DOI: 10.22122/jrrs.v14i6.3317 Published by Vesnu Publications

The Effect of Strassburg Sock Orthosis on Heel Pain and Quality of Life in Patient with Plantar Fasciitis Lesion

Tahmores Tahmasbi[1], Saideh Mohammadi[2]

Original Article

Abstract

Introduction: Plantar fasciitis is the most common reason for heel pain and the result of some repetitive trauma in calcaneus. People with plantar fasciitis need to be treated through some stretching techniques for plantar fascia and calf muscles, and some anti-inflammatory treatments.

Materials and Methods: In this randomized clinical trial study, 28 patients with plantar fasciitis were selected through convenience sampling method. Individuals with morning pain and tenderness in the insertion of plantar fascia were included, and were assigned in two control and experimental groups. Individuals with a history of surgery, dislocation, and fracture in the lower limb were excluded. Then, they were referred to technical orthopedic clinics for night splinting. The heel pain and quality of life were assessed through Visual Analogue Scale (VAS) and Foot Ankle Outcome Questionnaire, respectively, before treatment, and at the end of the first, fourth, and sixth weeks. The collected data were compared between the groups using independent t test with a significant level of $P < 0.05$.

Results: Regarding pain, daily activity, and sport, there were significant differences between the control and experimental groups at the fourth and sixth weeks. In terms of foot and ankle problems and quality of life, there were significant differences between the control and experimental groups at the first, fourth, and sixth week.

Conclusion: The current study indicates that prefabricate orthotic may be effective in pain relief of the heel, improvement of daily activities, and doing sport over time. Ultimately, the use of this splint increases the quality of life and decreases foot and ankle problems in the people with plantar fasciitis.

Keywords: Plantar fasciitis, Prefabricated orthosis, Splints, Heel pain

Citation: Tahmasbi T, Mohammadi S. **The Effect of Strassburg Sock Orthosis on Heel Pain and Quality of Life in Patient with Plantar Fasciitis Lesion.** J Res Rehabil Sci 2019; 14(6): 325-31.

Received date: 21.11.2018 Accept date: 29.12.2018 Published: 04.02.2019

Introduction

Plantar fasciitis is one of the causes of increased pain in the plantar fascia caused by repeated injury and trauma to the calcaneus. Plantar fasciitis is the most common cause of heel pain in adults (1). Inflammation is actually the major part of this lesion. However, recent studies suggest that some symptoms in this disease are other than inflammation and deformity (2,3). In the United States, more than two million individuals complain of plantar fasciitis annually, with 11 to 15% of visits due to heel pain (4). This pain is more common in the physically active individuals like runners, but it is generally reported in the public, especially women aged 40 to 60 years (5-7).

Plantar fasciitis is caused by various factors. Recent studies have suggested obesity or sudden weight gain, decreased ankle dorsiflexion, and activity in occupations that require long standing to be the causes plantar fasciitis (8). People with flatfoot (Pes Planus) are more likely to develop this complication (1). However, people with high arch (Pes cavus) are also at risk for plantar fasciitis due to the lack of effective distribution of force during exercise (8-10). Individuals who stand for long time due to their occupation are at high risk for this complication due to repeated stretching of the foot fascia (5,7,8). Calcaneal spur is often one of the causes of heel pain and one of the factors that increase the risk of plantar fasciitis. Almost half of people with plantar fasciitis suffer from a calcaneal spur as well. However, it is unclear to what extent the

1- Instructor, Department of Prosthesis and Orthotics, School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran
2- Department of Prosthesis and Orthotics, School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran
Corresponding Author: Tahmores Tahmasbi, Email: t_tahmasbi@yahoo.com

calcaneal spurs affect these conditions (11).

The most common symptom in individuals with plantar fasciitis is pain in the area under the heel. Following waking up in the morning and walking a few steps, these individuals feel severe pain in the heel that sometimes impede their activity. The pain can be severe to the extent that it can make the individual limp. Then, the pain decreases during the day. In general, the pain is noticeable mainly when weight-bearing exercises are performed and pain increases with increasing activity (1). The treatment process usually lasts 1 to 6 months, but sometimes takes longer (8).

The best treatment option available for plantar fasciitis is resting and lack of doing heavy activities resulting in this complication (5,7,8). The treatments include suitable footwear, foot arch support and orthoses, stretching and strengthening, splinting, surgery, anti-inflammatory drugs, shockwave therapy, magnetic insoles, acupuncture, and observation of diet (1).

Posterior night splinting causes ankle dorsiflexion and provides a gentle, continuous stretch for the plantar fascia, allowing the heel to function better. Physicians can use traditional or prefabricated splints (12). Night splinting leads to the plantar fascia stretching, thereby preventing morning pain and dryness and stiffness, which are common symptoms of the disease (13).

Landorf et al. examined the effect of foot orthoses in treating plantar fasciitis in the short-term and long-term and found that although orthoses have short-term beneficial effects on foot function and reduce pain to some extent, they do not have much effect in the long-term (14). A comprehensive systematic study was carried out by Boatwright et al., in which several studies performed on the effect of night splinting (posterior, anterior, night splint sock, and a new splint called Dynasplint) on the treatment of plantar fasciitis were reviewed. The summary of these studies has shown that night splinting can be useful in the treatment of the common symptoms of this disease (15).

One of the problems with using a night splint is to convince the person to use this type of splint while sleeping, because the force created by the front parts of the device leads to stretching the foot and, hence in the plantar fascia. In this structure, which is associated with the pain of inflammation, providing tensile force in the early stages causes pain and motor limitation in the individual. Therefore, the tendency to use this splint is reduced, especially in the early days of treatment, when sleeping and resting. The posterior night splint seems to maintain heel dorsiflexion and stretching of the toes and provides a gentle, permanent stretch for the plantar fascia that allows the heel to function. The difference of the orthoses used in the present study with other studies is in the materials used as well as its modified structure with similar types, which may reduce the difficulty of using orthoses due to this structure and type of materials used and also the tensile forces (manufacturer's claim) and is not abandoned like other splints. The designer of this splint claims that by continually inactive stretching during rest and sleep, the splint puts the plantar fascia and the gastrocnemius soleus in their natural length state, preventing the night contractions of the calf and plantar fascia muscles during sleep and thus, relieving pain in the first steps (9). Therefore, the present study is performed aiming to compare the effect of Strassburg sock orthosis on pain and quality of life (QOL) of patients with plantar fasciitis with drug and physiotherapy interventions.

Materials and Methods

The study population consisted of individuals who had been diagnosed with the plantar fasciitis disorder by the orthopedic, physical medicine, physiotherapy, and other related specialties and were referred to technical orthopedic clinics to receive night splinting. Prior to conducting the study, ethical permission was obtained and the method of implementation was registered on the Iranian Registry of Clinical Trials (IRCT) website. The study subjects were selected through public and private technical orthopedic clinics in Isfahan, Iran by using the convenience sampling method. Then they were randomly assigned into two groups of control and intervention, each with 15 individuals.

The study was accomplished in the technical orthopedic departments affiliated to Isfahan University of Medical Sciences during autumn and winter 2016-2017. The number of subjects was considered to be 30 based on the prevalence rate and similar studies (10). A written consent was obtained from all qualified participants. The study inclusion criteria included heel pain, especially in the early morning steps and tenderness at the junction of the fascia to the calcaneus bone (16). Similarly, the exclusion criteria were a history of foot surgery, dislocation, fracture in the lower extremity, injury to the feet during the past three months, Tarsal tunnel syndrome (TTS), and calcaneal spur (diagnosed using radiological imaging) (17).

The two common groups of treatments, including drug therapy and physiotherapy were used to treat plantar fasciitis (7). In the control group, only the usual treatment such as painkillers and anti-inflammatory drugs or the pain and inflammation reduction modalities were given in physiotherapy, but the intervention group received splint in addition to the usual treatment. the data obtained were collected and evaluated in three stages. In the first session, the pain and QOL of the patients were assessed and recorded. In the intervention group, a splint was presented to the patients and was taught how to be used during the night. To do this, the individual's foot was angled 90 degrees relative to his calf and his toes were placed in the dorsiflexion mode and the individual was asked to keep the orthosis on his foot all night (18). If a subject could not use the orthosis for at least six hours during the night, has was excluded from the study. The participants were asked to come back for evaluation after receiving the splints in specified sessions after four and six weeks (19). The duration of the splinting was considered as six weeks.

The variables evaluated included pain using the visual analogue scale (VAS) and daily activities, exercise, recreation, and QOL based on the score of the Persian version of the Foot and Ankle Outcome Score (FAOS) questionnaire. VAS is the easiest tool to assess the severity of pain that is easily understood and has a scoring range of 0 to 10, with 0 to 10 indicating the lack of pain and the highest severity of pain, respectively. The FAOS questionnaire is comprised of five main sections and 42 items that can be applied for the 20-60 year old individuals. The items in this tool are in a five-option order and for statistical assessments, the responses are categorized with scores 0 to 4. The reliability and validity of the Persian version of the FAOS scale were reported to be appropriate for foot and ankle diseases by the Negahban et al. (18).

The Strassburg Sock™ Night Splint (Germany) used in the present study is a sock consisting of 80% nylon and 20% Lycra (an elastic material). This orthosis covers from the tibial tuberosity and extends to the end of the toes and has two bands, one at the calf area and the other at the tip of the toes, which helps keep the foot in proper position during the use of the splint (Figure 1).

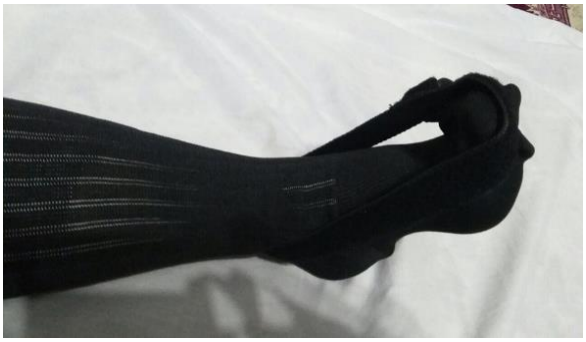

Figure 1. Strassburg Sock™ Night Splint

The normality of the data distribution was evaluated using the Shapiro-Wilk test. In addition, the data collected from the intervention and control groups were compared in the end. The paired t-test or Wilcoxon test was used to evaluate the intragroup differences and the independent t-test or Mann-Whitney test was employed to compare the two groups. Finally, the data were analyzed in SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA) and $P < 0.05$ was considered as the significance level.

Results

Initially, 30 patients were enrolled in the study, among whom one in the control group due to using the treatment during the project implementation and one in the intervention group due to inability to use the orthosis were withdrawn from the study (Figure 2).

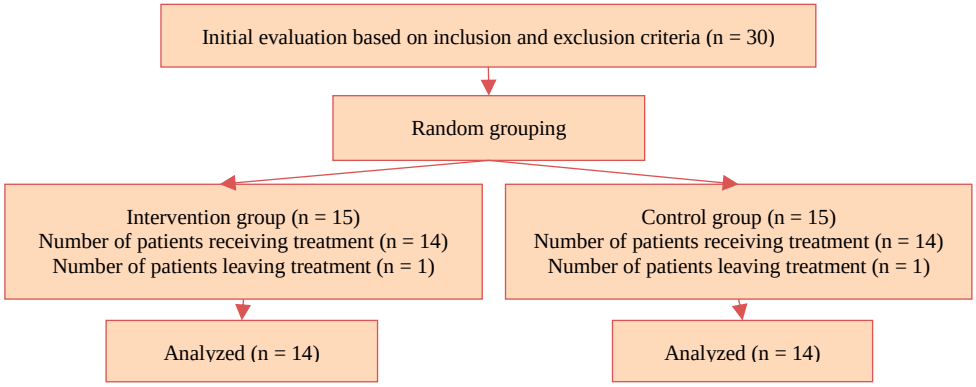

Figure 2. CONSORT diagram of the study process

Table 1. Demographic information of participants

Variable Group	BMI (kg/m^2)	Weight (kg)	Height (cm)	Age (year)
Intervention	23.63 ± 2.12	64.32 ± 7.32	167.63 ± 7.80	35.65 ± 5.60
Control	22.49 ± 1.96	65.23 ± 4.96	169.36 ± 8.10	37.12 ± 5.40
P value	0.14	0.79	0.35	0.23

Data are reported as mean ± standard deviation (SD).

Finally, 28 subjects were examined, with the demographic characteristics presented in table 1. Given the results of the independent t-test, there was no significant difference between the groups in the variables of age, height, weight, and body mass index (BMI) ($P > 0.05$). Therefore, the condition of randomization of the groups was met.

The Shapiro-Wilk test results indicated a normal distribution for all variables. The independent t-test was employed to investigate the significance of the variables between the two groups at baseline, first week, fourth week, and sixth week. On the basis of the results, there was no significant difference between the two groups at baseline ($P > 0.05$). The findings also showed that there was a significant difference between the intervention and control groups in the variables of intensity of pain, daily activities, and exercise and recreation in the fourth and sixth weeks. The results also suggested that there was a significant difference between the two groups in the variables of foot or ankle discomfort and QOL in the first, fourth, and sixth weeks (Table 2).

The VAS test power in the first, fourth, and sixth weeks was 69, 80, and 78, respectively.

Discussion

Plantar fasciitis is a sign of deformation in the plantar fascia caused by repeated injury and trauma to the calcaneus (1). In the present clinical trial, the effect of Strassburg night splint was investigated on the severity of pain, foot and ankle discomfort, daily activities, exercise and recreation, and QOL of individuals with plantar fasciitis. The findings showed no significant difference between the control and intervention groups in the variables of severity of pain, daily activities, and exercise and recreation in the first week, however this difference was significant in the fourth and sixth weeks. Additionally, regarding the QOL and foot and ankle discomfort, significant differences were observed between the two groups in all the first, fourth, and sixth weeks.

Effect of Strassburg night sock splint on pain severity: Given the results, the Strassburg night sock splint reduced pain in patients with plantar fasciitis in the fourth and sixth weeks. Therefore, the prefabricated Strassburg orthosis has been effective in reducing heel pain over time, in other words, this splint should be used for at least four weeks so that its positive therapeutic outcomes could be observed.

This result is consistent with the findings of the studies by Roos et al. (13), Mehlhorn et al. (20), Boatwright et al. (15), and Alghadir (17). The results of a study conducted by Lee et al. suggested that foot orthosis with night splint can be effective in reducing heel pain in patients with plantar fasciitis (21).

Table 2. Comparison of variables studied using independent t-test

Variable	Week	Control group	Intervention group	P-value
Foot and ankle problems	Week 1	4800 ± 4.58	41.80 ± 8.91	0.020
	Week 4	48.40 ± 4.58	39.50 ± 7.60	0.001
	Week 6	47.90 ± 5.50	38.50 ± 6.89	< 0.001
Pain	Week 1	47.90 ± 5.50	39.80 ± 12.31	0.489
	Week 4	43.60 ± 15.87	25.70 ± 7.81	< 0.001
	Week 6	42.20 ± 14.44	18.20 ± 5.31	< 0.001
Daily activity	Week 1	34.80 ± 8.16	34.30 ± 14.31	0.906
	Week 4	34.30 ± 8.08	20.70 ± 8.95	< 0.001
	Week 6	33.70 ± 8.26	14.90 ± 6.72	< 0.001
Sport	Week 1	44.00 ± 8.54	39.60 ± 24.14	0.441
	Week 4	45.00 ± 7.07	23.50 ± 14.34	< 0.001
	Week 6	46.30 ± 7.19	21.00 ± 13.04	< 0.001
Quality of life	Week 1	61.10 ± 13.01	74.50 ± 15.40	0.020
	Week 4	60.20 ± 11.39	45.50 ± 13.12	0.003
	Week 6	59.30 ± 10.89	35.20 ± 8.35	< 0.001

Data are reported as mean ± standard deviation (SD).

The difference between the present study with previous ones is in the type of orthosis used. The orthosis used in the present study differed from those used in the afore-mentioned studies (13,15,17,20) in terms of the materials used in the orthosis and bonding of the stretch strap to the end of the orthosis. The material with its structure prevents the overall deformation of the orthosis due to the forces applied and it is easier for the patient to bear. Moreover, the stretch strap has a better angle and place of junction.

Effect of Strassburg night sock splint on appropriate time to relieve pain: The results of the study performed by Drake et al. highlight the short-term (four-week) effects of orthosis to relieve heel pain and generally, symptoms due to plantar fasciitis (22). Landorf et al. concluded that although orthoses have short-term (two-to-four-week) beneficial effects on foot function and reduce pain to some extent, they do not have much effect on long-term (six weeks or more) (14). However, Roos et al. declared that orthoses can be accompanied by both short-term and long-term effects (13). The findings in the present study also confirmed that the timely use of orthoses can lead to the short-term (two to four weeks) and long-term (six weeks) effectiveness on reducing pain and ankle and foot discomfort, in addition to enhancing daily activity, recreation and exercise, and QOL.

Effect of Strassburg night sock splint on foot and ankle discomfort, activity and exercise, and QOL of patients with plantar fasciitis: Significant differences were observed in the variables of foot or ankle discomfort and QOL over a six-week period, i.e., the Strassburg night splint reduced foot or ankle discomfort and promoted the QOL. In fact, the positive effect of orthosis on reducing heel pain will automatically increase the patient's activities and improve their QOL, and the patient will be able to perform daily activities better than before. However regarding the exercise and daily activities, this orthosis is required to be used at least four weeks so that its positive effect can be observed on the activity and exercise of a person with plantar fasciitis.

The results of this study regarding QOL and daily activity and exercise are in line with the findings of the study by Lee et al. In fact, using night splints beside the current treatments (based on the results of the present study) or accommodative shoes (based on the results of the study by Lee et al. (21)) may bring about better effects in treating patients with plantar fasciitis.

Limitations

The limited follow-up period for evaluating the variables (six weeks) due to the limited time of the M.Sc. period was among the limitations of the present study.

Recommendations

Given the high incidence rate of plantar fasciitis among the young and adult individuals, particularly in athletes, preventing this complication and its painful side effects, as well as the effective treatment of the lesion are of great importance. Comparison of the Strassburg night splint with other treatments such as muscle stretching or common orthoses would also be efficient. Monitoring individuals over a long period from the end of the intervention and measuring other variables that are negatively affected by chronic plantar fasciitis, such as the ankle joint range of motion (ROM) or other gait indices, can lead to effective outcomes.

Conclusion

The application of the Strassburg night splints seems to be be helpful in reducing heel pain in individuals with plantar fasciitis. Following pain relief, the patient's daily activity may also improve, and the combination of these changes can lead to improving his QOL within six weeks.

Acknowledgments

The present study was extracted from a M.Sc. thesis in technical orthopedics discipline with the number 395375, code of ethics IR.MUI.REC.1395.3.375, and IRCT code IRCT2018111304166N1 approved by Isfahan University of Medical Sciences. The authors would like to appreciate the head of the department of technical orthopedics, Dr. Pourgasem. The authors also appreciate the Clinical Council and the Deputy of Research and Technology, Isfahan University of Medical Sciences as well as all patients who

collaborated in the implementation of this study.

Authors' Contribution

Tahmores Tahmasbi: Study design and ideation, attract funding for the study, providing study equipment and samples, data collection, analysis and interpretation of results, specialized statistics services, manuscript preparation, verification of the manuscript for submission to the journal office, responsibility to maintain the integrity of the study process from beginning to publication; Saideh Mohammadi: Study design and ideation, attract funding for the study, providing study equipment and samples, data collection, analysis and interpretation of results, specialized statistics services, manuscript preparation, verification of the manuscript for submission to the journal office, responsibility to maintain the integrity of the study process from beginning to publication.

Funding

The present study was based on a secondary analysis of part of the information extracted from a M.Sc. thesis in technical orthopedics with code of ethics IR.MUI.REC.1395.3.375 and registration code IRCT2018111304166N1, with funding by Isfahan University of Medical Sciences. This university has been involved in collecting data, analyzing and reporting them, preparing the manuscript, and final approval of the paper for publication.

Conflict of Interests

The authors declare no conflict of interest. Mr. Tahmores Tahmasbi attracted funding for basic studies related to this study from Isfahan University of Medical Sciences and has been working at this university since 1994. Ms. Saideh Mohammadi has been a postgraduate student in Technical Orthopedics Department of Prosthesis and Orthotics, School of Rehabilitation Sciences, Isfahan University of Medical Sciences since 2014.

References

1. Roxas M. Plantar fasciitis: Diagnosis and therapeutic considerations. Altern Med Rev 2005; 10(2): 83-93.
2. Lemont H, Ammirati KM, Usen N. Plantar fasciitis: A degenerative process (fasciosis) without inflammation. J Am Podiatr Med Assoc 2003; 93(3): 234-7.
3. Aldridge T. Diagnosing heel pain in adults. Am Fam Physician 2004; 70(2): 332-8.
4. 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 Int 1999; 20(4): 214-21.
5. Singh D, Angel J, Bentley G, Trevino SG. Fortnightly review. Plantar fasciitis. BMJ 1997; 315(7101): 172-5.
6. Riddle DL, Pulisic M, Sparrow K. Impact of demographic and impairment-related variables on disability associated with plantar fasciitis. Foot Ankle Int 2004; 25(5): 311-7.
7. Buchbinder R. Clinical practice. Plantar fasciitis. N Engl J Med 2004; 350(21): 2159-66.
8. Young CC, Rutherford DS, Niedfeldt MW. Treatment of plantar fasciitis. Am Fam Physician. 2001; 63(3): 467-75.
9. Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabaharan V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: A randomized controlled trial. JAMA 2002; 288(11): 1364-72.
10. Tallia AF, Cardone DA. Diagnostic and therapeutic injection of the ankle and foot. Am Fam Physician 2003; 68(7): 1356-62.
11. DeMaio M, Paine R, Mangine RE, Drez D. Plantar fasciitis. Orthopedics 1993; 16(10): 1153-63.
12. Cole C, Seto C, Gazewood J. Plantar fasciitis: Evidence-based review of diagnosis and therapy. Am Fam Physician 2005; 72(11): 2237-42.
13. Roos E, Engstrom M, Soderberg B. Foot orthoses for the treatment of plantar fasciitis. Foot Ankle Int 2006; 27(8): 606-11.
14. Landorf KB, Keenan AM, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis: A randomized trial. Arch Intern Med 2006; 166(12): 1305-10.
15. Boatwright S, Hutchinson S, Saurman S, Méndez S, Wanyo S, Howard P. The effect of night splints in the treatment of plantar fasciitis: a systematic literature review" (2016). Department of Physical Therapy Capstone Posters
16. Tahririan MA, Motififard M, Tahmasebi MN, Siavashi B. Plantar fasciitis. J Res Med Sci 2012; 17(8): 799-804.
17. Alghadir A. Conservative treatment of plantar fasciitis with dorsiflexion night splints and medial arch supports: A prospective randomized study [PhD Thesis]. Pittsburgh, PA: University of Pittsburgh; 2006.
18. Negahban H, Mazaheri M, Salavati M, Sohani SM, Askari M, Fanian H, et al. Reliability and validity of the foot and ankle outcome score: A validation study from Iran. Clin Rheumatol 2010; 29(5): 479-86.

19. Probe RA, Baca M, Adams R, Preece C. Night splint treatment for plantar fasciitis. A prospective randomized study. Clin Orthop Relat Res 1999; (368): 190-5.
20. Mehlhorn A, Hirschmuller A, Sudkamp NP, Schmal H. A dorsal night splint with continuous extension of the big toe for treatment of plantar heel pain. Fuss und Sprunggelenk 2014; 12(1): 42-7.
21. Lee WC, Wong WY, Kung E, Leung AK. Effectiveness of adjustable dorsiflexion night splint in combination with accommodative foot orthosis on plantar fasciitis. J Rehabil Res Dev 2012; 49(10): 1557-64.
22. Drake M, Bittenbender C, Boyles RE. The short-term effects of treating plantar fasciitis with a temporary custom foot orthosis and stretching. J Orthop Sports Phys Ther 2011; 41(4): 221-31.