

The effects of Foot Orthoses on Pain Management of People with Plantar Fasciitis

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Abstract

Introduction: Plantar fasciitis is the most common cause of plantar heel pain, accounting for almost 15% of all foot-related complaints. Arch supports and heel pads are the main foot orthotics to manage the heel pain. Despite the high prevalence of plantar fasciitis, information about the effectiveness of different orthoses is still scarce. This study was aimed to compare the effectiveness of using an arch support and a silicone heel pad in the pain management of people with plantar fasciitis.

Methods: Forty subjects (mean ± SD age; 44.46 ± 9.7 years) with unilateral plantar fasciitis were recruited in this randomized clinical trial study. They randomly and equally allocated to the intervention groups (the soft arch support insole and silicone heel pad). The primary outcomes were pain and foot function. Outcomes were measured while participants were administered prior to receiving the allocated intervention and after 6-week follow up period. In the admission and follow-up sessions, the heel pain was scored via visual analogue scale (VAS) and the foot function were measured by foot and ankle outcome score (FAOS) questionnaire. Data were analysed by Mann-Whitney test.

Results: Foot orthoses significantly improved the foot function, reduce the heel pain ($p < 0.001$). There was no significant difference between two orthoses in pain relief ($p = 0.094$). The results indicated that both silicone heel pad and soft insole had successful outcomes in the management of plantar fasciitis over a 6-week period.

Conclusion: The silicone heel pad and the soft insole with arch support are effective to reduce heel pain and improve the activity level in people with plantar fasciitis.

Keywords: Plantar fasciitis; Heel pain; Foot orthoses

Introduction

Plantar fasciitis is an inflammatory condition caused by cumulative stresses at the origin of plantar fascia [1]. It is the most common cause of plantar heel pain, accounting for almost 15% of all foot-related complaints [2-5]. Plantar fasciitis is very common in middle-aged people; the average age of subjects experienced this pain is 48 years [6-9]. Local plantar pain is usually getting worse at initial weight bearing in the morning [7]. The induced pain by plantar fasciitis can restrict an individual's physical activity [10] and lead to a poor quality of life [11]. The aetiology of this lesion is multifactorial however the mechanical overloading of the plantar fascia is known as the primary underlying mechanism of plantar fasciitis [12].

A variety of treatment methods have been reported for this condition in the literature includes corticosteroid injection, anti-inflammatory medications, physical modalities, stretching exercises, surgical interventions, and orthoses [1]. The first-line treatment option is orthotic management which is low-cost, non-invasive and economically, more acceptable choice [3,13-16]. An effective foot insole should modify excessive mechanical stresses and prevent overloading strains on the plantar fascia [17]. Nevertheless, the

previous research mainly focused on the methods of fabrication [18-23] or the cost comparisons of different orthoses [19,24,25]. Yet, there is little known from the published studies to draw a conclusion about the effectiveness of different orthoses which should be designed according to the aetiology of plantar fasciitis. The complex structure of the plantar arch provides dynamic flexibility for load acceptance at the foot and ankle complex [26]. In addition, the quality and thickness of the fat pad under the calcaneus also implicated as a factor influences the pressure under the heel [27]. Therefore, the atrophy of heel pad and flatter plantar arch are reported as the main contributing factors of the increased strain in the fascia [28,29] and should be properly considered in an orthotic selection. The rubber heel pad is a commonly used orthosis to absorb the mechanical impacts exerted on the origin of fascia at the heel [3,30]. The soft insole with an accommodated medial arch is another prescription used for this lesion that supports the medial longitudinal arch and reduces the tension throughout the whole plantar fascia length [31-33]. Therefore, the objective of the present study was to explore the effectiveness of these two treatment concepts through their effects on the pain and function. It has been hypothesized that either silicone heel pad or soft insole with arch support could result in the pain reduction and the foot function improvements in the users.

Methods

The design was a randomized clinical trial. The protocol was approved by the Ethics Committee of Isfahan University of Medical Science, Iran (REC.MUI.139200076). Participants were invited by advertising in a local orthopaedic clinic (Alzahra hospital, Isfahan, Iran) and recruited as many as were referred. All subjects read and signed the informed consent form prior to participation in this research. They included forty adults (30 women, 10 men; mean age \pm SD: 44.46 ± 9.7 years) diagnosed with unilateral plantar fasciitis by an orthopaedic specialist. Individuals were assessed for trial eligibility at initial assessment. The diagnosis was made based on clinical history and physical assessment. Subjects diagnosed by PF were referred to an Orthotics Clinic (Isfahan University of Medical Sciences, Isfahan, Iran).

Subjects with any previous lower limb surgery or injection, any systematic disorders like arthritis, diabetes, gout and pregnancy were excluded from the trial. The orthoses were the only treatment for patients during the intervention period. People who received any medication or other modalities during observation time were excluded from study to prevent any bias. Following initial assessment, subjects were randomly and equally assigned to one of the two intervention groups. The randomization order was determined by drawing a concealed envelope from a bag by a researcher. One group received a full-length soft arch support and other did silicone heel pad.



Figure 1: Soft arch support insole.

The soft insole with arch support was medium density polyurethane foam which is encapsulated in two layers of cushion foam. It was a toe-heel insert that supported longitudinal arch and provided a soft bed for painful heel (Figure 1). The heel pad was a rubber-based (Silicone) heel length insole that provides a cupped design for heel bed. The lower density material (blue-coloured) was incorporated in the central zone of the heel to provide local shock absorption under the heel (Figure 2).

All participants were blinded to their group assignment, while the examiner was completely aware. Researcher described to participants existing situation. They suggest them to use their insole daily in this 6-week period. Main outcome measures were pain and foot function during ADL. The foot and ankle outcome score (FAOS) questionnaire was used to collect the data about the quality of ankle-foot complex function. The FAOS is a patient-reported questionnaire which measures pain, symptoms, activities of daily living and also ability to perform sport [34].



Figure 2: Silicone heel pad.

All outcomes in FAOS were given the score from 0 to 100. Zero means severe symptom and 100 indicated no symptom. This questionnaire was validated in Persian language and we used it to gather the specific data [35]. Pain variable was recorded by VAS pain scale (from 0-100 mm) at randomization session and just after 6-week of receiving the orthoses. In this scale, 0 shows no pain and 10 indicate the worst imaginable pain (Figure 3). Other variables such as age, sex, weight, pain type and location, the heel condition, and ADL evaluated by the investigator. Each participant had their orthoses fitted individually to ensure correct fit and size. Sizing was in accordance with the manufacturer's instruction and was checked with educated researcher. All participants were asked to wear the selected orthosis in standard shoe, do usual daily activity and refer again after 6 weeks to follow up and re-evaluation.

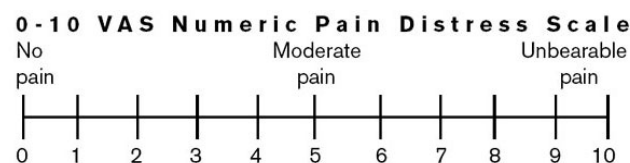


Figure 3: Visual analogue scale (VAS).

Data were analysed by SPSS software, version 17 (SPSS Inc., Chicago, IL, USA). The normality assumption for all variables was checked using Shapiro-Wilk test. Due to violation of normality assumption, the non-parametric Mann-Whitney test was used for statistical analysis of the data. The significance level was set at 0.05.

Results

Data were collected from forty subjects with plantar fasciitis (30 women, 10 men). The mean (\pm SD) age was 44.46 ± 9.7 years and mean (\pm SD) weight was 72.89 ± 14.75 kg. Acceptance of orthoses after the assessment session was good. Sharpness pain was the most common complaint (32 subjects) and 17 participants diagnosed with heel pad atrophy. Twelve participants had pain at day; eighteen subjects reported the nocturnal pain as well as the daytime pain. Symptoms were

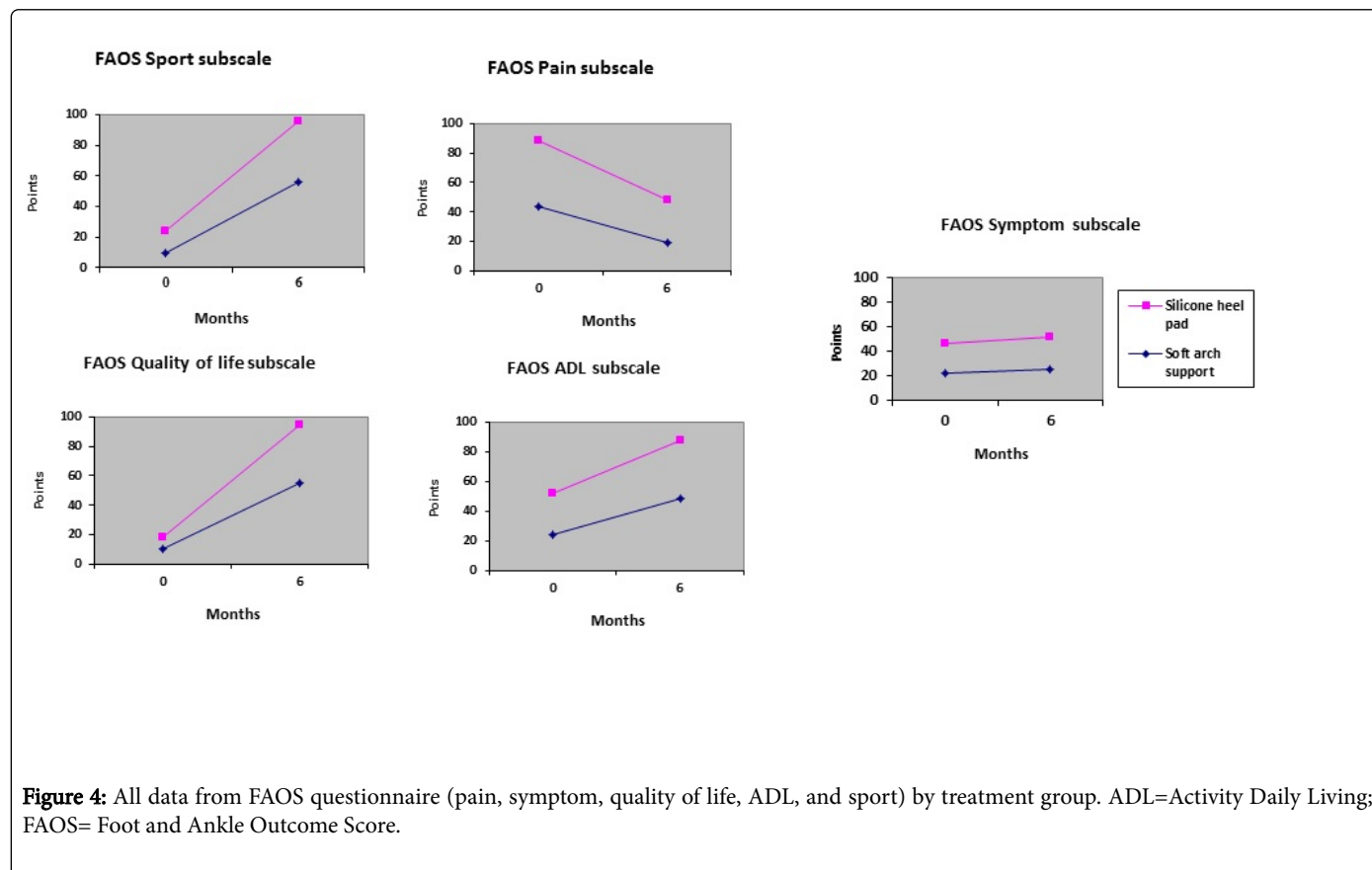
getting worse for 8 people in the early morning. 2 subjects had pain after sport activity and no one did experience any pain during the night.

The baseline characteristics of each group, including age, sex, weight, and the duration of foot pain were recorded in Table 1. Two groups were similar in the baseline outcomes; No significant difference was observed in age, weight, and duration of the lesion between two groups ($p=0.075$). There was no significant difference between pain ($p=0.98$) and foot function between two groups in the first and follow-up sessions ($p=0.05$). Pain was significantly reduced after using

orthoses; there was no significant difference between two types of orthoses in the reduction of the heel pain ($p=0.23$). Following six weeks, the change in the maximum pain indicated that the use of an orthosis in each group lead to pain relief ($p<0.001$) but the interaction of orthosis type and the time was not significant ($p=0.094$). According to the Spearman's Rho test the body weight had a direct association with the pain score ($r=0.345$; $p=0.001$). Figure 4 gives data at the initial assessment and 6-week follow up sessions and shows the treatment effects for quality of foot and ankle function and other outcome measures.

	Arch support (n=20)	Heel pad (n=20)	Total (n=40)
Age (years Mean \pm SD)	44.45 \pm 9.3	44.47 \pm 10.42	44.46 \pm 9.7
Weight (Kg Mean \pm SD)	77.45 \pm 13.93	68.10 \pm 14.39	72.89 \pm 14.75
Female, n(%)	16 (80%)	14 (70%)	30 (100%)
Male, (%)	4 (20%)	6 (30%)	10 (100%)
Duration of foot pain (months)	7.6 \pm 6.3	8.2 \pm 5.13	7.8 \pm 5.2

Table1: Baseline characteristics of participants in each group.



Discussion

The objective of the present study was to investigate the effectiveness of two treatment concepts through their effects on the pain and function. It has been hypothesized that either silicone heel pad or soft insole with arch support could result in the pain management and the

foot function improvements in the users. The results of this study indicated that both silicone heel pad and soft insole with arch support had successful outcomes in the management of plantar fasciitis over a six-week period. There was no substantial difference in the overall pain relief and foot function improvement between these two types of foot orthoses (Table 2).

Group	No.	Pre-intervention (Mean ± SD)	Post-intervention (Mean ± SD)	p
Soft arch support	20	4.40 ± 0.68	1.94 ± 0.53	0.007*
Silicone heel pad	20	4.45 ± 0.68	2.85 ± 1.26	0.008*

*significant differences between data.

Table 2: Pain score before-after intervention.

The result of the current study is in the same direction with previous trials those reported no difference in pain reduction between orthoses [3,18,36]. Martin et al. [36] showed that soft insole with arch support was effective in the treatment of plantar fasciitis, but there was no difference between prefabricated and custom-made orthoses studies in the pain reduction. Pfeffer et al. [3] demonstrated that foot insole (including the silicone heel pad and the soft arch support) were more effective than night splints and calf stretching in a trial 8-week follow-up. Baldassin et al. [18] has shown that both prefabricated and custom-made orthoses had significant reductions on pain level after 8 weeks. It has been reported that foot insoles have the pain reduction effects for the immediate and short-term usage [14]. In the current study the short and medium-term effects of insoles on the pain and foot function is also demonstrated. Both orthoses used in the present trial was prefabricated orthoses. These types of insoles were selected according to two different concepts; it was hypothesized that providing an arch support in combination with the cushioning material provides an extra mechanical effectiveness through the controlling of the foot pronation [1,37]. Over-pronation contributes to excessive foot mobility, which can increase the stresses applied to the musculofascial tissue on the foot, increasing the discomfort and pain [38-40]. A reduction of foot pronation during weight bearing conditions can slack off the tension in the fascia and reduce the heel pain [41].

The results of the current study demonstrate that there is a negative correlation between participants' weight and the pain relief effects of orthose, it means pain and discomfort in over-weight people was greater than normal-weight subjects and using the orthoses showed to be more effective in people with normal weight. The excess weight is one of the contributing factors to cause the heel pain [42] as confirmed in the present trial. The excessive tension on fascia can create micro tears and local inflammation [43]. Repetitive stretching and tearing can cause the fascia to become irritated or inflamed and the healing process can be hindered [1].

Limitations

Pain was the primary parameter measured in this study since it is clinically relevant to the pathology of the lesion and widely used in other studies. The demographic characteristics of the groups were similar, indicating that randomization process were effective. It should be taken into account that spontaneous improvement of plantar fasciitis occur 10 to 12 month after the onset of symptoms and pain limits the functions mainly in the first months [16]. A cautious interpretation of this finding is recommended since many participants had a long-term history of plantar fasciitis once enrolled in this trial. Such people could be spontaneously improved due to the nature of lesion nad by progress in the healing process not only the orthotics management. Both insoles used in this study slightly raised the heel and mid-foot this alters the foot and ankle biomechanics. If users have any problems to accommodate with this condition it would cause

harmful effects for users. Caution is required while prescribing a shock absorbing heel pad for people with balance disability or who have a problem in the forefoot area.

Conclusion

Orthotic management was effective in the treatment of plantar fasciitis. Two types of orthoses did not have a significant pain improvement or function improvement in this study.

Clinical Implication

It is recommended that an elastic foot orthoses, that either contours the heel or support the longitudinal arch of the foot, is an effective intervention in the pain management of people with plantar fasciitis.

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