 1.9 (range 0–8; SD 1.7; Fig. 1b) in these patients. None of them developed pain in the lateral compartment. There was no statistical difference between the VAS score following the Brace-Test and the postoperative result after valgus HTO (n.s.). In detail, the VAS score postoperatively was equal to the Brace-Test result in ten (34.5 %), better in 13 (44.8 %), and worse than one point in three (10.3 %) patients. According to our definition, the Brace-Test was able to predict the final outcome in 26 of 29 (89.6 %) patients (95 % CI 72.6–97.8 %). The VAS score decreased in one patient from 1 to 3, in one case from 2 to 4, and in one patient from 2 to 8.

There was statistically no significant correlation between the amount of varus malalignment (n.s.), the BMI (n.s.), the age (n.s.), and the reduction in the VAS score following the Brace-Test.

Overall, 19 (39.6 %) patients with a positive Brace-Test decided for a conservative treatment and refused an operation due to their occupational activity or private circumstances. Eleven of them initially continued the brace treatment. Six of them quit this treatment within 1 year due to fussiness, incommodiousness, bad fit, skin lesions, or claims from their health insurance. Five patients kept on wearing the brace in case of expected physical stress.

Without the device, three of the 19 patients with grade IV ($n = 2$)/grade III ($n = 1$) lesions medially without any chondral lesions laterally ($n = 3$) who decided for a conservative treatment despite a positive Brace-Test had no deterioration without the device after 1 year and maintained the result of the test.

In three patients with grade IV defects medially ($n = 3$), grade 0 ($n = 1$)/grade 2 ($n = 1$)/grade 3 ($n = 1$) defects

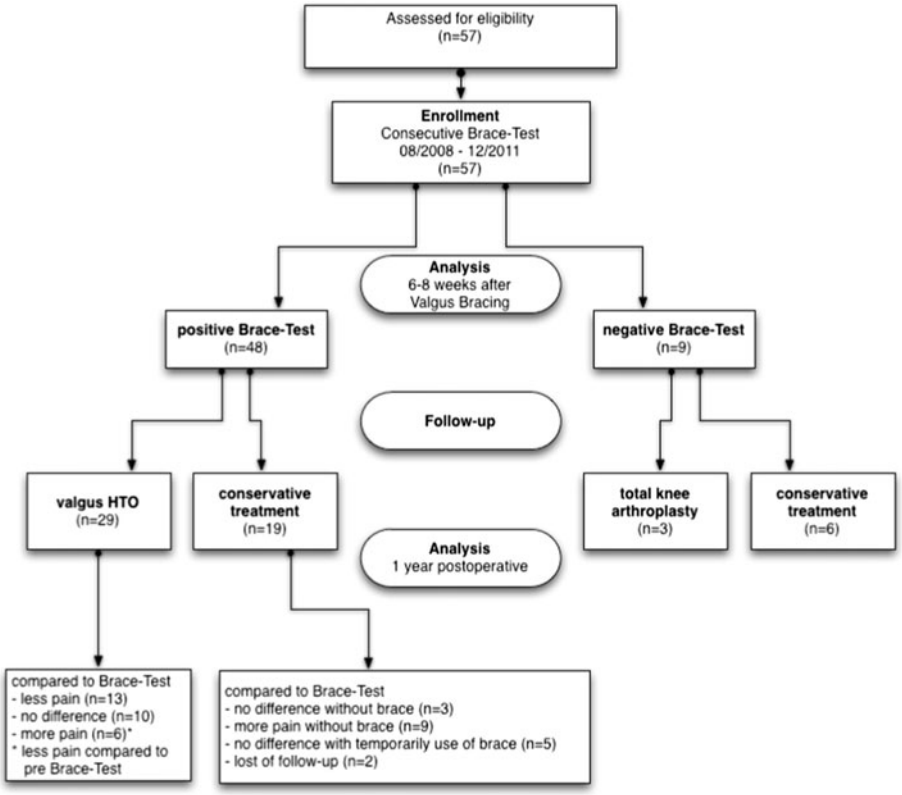

Fig. 2 Flowchart of patients' enrolment

laterally, and grade 0 ($n = 1$)/grade 2 ($n = 1$)/grade 3 ($n = 1$) lesions patellofemoral out of nine subjects with a negative Brace-Test, a total knee replacement was performed (Fig. 2).

Discussion

The main finding of the study is that unloading of the medial compartment in case of symptomatic varus malalignment leads to significant pain reduction in the affected compartment and can be achieved either non-invasively by using a malalignment adjusting brace or invasively by valgus HTO with no significant difference between these two treatment alternatives.

There are several conservative and surgical options available to relieve symptoms by reducing the unphysiological joint loading due to malalignment [34]. In this study, a valgus HTO was considered as an adequate surgical option. All patients suffered from symptomatic unicompartmental osteoarthritis of the knee due to varus malalignment, which can be well addressed by valgus HTO [1, 2, 18]. However, from a patients' perspective, 82.5 % of the included patients were initially sceptic regarding the invasiveness of an osteotomy. In addition, positive clinical findings and low-grade chondral alterations in the MRI were found in 24.6 % and in 52.6 % of the contralateral compartment, respectively, which may led the orthopaedic surgeon being cautious in indicating a correcting osteotomy. Due to the unpredictable effect of a correcting osteotomy on even non-symptomatic structural alterations within the contralateral compartment, a non-invasive simulation for testing the consequences of a correcting osteotomy on these alterations would be beneficial for both the patient and the orthopaedic surgeon.

The aim of this prospective descriptive case series was therefore to evaluate the predictive value of wearing a valgus producing knee brace on the effect of pain relief after a valgus producing osteotomy. This trial was initiated to prove whether the—at least temporary—benefit of a malalignment correcting brace would lead to similar clinical results compared to the postoperative outcome of a correcting osteotomy. We evaluated a preliminary conservative therapeutic treatment option for simulation of a surgical malalignment correction as close as possible to establish a tool predicting the expectable pain reduction and selecting the proper patients.

Overall, the results of our study demonstrated a significant pain reduction within the affected compartment following 6–8 weeks of wearing a valgus producing knee brace in 93 % of the patients. In four patients, who were classified as non-responders, however, unloading the symptomatic compartment with a brace did not relieve the symptoms due to a remaining symptomatic meniscal tear,

adjacent grade IV chondral lesions in the medial trochlea groove, osteonecrosis of the medial compartment, and a varus malalignment >6°. In the latter case, the observation that patients with less malalignment tended to better clinical results with respect to the VAS score following the Brace-Test might be the reason for this failure. However, this observation was statistically not significant.

The unloading brace led to pain relief in the symptomatic compartment without initiating symptoms in the lateral compartment in 84.2 %. This was stated as a positive test result. In these patients, a valgus HTO was considered as a proper surgical option. Subsequently, 60.4 % of these patients were operated. All of them had a beneficial effect after 1 year postoperatively with significant pain reduction medially without initiated symptoms laterally. There was no significant difference in the VAS score after the treatment with the brace and the osteotomy. This finding is probably due to the unloading effect of the affected compartment, which can be achieved either by an osteotomy or by an unloading brace. Our results show that a positive Brace-Test may be useful for the selection of eligible patients for an osteotomy in critical or borderline indications and also to predict the postoperative pain relief. In three patients, the postoperative VAS score was worse than one point compared to the result of the Brace-Test. However, only in one case, there was a difference in more than two points. This patient had remarkable irritations due to the medially lying plate implant, which might be the causative factor.

Despite 54.4 % stated the Brace-Test "uncomfortable", 22.9 % of patients with a positive Brace-Test initially continued the treatment. However, the compliance due to the device decreased within 1 year. Overall, 10.4 % of patients with a positive effect kept on temporarily using the device after 1 year. A durable beneficial effect without the brace was rarely seen in our study ($n = 3$). This was achieved by using wedged insoles ($n = 1$) or reducing strain force due to avoiding physical stress in context of sporting activities ($n = 1$), or marked body-weight loss ($n = 1$). These results show that unloading of the symptomatic compartment is crucial to maintain a durable benefit.

Despite Krohn et al. concluded a beneficial effect by the use of foot orthoses, several randomized controlled trials failed to demonstrate durable improvement with lateral heel wedges in medial compartment gonarthrosis [3, 22, 24, 28]. Better clinical results and a reduction in the varus moment were attained with the use of unloading knee braces [22, 31, 32]. Haladik et al. [14] reported about a significantly improved WOMAC score without an increased joint space in ten patients treated with an unloading brace. Pollo et al. [31] showed a reduction in the knee varus moment of 13 % and the medial compartment load of 11 % on average, which was associated with a decreased pain and increased activity level. Komistek et al. [21] measured a 1.2-mm change in joint space width using a fluoroscopic digital radiograph in patients treated with an unloading brace. Dennis et al. [9] showed a condylar separation in degenerative compartments by video-based fluoroscopy during gait, which demonstrated the clinical effectiveness of a valgus producing brace due to the change in the alignment. In contrast, a randomized clinical trial by Brouwer et al. [7] found only a small difference in pain relief between patients treated with a brace and those without using a brace after twelve months with borderline significance. However, noncompliance due to discomfort, bulkiness, and cumbersomeness was high in this study. In fact, only 58.3 % patients completed the twelve months brace treatment [7]. In our study, all patients completed the Brace-Test within the recommended period, but often characterized the bracing as uncomfortable and impractical.

The intension of this survey was to analyse the effect on pain reduction or transformation following a 6–8-week period of unloading the knee with a brace in order to predict the clinical effect of a valgus HTO, especially in sceptic patients or critical and borderline indications. However, despite a high predictability was observed in our data, further investigations are necessary to assure the correlation between the results of both treatment modalities after an increased follow-up.

There are some limitations in this study. There is no control group, which was given a standard off-the-shelf hinged non-offloading knee brace. For this reason, a potential placebo effect of the unloading brace cannot be completely eliminated. However, previous studies showed medial condylar separation, decreased medial compartment loads and knee adduction moments and superior clinical results with an unloading brace [10, 17, 20, 30, 31]. Further, there is a patient selection bias, since there was a significant patient number with a positive Brace-Test who did not subsequently receive a correcting osteotomy. In addition, we cannot state how patients with a negative Brace-Test would perform following a secondary osteotomy due to ethical aspects.

However, a Brace-Test does give both the patient and the orthopaedic surgeon more detailed preoperative information regarding the factor malalignment and corresponding pain level and is a helpful option to test the expectable unloading effect following an osteotomy. It can be used in the day-by-day clinical work to select proper patients for a valgus HTO.

Conclusion

This study shows that the temporary use of an unloading valgus producing knee brace may well predict future

outcome of HTO surgery in terms of expectable postoperative pain relief. This gives both the patient and the orthopaedic surgeon more detailed preoperative information, especially in critical or borderline indications.

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