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Effect of different orthotic concepts as first line treatment of plantar fasciitis

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ABSTRACT

Background: Evaluation of the effectiveness of three different types of prefabricated foot orthotics in the treatment of plantar fasciitis.
Methods: Prospective, randomized head-to-head trial in 30 adults (21 women, 9 men) with plantar fasciitis without any anatomic alterations. Three different prefabricated orthotics were tested (thin, non supportive orthotic (NO); soft supportive foam orthotic (FO); foam covered rigid self-supporting plastic orthotic (PO)). The follow up was 3 weeks. Main outcome measures were maximum and average pain (VAS), duration of pain per day, walking distance and subjective comfort.
Results: There was no significant effect of NO on maximal pain and average pain. FO and PO had a significant effect on pain levels ($p < 0.05$) whereas PO was superior concerning pain reduction and the time until the onset of effect ($p < 0.05$).
Conclusions: PO are superior regarding pain reduction and pain free time when compared to FO. NO did not demonstrate a significant effect in the test setup used.

1. Introduction

Plantar fasciitis is a painful degenerative disease of the insertion the plantar fascia, which is a thick fibrous band of connective tissue originating on the bottom surface of the calcaneus (heel bone) and extending along the sole of the foot towards the five toes [1]. The disease is caused by a loss of elasticity of the plantar fascia over time, which leads to a mechanical overload of the fascial structures in the insertion point at the anterior calcaneus [2].

Known risk factors for the development of plantar fasciitis are high sports activity [3,4], as well as forefoot pronation and high pressure under the forefoot, often in combination with a shortening of the heel cord [5–7]. Riddle et al. found that an increased body mass index (BMI) was associated with disability in plantar fasciitis, whereas measures of pain intensity, ankle dorsiflexion, age, gender, chronicity, and time spent weight bearing were not related to disability [8].

In more than 80% of patients, the symptoms disappear within a year, regardless of the chosen course of therapy [9,10]. The risk of developing the disease increases with pre-existing pes planovalgus and/or pes cavus [11]. Since the goal of conservative treatment is to reduce pain and shorten the duration of disease [12], stretching exercises, cold applications, NSAIDs and the use of orthotics are considered established conservative methods [13,14]. Landorf et al. found a short term benefit for customized and prefabricated orthotics, however both did not have a long-term beneficial effect compared with a sham device [14].

Currently available orthotics rely on different mechanical concepts. While some products soften the sole of the hind foot to reduce the maximum pressure at heel strike [15], others provide hind foot stabilization and medial midfoot support to slack off the plantar fascia [16–18]. The purpose of this study was to compare three of the most common mechanical orthotic concepts in a prospective, randomized, controlled cohort study.

2. Materials and methods

For this prospective, randomized head-to-head trial three different types of orthotics were chosen which represent the different mechanical approaches to treat plantar fasciitis.

After the study was approved by the Institutional Review Board (IRB) and registered by the German Register for Clinical Trials (DRKS00000742), informed consent was obtained from the patients to participate in the study [19,20].

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The orthotics were characterized by the following parameters:

- Group 1 (Fig. 1): Thin, non supportive orthotic, made of polyethylene (PE), while the cushion under the heel and forefoot areas is made of thin polyurethane (PU). Besides trimming for sizing purposes, no further adjustments are possible.
- Group 2 (Fig. 2): Soft supportive foam insert, based on a voluminous EVA-blank (Ethylene Vinyl Acetate) with a layered, recessed polyurethane cushion zone. Individualization for each patient is possible with the help of an orthopaedic technician.
- Group 3 (Fig. 3): Foam covered rigid self-supporting plastic orthotic (Fig. 4), with a central plantar heel recess, and a plantar fanning in combination with two layers of PU padding. The cushion layer shows a different resilience. Customization from an orthopaedic technician is possible.

All orthotics used an identical coating, however in direct comparison differences in the shape and material could be identified. To exclude selection bias as far as possible, the study persons did only get the orthotic they were randomized to.

Thirty consecutive patients with a diagnosis of plantar fasciitis after exclusion of other differential diagnoses were included in the study. The diagnosis was made by clinical examination in combination with an MRI. Physical examination revealed a well-localized pain in the area of the medial calcaneal tuberosity and occasionally in the central portion of the plantar fascia origin at the calcaneus in combination with normal skin sensation. Typical findings in the MRI were a thickening of the plantar fascia at the fibre–bone-junction, local bone oedema in that area and in 70% a bony spur formation. The MRI were investigated for indirect signs of nerve entrapment like fatty degeneration of plantar muscles and muscular oedema. All patients were seen initially and during the follow ups by two of the investigators (fellowship trained foot and ankle specialists). The three groups showed no statistical differences in age distribution, sex and body mass index (Table 1). The orthotics were the only treatment the patients received during the observation period. The patients were informed about the concept of the study including that during the study period of three weeks, the orthotics had to be the only treatment. Additional medication and exercises used for all kind of medical conditions was documented by the patients to exclude any bias. Exclusion criteria included: patients with operations in the area of the heel, injection treatments within the last six months, and patients with inflammatory joint diseases, neurological diseases and metabolic disorders. Also exclusionary were foot deformities that required earlier treatment including cavus foot, congenital pes planovalgus or other forms of hindfoot malalignment. There was one drop out. The lot of the drop out patient was put back to the lottery wheel to ensure a randomization of all included patients.

Fig. 2. Orthotic used by group 2 (view with a partially lifted top layer).

Following initial examination by a foot and ankle specialist, patients were randomly assigned to one of the three branches of therapy. Although there was the option for a further adaptation of the orthotics in group 2 and 3, the technician trimmed only for the appropriate foot size to rule out any influence by individualization. The observation period was limited to three weeks by the IRB, during which time the orthotic was the only therapeutic intervention. Patients who initially agreed to participate in the study completed the three week documentation period, during which time they recorded the following parameters on a weekly basis: maximal pain experienced during the week, average pain level and duration of pain, average usage time of the orthotics per day, type of shoes used, average estimated daily walking distance, and subjective comfort. The visual analogue scale (VAS) was used to record maximal and average pain, as well as subjective comfort at a scale from 0 (no pain/discomfort) to 10 (maximal pain/discomfort). In addition to recording of any medication taken during the study period, physiotherapy and exercises were also documented to exclude any bias by additional treatment. The query parameters were validated using a standardized documentation sheet that was completed by patients each week. After using the Levene's test, an inferential statistic used to assess the equality of variances, the Analysis of Variance (ANOVA) was used to compare the means of the groups. The post hoc analysis was used to identify significant differences between the groups.

Fig. 1. Orthotic used by group 1 (plantar view).

Fig. 3. Orthotic used by group 3 (plantar view).

Fig. 4. Core of orthotic used by group 3.

Additionally, the *T*-test for dependent samples and Wilcoxon signed-rank test were used to analyze therapeutic effects over time.

3. Results

The following deposits were included in the review:

- Group 1: Thin, non supportive orthotic, made of polyethylene (Fig. 1)
- Group 2: Soft supportive foam insert, based on a voluminous EVA-blank (Fig. 2)
- Group 3: Foam covered rigid self-supporting plastic orthotic (Figs. 3 and 4)

The three groups consisted of 10 randomly assigned test subjects. Demographic details of the three test groups are shown in Table 1. No patient had to be excluded due to the use of additional NSAID. None of the patients reported any exercises for stretching of the plantar fascia. There was no significant difference in the shoes used during the study period and in the usage time of the orthotics (see Table 1) (Kruskal Wallis Test).

Detailed data on the pain levels are given in Table 2. The maximum pain before therapy was 71.7 (SD 14.4) in Group 1, 67.3 (SD 25.3) in Group 2, and 63.7 (SD 24.4) in Group 3. During the observation period, Groups 2 and 3 experienced a significant ($p < 0.05$) reduction in maximum pain (Wilcoxon test for not normally distributed samples). Group 2 demonstrated a significant ($p < 0.05$) reduction of the maximum pain after 2 weeks, while Group 3 demonstrated a similarly significant reduction ($p < 0.05$) of the maximum pain after only 1 week. While there was a reduction of the mean maximal pain (71.2–56.2) in group 1, this was not statistically significant with the numbers available.

The average pain at baseline was 47.1 (SD 13.6) in Group 1, 35.8 (SD 14.8) in Group 2, and 43.7 (SD 16.2) in Group 3. A significant reduction in the average pain level ($p < 0.05$) was observed in Groups 2 and 3 (Wilcoxon test).

Based on the available numbers, the altered pain levels had no significant effect on the walking distance in either group (Fig. 5); there was no significant difference between the groups during the study period. The subjects' subjective comfort assessment showed a significant ($p < 0.05$) superiority of the soft supportive foam insert, based on a voluminous EVA-blank (group 2) and the foam covered rigid self-supporting plastic orthotic (group 3) (Fig. 6). The foam covered rigid self-supporting plastic orthotic ranked slightly higher than the soft supportive foam insert, based on a voluminous EVA-blank in terms of comfort, but the difference was not statistically significant with the numbers available.

4. Discussion

In the present study, three different orthotic concepts were compared for patients with a diagnosis of plantar fasciitis. The observation period was set at three weeks because a patient is expected to experience a noticeable effect on his or her pain level within this period. If no significant reduction of pain occurs within those three weeks, patient expect a change of treatment strategy or additional further action. For the purpose of this study, additional therapeutic measures were deliberately excluded during the three-week study period.

4.1. Strengths and limitations of the study

The study was carried out in an orthopaedic outpatient clinic because patients frequently seek orthopaedic attention for this disease right away. Based on the analysis performed prior to this study, a group size of 10 persons could show a statistical difference when the mechanical superiority of a tested orthotic concept is shown. The main focus of the study was the criteria pain, as it is crucial for the quality of life in patients with plantar fasciitis [21]. The time frame as suggested by the IRB was short with only three weeks. As with all randomized trials, some limitations are observed. The IRB requested at least any treatment in patients presenting with pain levels often higher than 6 in the VAS. The focus of the study was on different types of orthotics, so a thin non supportive orthotic chosen as control group. There was no control group without any treatment. The sex distribution was not homogeneous in the groups. The proportion of male subjects ranged between 20% (group 1) and 40% (group 3). While the allocation to one of the therapy groups was randomized, blinding in regards to the actual intervention (arch support) was not possible. However, the patients did only get the orthotic they were randomized to, to exclude a selection bias by the type of orthotic as far as possible. A comprehensive history of pain or the inclusion of depression scores was also not possible in the current study setup.

Table 1
Demographics of the three groups.

	Age (ø ± SD)	Male/female	BMI (ø ± SD)	Pain in weeks (ø ± SD)	Usage time of the orthotics [h/day] (ø ± SD)	Shoes used
Group 1	51.6 ± 12.5	2/8	27.4 ± 2.9	8.6 ± 4.9	8.8 ± 3.9	6 Business shoe 2 Comfort shoe 2 Safety shoe
Group 2	53.8 ± 13.2	3/7	27.4 ± 3.9	10.7 ± 7.5	9.1 ± 2.9	7 Business shoe 2 Comfort shoe 1 Safety shoe
Group 3	53.9 ± 14.9	4/6	28.7 ± 5.0	9.7 ± 4.5	8.7 ± 3.4	7 Business shoe 1 Comfort shoe 2 Safety shoe
	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

Table 2
Pain level (VAS) during treatment.

	Prior to treatment		After 1st week of treatment		Wilcoxon test	After 2nd week of treatment		Wilcoxon test	After 3rd week of treatment		Wilcoxon test
	Max. ± SD	ø ± SD	Max. ± SD	ø ± SD	Chance to baseline value after 1 week of treatment	Max. ± SD	ø ± SD	Chance to baseline value after 2nd week	Max. ± SD	ø ± SD	Chance to baseline value after 3rd week of treatment
Group 1	71.7 ± 14.4	47.1 ± 13.6	69.1 ± 23.8	52.5 ± 22.1	$p = 0.683$	63.2 ± 31.0	49.1 ± 31.1	$p = 0.415$	56.2 ± 35.3	46.0 ± 33.9	$p = 0.173$
Group 2	67.3 ± 25.3	35.8 ± 14.8	64.1 ± 27.8	38.8 ± 23.5	$p = 0.407$	54.7 ± 30.4	29.8 ± 19.0	$p = 0.059$	44.1 ± 29.1	20.3 ± 20.1	$p = 0.009$
Group 3	63.7 ± 24.4	43.7 ± 16.2	37.1 ± 19.4	28.6 ± 16.7	$p = 0.008$	25.9 ± 16.7	17.4 ± 12.7	$p = 0.005$	20.2 ± 21.7	15.6 ± 14.9	$p = 0.005$

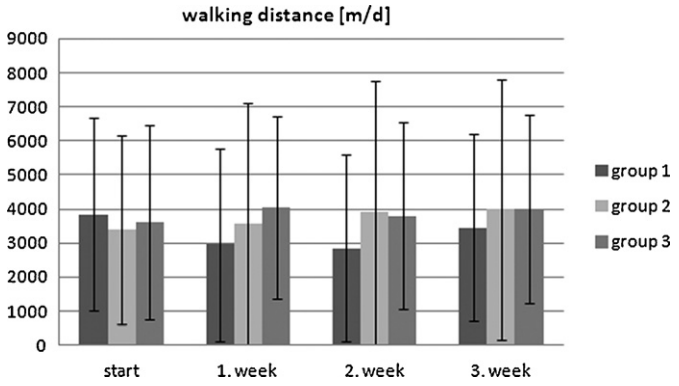

Fig. 5. Average walking distance per day.

4.2. Consistency with other studies

During the last 10 years, six randomized controlled trials looking into the beneficial effect of orthotics on plantar fasciitis were published with at least two groups of patients. Lynch et al. examined the effect of inserts in 85 patients [22]. After three months, the orthotic appeared to be superior to medication or visco-elastic heel cushions. Pfeffer et al. published a multicenter study involving 236 patients [23]. Patients who used a prefabricated insert with or without stretching had a higher improvement rate than those assigned to stretching only ($p = 0.022$) and those who stretched and used a custom orthosis ($p = 0.0074$). They concluded that, when used in conjunction with a stretching program, a prefabricated shoe insert is more likely to produce improvement in symptoms as part of the initial treatment of proximal plantar fasciitis than a custom polypropylene orthotic device. Turlik et al. [24] compared Urethane heel cushions and functional deposits and, after a three month observation period, the functional inserts showed better results. However, several limitations regarding measurements of the results were observed. Martin et al. [25] conducted a study using three groups in which custom made orthotics were compared against preformed orthotics and night splints. After three months, there was no significant difference between the three groups, but the results are viewed critically due to a 24% drop out rate. Landorf et al. [14] showed that custom-made orthotics and pre-formed orthotics have similar effects in the treatment of plantar fasciitis at three months and 12 months of follow-up. Baldassin et al. [12] compared a pre-foam insert to a custom-made insert during an eight week observation period. Both groups showed a significant reduction in pain levels, but the custom-made insert showed no superiority. In summary, two studies have shown custom made orthotics to be superior to pre-formed orthotics, whereas the remaining studies were unable to confirm these findings. The term "pre-formed" orthotics covers a wide range of different products. On one side of the spectrum, the simple shapes include silicone heel pads or layered, soft EVA (Ethylene Vinyl Acetate) foam inserts without three-dimensional structure. These are in contrast to the orthotics made out of materials with different stability. There are different theories why more stable orthotics have demonstrated a faster onset in pain relief. The stiff core and the three dimensional structure in combination with the cushioning of the heel provides an additional mechanical effect for the foot skeleton by the reduction of pronation [26,27]. A reduction in pronation has already been proven to be beneficial in disorders of other structures supporting the longitudinal arch like the posterior tibial tendon [28,29]. It can be discussed that there might be a similar effect in the plantar fascia with an unloading of the fibre–bone-junction at the calcaneous. In addition, the goal to slack off

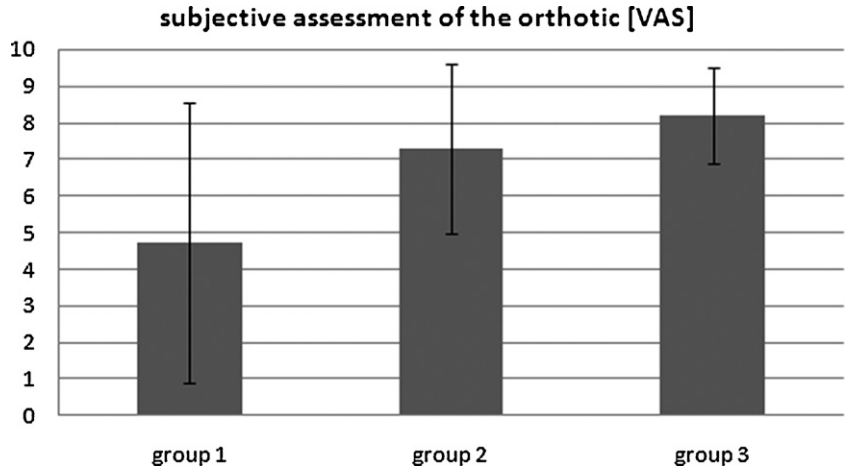

Fig. 6. Subjective assessment of the orthotic [VAS] (0 = worst, 10 = best).

the plantar fascia might be further promoted by the support of the regions medial and lateral of the plantar fascia bundle with unloading of the plantar fascia itself.

A final but in daily practice important aspect is to provide the highest possible relief and stability while at the same time maintaining a thin insert to allow for compatibility with a variety of shoes. The latter is a common obstacle to the acceptance of inserts by the patient. This matter can also be addressed by orthotics concepts with a rigid core.

The present study supports the hypothesis that there is a level of superiority in multilayered, three dimensional arch supports over the pure foot cushioning, both in terms of pain reduction and in terms of a faster onset of action. Three dimensional arch supports with an unloading of the whole plantar fascia seem to be the first choice of orthotics in the first line treatment of plantar fasciitis.

Level of evidence

II (Prospective randomized trial with blinding).

Conflict of interest

Markus Walther has received travel expenses by OFA Bamberg, Steitz Secura, Bauerfeind and Adidas.

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