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Anatomy-Based Analysis of Silicone Heel Pad Efficacy in Treating Plantar Fasciitis Yasir Iqbal,¹ Adnan Badar,² Salman Yunas,³ Muhammad Zahir Shah,⁴ Sajid Akhtar,⁵ Sultan Mahmood,⁶

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ABSTRACT

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

Patients and Methods: This descriptive case series study enrolled 100 patients with symptomatic plantar fasciitis to treatment with silicone heel pad, aged ≥18 years were selected from outdoor orthotics departments of HOPE Rehabilitation Center in Lahore, Pakistan from $1^{\rm st}$ March 2013 to 31st September 2013. All patients were assessed at 6 months. Patient characteristics, Post operative assessment at one and six month i.e. pain relief (which is measured on both %Max TOTPAR and PID% scale) were recorded, while data was analyzed by using SPSS version 20. P-value ≤ 0.05 was taken as significant.

Results: There were total 100 patients of which 63(63%) were female while 37(37%) were male. The mean age of the patients was 44.25±12.75 years. Out of hundred; five patients became lost to follow up and eight patients changed their initial treatment during the 6 month follow-up period because did not experience relief. Results showed significant improvement in pain at four weeks was 88% as compare to six month 74%. We observed statistically significant differences in outcome assessments (pain relief) by using silicone heel pad in patients with the plantar fasciitis at six month compared to one month follow-up as (72%; P-value=0.039).

Conclusion: Silicone heel pad is effective in mediating pain relief for patients with plantar fasciitis at one and six month.

Key Words: Osteoarthritis, plantar fasciitis, silicone heel pad.

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INTRODUCTION

The plantar fascia or plantar aponeurosis is dense, multilayered fibrous connective tissue on the sole of the foot. It is made up of approximately 2 to 4 mm thick fibrous band i.e. (medical, central and lateral), which is located on the plantar surface of the foot. This fascia assists in forming the longitudinal arch of the foot. ²

The Planter fascia originates from the plantar aspect of the medial calcaneal tubercle, as its originates near the medial process of the medical 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 pain,² also estimated to affect 2 million people in the United States alone.

The prevalence rate of the population may present with plantar fasciitis is 2.5% up to 10%,⁵ with 83% of these patients being active working.⁶ While among 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 conservatively consisting of rest, oral nonsteroidal anti-inflammatory drugs, that's can be given for several weeks and surgical have been adopted, with good-to-excellent clinical results.⁹

Although most cases of plantar fascia can be successfully managed with a conservative approach. Surgery should be considered only after failure of the conservative treatment¹⁰.

Silicone heel pad non-invasive modalities made of a skin-like medical grade silicone that resists to bacterial growth and does not dry out, provides a useful balance between support and flexibility which is readily accepted by the plantar fasciitis patients also may 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 it has a very long life expectancy. ¹¹

As silicone is a cheap safe and effective accommodating noninvasive material for plantar fasciitis patients with no complication. This study is designed 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 wide scale in our population. As per available resources, there is no local data available therefore this study will be a good addition in the relevant medical literature.

MATERIALS & METHODS

This descriptive case series study included 100 consecutive patients who underwent conservative treatment, both male and female, aged >15 years were selected from outdoor orthotics departments of HOPE Rehabilitation Center in Lahore, Pakistan from 1st March 2013 to 31st September 2013.

Patients were fulfilling the criteria of diagnosis of plantar fasciitis according to the guidelines of the American College of Foot and Ankle Surgeons (ACFAS) heel pain committee¹² as (medical record and who experiencing 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 morning by standing after prolonged sitting and tenderness localized to the origin of the plantar fasciitis on the medical calcaneal tubercle) and elicited by dorsiflexion and palpation of the inferior heel were considered to have PF were included while; all cases of previous foot surgery, foot trauma, tarsal tunnel syndrome and other medical causes with patients with generalized inflammatory disorder i.e. (gout disease, ankylosing spondylitis, rheumatoid arthritis or lupus) and other medical cause with similar symptom and signs were excluded from the study. After examining the patient and relevant investigations, an informed consent was obtained from each patient. All the patients who fall under inclusion criteria received treatment with silicone heel pad. All patients were examined by a doctor. Pain killer (NASIDS) such as ibuprofen, naproxen or diclofenac sodium was given to the patient for 1 week.

Demographic history was noted for each patient by interview and direct observation i.e. gender, age, BMI (calculated by weight/squared height ratio). The patients were assessed for the outcome parameter i.e. proportion of pain relief (defined as the cut-off point for both the % Max TOTPAR and the PID% was 33%)^{13,14}. The follow up of the patients was done at one month and six month after intervention by an examiner, data was collected on phone. All the information was collected on a specially designed Performa.

Statistical analysis:

Data was analyzed by using SPSS (Statistical Package for Social Sciences) Version 20.0 for Window. Mean \pm S.D was given for quantitative variables. Frequencies, percentages and graphs were given for qualitative variables. Outcome assessments (pain relief) were analyzed using chi-square test to observe the efficacy of the silicone insole (treatment), 5% level of significance was used. All tests applied were two tailed.

RESULTS

Among 100 patients who were subjected to the treatment and their pain relief was assessed only 87 patients who completed the trial and five patients were lost to follow-up as (3 patients at one month and 2 patients at six month), while eight patients changed their initial treatment during the six month follow-up period and no patient changed their initial treatment during one month follow-up.

SMALE EPRALE

37.00%
37

Out of 100 patients of which 63(63%) were male while 37(37%)

were female. The mean age of the patients was 44.25±12.75 years and the average of BMI was 25.00±2.22 as shown in table I.

Three patients at one month were lost to follow-up while, out of 97 cases 64 patients had pain relieved after using silicone heel pad and thirty-three patients were remained painful after using silicone heel pad treatment. No patients changed their initial treatment at one month follow-up.

Out of 33 patients who remained painful after using treatment at one month, two patients became lost to follow-up and seven patients changed their initial treatment during the six month follow-up. Out of 24 cases 10 patients had pain relieved and fourteen patients remained painful after using silicone heel pad treatment at six month follow-up while the difference was statistically significant as p-value > 0.05.

Table-1: Patient Characteristics

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

Table-2: 1st and 6th month after effect of silicone insole for the assessments of pain relief on plantar fasciitis patients

	1st month	6 th month	P-value
Yes	64/97(65.97%)	10/24(41.67%)	0.036
no	33/97(34.03%)	14/24(58.33%)	

DISCUSSION:

A silicone heel pad is affordable and readily available non-operative treatment for the treatment of plantar fasciitis patients. The present study provides evidence that the silicone insole is an effective treatment for plantar fasciitis patients. With time and a good conservative treatment plan, approximately 84% of patients were resolve their condition or reach a tolerance level where it does not have much effect on their lifestyle as it showed significant improvement in pain at 4 week and six month follow-up.

Our results were comparable with the previous literature by Pfeffer G ¹⁵et al demonstrated that silicone insole was more effective treatment for plantar fasciitis patients. Results showed significant improvement in pain at eight weeks was 95% (88% for a felt pad, 81% for a rubber heel cup) as compare to custom-made orthotic devices and stretching alone (68% and 72%).

Another study by Garrett T ¹⁶ et al analyzed the effectiveness of silicone inserts as a conservative treatment for patients with plantar fasciitis, initiated that silicone insole was significantly effective in reducing pain and increasing functions in the short term.

Yucel U et al 17 compared the full-length silicone insoles with ultrasound-guided CSI in patients with plantar fasciitis, both treatments showed significant improvement in pain relief additionally, pain score was more improve in injection group than in insole group as 6.45 ± 1.23 vs. 6.95 ± 0.94) at 1 month but not at six months. Further found statistically significant difference in mean pain score before and after treatment (6.95 \pm 0.94 vs. 4.65 ± 1.34 ;P-value <0.05).

Crawford F et al ¹⁸ provided limited evidence that heel pads are associated with better outcomes than custom made orthoses in people who stand for more than eight hours per day.

Landorf KB et al¹⁹ accomplished that prefabricated insole was more likely to produce improvement in pain as part of the initial treatment of proximal plantar fasciitis as compare to other orthotic devices, we demonstrated the similar results

Further study by Lynch DM et al²⁰ found that silicon insole is less effective in providing short-term pain relief as compare to mechanical treatment (30% vs. 70%) or anti-inflammatory treatment 33%.

Kulcu DG et al²¹ scutinized the effect of the silicone insoles as compare to without insoles, initiated no beneficial effect in normalizing forces acting on the foot and relieve pain, as no statistical significant difference was found between the pre and post operative mean pain score.

Bonanno et al ²² 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 DG ²¹ and Bonanno et al ²² showed different results due to the small sample size or different age structure with co-morbid condition like obesity. Different ethnic background could be another reason for different results.

CONCLUSION

Silicone insole is recommended first-line treatment for patients with plantar fasciitis. All patients who had a job of prolonged standing were less likely to do well indicating a need for rest for those silicone heel pad was found to be more effective and safe treatment as it significantly improve pain at one month follow-up.

In many literatures 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 whose BMI > 30. We could not find out 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 only silicon heel pads for plantar fasciitis.

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