Manuscript Details

Manuscript number	YFOOT_2016_9
Title	A Retrospective pilot study of a novel sandal for the treatment of heel and foot pain; The Healing Sole™ clinical trial
Article type	Research paper

Abstract

A retrospective pilot study involving 22 patients (36 feet) with a history of chronic foot pain in the heel and/or instep that determined the effectiveness of an innovative device as a treatment. The Healing Sole™ is a specifically designed flip-flop type shoe that combines multiple clinical treatment modalities in one convenient device conceived to provide an alternative treatment for this malady without changing overall foot alignment. Subject participants answered questionnaires on foot pain and function (FAOS, FADI, LEFS, NPS). The results demonstrated that the mean NPS score for the worst pain last week day 0 was 6.91 (±2.2) and at endpoint was 4.32(±2.78) p=.0014. The mean pre-study NPS score for the average pain last week was 6.14(±2.66) and post-study it was 3.05(±2.13)p=.0001. There was an overall improvement in functional and pain scores as demonstrated by the FAOS (sports, pain, activity and quality of life subscales) with most being significant. The LEFS also demonstrated improvement in responses over the study period. The FADI Index trended positive. There were no adverse events. 94% stated that they would recommend the device to others. These results show this device (flip-flop for heal pain) to be a successful method for the treatment of chronic foot pain.

Keywords	Foot pain; Plantar fasciitis; Windlass; Arch pain; Plantar fascia

Corresponding Author	meredith warner
Corresponding Author's Institution	Warner Orthopedics and Wellness
Order of Authors	meredith warner, James Altazan, Stephen Levins, Kayla Watson, Katelyn Ohmer

Suggested reviewers	Chance Henderson, Clif Richardson

Submission Files Included in this PDF

File Name [File Type]

signed cover letter.pdf [Cover Letter]

title page for submission.docx [Title Page (with Author Details)]

MANUSCRIPT LESS ABSTRACT.docx [Manuscript (without Author Details)]

Figure 1.docx [Figure]

Figure 2.docx [Figure]

Table 1.docx [Figure]

Table 2.docx [Figure]

Table 3.docx [Figure]

Table 4.docx [Figure]

Funding Sources.docx [Conflict of Interest]

CONFLICTS.docx [Conflict of Interest]

HIGHLIGHTS.docx [Highlights]

To view all the submission files, including those not included in the PDF, click on the manuscript title on your EVISE Homepage, then click 'Download zip file'.

Warner orthopedics & wellness

Meredith Warner, MD MBA

www.WarnerOrthopedics.com

June 10, 2016

Editor-in-Chief: R.J. Abboud

A Retrospective pilot study of a novel sandal for the treatment of heel and foot pain; The Healing Sole™ clinical trial

The Foot

Dear Sir:

I am submitting the enclosed manuscript entitled "A Retrospective pilot study of a novel sandal for the treatment of heel and foot pain; The Healing Sole™ clinical trial" for consideration for publication in "The Foot".

This is a retrospective pilot study (case series) that examined the effectiveness of this device for the treatment of heel pain. Multiple validated foot scores were utilized along with the numeric pain scale. 22 patients were included in the study (36 feet). The results demonstrated clinically significant improvements in pain and function regarding initial heel and foot pain. This is an innovative device that is designed to be a simple and effective consumer medical device; the hope is that it can reduce overall costs for patients. The device incorporates multiple treatment modalities for foot pain but does not seek to produce realignment of the foot while providing treatment.

Authors:

Meredith Warner MD MBA, James Altazan PA-C, Steve Levins PT, OCS, FAAOMPT, Kayla Watson, Katelyn Ohmer

All of the authors listed on the title page have contributed to the manuscript, and read and approved of the submission.

Study performed at Warner Orthopedics and Wellness; a private clinic in Baton Rouge Louisiana; IRB approval was waived by the organization as this was a retrospective study and all identifiers were eliminated..

Corresponding Author:

Meredith Warner MD MBA

Warner orthopedics & wellness

Meredith Warner, MD MBA

www.WarnerOrthopedics.com

18161 East Petroleum Dr.

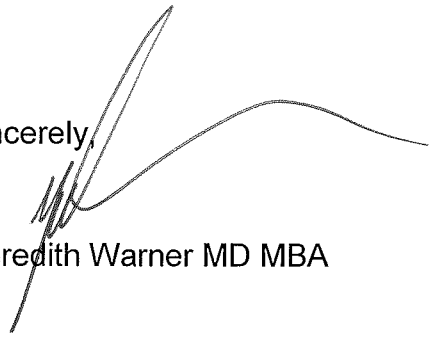
Baton Rouge, Louisiana 70809

225-754-8888

drwarner@warnerorthopedics.com

Thank you for your consideration.

Sincerely,



Meredith Warner MD MBA

Pages:20

Words:3824

Tables:4

Figures:2

References:44

Contact: Meredith Warner

Email: drwarner@warnerorthopedics.com

Guarantor: Meredith Warner

A Retrospective pilot study of a novel sandal for the treatment of heel and foot pain; The Healing Sole™ clinical trial

Meredith Warner MD MBA[1]

James Altazan PA-C[1]

Stephen Levins PT, OCS, FAAOMPT[2]

Kayla Watson[3]

Katelyn Ohmer[4]

[1] Warner Orthopedics and Wellness, 18161 East Petroleum Drive, Baton Rouge, Louisiana 70809;

[2]LevinsPhysio, 15029 Highland Road, Baton Rouge, Louisiana 70810;

[3]Auburn University student; Warner Orthopedics and Wellness

[4] Louisiana State University student; Warner Orthopedics and Wellness

Keywords: plantar fasciitis, heel pain, foot pain, nonoperative, flip-flop, sandal

INTRODUCTION:

Plantar fasciitis is a common and often debilitating condition in the foot characterized by medial and inferior heel pain. Occasionally this pain is near or at the instep or at the lateral and inferior heel. Traditionally, this condition is treated with steroid injections, alignment orthotics, special shoes, anti-inflammatory medications and even surgery; however, there is not a significant amount of evidence to support any of these treatments conclusively. Most of the usual treatments also have a large side-effect profiles. There is a need for a cost-effective OTC device to treat this debilitating and common condition.

Despite a lack of significant evidence to support the traditional treatments, third-party payers cover many of these treatments. Nonetheless, each of these treatments requires considerable utilization of the healthcare system and associated cost to the patient. It is our hypothesis that this device (flip-flop for heel/foot pain) could provide a consumer-medical device that will empower patients to manage this pain without expensive and possible dangerous treatments.

This treatment device (The Healing Sole) is embodied in the form of a flip-flop. We believe that such a consumer medical device could be a safe and effective form of treatment for this common condition. Our initial clinical examination of this device was as an augment to existing treatments or a stand-alone treatment in order to assess for adverse events, patient satisfaction and effectiveness as a treatment.

A group of 22 patients with chronic moderate to severe heel/foot pain used this device for 4-8 weeks. 7:22 were undergoing concurrent treatment, 15:22 were under no treatment plan. We analyzed pre and post-use validated foot pain and function scores as well as the numeric pain scale in order to determine if this was a good treatment modality. We recorded adverse events and also asked about patient satisfaction. Ultimately, we found that this device (flip-flop for foot pain) was in fact a safe and effective treatment for patients.

The plantar fascia is a thick bundle of tissue that originates at the inferior calcaneus, runs along the foot then interdigitates distally at the forefoot. The plantar fascia acts as a tie-rod for the longitudinal arch of the foot and is integral to foot function and strength.[1]

At the great toe, the fascia has a strong attachment and performs the function of a windlass. The windlass supports and cushions the foot during gait.

There are many descriptors of the symptoms of plantar fasciitis available in the literature. The majority of clinical descriptions for plantar fasciitis include pain at the inferior (plantar) and medial heel.[2] This pain is intense with the first steps in the morning and after sitting for a couple of hours. Usually, there is no inciting event for this pain and condition. However, the pain is sometimes precipitated by a change in activity or footwear and increases in weight bearing and/or periods of immobilization. The pain usually improves with use of the foot as the fascia is stretched. The pain of plantar fasciitis is often disabling and can last up to 24 months if left untreated. The peak incidence is between ages 40 and 60. About 10% of the population will be affected by this disorder.[3-7]

Common interventions for plantar fasciitis include night splints, stretching, taping, manual therapy, passive therapy, activity limitations, immobilization, limiting weight bearing, massage, steroid injections, anti-inflammatory medications, and surgery. Often, orthotics are used to alter the native alignment of the foot and unload the plantar fascia; this changes the biomechanics of gait to help symptoms. All treatments carry side effects and risks. In addition, most treatments produce a considerable financial burden.

It was our hypothesis that a medical device (flip-flop for heel pain) designed to improve foot health, function and efficiency of gait could allow a patient to self-treat this condition without expensive treatments that have a larger risk profile. This device was not meant to replace a physician's advice. We examined the efficacy of the device as an augment and/or sole treatment modality. Of the 22 participants 7 were engaged in simultaneous treatment and 15 were not. Therefore, the device (flip-flop for heel/foot pain) was the only difference in 15:22 regimens for the study. The device was configured as a common flip-flop to improve patient compliance and comfort.

Our hypothesis was that this device is an effective and safe adjunct to treatment for plantar fasciitis. Treatment outcomes included pain and function improvements. This was a preliminary study into patient's perceptions of the efficacy of this device for the treatment of heel pain and plantar fasciitis.

Methods:

The device tested was designed to synergistically incorporate various clinical methodologies that are used to treat this condition. The device consists of a rocker-bottom sole, structural base, metatarsal bar, raised great toe, cushion-zone at the medial 1/3 of the heel and specialized low-profile arch bar. There is no other device available that combines these six treatment modalities for simultaneous use. This innovative device is currently patent-pending with the USPO. **FIGURE 1**

Retrospective data were collected from October 2015 through December 2015 at Warner Orthopedics and Wellness (Baton Rouge, Louisiana). The survey results were from this subject pool and not intermingled with others; there were no medications or procedures studied. The data and private health information was safeguarded throughout; all possible identifiers were removed during the study and analysis. Therefore, informed consent and institutional review were waived. There were no sources of financial support provided for this study; the authors have no outside conflicts to report. Statistical analysis involved the Student's T-test for comparison of two groups (pre-intervention and post-intervention). Statistical analysis occurred through http://www.physics.csbsju.edu/cgi-bin/stats/t-test_paste.n.plot.

The duration of heel pain for the participants ranged from 1 year to 3 years of pain prior to use of the device (average was 26 months). 33 surveys were included in the initial study group. 22 participants responded. This yields a response rate of 66.6%. The follow-up time period ranged from 19 days to 87 days. The subjects were asked to wear the shoe part-time. Specifically, it was recommended that the device be used 4-6 hours per day, typically after work; weekend use could be constant if desired. As well, the device was used for the first few steps in the morning. The subjects completed surveys at day 1 of use of the device and then again at the 30 to 60 day point. This study allowed for the assessment of the short-term safety and efficacy of the device for the treatment of heel pain and plantar fasciitis.

The patients were all adults and able to effectively answer the questions as presented. All patients were asked about adverse events; none occurred. Therefore, there was a 0% complication or adverse event rate with the use of the flip-flop. In addition, there were no device failures reported. Another long-term study is currently underway including this cohort and at 9 months there are still no adverse events and/or device failures reported.

The average age of the group testing the device (flip-flop for heel/foot pain) was 42 years old. The average BMI (body mass index) was 26 (range 17-57). The respondents were predominantly female with 3 males in the group. **TABLE 1**

95% of participants stated that they would recommend this device to family and friends. This demonstrates near-universal patient perception of effectiveness, comfort and utility.

The participants included 7 engaged in simultaneous treatment. At the study onset, the subjects not currently in treatment (15:22) had failed prior treatment (at least 2 months prior to study start). Therefore, the device (flip-flop for heel/foot pain) was the only difference in their treatment regimens for the timeframe of the study (60 days). **TABLE 2**

Multiple scoring systems were utilized to assess effectiveness of the device as an intervention. The numeric pain scale (NPS), the Foot and Ankle Outcome Score (FAOS), the Foot and Ankle Disability Index (FADI) and the Lower Extremity Functional Score (LEFS) were tested. Each subject was asked if they would recommend the device to a family member or friend with foot pain. Any adverse events were recorded. The student's t-test was utilized to compare pre and post-intervention scores in the group. The probability of obtaining a result equal to the findings or what was observed when the null hypothesis is true was calculated (p-value). This was considered significant if there was a 5% chance of that happening (0.05).

The numeric pain scale is a validated method of assessing the subjective symptom of pain. This is an 11-point scale (0-10) that allows a patient to describe their pain at any given moment in a manner that is later comparable and reproducible. This scale (and others) is typically not utilized outside of a week due to the problems associated with human memory. It has been validated for use in examinations of the lower extremity.[8] A change of 2 to 3 points is considered to be the minimally detectable change (MDC). A change of 1 point is thought to be the minimally clinically important difference. There is excellent internal consistency for this score within the age group of this study. [9,10] Our results demonstrated a positive minimally clinically important difference and also an acceptable minimally detectable change.

The FAOS was developed as an alternative to less reliable outcome scores for foot and ankle problems. This questionnaire has been utilized for plantar fasciitis studies previously and consists of 5 lichert subscales; the subscales tested are pain, other symptoms, function in daily life, function in sports and also overall quality of life for the foot and ankle. A normalized score is calculated for each subscale; this provides an outcome profile.[11,12] Each score is converted into a percentage of maximum function.

The FADI is formed of two separate scales; these are the FADI (26 items) and the FADI Sport (8 items).[13] There are 4 pain-related items and 22 activity–related items. This

scale was developed to assess athletes. We utilized it to ensure that subtle differences in the athletic portion of the population were not missed. Each of the 34 items is scored on a 5-point Likert scale from 0 (unable to do) to 4 (no difficulty at all). The 4 pain items of the FADI are scored 0 (none) to 4 (unbearable). The FADI has a total point value of 104 points, whereas the FADI Sport has a total point value of 32 points. The FADI and FADI Sport are scored separately as percentages, with 100% representing no dysfunction. The FADI and FADI Sport are scored separately and then transformed into percentages.

The LEFS analyzes an individual's ability to perform daily tasks.[14] It is often used to assess initial function and to monitor ongoing progress and improvement. It is also used to analyze the effectiveness of a given intervention. The scale is scored as a percentage of an individual's maximum function. This scale demonstrates reliability compared with the SF-36 for assessment of outcomes.

RESULTS

The results demonstrated that the mean NPS for the worst pain last week prior to the study was 6.91 (±2.2) and after the study it was 4.32(±2.78). This 62% improvement was statistically significant (p=.0014). The mean pre-study NPS score for average pain last week was 6.14(±2.66) and post-study it was 3.05(±2.13). **TABLE 3** This 49.6% improvement was significant (p=.0001). **FIGURE 2**

FAOS

The FAOS results are summarized in Table 4. The trend was for overall improvement in function; the sports subscale was not found to be significant.

The FAOS symptom-scale results improved from an average of 63% to that of 70%. This represented an improvement in symptoms of about 11% overall.
The FAOS pain score improved from 64% to 75% or a 17% improvement in pain perception (less pain interfered in daily life). The activities of daily living subset also improved from 75 to 81%; this demonstrated an increase in basic functioning of 8%. The sports subscale also showed improvement with use of THS; it moved from 62% to 73%. The sports functionality of the participants therefore improved by 18%. Finally, the quality of life also improved by 33%. This was a large increase in overall wellbeing and the score increased from 42% to 56%.

The FAOS illustrated remarkable improvement in sports function and quality of life and excellent improvement in pain and symptoms. Only activities of daily living had simply a moderate improvement. **TABLE 4**

FADI

The FADI percentile moved from 62.5 (±20.7) to 71.1(±16.5); the p-value was 0.13. This was not significant. The FADI subscale for sports was not statistically significant. This value moved from 29.2(±26.5) to 38.4(±28.1) and the p-value was 0.28. This foot function scoring system is very athlete-oriented and many of the participants answered N/A to the questions. Overall, there was a decrease in the disability due to foot pain. The percentage of function moved from 63% to 68% in the FADI module 1. For the sports module, the percentage moved 4 points from 31.7% to 35%. These scores represent a mild increase in function or decrease in disability. The FADI was developed to detect mild changes in high functioning subjects. This group was not an athlete specific group. Nonetheless, the FADI too showed that the intervention of THS was favorable.

LEFS

The scores for the Lower Extremity Functional Scale improved overall as well. The average pre-intervention score was 51.9. This improved to an average of 60. (When converted to percent-of-maximum-function the numbers moved from 65% to 74%). There was improvement in function of 12% per participant. Our results demonstrated a change from 63.6(±24) to 78(±17.8). The p-value was found to be 0.031. This was significant.

The combination of the NPS, FADI, FAOS and LEFS have allowed us to determine this device is an effective adjunct for and treatment of plantar fasciitis/heel pain. This study demonstrated clinical improvement in each validated scoring scale. Based on these results this device has been proven to assist in the recovery and treatment of heel/instep pain.

This improvement was demonstrated rather quickly over an average of 30 days. In addition, the group was an average age of 42 with an average BMI of 26. (20% overweight). This population group is very representative of the average American with heel/foot pain. There were no adverse events reported from the intervention of the device (flip-flop for heel/foot pain). In addition, there were no side effects. Based on this short-term study, this consumer-medical device (flip-flop for heel/foot pain) is a safe and effective method to treat foot pain, specifically heel and instep pain.

DISCUSSION:

This device was created as a stiff and structural flip-flop to allow better foot recovery and consequently better performance during normal activities, and to increase efficiency and power of the foot.[15,16] Stiffer shoes (particularly at the midsole/foot) allow for energy savings in the foot and improve performance.

Ligaments, tendons and the plantar fascia are all passive contributors to the performance of the foot during use (standing, running, walking, etc.) In theory, resting, stretching and de-stressing these structures will promote faster recovery and pain relief. This device has been designed with that in mind. It has been shown that sandals resist torsion of the foot when compared to barefoot running; sandals are protective of the foot even during running (compared to barefoot). [17]

The windlass mechanism, described in 1954, provides a tightening of the plantar fascia with metatarsophalangeal dorsiflexion.[18] The tension at the tie rod of the arch supports the integrity of the longitudinal arch and also allows the foot to become stiff enough for forward propulsion. It is known that the better the windlass mechanism, the greater the force transmission from leg to foot. An intact and performing windlass mechanism in the foot produces maximum force during running and walking. This also allows for the most efficient use of the plantar fascia. This device was designed with the windlass mechanism in mind. A passive stretch and relaxation of the fascia is built into the shoe using this mechanism.[19]

A rocker bottom sole was chosen in order to reduce stress across all structures of the foot during use. This was designed to limit motion of the MTP joints during push-off and to allow for the gentle stretch of the plantar fascia via the windlass mechanism during gait. Without a rocker bottom sole, the great toe lift would be detrimental and not helpful. However, we believe that with the rocker bottom sole, the windlass mechanism may engage throughout the gait cycle. Shoe modifications with a rocker bottom sole have also been shown to help with the pain of plantar fasciitis previously.[20,21]

It is often thought that changing the alignment of the foot is especially effective in the treatment of foot pain. However, over time the shape of the foot has been associated with hip, knee and ankle pain but not with plantar fascia mediated pain.[22] Studies of foot posture and pain present conflicting results. The results of the studies often rely upon the level of physical activity and type of participants.[23-26] In addition, altering alignment

of the foot should be done in conjunction with a physician and/or someone conversant with foot biomechanics.[27-30] Therefore, this device was designed to not alter alignment of any given foot (user) but rather to simply provide methods that allow for stretching, rest and reduced loads (increased efficiency) across the foot regardless of the native posture. It was our hypothesis that altering the alignment of the foot during the use of the device was not necessary. There is not a lot of evidence to support the thought that foot shape predisposes to heel pain.[23,31]

This device also incorporates a low and wider profile arch 'support' zone at the midpoint of the sandal. Because the great toe rise naturally depresses the first metatarsal and creates arch integrity, a traditional arch support was not necessary and deemed detrimental for this device's comfort. The arch zone therefore consists of a low-profile support that is configured to float the metatarsophalangeal joints and the ball of the foot. Due to the structural nature of the shoe and the sole's radius of curvature at the point of flexion of those joints, the device synergistically also allows for the removal of stress from the forefoot during use.

The results of this study demonstrate this device is supportive of the foot and allows for the enhanced recovery and augmented treatment of plantar fasciitis and heel pain. The study showed excellent results within 30-60 days of part-time use of the shoe. Nearly 100% (95%) of participants stated that they would recommend this device to others; this proves the clinical perception of effectiveness. The device allowed for an improvement of function and a reduction in pain. These changes were deemed clinically significant and were associated with treatment safety as well.

Limitations of the study are that it was short-term and only included the participation of 22 subjects. While the response rate of 66.6% was excellent, a larger cohort may give more power and statistical significance to results. This study was completed to demonstrate the effectiveness of the device as a possible adjunct to treatment rather than only as a stand-alone intervention. Further study should include a controlled and prospective evaluation of this device against other common treatment modalities. Finally, this was a short-term study with a follow-up period of only 30 to 60 days. Ongoing work will demonstrate the analysis of this device with longer use.

Of the study group, 7 were undergoing concurrent treatment along with the use of the device. This treatment was physical therapy for 5 of the 7, a boot initially for 1 of the 7 and a single injection of Toradol at the plantar fascia for 2 of the 7. 15 of 22 participants had had treatment for their heel and foot pain in the past, prior to this intervention, but no treatment had been rendered for at least 2 months prior to intervention. Outcomes of those undergoing treatment were included with those without treatment; these results should potentially be separated.

Plantar fasciitis is common and is the source of about 15% of all foot symptoms that require professional care. It is also thought to be responsible for 10% of running injuries. As well, it is a common affliction of military personnel.[32,33]

This device achieves good results when compared to other interventions. In a 9 month follow-up study of patients that had an open or endoscopic plantar fascia release the participants had 28.65 days of disability.[34] 17 patients who underwent a latticed plantar fasciotomy had significant improvement in the Mayo score from 12.06 to 89.76 at a mean of 16 months [35] Karls compared the effectiveness of corticosteroid injections against platelet rich plasma injections and tenoxicam injections and found equal efficacy; corticosteroids were more effective than placebo.[36] A meta-analysis of corticosteroids against placebo for plantar fasciitis looked at 4 studies with 289 patients. This study noted that there was better pain relief after one month with an injection of steroid than placebo. However, there was no difference in the VAS at 2 months. The authors opined that corticosteroid injections may provide pain relief for a short period of time, but the efficacy soon disappears.[37] Another study looked at extracorporeal shockwave therapy and corticosteroid injections and found that while 56% of the ECSWT group failed at 3 months, 15% of the steroid group did as well. There was basically an 82-85% response to treatment rate in each group.[38] A case series (58 patients) examined platelet rich plasma injections for the treatment of plantar fascia. The Foot Function Index score of this group improved from 69.4 to 31.8 with this intervention. Again, there was about an 80% response rate.[39]

Liden demonstrated in a randomized trial of radiotherapy a decrease of 44 points in the VAS with treatment after 3 months. This was a retrospective analysis of 22 patients and the pre-intervention VAS was 8.12 and moved to 1.96 at 3 months and then to 2.07 at 6 months.[40] Finally, Le Ye analyzed ultrasound-guided pulsed radiofrequency treatment of the gastrocnemius to manage plantar heel pain. This study compared the results of an intervention group against those of a sham-intervention group. The VAS for the 1st step in the morning was the outcome point and decreased in the treatment group by 48% at 3 months; the sham group improved by 14.9%. This reduction was 40% at 6 months and 23% in the sham group at 6 months.[41]

Our results compare favorably with most treatments in the literature.[42-44] We found a statistically significant improvement in pain and function over the study period for the LEFS, FAOS (all but the sports subscale) and the NPS. The FADI (sports) trended positively but was not significant. There were no adverse events reported due to the device during the study; there were no device failures either. Finally, a full 95% of patients would recommend this device to others, both friends and family, for the treatment of heel and foot pain.

This study demonstrates the effectiveness and usefulness of this device (flip-flop for heel/foot pain) for the treatment and augmentation of treatment of heel and instep pain. We feel this data demonstrates the clinical utility of this device.

REFERENCES:

1. Neufeld SK, Cerrato R. Plantar fasciitis: Diagnosis and treatment. J Am Acad Orthop Surg 2008; 16: 338–346.

2. Gill LH. Plantar fasciitis: Diagnosis and conservative treatment. J Am Acad Orthop Surg 1997; 5: 109–117.

3. Buchbinder R: Clinical practice. Plantar fasciitis. N Engl J Med, 2004, 350: 2159-2166.

4. Woolf AD, Pfleyer B: Burdon of major musculoskeletal conditions. Bull World Health Organ 2003; 81: 646–56.

5. McPoil TG, Martin RL, Cornwall MW, et al: Heel pain- plantar fasciitis: clinical practice guidelines linked to the international classification of functioning, disability and health from the orthopaedic section of the American Physical Therapy Association. J Orthop Sports Phys Ther 2008; 38(4): A1-18.

6. Schepsis AA, Leach RE, Gorzyca J: Plantar fasciitis. Etiology, treatment, surgical results, and review of the literature. Clin Orthop 1991; 266:185-96.

7. Furey JG: Plantar fasciitis. The painful heel syndrome. J Bone Joint Surg Am 1975; 57:672-3.

8. Herr, K. A., Spratt, K., et al: Pain intensity assessment in older adults: use of experimental pain to compare psychometric properties and usability of selected pain scales with younger adults. Clinical J Pain 20(4): 207-219.

9. Farrar, J. T., Young, J. P., Jr., et al: Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 94(2): 149-158.

10. Stratford, P. W. and Spadoni, G: FEATURE ARTICLES-The reliability, consistency, and clinical application of a numeric pain rating scale. Physiotherapy Canada 53(2): 88-91.

11. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M: Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int 1994;15:349–53.

12. Johanson NA, Liang MH, Daltroy L, Rudicel S, Richmond J: American Academy of Orthopaedic Surgeons lower limb outcomes assessment instruments: reliability, validity, and sensitivity to change. J Bone Joint Surg Am 2004; 86:902.

13. Hale SA, Hertel J: Reliability and Sensitivity of the Foot and Ankle Disability Index in Subjects With Chronic Ankle Instability. *Journal of Athletic Training* 2005; 40(1):35-40.

14. Binley JM, Stratford PW, Lott SA, Riddle DL: The Lower Extremity Functional Scale (LEFS): Scale Development, Measurement Properties, and Clinical Application. J Amer Physical Ther Ass Apr 1999; 79 (4): 371-383.

15. Stefanyshyn, D.J., & Nigg, B.M: Mechanical energy contribution of the metatarsophalangeal joint to running and sprinting. Journal of Biomechanics 2001; 30: 1081-1085.

16. Stefanyshyn, D.J., & Nigg, B.M: Influence of midsole bending stiffness on joint energy and jump height performance. Medicine & Science in Sports & Exercise 2000; 32: 471-476.

17. Morio, C., Lake, M.J., Gueguen, N., Guillaume, R., & Baly, L: The influence of footwear on foot motion during walking and running. Journal of Biomechanics 2009; 42: 2081-2088

18. Hicks JH. The mechanics of the foot, II: the plantar aponeurosis and the arch. J Anat 1954; 88:25–30.

19. Carlson, R.E., Fleming, L.L., & Hutton, W.C.:The biomechanical relationship between the tendoachilles, plantar fascia and metatarsophalangeal joint dorsiflexion angle. Foot Ankle International 2009; 21(1): 18–25.

20. Fong, DT, Pang KY, Chung MML, et al: Evaluation of combined prescription of rocker sole shoes and custom-made foot orthoses for the treatment of plantar fasciitis. Clin Biomech 2012;27:1072-7.

21. Mizel MS, Marymont JV, Trepman E: Treatment of plantar fasciitis with a night splint and shoe modification consisting of a steel shank and anterior rocker bottom. Foot & Ankle International 1996; 17:732-5.

22. JL Riskowski, AB Dufour, TJ Hagedorn, Howard Hillstrom, VA Casey, and MT Hannan: Associations of Foot Posture and Function to Lower Extremity Pain: The Framingham Foot Study. Arthritis Care Res (Hoboken). 2013 November ; 65(11): 1804–1812.

23. Martin RL, Davenport TE, Reeischl SF, et al. Heel pain-plantar fasciitis: revision 2014. J Orthop Sports Phys Ther 2014; 44: A1-A33.

24. Burne SG, Khan KM, Boudville PB, Mallet RJ, Newman PM, Steinman LJ, et al: Risk factors associated with exertional medial tibial pain: a 12 month prospective clinical study. Br J Sports Med 2004; 38(4):441–5. [PubMed: 15273181]

25. Williams DS 3rd, McClay IS, Hamill J: Arch structure and injury patterns in runners. Clin Biomech 2001; 16(4):341–7.

26. Mei-Dan O, Kahn G, Zeev A, Rubin A, Constantini N, Even A, et al: The medial longitudinal arch as a possible risk factor for ankle sprains: a prospective study in 83 female infantry recruits. Foot Ankle Int 2005; 26(2):180–3. [PubMed: 15737262]

27. Ribeiro AP, Trombini-Souza F, Tessutti V, Rodrigues Lima F, Sacco ICN, João SMA: Rearfoot alignment and medial longitudinal arch configurations of runners with symptoms and histories of plantar fasciitis. Clinics 2011; 66(6):1027–33.

28. Burns J, Crosbie J, Hunt A, Ouvrier R: The effect of pes cavus on foot pain and plantar pressure. Clin Biomech 2005; 20(9):877–82.

29. Irving DB, Cook JL, Young MA, Menz HB: Obesity and pronated foot type may increase the risk of chronic plantar heel pain: a matched case-control study. BMC Musculoskelet Disord 2007; 8:41. [PubMed: 17506905]

30. Dahle LK, Mueller MJ, Delitto A, Diamond JE: Visual assessment of foot type and relationship of foot type to lower extremity injury. J Orthop Sports Phys Ther 1991; 14(2):70–4.

31. Gross KD, Felson DT, Niu J, Hunter DJ, Guermazi A, Roemer FW, et al: Association of flat feet with knee pain and cartilage damage in older adults. Arthritis Care & Research 2011; 63(7):937– 44. [PubMed: 21717597]

32. Sadat-Ali M: Plantar fasciitis/calcaneal spur among security forces personnel. Mil Med 1998;163:56-7.

33. Scher DL, Belmont PJ, Bear R, Mountcastle SB, et al: The incicdence of plantar fasciitis in the United States Military. JBJS 2009; 91A(12):2867-2872. http://dx.doi.org/10.2106/JBJS.I.00257

34. Tomczak RL, Haverstock BD: A retrospective comparison of endoscopic plantar fasciotomy to open plantar fasciotomy with heel spur resection for chronic plantar fasciitis/heel spur syndrome. J F&A Surgery 1995; 34(3):305-311.

35. Yanbin X, Haikun C, Xiaofeng J, Wanshan Y, Shuangping L. Treatment of chronic plantar fasciitis with percutaneous latticed plantar fasciotomy: J F&A Surg. 2015; 54(5):856-859.

36. Karls SL, Snyder KR, Neibert PJ: Effectiveness of corticosteroid injections on the treatment of plantar fasciitis. J Sport Rehab 2015; 25(2):202-207.

37. Zonghuan L, Aixi Y, Baiwen Q, et al: Corticosteroid versus placebo injection for plantar fasciitis: A meta-analysis of randomized controlled trials. Exp and Ther Med 2015; 9:2263-2268.

38. Mohsen M, Mobarakeh M, Hassanzadeh Z, Mirbolook A, et al: Treatment outcomes of corticosteroid injection and extracorporeal shock wave therapy as two primary therapeutic methods for acute plantar fasciitis: A prospective randomized clinical trial. J F&A Surg 2015; 54(6):1047-1052.

39. Van Egmond JC, Breugem SJ, Criessen M, Bruijn DJ: Platelet-rich-plasma injection sseems to be effective in treatment of plantar fasciitis: a case series. Acta Orthop Belg 2015; 81(2): 315-320.

40. Liden B, Simmons M, Landsman AS: A retrospective analysis of 22 patients treated with percutaneous radiofrequency nerve ablation for prolonged moderate to severe heel pain associated with plantar fasciitis. J F&A Surg 2009;48(6): 642-647.

41. Le Ye, Mei A, Mingli L, Minghong G. et al: A comparative efficacy evaluation of ultrasound-guided pulsed radiofrequency treatment in the gastrocnemius in managing plantar heel pain: a randomized and controlled trial. Pain Med 2015; 16:782-790.

42. Davis PF, Severud E, Baxter DE: Painful heel syndrome: results of non-operative treatment. Foot Ankle Int 1994;15:531-5.

43. Martin RL, Irrgang JJ, Conti SF: Outcome study of subjects with insertion plantar fasciitis. Foot Ankle Int 1998;19:803-11.

44. Digiovanni BF, Nawoczenski DA, Lintal ME, et al: Stretching enhances outcomes in patients with chronic heel pain. A prospective, randomized study. J Bone Joint Surg Am 2003; 85-A:1270-1277.

http://www.physics.csbsju.edu/cgi-bin/stats/t-test_paste.n.plot

Figure 1

THE
HEALING SOLE™

The Healing Sole Features

1. RAISED TOE:
Allows the great toe to extend slightly & reduces stress on the plantar fascia

2. COMPRESSIBLE HEEL
Allows for a controlled "give" to reduce pressure on the painful part of the heel

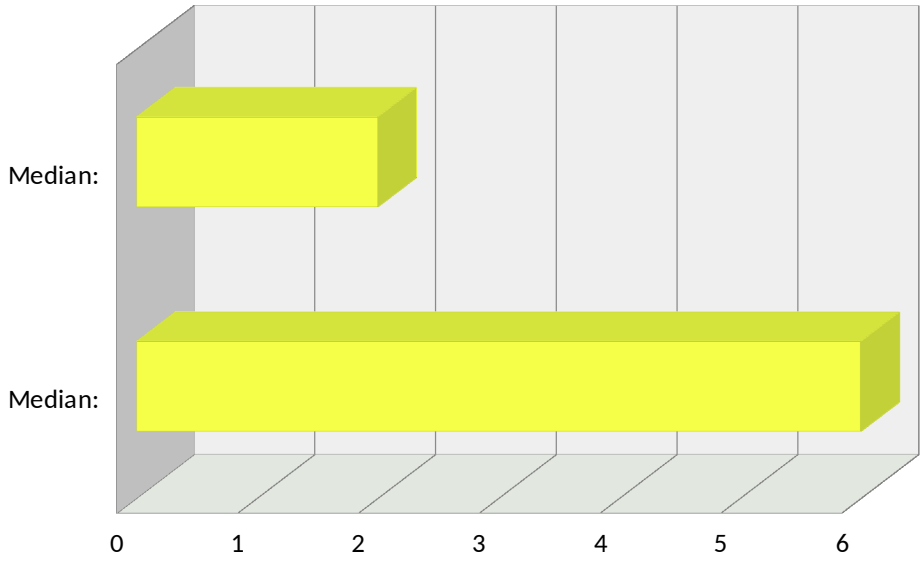
3. RAISED ARCH
Supports the arch to give additional comfort during recovery

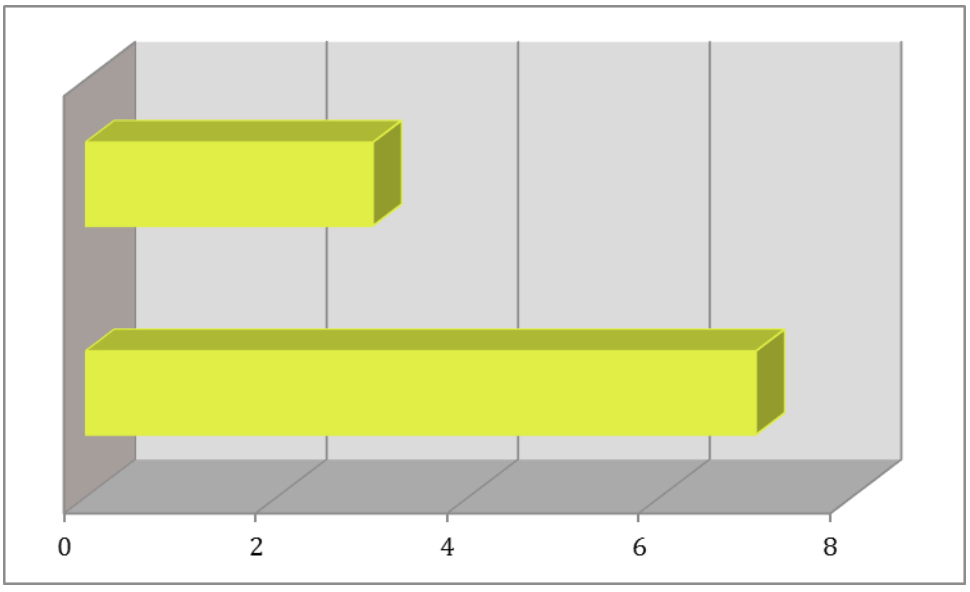
4. ROCKER BOTTOM SOLE
Reduced stree on the arch & reduces tension on the plantar fascia

5. NEOPRENE STRAPS:
The neoprene straps provide stability with a secure yet flexible fit

Figure 2

Top chart is worst pain last week at Day 0 (lower bar) and End of Study (upper bar)





Bottom chart is average pain last week at Day 0 (lower bar) and End of Study (upper bar)

Table 1

Age	Height (inches)	Weight (pounds)	BMI	Gender
40	64	210	36	F
60	6	206	33.2	F
62	70	200	28.7	M
38	63	320	56.7	F
56	68	180	27.3	F
36	65	102	17	F
68	67	150	23.5	F
53	64	187	32.1	F
56	71	295	41.1	F
48	60	158	30.9	F
32	64	249	42.7	F
59	69	205	30.3	F
45	63	147	26	F
47	63	129	22.3	F
45	67	172	27.41	F
63	70	160	23	M
38	60	106	20.7	F
50	69	180	26.6	M
33	59	125	25.2	F

Two subjects did not allow weight to be recorded; we did not include them in the demographics

Table 1 - Demographics

Table 2 – Patients variables

month pain started	months of pain prior to	other treatment 1=y 2=n	treatment	#feet
Jul-15	3	2		2
12-Jun	40	2		2
Feb-13	32	1	1 injection	2
Jun-13	34	1	PT, 1 injection	2
Jun-15	4	1	PT, nerve release	2
13-May	29	2		2
14-Jul	15	2		1
Jan-14	22	1	PT	1
13-May	29	2		1
Dec-13	30	2		1
Oct-13	24	2		2
15-Apr	6	2		2
Jun-13	34	2		1
Dec-12	42	2		2
Dec-12	42	1	PT	2
Mar-15	7	2		2
Aug-13	26	1	Boot	2
Jul-14	15	2		2
Oct-11	48	1	PT	2
Jun-14	22	2		2
Jul-13	33	2		1

Table 3

PARTICIPANT 21 pre and post intervention responses	WORST PAIN LAST WEEK – DAY 0	WORST PAIN LAST WEEK – DAY 60	AVE. PAIN LAST WEEK DAY 0	AVE. PAIN LAST WEEK – DAY 60
1	6	3	4	1
2	10	6	10	6
3	7	6	6	5
4	7	7	5	4
5	7	8	6	7
6	7	8	7	5
7	8	3	8	2
8	3	2	2	2
9	6	5	3	2
10	10	1	10	1
11	9	1	9	1
12	9	7	9	6
13	8	2	8	2
14	10	8	10	3
15	6	4	4	2
16	5	0	5	0
17	7	2	5	1
18	5	3	5	2
19	1	2	1	2
20	6	3	4	3
21	7	8	4	5
22	7	8	7	

Table 3 – NPS Scores

Table 4

Subscale	**Pre-study score**	**Post-study score**	**P-value**
FAOS	62.9(±14.3)	73.2(±13.8)	0.02
FAOS activity	74.6(±19.3)	84.9(±12.6)	0.043
FAOS pain	63.3(±17.4)	78.4(±13.9)	.00029
FAOS QOL	41.5(±21.4)	58.5(±17.5)	0.0062
FAOS sports	61.1(±31.9)	76.6(±22.5)	0.071

Table 4 – FAOS scores

Funding Sources:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CONFLICTS:

The corresponding author has a patent application filed on The Healing Sole. Otherwise, there are no conflicts to report.

HIGHLIGHTS:

- An innovative novel method of treating plantar fasciitis and foot pain is tested in a pilot clinical study
- The NPS, LEFS, FAOS (except sports subscale) improved with use of novel device; 94% of subjects would recommend device for treatment of foot pain; there were no complications from use of this device
- This novel method of treating heel pain holds promise for a cost-effective and safe consumer medical device to treat foot pain