

Effect of the silicone heel pad on plantar fasciitis

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Abstract

Objectives: To evaluate the effect of silicone heel pad in the management of pain in plantar fasciitis patients.

Methods: The descriptive case series study was conducted at Hope Rehabilitation Centre, Lahore, from March 1 to September 30, 2013, and comprised patients aged ≥ 18 years with symptomatic plantar fasciitis who were treated with silicone heel pad. All patients were assessed at one month and six months for pain relief measured on % Maximum Total Pain Relief and Pain Intensity Difference percentage scales. Data was analysed using SPSS 20.

Results: Out of 100 patients, 37(37%) were male and 63(63%) were female. The mean age of the patients was 44.25 ± 12.75 years. Five (5%) patients were lost to follow-up during the study, while 7(7%) patients changed their initial treatment because they did not experience relief.

Silicone heel pad reported a better outcome measure associated with the patient's heel pain as 74(84.09%) patients resolved their condition or reached a tolerance level and showed preferable reduction in heel pain. There were statistically significant difference between pain relieved and treatment duration ($p=0.039$).

Conclusion: Conservative intervention with silicone heel pad showed relief from heel pain and it allowed the patient to manage the condition more effectively with no complications but for shortterm. It was less effective in the long term.

Keywords: Osteoarthritis, Plantar fasciitis, Silicone heel pad. (JPMA 65: S-123 (Suppl. 3); 2015)

Introduction

The plantar fascia or plantar aponeurosis is dense, multi-layered fibrous connective tissue on the sole of the foot.¹ It is made up of approximately 2 to 4mm thick fibrous band (medial, central and lateral), which is located on the plantar surface of the foot. This fascia assists in forming the longitudinal arch of the foot² that is especially designed to disperse weight around the plantar medial tubercle of the calcaneus. Sometimes using a heel lift is helpful in shifting pressure to the forefoot.

The planter fascia originates from the plantar aspect of the medial calcaneal tubercles it originates near the medial process of the medial calcaneal tubercle and inserts onto the plantar ligamentocapsular complex of the first through fifth metatarsal heads.³ The origin of the plantar fascia is the most "fixed" point of this structure, and it is this site that is most prone to injury From there, the fascia extends along the sole of the foot before inserting at the base of the toes, and supports the arch of the foot.⁴

Plantar fasciitis is one of the most common causes of heel pain² estimated to affect 2 million people in the United States alone.

The prevalence rate is 2.5% up to 10%,⁵ with 83% of these patients having active working life.⁶ Among the asymptomatic population, it was found to be between 4% to 22%.⁷ Incidence rate is found to be approximately 11-15% at the age 40-60 years.⁸ There are various treatment modalities for plantar fasciitis, including conservative approach of resting, oral non-steroidal anti-inflammatory drugs (NSAIDs) that can be given for several weeks, and surgical approaches with good to excellent clinical results.⁹

Although most cases of plantar fascia can be successfully managed with a conservative approach, but surgery is considered after the failure of the conservative treatment.¹⁰ However, there is no single universally accepted way of treating this condition.

Silicone heel pad non-invasive modalities made of a skin-like medical-grade silicone that resists bacterial growth and does not dry out, provides a useful balance between support and flexibility which is readily accepted by the plantar fasciitis patients. It may also be helpful when worn overnight to position the foot and heel to provide pain relief and a gentle stretch. It will not flatten under repeated pressure from walking or standing and has a very long life expectancy.¹¹ Silicone heel pads for plantar fasciitis are used to help relieve the tension and resultant inflammation associated with plantar fasciitis inflammation and degeneration of the thick band of tissue that supports the sole of the foot.

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Silicone is a cheap, safe and effective accommodating non-invasive material for plantar fasciitis patients with no complications. The current study was planned to evaluate the effect of the silicone heel pad on the assessment of pain relief among plantar fasciitis patients to understand its acceptability and low risk in cases of plantar fasciitis, so that a decision can be made regarding the implementation of this technique at a large scale in our population.

Material & Methods

The descriptive case series study was conducted at Hope Rehabilitation Centre, Lahore, from March 1 to September 30, 2013, and comprised patients aged ≥ 18 years with symptomatic plantar fasciitis who were treated with silicone heel pad.

Plantar fasciitis diagnosis was made according to the guidelines of the American College of Foot and Ankle Surgeons (ACFAS) Heel Pain Committee.¹² This was based on medical record as well as significant history of planter heel pain with symptomatic duration of at least 2 month i.e. initiated by weight-bearing, pain provoked by the first few steps in the morning, by standing after prolonged sitting and tenderness localised to the origin of the plantar fasciitis on the medial calcaneal tubercle. Dorsiflexion and palpation of the inferior heel were also considered. All cases of previous foot surgery, foot trauma, tarsal tunnel syndrome and other medical causes and patients with generalised inflammatory disorder (gout disease, ankylosing spondylitis, rheumatoid arthritis or lupus) and other medical causes with similar symptom and signs were excluded.

After examining the patient and relevant investigations, informed consent was obtained from each patient. All the patients received treatment with silicone heel pad. All patients were examined by a doctor. NASIDs, such as ibuprofen, naproxen or diclofenac sodium, were given to the patients for 1 week.

Demographic history was noted for each patient. This included gender, age and body mass index (BMI). The patients were assessed for the outcome parameter i.e. proportion of pain relief, which was defined as the cut-off point for both the %Max Total Pain Relief (TOTPAR) and the Pain Intensity Difference (PID%) scales being 33%.^{13,14} The follow-up was done at one month and six months after the intervention. Data was collected on phone using a specially-designed proforma.

Data was analysed using SPSS 20. Mean \pm standard deviation (SD) was given for quantitative variables. Frequencies, percentages and graphs were given for

qualitative variables. Outcome assessments (pain relief) were analysed using chi-square test to observe the efficacy of the silicone insole (treatment), Five per cent level of significance was used. All tests applied were two tailed.

Results

Out of 100 patients, 37(37%) were male and 63(63%) were female (Figure-1). The mean age of the patients was 44.25 ± 12.75 years and mean BMI was 25.00 ± 2.22 (Table-

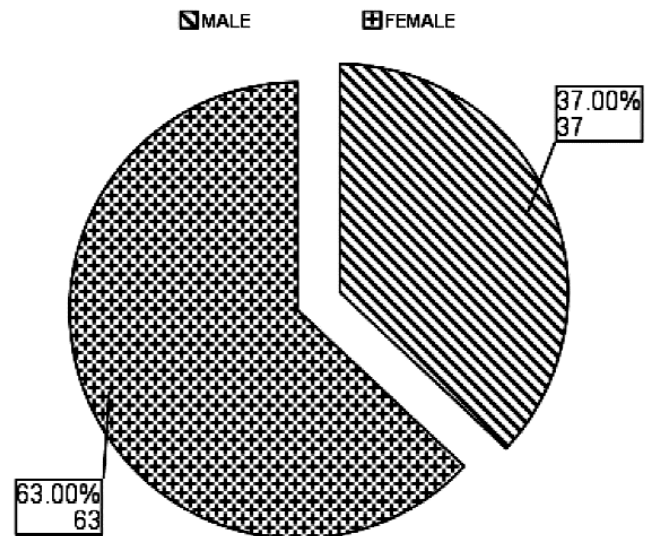


Figure-1: Frequency distribution of the gender.

1). Five (5%) patients were lost to follow-up during the study, while 7(7%) patients changed their initial treatment because they did not experience relief (Figure-2).

Of the 88 patients who completed the six-month follow-up, 74(84.09%) resolved their condition or reached tolerance level.

At one month, 3(3%) patients were lost to follow-up, and

Table-1: Patient Characteristics.

Gender	Male	63(63%)
	Female	37(37%)
Age		44.25 ± 12.75
Body Mass Index		25.00 ± 2.22
Follow-up Pain relief (after 1 month)		64(65.97%)
Follow-up Pain relief (after 6 month)		10(41.67%)

Table-2: One-month and six-month effect of silicone insole.

	1st month	6th month	Total	P-value
Yes	64/97(65.97%)	10/24(41.67%)	74/88(84.09%)	0.036
No	33/97(34.03%)	14/24(58.33%)	21/31(67.74%)	

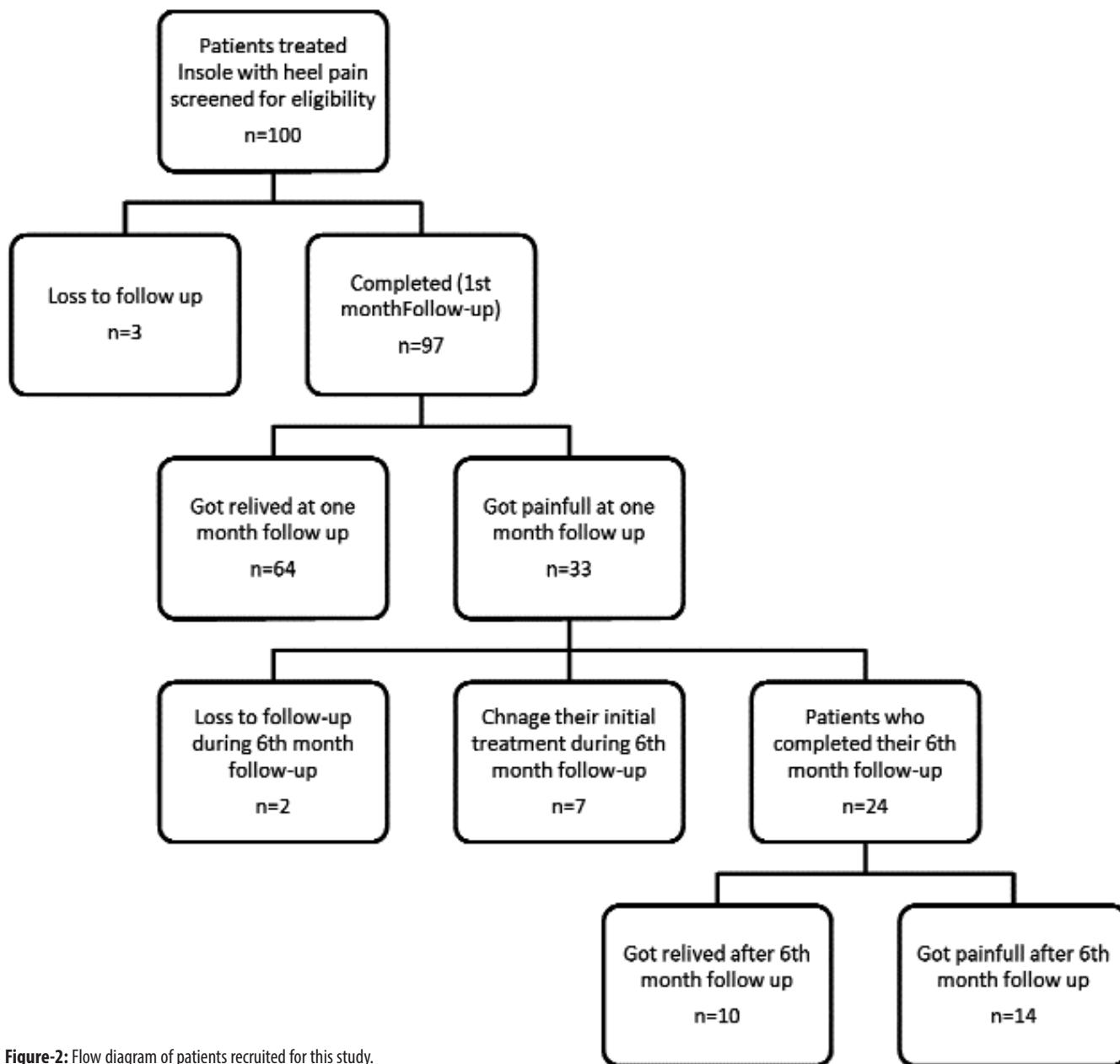


Figure-2: Flow diagram of patients recruited for this study.

64(64%) got relieved while 33(33%) remained in pain. No patient changed the initial treatment after one-month follow-up.

The 33 patients who were still in pain at one month were followed up for 3 months. During the six-month follow-up, 2(6%) patients were lost to follow-up and 7(21%) changed their initial treatment.

Of the remaining 24(73%) cases, 10(42%) patients got relief and 14(58%) still had pain. There was statistically significant difference between pain relieved and

treatment duration ($p \leq 0.05$) (Table-2).

Discussion

The study demonstrated that men were at increased risk of plantar fasciitis (63%) compare to female (37%). Taunton¹⁵ and Lapidus PW et al.¹⁶ reported higher percentage of men in the heel pain group compared to females (55.8% vs. 44.18%).

Yucel U et al.¹⁷ established that plantar fasciitis is more prevalent in female patients compared to male patients (76.6% vs. 23.3%). Another study¹⁸ found that plantar

fasciitis was more in women than men (67.79% vs. 32.21%). This disparity may be due to bias in selection of women.

The present study provides evidence that plantar fasciitis patients were older (44.25 ± 12.75 years). Yucel U¹⁷ and Turlik MA et al.¹⁹ presented similar results (47.4 ± 7.9 and 46.2 ± 6.4 years).

The present study showed that silicone heel pad is affordable and readily available non-operative treatment for the treatment of plantar fasciitis patients. It provides evidence that the silicone insole is more effective treatment for plantar fasciitis patients. With time and a good conservative treatment plan, 84.09% patients were able to resolve their condition or reach a tolerance level where it did not have much effect on their lifestyles. It showed preferable reduction in some aspects of pain in plantar fascia in the short term as patients got relieved more at one month (65.9%) while less at six month (41.67%).

There were only a few studies to assess whether stretching is effective compared to control or other interventions, for either pain or function. However, there is some evidence that plantar fascia stretching may be more effective than Achilles tendon stretching alone in the short-term. Appropriately powered randomised controlled trials (RCTs), utilising validated outcome measures, blinded assessors and long-term follow up are needed to assess the efficacy of stretching.

Our results are comparable with those of Pfeiffer G et al.¹⁸ who demonstrated that silicone insole was a more effective treatment for plantar fasciitis patients. Results showed significant improvement in pain, 95% (88% for a felt pad, 81% for a rubber heel cup) patients resolved their condition or reached a tolerance level compared to custom-made orthotic devices and stretching alone (68% and 72%) at 8 weeks. As felt pad and rubber heel cup also provide cushioning effect, our results demonstrated higher incidence of pain relief.

Another study²⁰ analysed the effectiveness of silicone inserts as a conservative treatment for patients with plantar fasciitis, and found that silicone insole was significantly effective in reducing pain and increasing functions in the short term.

Yucel U et al¹⁷ established that 80% of patients resolved their condition or reached a tolerance level after using full-length silicone insoles. It further found statistically significant difference in mean pain score before and after treatment (6.95 ± 0.94 vs. 4.65 ± 1.34 ; $p < 0.05$).

Crawford F. et al²¹ reported improvement in 72% patients at 6-month follow-up. Our study showed slightly higher incidence of pain relief due to small sample size.

Landorf KB et al.²² noted that prefabricated insole was more likely to produce improvement in pain (74%; 23.4 point improvement after 3 months) as part of the initial treatment of proximal plantar fasciitis compared to other orthotic devices. Our results are similar.

A study by Lynch DM et al.²³ found that silicon insole was less effective in resolving pain or allowing a tolerance level compared to mechanical treatment (30% vs. 70%) or anti-inflammatory treatment (33%).

Kulcu DG et al.²⁴ scrutinised the effect of the silicone insoles compared to patients without insoles, and reported no beneficial effect in normalising forces acting on the foot and relieving pain ($p > 0.05$).

Bonanno et al.²⁵ found that silicon heel cup, soft foam heel pad, and heel lift were less effective at reducing pain under the heel in older people (>65 years of age) with heel pain.

In contrast to our study, Lynch DM,²⁰ Kulcu DG²¹ and Bonanno et al²² showed different results due to the small sample size or different age structure with co-morbid condition like obesity. Different ethnic backgrounds could be another reason for different results.

In many studies, silicone heel pad treatment was not assessed alone. It is very difficult to assess the effectiveness of each individual treatment. We also could not figure out whether the silicon heel pad was more effective for patient with BMI >30. We could not find the reason for not alleviating the symptoms in 34% in one month and 58% in 6 months study period who got silicone heel pad treatment. There could be some other factor causing the symptoms in plantar fasciitis that need to be explored. There is a need for further study with bigger sample size and longer follow-up to get more authenticity in prescribing silicon heel pads for plantar fasciitis.

There were too few studies to assess whether or not silicone insole is effective for heel pain. However, there is some evidence that silicone insole may be more effective for plantar fascia patients in the short term. Appropriately-powered randomised controlled trials utilising validated outcome measures and blinded assessors are needed to assess the efficacy of heel pad.

Conclusion

Conservative treatment with silicone heel pad

demonstrated relief from heel pain and allowed the patient to manage the condition more effectively. Besides, silicone heel pad treatment has shown short-term recovery times to be faster with decrease in pain levels, although long-term recovery times have been slow with slight increase in pain levels.

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