FOOT & ANKLE INTERNATIONAL

Foot Orthoses for the Treatment of Plantar Fasciitis

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ABSTRACT

Background: **The literature suggests mechanical interventions such as foot orthoses and night splints are effective in reducing pain from plantar fasciitis. There is, however, a lack of controlled trials. We studied the effects of foot orthoses and night splints, alone or combined, in a prospective, randomized trial with 1-year followup.** ***Methods:*** **Forty-three patients (34 women and nine men with a mean age of 46 years) with plantar fasciitis were randomized to receive foot orthoses ($n = 13$), foot orthoses and night splints ($n = 15$), or night splints alone ($n = 15$). Data were available for 34 (79%) patients after treatment (12 weeks), and for 38 (88%) at 1-year followup. Pain, functional limitations, and quality of life were evaluated with the Foot and Ankle Outcome Score.** ***Results:*** **All groups improved significantly in all outcomes evaluated across all times ($p < 0.04$). At 12 weeks, pain reduction of 30% to 50% compared to baseline were seen ($p < 0.03$). At 52 weeks, pain reduction of 62% was seen in the two groups using foot orthoses compared to 48% in the night splint only group ($p < 0.01$). Better compliance and fewer side effects were reported for orthosis use. At 12 months, 19 of 23 patients reported still using foot orthoses compared to 1 of 28 still using the night splint.** ***Conclusions:*** **Foot orthoses and anterior night splints were effective both short-term and long-term in treating pain from plantar fasciitis. Parallel improvements in function, foot-related quality of life, and a better compliance suggest that a foot orthosis is the best choice for initial treatment plantar fasciitis.**

Key Words: Foot and Ankle Outcome Score; Night Splint; Plantar Fasciitis

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INTRODUCTION

Plantar fasciitis is an inflammatory reaction from chronic irritation of the plantar fascia at its origin at the calcaneus.[13] Plantar fasciitis is characterized by pain and tenderness under the heel on weightbearing, resulting in limitations of physical activity. The condition affects about 10% of the population at some time during life.[7] Little is known of the clinical course of the condition, and some patients may recover spontaneously, indicating a need for controlled treatment trials. A recent Cochrane review on interventions for treating plantar heel pain concluded that there is limited high-level evidence upon which to base clinical practice and asked for well designed and conducted randomized trials.[6]

Treatment of plantar fasciitis aims at affecting the anatomical, biomechanical, and environmental factors that may contribute to development of plantar fasciitis. Mechanical treatments, including foot orthoses and dorsal night splints, have been described.[2,8,10,14,15,18–20] Foot orthoses are believed to optimize biomechanical loading of the foot, more specifically to decrease excessive pronation, off-load the plantar fascia at its origin, and recreate the shape of the heel pad.[12] However, conflicting results are reported regarding the ability of foot orthoses to decrease excessive pronation.[4,5,9,16,17,21]

Night splints are applied to stretch the plantar fascia to prevent morning pain and stiffness, a typical feature of plantar fasciitis. The evidence of the efficacy of night splints is not conclusive, in part because many patients could not tolerate the dorsal, or posterior, night splint used in previous studies.[6]

To study the effects of custom-fitted orthoses and an anterior rather than posterior night splint for treatment of plantar fasciitis, we evaluated the effects on pain and function in a prospective, randomized trial.

MATERIAL AND METHODS

Patients

Patients between the ages of 20 and 60 years seeking treatment for plantar fasciitis were candidates for inclusion

in the study. Inclusion criteria included an activity level before the current symptoms that was at least equivalent to heavy household work, heavy yard work, or walking on even ground, at least moderate pain when performing physical activities, and duration of symptoms of more than 4 weeks. Patients who fulfilled these written inclusion criteria were referred to one examiner, a physical therapist not involved in the intervention or evaluation of the study, who randomized the patients by pulling an envelope from a box holding 60 randomly ordered envelopes, 20 for each treatment group. The examiner also did a clinical examination and verified the diagnosis.

From September, 1998, to July, 2001, 43 patients (34 women and nine men) were recruited by 23 primary care physicians and referred to one examiner. Their mean age was 46 (range 22 to 63) years. Seventeen patients (40%) were active in sports before the current symptoms, and 42 patients (96%) reported pain daily or always. The median symptom duration before treatment was 4.2 (range 1 to 240) months, and 33 patients (74%) reported having had symptoms for more than 3 months. Eighteen patients (43%) reported having tried other treatments previously, often in combinations. The most common previous treatments were oral anti-inflammatory medication (11), shoe modifications (10), and cortisone injection (eight). There were no significant differences in sex, age, activity level, symptom duration or baseline status between the groups.

The patients were randomized to receive either foot orthoses (13), foot orthoses and night splint (15) or night splint only (15). Data were available for 34 (79%) patients after treatment (12 weeks), and for 38 (88%) patients at the 1-year followup (Figure 1). No patients were excluded after baseline and the loss to followup was due to patients not returning questionnaires. Two patients in the combined orthosis and splint group did not return any questionnaires.

Study Design

The design was a randomized study with three treatment groups: foot orthosis, night splint, or a combination of both treatments. The combined group was added since it was hypothesized that the effects of the treatments might be additive. After 12 weeks, patients were allowed to cross over to another treatment if they so desired.

The outcome was evaluated by the Foot and Ankle Outcome Score (FAOS), a patient-administered questionnaire, at baseline and at 6, 12, 26, and 52 weeks after initiation of treatment. To minimize bias, the questionnaire was mailed to the patients and returned to the study coordinator who was not involved in the clinical trial.

The study protocol was approved by the Ethics Committee at the Medical Faculty of Lund University.

Foot Orthoses

A plaster cast was taken with the patient lying prone, i.e. nonweightbearing. During casting the subtalar joint and the midtarsal joint were placed in a neutral alignment. The alignment was achieved by manipulation manually and no wedges or posts were used during casting. The cast was total contact with the longitudinal arch. Bilateral foot orthoses were fabricated by the first author (ER) for all patients (Figure 2). The orthoses were made of ethyl-vinyl-acetate (EVA) material with a density of 55 shore A and were fitted into the patients' shoes.

Anterior Night Splint

An anterior night splint, which is thought to reduce morning pain and stiffness, was used to hold the foot in 90 degrees of dorsiflexion. Maintaining a foot position of neutral plantigrade, a 3.2 mm thickness of Omega Plus (North Coast Medical, USA) a low temperature thermoplastic material, was draped directly onto the anterior lower leg and foot of

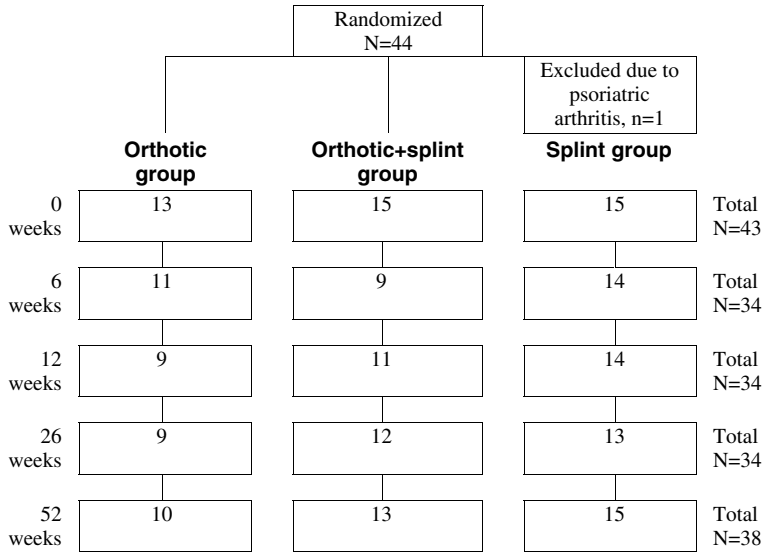

Fig. 1: Flow chart of patients in the study.

Fig. 2: Foot orthosis in the study.

each patient. Each template of material was 70 mm wide and of length equal to the measure from the tibial tuberosity to the metatarsal heads. Reinforcement was applied at the level of the anterior ankle crease before heating. Skin protection was afforded by a stockinette. Once cooled, a liner of 3-mm low-density polyethylene was added, along with four Velcro straps for securing the night splint. These were placed immediately inferior to the tibial tuberosity at the proximal malleoli, at the level of the midtarsal joint and across the metatarsal heads (Figure 3). Each patient was directed on proper application of the orthosis and on its night time use only. Possible problems that might be encountered also were discussed. Anterior night splints have advantages over posterior ones in that the orthosis does not have to be removed for walking. Also, because a smaller surface area of the leg is covered, better heat dissipation is experienced, thus improving comfort.

Daily Logs

To determine compliance with the treatments and possible side effects, the patients kept daily logs that were returned by mail at 6 and 12 weeks. Compliance was assessed on a weekly basis. Daily use of the orthosis was recommended. Good compliance was defined as using the orthosis at least 75%, e.g. 5 days a week. Recommended use of the night splint was 7 nights a week. Similarly, good compliance was defined as using the night splint at least 75%, e.g. 5 nights a week. Side effects (examples given included pressure-related pain and sleep disturbances) also were evaluated weekly.

Outcome Measures

Foot and Ankle Outcome Score

Symptoms, function, and foot and ankle-related quality of life were evaluated by a mailed survey, the Foot and Ankle Outcome Score (FAOS) (www.koos.nu). A formal validation has been carried out in subjects with lateral ankle ligament injury.[23] The test-retest reliability is high, indicating the FAOS that is an accurate measure with high ability to measure small changes over time. This was confirmed in a trial of eccentric exercise in Achilles tendinopathy.[24] The

Fig. 3: Anterior night splint.

Foot and Ankle Outcome Score is an adaptation of the Knee Injury and Osteoarthritis Outcome Score (KOOS)[23,26,28] and assesses patient-relevant outcomes in five separate subscales: pain, other symptoms, activities of daily living, sport and recreation function, and foot and ankle related quality of life. Pain was considered the primary outcome. A percentage score from 0 to 100 was calculated for each subscale, 100 representing best possible score. For the KOOS, a 10-point score change indicates a clinical change.[25] Since the subjects of the current study were of similar age and activity level to the subjects evaluated by the KOOS, we decided to apply a 10-point change to indicate a clinical improvement in the present study.

Sporting activities

Difficulty during sporting activities was assessed on a five point scale (no, mild, moderate, severe, extreme). The answers were categorized into none or mild difficulty and moderate to extreme difficulty.

Statistics

To safely deal with protocol violations such as noncompliance and cross-over between treatments, the analyses were based on the groups as randomized, e.g. intention to treat analysis was used. Non-parametric statistics were used. Post-treatment change across all times was assessed by Friedman's test. When this test was significant, post-treatment change at 6, 12, 26, and 52 weeks compared to baseline was assessed by Wilcoxon's signed rank test. The Kruskal-Wallis test was used when comparing three groups, and the Mann-Whitney U-test was used when comparing two groups. The Chi-square test was used for comparison of proportions.

A power analysis was carried out before the study. It was determined that 60 patients were needed to detect a clinically significant mean score difference between groups of 10 points, with an estimated standard deviation of 15, in the FAOS subscale pain with 80% power and at a significance level of 0.05.

RESULTS

Change over time within the groups

All groups improved significantly in all five FAOS subscales across all times, $p < 0.04$ (Table 1). At 12 weeks, pain reductions of 30% to 50% compared to baseline were seen in the three groups ($p < 0.03$). On an individual level, eight of nine patients in the orthosis only group improved clinically ($\geqslant$10 points) compared to eight of 11 in the combined group and 10 of 14 in the splint only group. Similar results were seen for improvement in the other FAOS subscales covering other symptoms, function in daily life, sport and recreation function, and foot and ankle related quality of life. The improvement continued over time.

Comparison Between Groups

With the numbers available, no significant differences were found in pain among the three groups at any point in time ($p = 0.12$ to 0.89). When comparing the orthosis-only group and the splint-only group a clinically important (>10 points) but nonsignificant difference in sport and recreation after 26 weeks of treatment was seen (88 compared to 67, $p = 0.08$). At 52 weeks, a significantly higher pain reduction of 62% was reported for the two groups treated with orthoses (alone or in combination with splint), compared to a pain reduction of 48% for the splint alone group ($p < 0.01$).

Difficulty During Sporting Activities

Forty-one of 43 patients were involved in sports. At the beginning of the study, 27 of 41 (66%) patients in all treatment groups analyzed together reported moderate to extreme difficulty during sports. After 6 weeks of treatment, 13 of 31 (42%) patients who were available and played sports reported difficulty, and after the treatment period at 12 weeks, 13 of 28 (46%) patients reported difficult. During the followup period at 26 and 52 weeks, 7 of 29 (24%) and 9 of 35 (26%) patients, respectively, who were available and played sports reported difficulty.

Compliance

Compliance was good (at least 75% of recommendation) for both treatments. At 12 weeks 14 of 20 (70%) reported good compliance with orthoses and 15 of 25 (60%) with the night splint. The numbers were too small in each group to calculate the association between compliance and outcome.

Table 1: Foot and Ankle Outcome Score (FAOS) subscores (Mean ± SD) on a 0–100 worst-best scale

	Pain	Symptoms	ADL	Sport/Rec	QOL
Baseline					
Orthosis	56 ± 12	70 ± 12	65 ± 19	53 ± 25	36 ± 17
Ortho + splint	50 ± 18	64 ± 22	54 ± 25	35 ± 27	32 ± 16
Splint	53 ± 15	63 ± 11	65 ± 15	40 ± 19	32 ± 12
6 weeks					
Orthosis	69 ± 19	74 ± 19	75 ± 18	62 ± 30	39 ± 21
Ortho + splint	68 ± 14	77 ± 20	78 ± 12	57 ± 20	46 ± 21
Splint	69 ± 18	75 ± 12	78 ± 14	61 ± 19	42 ± 16
12 weeks					
Orthosis	76 ± 26	76 ± 22	76 ± 24	62 ± 32	55 ± 28
Ortho + splint	76 ± 17	78 ± 14	83 ± 17	59 ± 29	54 ± 26
Splint	70 ± 15	76 ± 14	75 ± 15	63 ± 20	46 ± 17
26 weeks					
Orthosis	85 ± 13	87 ± 13	87 ± 16	88 ± 17	71 ± 27
Ortho + splint	77 ± 14	76 ± 25	85 ± 14	69 ± 26	60 ± 24
Splint	76 ± 18	80 ± 15	83 ± 14	67 ± 26	56 ± 22
52 weeks					
Orthosis	89 ± 16	90 ± 12	90 ± 15	83 ± 22	78 ± 24
Ortho + splint	82 ± 16	85 ± 14	88 ± 16	78 ± 23	65 ± 25
Splint	79 ± 20	82 ± 17	82 ± 18	73 ± 26	64 ± 26

ADL = Activities of Daily Living, Sport/Rec = Sport and Recreation Function, QOL = foot and ankle-related Quality of Life.

Side Effects

During the first week of treatment, nine of 15 patients in the splint only group reported side effects such as pressure, pain, and sleep disturbances. In the combined group, six of 15 patients reported similar problems while only three of 13 patients in the orthosis only group reported side effects such as pressure-related pain and tiredness of the foot. The number of patients reporting side effects decreased over time and during weeks 2 to 12 of the treatment period one patient in the orthosis only group reported side effects (tiredness of the foot) compared to two to four patients in the combined group and two to five patients in the splint only group.

Cross-over Between Treatments

At 12 months, four patients reported having tried other than the allocated treatment. Two patients from the splint only group had tried foot orthoses and reported a good effect on a five-point scale. One patient from the combined group had tried a topical agent (anti-inflammatory gel) with some effect and one patient from the foot orthosis only group had tried homeopathy with poor effect.

At 12 months, 19 of 23 who were randomized to foot orthoses reported continued use the foot orthoses. One subject still used the night splint.

DISCUSSION

This is a prospective, randomized study using a subscale of a validated outcomes measure. An orthosis molded to the foot and an anterior night splint were effective in reducing pain from plantar fasciitis both at 3 and 12 months. This study adds information on patient tolerance in wearing custom molded orthoses and the enduring effects of these devices. Additional information gleaned from this study was that an anterior night splint can be used instead of a dorsal one which may improve patient compliance. The design of the study and the outcome measures add to the higher levels of evidence of future meta-analyses on treatment of plantar fasciitis.

In all treatment groups, pain reduction was present as early as 6 weeks and lasted for 1 year (Table 1). However, secondary outcomes such as improvements in function, foot-related quality of life, and tolerance of the device supported the use of foot orthoses over night splints. During the treatment period, compliance was higher for orthosis use, and fewer side effects were reported. At the 1-year followup, over 14 of 20 (70%) reported still using the orthosis compared to only one patient still using the night splint. Our results were obtained using custom-fitted foot orthoses. It is unknown if similar results would be obtained using less expensive prefabricated orthoses. However, a biomechanical study showed individually fitted foot orthoses to be superior to prefabricated orthoses in reducing tension in the plantar aponeurosis.[11] We, thus, recommend the use of individually fitted foot orthoses.

The rationale for the development of an anterior night splint was the discomfort induced by the dorsal night splint reported by patients in the clinic and in the literature.[6] An anterior night splint has several advantages over a dorsal one; it is possible to walk with and it covers less skin. Still, many patients reported side effects, such as pressure, pain, and sleep disturbances, especially during the first week. However, even after a few weeks a substantial number of patients reported side effects that probably contributed to the decrease in compliance seen over time. To fully evaluate different models of night splints comparative studies are needed.

Although the recruitment period was almost 3 years and involved more than 20 primary care physicians, we were not able to recruit the 60 patients required to show statistical significance when clinically significant differences between the groups were present. Mean score differences that were statistically significant favored the orthosis group for pain, sport and recreation function, and foot-related quality of life at 26 and 52 weeks.

The questionnaire used for assessment of patient-relevant outcomes in this study has been found sensitive enough to detect treatment differences between small groups undergoing nonsurgical treatment for knee complaints,[3] and to our knowledge no validated outcome measures with known higher responsiveness were available.

The combined treatment group's outcomes were no better than the two groups receiving single treatments, indicating no additive effect of the two treatments.

Poor methodology is one suggested reason for the weak evidence for treatment of plantar fasciitis[6] and tendinopathy.[1] In a critical review on the outcome of surgery for chronic Achilles tendinopathy several methodological suggestions were given.[29] Most of these suggestions, when applicable for nonoperative interventions, were met in the present study. The patients were randomized to the different treatment groups and monitored four times during the 1-year followup. The number of patients not completing the course of study and reasons given were recorded and statistical analysis was used.[23,26–28] We used a rigorously developed and tested patient-relevant outcome measure assessing symptoms, functional limitations, and quality of life issues. For assessment of physical activity level, a reliable scale was used.[27] To minimize investigator bias, the questionnaire was mailed to the patients and returned by mail.[22] We assessed compliance with the protocols weekly and by having the patients record the use of orthoses and the splint. The records were returned by mail after 6 and 12 weeks.

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