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Short term results of dynamic splinting for hallux valgus — A prospective randomized study

Christian Plaass, Annika Karch, Armin Koch, Vivien Wiederhoeft, Sarah Ettinger, Leif Claassen, Kiriakos Daniilidisa, Daiwei Yao, Christina Stukenborg-Colsman

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Short term results of dynamic splinting for hallux valgus – A prospective randomized study

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\textbf{ABSTRACT}

Background Hallux valgus is a common diagnosis in orthopedics. Only a few studies have analyzed the effects of conservative therapy. Therefore, the current study analyzed the effect of a dynamic hallux valgus splint.

Methods Seventy patients were included in this prospective randomized trial. Patients with a hallux valgus were treated using a dynamic splint or underwent no treatment. Clinical and radiological parameters were evaluated.

Results We found no significant changes in hallux valgus angle, intermetatarsal I–II angle, AOFAS score, FAOS or SF-36 score between the groups. However, a significant between-group difference was found for pain during walking and running and in the FAOS subscale for pain and pain at rest at follow-up.

Conclusions Wearing a dynamic hallux valgus splint does provide some pain relief in patients with a symptomatic hallux valgus, but showed no effect on hallux valgus position.

Level of evidence: I.

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1. Introduction

Hallux valgus (HV) is one of the most common diagnoses in orthopedic practice. The prevalence of radiologic HV is up to 23\% in 18–65 year old women and >35\% in women older than 65\% [1]. Approximately half of these cases can become symptomatic. Women in their fifth to sixth decade are most often affected, and children show an incidence of 2\% [1,2]. The etiology of HV is not completely understood and appears to be multifactorial. Family history, female gender, occupational foot stress, shoe style and configuration of the first metatarsal and the first metatarso-phalangeal joint (MTP 1), have been correlated with HV [2–4].

Different conservative treatment options have been proposed for first-line treatment, including different kinds of physiotherapy (PT), orthoses and splints [5,6].

Orthoses have been proposed to reduce the elevated plantar pressure under the medial ray in patients with HV and reduce pain [7–9]. When combined with a toe separator, orthosis may also help to correct alignment, at least when the orthoses are used consistently [10]. In a prospective series examining the effect of orthosis on juvenile and adult HV patients, no effect on HV position and progression was observed [11,12]. Two-thirds of the patients treated using an orthosis for HV still required surgery, which is comparable to patients who do not receive orthosis [13].

Splints are used in the treatment of HV, mostly postoperatively, to secure the soft-tissue balancing [14,15]. Du Plessis et al. [5] found a reduction in pain in patients wearing night splints, but less than in patients treated using manual therapy and they did not assess the influence of HV position. Milachowski and Kraus [16] showed a reduction of the hallux valgus angle (HVA) through a worn HV splint, but did not analyze the effect on pain or function.

A method to improve joint mobility used in many areas of orthopedic treatment is continuous traction on a joint. Previously, a dynamic Quengel splint for HV treatment has been shown to reduce the HVA, but no clinical data were collected [17].

To evaluate the clinical and radiological effect on HV of a dynamic splint, a prospective randomized study was performed.

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2. Material and methods

2.1. Study design

Between May 2011 and October 2013, patients scheduled for a surgical HV correction were included in a prospective randomized single-center study. The study was approved by the relevant ethics committee (MHH Nr. 1009–2009) and registered at the German clinical trials register (DRKS00013920). All patients provided their written informed consent.

Inclusion criteria were symptomatic HV and the potential to wear the splint for at least 3 months. Exclusion criteria were hindfoot deformities, degenerative changes in the MTP 1, pre-operated hallux valgus, hereditary soft-tissue disease, inflammatory skin disease, circulatory disorders, polyneuropathy and BMI > 40.

Patients were included after a complete clinical and radiological analysis and a confirmed diagnosis. All patients underwent a meticulous clinical analysis and completed a questionnaire during the inclusion visit (baseline) and at follow-up, at least 3 months later. During the study period, periodically, telephone interviews were performed to evaluate for pain, toe position and compliance.

The patients were randomly assigned in a 1:1 ratio to either treatment using a HV orthosis or no treatment. Randomization was performed centrally via fax. Assessment of the radiological outcomes was observer-blind.

2.2. Patients

A total of 70 patients were initially randomized, and of these 36 were assigned to the intervention group. During the study period, 15 patients did not complete the study. In both groups, six patients declined to further participate in the study for personal reasons. In the control group, one patient did not undergo a follow-up x-ray for the primary outcome evaluation and two patients declined to further participate in the study because of an inability to handle the questionnaires. Therefore, 26 patients in the control group and 29 in the intervention group underwent a full clinical and radiological follow-up. There were no significant differences for gender (p = 0.331), age (p = 0.151), side (p = 0.113), weight (p = 0.907), height (0.820) and length of follow-up (p = 0.511) between both groups (Table 1). In both groups, 25% of the patients had previous experience of wearing HV splints.

2.3. Splint

All patients in the treatment group received a controlled dynamic stretch HV brace (halluxaan, Albrecht GmbH, Stephan- skirchen, Germany) (Fig. 1). The brace allows for a prolonged stretch to correct contracted soft tissue and influence the HV position. All patients in the treatment group were instructed to set the adjustable Quengel mechanism, such that there was no pain but a perceptible traction, and to wear the brace during their rest time for as long as tolerated.

2.4. Outcome measures

2.4.1. Radiologic parameters

Weight bearing anterior-posterior (a.p.) and lateral foot x-rays were performed for diagnosis and at follow-up. All radiographs were performed using a computed radiography system (PCR eleva, Philips Healthcare, Best, the Netherlands). The intermetatarsal 1–2 angle (IMA) and HVA were measured as the primary outcome of the study [18]. All radiographic parameters were analyzed by two investigators independently blinded to each other. All radiographic analyses were performed using a server-based imaging platform (Vue Pacs, Carestream, Stuttgart, Germany). The reader studies were performed using certified displays for diagnostic radiological review.

2.4.2. Clinical parameters

All patients underwent a meticulous clinical analysis at baseline and during the final follow-up. The following clinical parameters were documented: MTP 1 range of motion (ROM), metatarsalgia and any lesser toe deformities. The American Orthopedic Foot and Ankle Society - hallux metatarsophalangeal interphalangeal scale (AOFAS), the short form-36 (SF-36), foot and ankle outcome score (FAOS) and a numeric rating scale (NRS) for pain were evaluated.

All patients in the intervention group were asked to judge the splint comfort on a 10-point Likert scale

2.5. Statistics and randomization

Statistical analysis was performed using SAS 9.3. The difference of change of HVA between the treatment and control group was set as the primary outcome. Change in HVA was defined as the follow-up value minus the baseline value and a difference from baseline of 5° was judged as relevant. A sample size calculation was performed prior to the study on the base of a t-test for independent samples with an expected difference of at least 5° and an estimated standard deviation of 7. The one-sided α-error was set as 0.025 and the β-error as 0.2. This resulted in a required number of 32 patients per group, and with an estimated drop-out rate of 10%, a recruitment aim of 35 patients per group.

Primary analysis was performed using the intention-to-treat-population (ITT), and for sensitivity analysis a per-protocol-population (PP) was used. Missing values in the ITT analysis were replaced by last observation carried forward. Treatment groups were compared using analysis of variance (ANOVA) adjusted for HVA in the primary analysis. The estimation of the intraclass correlation coefficient (ICC) of the radiological assessments is based on variance components of a one-way analysis of variance. Secondary analyses of further quantitative study endpoints were performed using ANCOVA adjusted for the respective baseline value. For categorical outcomes chi-square tests were conducted. Secondary analyses were based on the PP population. Descriptive baseline analysis was performed with corresponding t-tests for numeric and chi-square tests for categorical data. A p-value of less than 0.05 was considered to indicate statistical significance.

Table 1

<table>
<thead>
<tr>
<th>Table 1 Patient demographics. Measures for quantitative variable are provided as mean, with standard deviation (SD) and range.</th>
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<tbody>
<tr>
<td>Control group</td>
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<td>n</td>
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<td>Age (y)</td>
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<td>Male gender</td>
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<td>Left side</td>
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<td>Weight (kg)</td>
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<tr>
<td>Height (cm)</td>
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<tr>
<td>Time to follow-up (month)</td>
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Fig. 1. Halluxsan (Albrecht GmbH, Stephanskirchen, Germany) dynamic HV splint. Using the turning wheel, the Quengel mechanism can be tensed. A scale shows the amount of pretension. Thick padding protects soft tissues from pressure.

3. Results

3.1. Radiographic parameters

Neither the baseline-, the follow-up, nor the change in HVA (p = 0.378; p = 0.358; p = 0.784) and IMA (p = 0.368; p = 0.484; p = 0.948) differed significantly between the groups (Table 2). The ICC for IMA at baseline was 0.91 (CI: 0.86–0.94) and at follow-up it was 0.87 (CI: 0.79–0.92) and for HVA the equivalent values were 0.97 (CI: 0.95–0.98) and 0.97 (CI: 0.95–0.98), respectively, indicating a very good inter-reader agreement.

3.2. Clinical parameters

At baseline there was no significant difference between the groups for any tested clinical parameter (Table 3). There was no significant change in the MTP 1 ROM, AOFAS and SF-36 mental or physical score during the follow-up. Likewise, changes in the FAOS subscales for symptoms, quality of life (QoL), activities of daily living (ADL) and sports showed no significant differences. Pain scores at rest and while starting walking showed no significant difference. A significant difference was found regarding pain during walking and running (p = 0.039; p = 0.0072) and a strong trend regarding the pain subscale of the FAOS score (p = 0.170) was observed, which also showed a significant difference between the groups at follow-up (p = 0.027). However, none of the treated patients rejected surgery because of the effect of the brace.

3.3. Brace

All patients in the intervention group used the splint during the whole study period. The mean wearing time was 6.04 (± 1.4; 3–7) nights per week. Most patients (63.3%; 15/23) wore the splint between 2–4 h a day, while 13.6% (3/23) wore it for a shorter time and 22.6% (5/23) for longer. All but one patient returning the patient diary (23/36) used the Quengel mechanism during the study period and increased the traction by 1.58 ± 2.4 half turns. Patients used the option to change the traction of the brace 3.13 (4.26; 0–18) times during the study period.

The design and handling of the brace was judged as good or very good (1.44 (1.12; 0–4)) by all but one (1/25) patient.

The mean pain score when wearing the splint was 3.39 (2.3; 0–9). A total of 43.5% (10/23) of the patients in the intervention group reported no or slight pain (NRS 0 to 2) when wearing the splint, while 30.4% (7/23) reported moderate pain (NRS 3–6) and 13% (3/23) reported severe pain (NRS > 7). The pain was located in the MTP 1 in 83.3% (16/19) of the treated patients, in the intermetatarsal in 11.1% (2/19) and in other locations in 5.6% (1/19). Pain when wearing the brace was constant during the study period in all but four patients. These reported strong or moderate pain relief when wearing the brace during the study period.

During the 12-week phone follow-up, only one (4%; 1/25) patient in the intervention group observed a subjective deterioration in the HV position, but three (12%, 3/25) observed a slight improvement in the HV position, after wearing the splint. In contrast, 29% (8/28) of patients in the control group observed a deterioration in the HV position and only 7% (2/28) observed an improvement (Table 4). While 16% (4/25) of the patients in the intervention group and 7% (2/28) in the control group experienced a reduction in HV pain, 12% (3/25) and 43% (12/28) experienced an increase, respectively.

A total of 80% (20/25) of the patients in the intervention group would recommend the splint to others.

4. Discussion

This prospective randomized study shows a reduction in pain during activity in patients with symptomatic HV when wearing a dynamic HV splint with a Quengel mechanism for several hours per day. Radiologically, no difference in the HV position was found, but fewer patients in the intervention group experienced a subjective deterioration in the HV position.

Table 2
Baseline and follow-up radiologic parameters are given as mean, standard deviation and range (HVA: hallux valgus angle; IMA: intermetatarsal 1–2 angle).

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Follow-up</th>
<th>Change from baseline</th>
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<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Intervention</td>
<td>p</td>
</tr>
<tr>
<td>HVA</td>
<td>33.5 (9.2; 16.3–56.3)</td>
<td>35.4 (8.6; 17.1–54.6)</td>
<td>0.378</td>
</tr>
<tr>
<td>IMA</td>
<td>14.7 (3.5; 7.3–24.5)</td>
<td>15.4 (3.0; 9.9–22.4)</td>
<td>0.368</td>
</tr>
</tbody>
</table>

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In general, our results concur with the recent literature. Because of the pathomechanism of HV, the effectiveness of a conservative treatment is questionable [19,20]. However, orthoses are the most commonly used orthopedic tool for painful foot diseases [21]. A pain reduction effect produced using orthosis or insoles is well described by the recent literature [7]. A review from Ramírez et al. describes a possible positive effect on pain, physical function and hindfoot position in conditions such as flexible pes planus [23].

There is also some evidence that in people of less than 60 years of age with a painful bunion and no limitations of MTP joint motion, orthosis is effective compared with no treatment [7]. As the pathomechanism of HV involves a muscle and ligament imbalance [24], a positive effect of physiotherapy on symptoms and HV position and an even stronger effect when physiotherapy is used in combination with straightening tape bandages have been reported in some studies [25,5].

Tehraninasr et al. [26] compared the conservative treatment outcomes of an insole with a toe separator and a night splint, and the insole with a toe separator achieved good pain reduction while the night splint had no effect on pain reduction. Their explanation for this finding was that the night splint was used in a static way and no dynamic correction could be achieved. It has also been shown that the success of a custom-made insole is dependent on the experience and skills of podiatrists, pedorthists or orthotists [27]. Therefore, the customizable splint, employing a Quengel mechanism as the HV brace (halluxaxan, Albrecht GmbH, Stephan-skirchen, Germany) used in the current study might be more effective than static non-individualized splints.

The current study shows good acceptance of the dynamic brace by the study group. The reported pain during wearing of the brace was predominantly reported by the first patients included in the study, as these tended to increase the traction strength too quickly, which led to increased pain. Therefore, the instructions for brace use were adapted during the study and the patients were advised to adjust the Quengel strength such that there was a constant feeling of traction, but no related pain.

In general a change of 1 point on a 10-point pain-NRS is considered to be clinically significant in patients with chronic joint diseases [28]. Very few studies have focused on the minimum clinical important change in foot and ankle surgery. Therefore, the relevance of the found differences between the reported pain scores is difficult to assess. Applying the “1 point” rule from chronic joint diseases, differences in pain during running were clinically relevant with a deterioration of 1 point in the control group or clinical improvement of more than 1 point in the intervention group whereas changes in pain during walking from baseline remained below 1 point. However, the personal reports completed by the patients and the fact that the subscales for pain of the validated FAOS score [29,30] also show an effect, lead us to believe that the finding is meaningful.

As in several previous studies [7,26], our study shows no significant difference in the radiologic HV parameters in patients after using the brace. To the best of our knowledge, the study by Mirzashahi et al. [31] showing a significantly decreased HVA when using a HV splint is the only published study showing a HV splint-mediated effect on radiologic parameters, but only while the brace was worn. Despite the lack of objective x-ray data concerning amelioration of the HV position while no brace was worn, the treated patients reported less deterioration of the HV position during the study period. Together with the reduced pain score, the alteration of the periaricular soft-tissue alignment and improved articular congruence seem to have an influence on pain. This conclusion is also shared by a recent review by Fuhrmann et al. [19].

The limitations of the study include the relatively short treatment period and the pronounced HV position. As a tertiary

### Table 3

<table>
<thead>
<tr>
<th>Clinical score at baseline and follow-up. Data provided as mean ± standard deviation and range. p-values showing significance are printed in bold.</th>
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<tbody>
<tr>
<td><strong>Baseline</strong></td>
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<tr>
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<tr>
<td><strong>MTP 1 ROM</strong></td>
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<tr>
<td>85.9 (20.2; 50–120)</td>
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<tr>
<td><strong>FAOS</strong></td>
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<tr>
<td>41.1 (21.7; 17-55)</td>
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<tr>
<td><strong>Pain</strong></td>
</tr>
<tr>
<td>25.6 (15.2; 12–40)</td>
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<tr>
<td><strong>SF-36 physical</strong></td>
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<tr>
<td>63.2 (8.1; 55–72)</td>
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<tr>
<td><strong>Pain running</strong></td>
</tr>
<tr>
<td>5.3 (2.3; 1–8)</td>
</tr>
<tr>
<td><strong>Pain walking</strong></td>
</tr>
<tr>
<td>4.7 (2.3; 1–8)</td>
</tr>
</tbody>
</table>

References:

foot and ankle center, most patients already had a diagnosed HV deformity and mild or moderate HV positions were not observed in this group of patients. A second x-ray for such patients is typically justified when directly required (such as through exact preoperative planning). Therefore, we had to rely on patients willing to take part in and be available for a follow-up analysis. Because of the complex recruitment process, we could not generate a consecutive series of patients. A further limitation of the study is the high number of drop-outs during the study period, and most dropped out for personal reasons. There is a risk that the answers of the patients in the treatment group were influenced by social desirability. We tried to reduce this risk through data acquisition during telephone interviews and follow-ups by independent nurses or study doctors.

5. Conclusion
The current study shows that the treatment of patients with a symptomatic HV using a dynamic splint can reduce pain, delay subjective deterioration of the toe position and is well accepted by patients. It may be more effective in patients with a smaller, more flexible HV deformity than in the current study population. In the present study, the treatment did not influence the objective radiologic position of the hallux, and no patients rejected surgery because of the effect of the splint.

Conflict of interest
The study was financially supported by Albrecht GmbH, Stephanskirchen, Germany.

References
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