Effect of Prefabricated Insole with Shock Absorb Canal and Custom-Molded Insole on Pain and Function in Subjects with Plantar Fasciitis: A Pilot Study

Elahe Karami [a], Reza Vahab Kashani [a*], Monireh Ahmadi Bani [a], Aliyeh Daryabor [b]

a Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Science, Iran, Tehran; ***b*** Physiotherapy Research Center, School of Rehabilitation, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Corresponding Author:** Reza Vahab Kashani, Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Kodakyar st, Daneshjo Blvd., Evin, Tehran1985713834, Iran. ***E-mail: vahabkashani@yahoo.com

Submitted: 2020-05-09; **Accepted**: 2020-08-14; **Doi:** https://doi.org/10.22037/jcpr.v5i4.32267

Abstract

Introduction: The purpose of this study was comparison of the effect of custom-molded insole and prefabricated insole with shock absorb canal on pain and function in subjects with plantar fasciitis. **Methods and Materials:** In this pilot study, fourteen patients with plantar fasciitis were non-randomly assigned to two groups of 7 people. A group received the custom-molded insoles and another group received the prefabricated insoles with shock absorb canal. Before the use of the insoles in each group, the patients ' pain and function were recorded. The pain score was measured by Visual Analog Scale (VAS). For evaluating the function, patients were asked to complete the foot and ankle ability measurement questionnaire (FAAM).Then, patients in both groups used insoles for 6 weeks. After a 6-week use of the insoles, the pain and function were recorded for the second time. Wilcoxon test was used for the effect of insoles in each group (comparison before and after the intervention) and Mann-Whitney test for comparison between two groups. **Results:** In comparison within each group, the findings showed that the use of both insoles after 6 weeks led to a significant decrease in pain score and a significant increase in the score of daily activities as well as sports activities compared with before use of insoles (P<0.05). There were no statistically significant differences in pain and function scores between the two groups after using the insoles (P>0.05). **Conclusion:** According to the findings, there was no significant difference between the custom-molded insole and the prefabricated insole in improving pain and function of patients with plantar fasciitis. However, both types of insoles reduced pain and improved the function, with more acceptable to the prefabricated insole.

Key word: Custom-Molded Insole, Foot Orthosis, Heel Pain, Plantar Fasciitis

Please cite this paper as: Karami E, Vahab Kashani R, Ahmadi Bani M, Daryabor A. Effect of Prefabricated Insole with Shock Absorb Canal and Custom-Molded Insole on Pain and Function in Subjects with Plantar Fasciitis: A Pilot Study: A Pilot Study. J Clin Physio Res. 2020; 5(4): e25. Doi: https://doi.org/10.22037/jcpr.v5i4.32267

Introduction

Plantar fascia is a connective and hard tissue structure extended from the heel to the toes in foot plantar surface (1). This tissue provides stability for the "medial longitudinal arch" of the foot and also prevents its excessive stretching (2, 3). Plantar fascia also plays an important role in dynamic function during gait and normal mechanical function of the foot (2). Plantar fasciitis is a degenerative and inflammatory syndrome caused by recurrent trauma to the junction of the plantar fascia in the " inferior medial aspect the calcaneus of the calcaneus" (4-8), and is one of the most common causes of heel pain in adults (5, 7, 9). Pain and inflammation may also extend distally along the medial longitudinal arch (6). Plantar fasciitis affects approximately 10% of the general population (3, 6). This disorder is more prevalent in people with the age of 40-60 years old that often seen in women (3). This disorder is especially common in runners, obese people, and individuals with inflammatory arthritis (10, 11). Pain disorder is usually characterized by the first steps in the morning or after a long period of rest (6, 7, 9, 12, 13), which reduces people's ability to perform their daily activities (6, 9, 12). After the first steps, the pain usually decreases but gradually increases during the day with increasing weight bearing (3, 7-9, 12). Clinical features of this disorder are pain and tenderness in the inferior medial aspect of the heel and medial longitudinal arch (7, 14),decreased daily activities, and dysfunction (14).

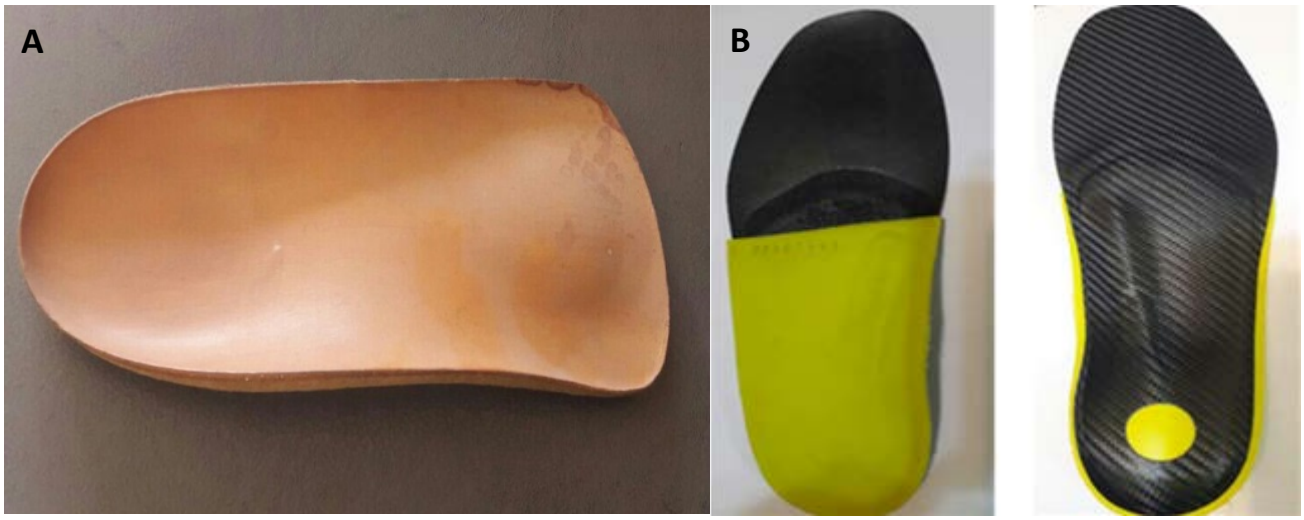

Figure 1. *A*) Custom made thermoplastic insole; *B*) Prefabricated carbon insole

Various factors are involved in the formation of plantar fasciitis, including pes planus, pes cavus, obesity, fat pad atrophy, leg length discrepancy (3, 8, 9, 15), excessive pronation of the subtalar joint (8, 16), improper shoes, and long -term standing and walking (8, 15, 17). There is a wide range of conservative treatments for plantar fasciitis, including: rest, physiotherapy, nonsteroidal anti-inflammatory drugs, steroid injections, shoe modification, arch support, heel cups, custom- molded insoles (orthoses), prefabricated orthoses, and night splints (7, 8, 14, 18). One of the most commonly used conservative treatments is orthoses. Foot orthoses are thought to reduce the symptoms of plantar fasciitis by reducing plantar fascia stretching while standing and walking (1, 11). These treatments are usually low risk and can affect the biomechanical factors that cause plantar fasciitis (19).

Clinical experience and studies showed that "custom-molded insoles" are usually approved as an intervention for plantar fasciitis (7). Custom- molded thermoplastic insole is made by molding method that can transfer the forces from the inflamed point to other points. In fact, these insoles should provide sufficient height for the medial longitudinal arch to prevent over-stretching of the plantar fascia, reducing shock, increasing weight distribution in the sole of the foot, and reducing stress on the plantar fascia and heel. (7, 20). Although the therapeutic effect of custom-molded insoles in reducing inflammation has been confirmed, researchers have not yet reached a definitive conclusion about the superiority of this type of insoles over prefabricated insoles. One of the limitations for custom-molded insoles is that the construction of this insole takes time due to being its custom- molded, the cost of its preparation for the patient is high (21), and the thermoplastic material used in this insole has a low impact absorption (17). Compared to custom-molded thermoplastic insoles, prefabricated insoles are prepared sooner, so it is preferable in terms of time. Therefore, prefabricated insoles, which have more impact absorption and smaller volume and can be worn in any shoes, can be a good treatment option.

There is also one kind of prefabricated insoles made of carbon composite and high quality materials. The upper surface of the sole is covered with soft foam and has foam canal in the medial longitudinal arch that covers the heel to the metatarsus head. This canal has shock-absorbing properties and relieves pressure from the painful heel, which a person with plantar fasciitis feels less pain when walking. The manufacturers of this type of insole claim that these insoles, due to their special structure (foam canal as well as the carbon materials used, create a high level of comfort. Those can be placed in any shoes and create an optimal walking pattern, which are effective in treating plantar fasciitis. Therefore, in this study, "carbon insole with shock absorber canal" was compared with custom-molded thermoplastic insole. We would expect that carbon insole with shock absorber canal could be more effective than custom-molded insole in reducing pain and increasing the function in people with plantar fasciitis in order to be used as an orthotic treatment in "orthosis and prosthesis" clinics. Therefore, the aim of this study was to compare the effect of custom- molded orthosis made of thermoplastic and prefabricated orthosis with shock absorb canal on pain and function in patients with plantar fasciitis.

Table 1. Comparison of pain and function variables in two groups of custom- molded insole and prefabricated insole [Mean (SD)] (*P<0.05)

Variables		Groups	Before intervention	After intervention	*P*-value (pre-test and post-test)
Pain		Custom- molded insole	6.14 (1.54)	3.28 (1.38)	0.018*
		Prefabricated insole	7.57 (2.22)	3.42 (2.22)	0.018*
		P-value (between two groups)	0.197	0.731	-
Function	Daily activities	Custom- molded insole	68.92 (13.85)	85.7 (9.95)	0.002*
		Prefabricated insole	60.11 (17.99)	86.9 (10.04)	0.006*
		P-value (between two groups)	0.481	0.966	-
	Sport activities	Custom- molded insole	68.84 (11.9)	80.07 (13.5)	0.028*
		Prefabricated insole	57.62 (16)	77.26 (17.25)	0.023*
		P -value (between two groups)	0.158	0.797	-

Methods and Materials

In this pilot study, 14 patients with plantar fasciitis, including 13 females and one male, were selected from convenience sampling by simple non-probability method and were non-randomly assigned to two groups of seven people. Inclusion criteria included individuals 18 years of age and older, individuals with a clinical diagnosis of plantar fasciitis by a physician, complaints of pain in the first steps, and maximal sensitivity to "internal calcaneal tuberosity " (21). People with a history of using custom-molded orthoses, people with inflammatory arthritis, those who had received other treatments as well as had injections in the last 6 months were excluded from the study (22, 23). This study was approved by the Ethics Committee of Tehran University of Social Welfare and Rehabilitation Sciences with the ethics code IR.USWR.REC.1397.027 and all individuals signed an informed written consent to participate in this study.
One group received a custom-molded insole and the other group received a prefabricated insole with shock absorb canal. The measured variables were pain and function. Pain was measured by the Visual Analogue Scale (VAS). This criterion consists of a standard straight line that is divided between 0-10 and from left to right. Zero means no pain and 10 means sever pain. Patient function was measured by the Foot and Ankle Ability Measurement Questionnaire (FAAM). This questionnaire is used to measure foot and ankle abilities, which includes 21 questions related to the "daily activities" subscale and 8 questions related to the "sports activities" subscale. The total score for daily activities is 84 and for sports activities is 32. The highest score indicates the highest function and the lowest score indicates the lowest function. Each item includes a "5-point Likert scale" (4 to 0) from "without problem" to "unable". Cronbach's alpha coefficient for daily and sports activities was 0.97 and 0.94, respectively. The Persian version of this questionnaire is a valid criterion for measuring physical function in patients with foot and ankle disorders (24). The subscales of daily life activities are basic daily tasks such as eating, bathing, getting dressed, going to the toilet and moving. The sports subscale evaluates more difficult tasks such as running, jumping, landing, etc. that are necessary for exercise.

In the custom-molded insole group, a cast was taken from the patient with prone position without bearing weight. The subtalar joint was in a neutral position during casting. By applying force to the metatarsals, we kept them in a hyperextension position. Thermoplastic orthosis was extended from the heel to three-quarters of the plantar surface of the foot (head of the metatarsus) with the longitudinal arch of the foot (Figure 1, A) (22). In the prefabricated insole group, a carbon insole was given the individuals according to their foot size. The insole had a carbon sole and a medial longitudinal arch made of foam canal, and the upper surface of the insole was covered with soft foam (Figure 1, B).

Patients in both groups used insoles for 6 weeks. Before using the insoles, patients' pain and function were measured. Patients in each group were then given one type of insole. After 6 weeks, finally, the patient's pain and function were recorded again.

Due to the small sample size in each group, non-parametric tests were used for statistical analysis. In order to evaluate the effect of insoles in each group, Wilcoxon test (comparison before and after the intervention) and Mann-Whitney test for comparison two groups were used. Statistical calculations were performed using SPSS IBM software version 23 with a significance level of 0.05.

Results

Mean, standard deviation, p-value before and after intervention in each group, and p-value for comparison of the two groups are shown in Table 1. The results did not show a significant difference between the two groups before therapeutic interventions (P>0.05). In comparison within the group (before and after the intervention), the results showed that the use of both custom-molded and prefabricated insoles led to a significant reduction in pain score (custom insole group: 2.86%, prefabricated group: 4.15%) and significant increase in daily

activity score (custom insole group: 16.78%, prefabricated group: 26.79%) as well as sports activities (custom insole group: 11.23%, prefabricated group: 19.64%) after 6 weeks compared to before use ($P<0.05$). In comparison between the two groups after 6 weeks of intervention, no significant difference was shown in any of the parameters ($P>0.05$).

Discussion

The aim of this study was to compare the effect of custom-molded thermoplastic insole and prefabricated insole on pain and function in patients suffering from plantar fasciitis. The results of insoles examination after 6 weeks of use compared to before use showed that both custom-molded insoles and prefabricated insoles significantly reduced the average pain intensity and increased the average function in patients. Comparing the two types of insoles with each other in the results of pain intensity and function, no statistically significant difference was observed between the two groups.

The present study was consistent with the study of Martin *et al.* (8). They stated that there was no statistically significant difference between the effect of custom-molded-insoles and prefabricated insoles on the pain of people with plantar fasciitis, and both insoles improved pain and function. Oliveira *et al.* (25) also studied on custom-molded thermoplastic insoles and prefabricated insoles for the treatment of people with plantar fasciitis. In both groups, pain improved when resting. In addition, the present study is consistent with a study by Hawke *et al.* (26) that examined the effects of custom-molded insoles on the pain of patients with plantar fasciitis. Baldassin *et al.* (21), in comparing custom- molded and prefabricated insoles, stated that custom- molded and prefabricated insoles are equally effective in reducing pain and increasing foot function in people with plantar fasciitis.

However, differences in measurement tools, the characteristics of the shoes used in the studies, the method of constructing insoles, the material used in insoles, and the participants' age make it difficult to make accurate judgments. However, in most studies, custom-molded insoles reduced the tensile stress applied to plantar fascia by maintaining the medial longitudinal arch, thereby reducing pain and increasing function. The custom insole of our study also had a medial longitudinal arch that may reduce stretch on the plantar fascia. However, the structure of this insole was made of hard thermoplastic, which has a low impact absorption property. In addition, the amount of foot movement may be reduced during its use and the dynamics of the foot may be impaired. On the other hand, the prefabricated insole used in this study had almost equal effect to the custom-molded insole in reducing pain and improving function. As a result, due to the unique features of this insole compared to custom-molded insoles and also the same effect of these two insoles in improving pain and function of people with plantar fasciitis, it seems that this insole can be a suitable alternative to custom-molded insoles. One of the features of this insole having foam canal is its shock-absorbing property, which can remove pressure from the painful heel and the person with plantar fasciitis feels less pain when walking. These insoles are durable due to their special structure (canal) and also the carbon materials used in them create a high level of comfort. They can be placed in any shoes, create a optimal walking pattern, and are affective in treatment of plantar fasciitis. With the use of these insoles, the need for molding required for custom- molded insoles is eliminated. Therefore, this type of prefabricated insole was delivered to the patient earlier and they were satisfied with this issue. In addition, these insoles had a smaller volume compared to custom- molded insoles, and therefore were easily placed in each shoe and reduced the cost of using standard shoes needed for custom- molded insoles. These features and the similarity of the effect of both insoles on measured parameters seem to be good reasons to replace the custom insole with a new prefabricated insole.

One of the limitations of the present study was the short follow-up time. In addition, the small sample size may indicate the lack of generalizability in the findings of this study.

Conclusion

There was no significant difference between custom- molded insole and prefabricated insole in reducing pain and increasing function in people with plantar fasciitis. Both types of insoles reduced pain and increased function after using them. The prefabricated insole was more accepted by patients due to its smaller volume and less preparation time than custom-molded insole.

Acknowledgment

We would appreciate all participants in the present study. We are grateful to the University of Social Welfare and Rehabilitation Sciences for providing the equipment.

Conflict of interest:

None

Funding support:

None

Authors' contributions:

Authors made substantial contributions to the conception, design, analysis, and interpretation of data.

References

1. Landorf KB, Keenan A-M, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis: a randomized trial. Archives of internal medicine. 2006;166(12):1305-10.
2. Kwong P, Kay D, Voner RT, White MW. Plantar fasciitis. Mechanics and pathomechanics of treatment. Clinics in sports medicine. 1988;7(1):119-26.
3. Healey K, Chen K. Plantar fasciitis: current diagnostic modalities and treatments. Clinics in podiatric medicine and surgery. 2010;27(3):369-80.
4. Cornwall MW, McPoil TG. Plantar fasciitis: etiology and treatment. Journal of Orthopaedic & Sports Physical Therapy. 1999;29(12):756-60.
5. Roxas M. Plantar fasciitis: diagnosis and therapeutic considerations. Alternative medicine review. 2005;10(2).
6. Seligman DA, Dawson DR. Customized heel pads and soft orthotics to treat heel pain and plantar fasciitis. Archives of physical medicine and rehabilitation. 2003;84(10):1564-7.
7. Gross MT, Byers JM, Krafft JL, Lackey EJ, Melton KM. The impact of custom semirigid foot orthotics on pain and disability for individuals with plantar fasciitis. Journal of Orthopaedic & Sports Physical Therapy. 2002;32(4):149-57.
8. Martin JE, Hosch JC, Goforth WP, Murff RT, Lynch DM, Odom RD. Mechanical treatment of plantar fasciitis: a prospective study. Journal of the American Podiatric Medical Association. 2001;91(2):55-62.
9. Lynch DM, Goforth W, Martin J, Odom R, Preece C, Kotter M. Conservative treatment of plantar fasciitis. A prospective study. Journal of the American Podiatric Medical Association. 1998;88(8):375-80.
10. Riddle DL, Pulisic M, Pidcoe P, Johnson RE. Risk factors for plantar fasciitis: a matched case-control study. JBJS. 2003;85(5):872-7.
11. Landorf KB, Keenan A-M, Herbert RD. Effectiveness of different types of foot orthoses for the treatment of plantar fasciitis. Journal of the American Podiatric Medical Association. 2004;94(6):542-9.
12. LeMelle D, Kisilewicz P, Janis L. Chronic plantar fascial inflammation and fibrosis. Clinics in podiatric medicine and surgery. 1990;7(2):385-9.
13. Wolgin M, Cook C, Graham C, Mauldin D. Conservative treatment of plantar heel pain: long-term follow-up. Foot & ankle international. 1994;15(3):97-102.
14. Crawford F, Thomson CE. Interventions for treating plantar heel pain. Cochrane Database of Systematic Reviews. 2003(3).
15. Warren BL, Jones CJ. Predicting plantar fasciitis in runners. Medicine and science in sports and exercise. 1987;19(1):71-3.
16. Kibler WB, Goldberg C, Chandler TJ. Functional biomechanical deficits in running athletes with plantar fasciitis. The American Journal of Sports Medicine. 1991;19(1):66-71.
17. Pfeffer G, Bacchetti P, Deland J, Lewis A, Anderson R, Davis W, et al. Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis. Foot & Ankle International. 1999;20(4):214-21.
18. Atkins D, Crawford F, Edwards J, Lambert M. A systematic review of treatments for the painful heel. Rheumatology. 1999;38(10):968-73.
19. Rasenberg N, Fuit L, Poppe E, Kruijsen-Terpstra A, Gorter K, Rathleff M, et al. The STAP-study: The (cost) effectiveness of custom made orthotic insoles in the treatment for plantar fasciopathy in general practice and sports medicine: design of a randomized controlled trial. BMC musculoskeletal disorders. 2016;17(1):31.
20. Kogler G, Solomonidis S, Paul J. Biomechanics of longitudinal arch support mechanisms in foot orthoses and their effect on plantar aponeurosis strain. Clinical Biomechanics. 1996;11(5):243-52.
21. Baldassin V, Gomes CR, Beraldo PS. Effectiveness of prefabricated and customized foot orthoses made from low-cost foam for noncomplicated plantar fasciitis: a randomized controlled trial. Archives of physical medicine and rehabilitation. 2009;90(4):701-6.
22. Roos E, Engström M, Söderberg B. Foot orthoses for the treatment of plantar fasciitis. Foot & ankle international. 2006;27(8):606-11.
23. Wrobel JS, Fleischer AE, Crews RT, Jarrett B, Najafi B. A randomized controlled trial of custom foot orthoses for the treatment of plantar heel pain. Journal of the American Podiatric Medical Association. 2015;105(4):281-94.
24. Mazaheri M, Salavati M, Negahban H, Sohani S, Taghizadeh F, Feizi A, et al. Reliability and validity of the Persian version of Foot and Ankle Ability Measure (FAAM) to measure functional limitations in patients with foot and ankle disorders. Osteoarthritis and Cartilage. 2010;18(6):755-9.
25. Oliveira HAV, Jones A, Moreira E, Jennings F, Natour J. Effectiveness of total contact insoles in patients with plantar fasciitis. The Journal of rheumatology. 2015;42(5):870-8.
26. Hawke F, Burns J. Brief report: custom foot orthoses for foot pain: what does the evidence say? Foot & ankle international. 2012;33(12):1161-3.