The Short-Term Effect of Extracorporeal Shock Wave in Treating Plantar Fasciitis: RCT

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Abstract

Background: Plantar fasciitis (PF) is one of the common musculoskeletal problems worldwide that has been treated using the extracorporeal shock wave therapy (ESWT). The purpose of this study was to investigate the short-term effectiveness of ESWT in reducing pain and improving function in people with PF.

Materials and Methods: A sample of 34 subjects with PF (21 female) was randomly assigned to either the ESWT treatment group (n=15) or the placebo control group (n=19). Each subject received 3 sessions of ESWT 1 week apart with a clasp on the heel for the placebo control group. Pain and functional level were examined using the Visual Analog Scale (VAS) and the Roles and Maudsley Score (RM) respectively at baseline, end of treatment and 3 weeks after the last intervention session.

Results: Participants in the ESWT treatment group had significant improvement in both VAS and RM at the end of the treatment and follow up. Whereas participants in the placebo group did not improve significantly at the end of the treatment neither in VAS nor in RM scores while reported significant improvement at the follow up in both outcome measures. When comparing results between groups, pain scores were higher in the placebo group at the end of treatment and follow up. However, no significant differences were observed between groups in outcome measures.

Conclusions: The use of ESWT demonstrated successful reduction in pain and improvement in functional level with individuals suffering from PF after a short-term follow up.

Keywords: Plantar fasciitis, Extracorporeal shock wave therapy, Pain, Function.

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Introduction

The plantar fascia runs along the plantar surface of the foot from the calcaneus to the forefoot. It acts to elevate the arch of the foot, stabilize the mid-foot and also act as a shock absorber upon weight-bearing through the lower extremity.(1) Plantar fasciitis (PF) is an inflammation of this fascia, usually resulting from a biomechanical dysfunction which leads to a high degree of tension, causing micro-trauma. It typically presents as pain in the

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plantar fascia at its origin on the calcaneus. Patients complain of pain with stretching of the plantar fascia, particularly when initially getting out of bed in the morning, though any instance of weight bearing following a period of non-weight bearing may elicit complaints of pain.[2] PF may become chronic as well, presenting as a constant and nagging ache in the plantar aspect of the foot throughout the day. Although there are many conservative and surgical treatment options available for PF, they can be inefficient and some are associated with side effects.[2]

Surgical treatment for PF is usually a last resort; after all other non-surgical treatments have been exhausted over a 6-12 month period without success.[1] Non-surgical treatments for PF include correction of mechanical abnormalities of the foot by the use of over-the-counter or custom-made orthoses or athletic taping, use of night splints, iontophoresis with anti-inflammatories and stretching of the Achilles tendon and/or plantar fascia.[3-6]

Extracorporeal shock wave therapy (ESWT) is a relatively new form of non-surgical treatment for PF. Extracorporeal shock waves (ESW) are acoustic waves of extremely high pressure and velocity. When the shock waves are directed at bone, multiple interfaces between soft tissue and bone result in reflection and deposition of shock wave.[7] The mechanism of action of ESWT is not known; however, it is suggested that it promotes healing by increasing neovascularization of degenerative tissue found in PF.[8,9] Several clinical trials on the use of ESWT for PF have resulted in conflicting evidence.

One study utilizing ESWT was conducted by the administration of one treatment of ESWT with ultrasound guidance.[10] Results indicated an improvement on the participants' visual analog scale (VAS) by 3 months post procedure.[10] Ogden's 2001 study evaluated the effectiveness 3 months post one treatment of ESWT, with a 40% good to excellent success rate in 3-4 rating criteria.[11] Kudo's study also addressed the effectiveness of one session of ESWT (with an approximate energy delivery of 1,300 mJ/mm2), and again, looked at VAS 3 months post-treatment.[12] With regards to first-step pain, 47% of participants reported a greater than 60% improvement in VAS scores from baseline.[12] Another study in 2006, conducted by Malay et al., reported 43% of participants in the group treated with one session of ESWT administered at 3800 shockwaves over 25 minutes achieved a statistically significant reduction in VAS pain at 3 months post treatment (versus 20% in the placebo group).[13]

Further research on the use of ESWT for the treatment of PF includes a 2003 study by Haake, et al. that refuted the above claims of improvement of PF with the use of ESWT. According to this study, a success rate of 34% in the treatment group and 30% in the placebo group at 12 weeks post treatment of 1 treatment every two weeks for 3visits was reported. No significant outcomes were noted for the treatment group versus the placebo group.[14]

While the majority of studies focused on success rates in a relatively long-term follow up post ESWT, our study attempts to address the short-term effectiveness (3 weeks after the end of treatment) of ESWT for the treatment of PF.

MATERIALS AND METHODS

Participants

A convenience sample of 34 patients was deemed eligible according to the inclusion and exclusion criteria outlined in Table 1. Written informed consent was obtained from participants. Participants were randomly and blindly assigned to either the ESWT treatment group (15 participants/44.1%) or the placebo control group (19 participants/ 55.9%) without their awareness of the group they were assigned in. The study was approved by the institutional review board.

Table 1. Inclusion and exclusion criteria

Inclusion criteria:

- Age ≥ 18 years.
- Willingness not to receive or implement any form of physical therapy for the duration of the trial
- Willingness to discontinue taking pain relieving medications (analgesics and non-steroidal anti-inflammatory medications) for at least 14 days prior to the baseline until the end of follow up
- An ability to walk 50 meters without the aid of support

Exclusion criteria:

- History of:
  - Intermittent claudication
  - Chronic limb ischemia including rest pain and or lower limb and foot ulceration
  - Chronic lower limb and foot oedema
  - Vascular surgery of the lower limb or foot
  - Plantar heel pain secondary to connective tissue disease
  - Surgery to the plantar fascia
  - Injection therapy in the heel in the previous three months
- Pregnancy
- Receiving treatment for PF during the previous 4 weeks
- The presence of peripheral arterial vascular disease defined as failure to palpate at least one pedal pulse and an ankle/brachial index < 0.9
- The presence of a chronic medical condition that might preclude participation in the study such as: malignancy, systemic inflammatory disorders (e.g., rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, septic arthritis), neurological abnormalities, sciatica, and/or chronic pain.

Intervention

Participants were recruited in this study between September 2011 and October 2012. All participants were examined medically by one physician and one physical therapist based on patient's history and physical examination in accordance with the clinical guidelines linked to the international classification of function, disability, and health from the Orthopedic Section of the American Physical Therapy Association.[15]

Demographic information was recorded including date of birth, gender, marital status, number of children, educational level, occupation, weight, height, duration and onset of symptoms, previous treatment, and affected side. Pain and functional level were examined using the Visual Analog Scale (VAS) and the Roles and Maudsley Score (RM) respectively on 3 occasions: baseline, end of treatment and 3 weeks after the last intervention session.

Participants were randomly assigned to receive either focused ESWT or an identical placebo treatment. After randomization to their respective treatment groups, participants were treated in the supine position with their feet completely off bed. The shockwave head was placed perpendicular to the point of maximum tenderness, which was located clinically by the physical therapist. The head was coupled to the identified area with gel to avoid energy loss. No local anesthetics or analgesic drugs were administered before or during the treatment.

Each participant received one 60 minute session of therapy, 1 day a week for 3 weeks, according to the procedures designed for his/her assigned group. Treatment for the ESWT treatment group consisted of ice application for 10 minutes prior to ESWT, the ESWT application, and ice application for 10 minutes post ESWT, followed by plantar stretching exercises 3 times, each time for 30 seconds post treatment. The placebo control group treatment was performed identically to the ESWT group but with a clasp on the heel that prevented transmission of the impulses from the applicator to the skin at the treatment site. This method is similar to the placebo treatments applied in double-blinded studies on ESWT for chronic PF by Haake et al.,[14] Kudo et al.,[12] and Malay et al.[13]

Equipment

In this study, a radial electrohydraulic system with low energy (energy flux density=0.25 mJ/mm²) was used. Focused shockwaves were generated by a Masterplus (MP 200) extracorporeal shockwave therapy system (Storz Medical, Tagerwilen, Switzerland).The device is mobile with hand pieces providing radial pressure wave impulses with very consistent energy. The parameters used in this study were2000 shocks in each session with 5 bars in the treatment group and 1 bar in the placebo control group. Regarding the frequency of the shock waves, in the first 800 shocks of the treatment, 1 Hz was utilized followed by 3 Hz for the intermediate phase and then returned to 1 Hz for the last 200 pulses.

Outcomes

The Visual Analog Scale (VAS): a 10-cm horizontal scale with 0 labeled “no pain” and 10 labeled “worst pain I have ever had”.

The Roles and Maudsley Score (RM): was utilized to evaluate functional outcomes. The RM includes a 4 point scale grading with 1 indicates "excellent" (no pain, full movement, and activity), 2 indicates "good" (occasional discomfort, full movement, and activity), 3 means "fair" (some discomfort after prolonged activity), and 4 means "poor" (pain limiting activities).[16]

Statistical analysis

The nonparametric test for 2 independent samples (Mann-Whitney U test) was used to examine the mean difference in pain and function between the ESWT treatment group and the placebo control group at the end of the treatment and follow up. The nonparametric test for 2 dependent samples (Wilcoxon Signed Ranks test) was used to examine the mean difference in pain and function within each group (ESWT and placebo groups) in the periods between baseline and end of treatment as well as between end of treatment and follow up.

The nonparametric Spearman rank order correlation coefficient rho was used to assess

the association between BMI and outcome measures scores. A Spearman correlation coefficient of >0.60 indicates strong correlation, 0.31 to 0.59 indicates moderate correlation, and <0.30 indicates poor correlation.

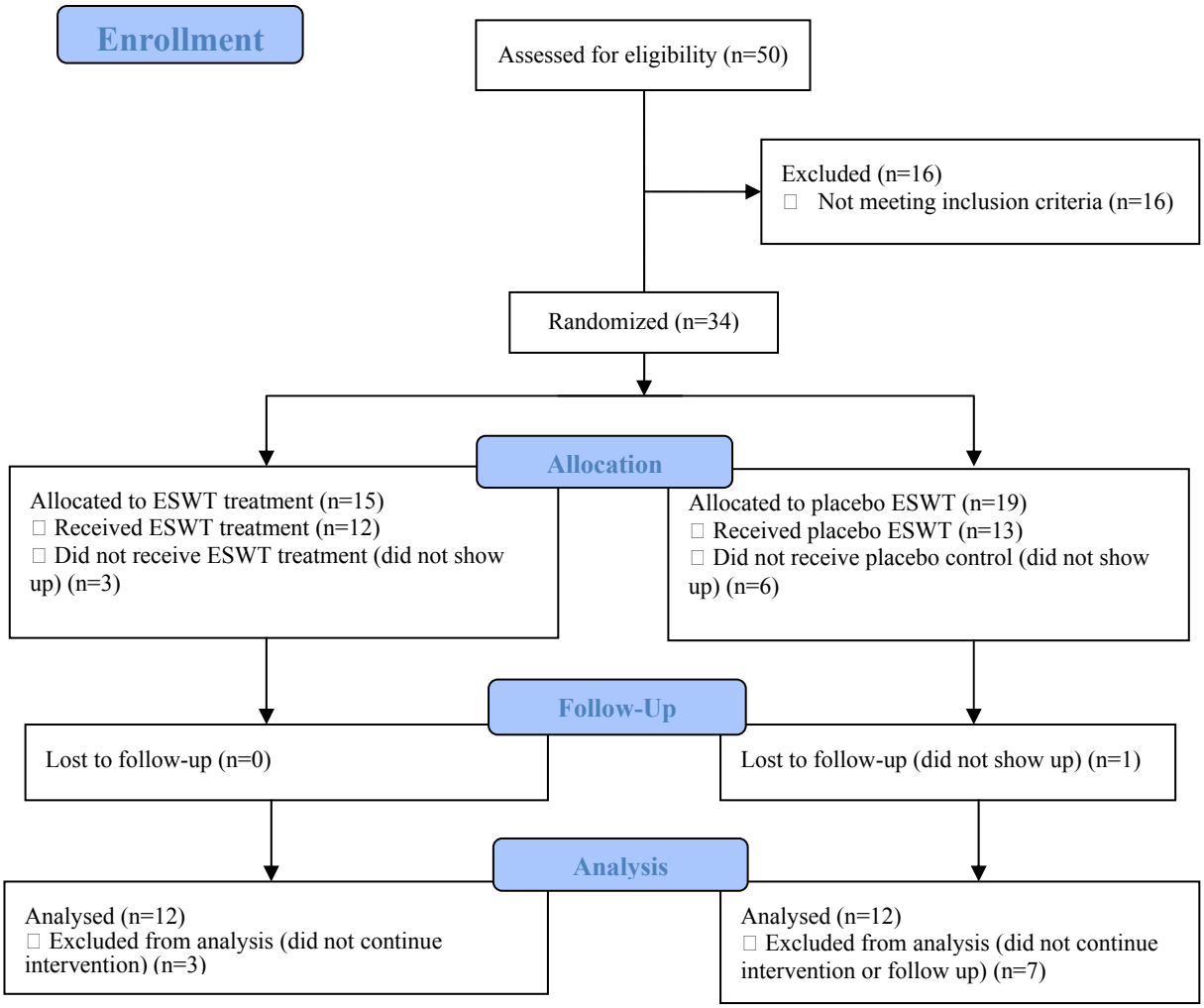

Figure 1: Flow chart of participants enrollment

RESULTS

Participants

Fifty patients were screened for eligibility and 16 were excluded because they did not meet inclusion criteria. Thirty four participants with PF were recruited and randomized in this study. At baseline, there were 15 participants in the ESWT treatment group and 19 participants in the placebo control group (Figure 1). There were no statistically significant differences between the two groups neither in demographic information nor in pain and functional outcomes. There were no significant differences in outcome measures between genders at baseline, after treatment, and at 3 weeks following treatment.

As viewed in Figure 1, of the 15 participants in the ESWT treatment group, 12 completed all three treatment sessions as assigned and 3 participants completed only

one session. All 12 participants who completed all 3 sessions also completed the follow-up assessment and were included in the analysis. For the 19 participants of the placebo control group, 13 completed all 3 treatment sessions, 2 participants completed 2 treatment sessions and 4 participants completed only 1 treatment session. Only the 12 participants completed the last follow-up assessment were included in the final analysis.

The characteristics of the 34 participants are presented in Table 2. Body Mass Index (BMI) statistics for thirty-three of these participants ranged from a low of 24.42 to a high of 51.07 with a mean of 31.43 (SD=5.67). Participants (n=34) were questioned as to whether or not they had children, with the range of children being 0 to 12.

Table 2. Characteristics of participants (n=34)

Characteristic	ESWT treatment group	Placebo control group	Total n (%)
Age groups:			
(30-40)	-	4 (21.10)	4 (11.80)
(41-50)	6 (40.00)	5 (26.30)	11 (32.40)
(51-60)	3 (20.00)	4 (21.10)	7 (20.60)
(>60)	6 (40.00)	6 (31.60)	12 (35.30)
Gender:			
Female	8 (53.30)	13 (68.40)	21 (61.80)
Male	7 (46.70)	6 (31.60)	13 (38.20)
Marital status:			
Married	10 (66.70)	18 (94.70)	28 (82.4)
Single	4 (26.70)	1 (5.30)	5 (14.7)
Widowed	1 (6.70)	-	1 (2.9)
Educational level:			
Illiterate	1 (6.70)	1 (5.30)	2 (5.9)
Elementary	3 (20.00)	-	3 (8.8)
Secondary	6 (40.00)	8 (42.10)	14 (41.2)
Degree	5 (33.30)	10 (52.60)	15 (44.1)
Occupation:			
No occupation	5 (33.30)	15 (78.90)	20 (58.8)
Long sitting	1 (6.70)	2 (10.50)	3 (8.8)
Long standing	2 (13.30)	2 (10.50)	4 (11.8)
Labor work	5 (33.30)	-	5 (14.7)
Side affected:			
Right foot	2 (13.30)	5 (26.30)	7 (20.6)
Left foot	6 (40.00)	8 (42.10)	14 (41.2)
Both feet	7 (46.70)	6 (31.60)	13 (38.2)
Onset:			
Sudden	6 (40.00)	8 (42.10)	14 (41.2)
Gradual	9 (60.00)	11 (57.90)	20 (58.8)

Pain and Functional Outcomes

At baseline, VAS of 34 participants ranged from 1-10 (mean=6.44, SD 2.26) and RM of 33 participants ranged from 2-4 (mean=3.06, SD 0.70). At the end of the third treatment session, VAS of 25 participants was in a range of 2 to 10 (mean=5.44, SD 2.29) and RM of 25 participants in a range of 2 to 4 (mean=2.8, SD 0.64). At 3weeks following final treatment, VAS of 24 participants ranged from 0 to 10

(mean=3.38, SD 2.80) and the RM score of 24 participants ranged from 1 to 4 (mean=1.86, SD 1.06).

Within group comparison (Wilcoxon Signed Ranks test)

Table 3 presents the means and standard deviations of outcome measures scores in the treatment and placebo groups during baseline, end of treatment, and follow up periods. Patients in the ESWT treatment group had significant improvement in VAS at the end of the treatment (mean rank=5.61, *P*=0.02) as well as at the 3 weeks follow up (mean rank=4.00, *P*=0.02). Patients in the ESWT treatment group had also significant improvement in RM score at the end of the treatment (mean rank=3.50, *P*=0.01) as well as at the 3 weeks follow up (mean rank=4.00, *P*=0.02).Whereas patients in the placebo group did not significantly improve at the end of the treatment neither in VAS (mean rank=4.88, *P*=0.35) nor in RM scores (mean rank=1.50, *P*=0.18). However, patients in placebo group reported significant improvement at the 3 weeks follow up in both VAS (mean rank=5.39, *P*=0.03) and RM scores (mean rank=4.70, *P*=0.03).

Between group comparison (Mann-Whitney U test)

There was no significant difference found in VAS (*P*=0.77) and RM (*P*=0.30) at baseline between the assigned groups. Therefore, they started as homogenous groups without significant differences due to randomization. Pain scores using VAS were higher (worse) in the placebo group after treatment (mean rank=15.38) versus the treatment group (mean rank=10.42), as well as at 3 weeks following treatment (placebo mean rank= 12.00, treatment mean rank= 9.67). However, there were no significant differences found in the VAS (*P*=0.09) and the RM (*P*=0.74) neither at the end of treatment nor at the 3 week follow-up [the VAS (*P*=0.39) and the RM (*P*=0.38)].

Table 3. Mean and SD of Visual Analogue Scale (VAS) and Roles and Maudsley (RM) scores in the treatment and placebo groups during baseline, end of treatment, and follow up periods

	Treatment group		Placebo group	
	VAS	**RM**	**VAS**	**RM**
Baseline	6.20±2.31	3.20±.68	6.63±2.27	2.94±.73
End of treatment	4.67±2.06	2.83±.58	6.15±2.34	2.77±.73
Follow up	2.56±1.33	1.56±.73	4.00±3.46	2.08±1.24

Correlation

When BMI was correlated with outcome measures, a significant moderate correlation (*r*=0.45; *P*<0.05) was found between pain scores at baseline and BMI only (Table 4). However, correlations between outcome measures revealed several significant correlations. Significant correlations were found between pain and functional scores at baseline (*r*=0.38; *P*<0.05), end of treatment (*r*=0.43; *P*<0.05), and follow up (*r*=0.72; *P*<0.05) (Table 4).

Discussion

The main purpose of our study was to assess the short-term effectiveness of 3 weekly sessions of ESWT in reducing pain and improving function in patients suffering from PF. In our study, participants in the ESWT treatment group had significant reduction in pain at the end of treatment as well as at short-term follow up after treatment. Additionally,

participants in the ESWT treatment group had also significant functional improvement at the end of treatment as well as at short-term follow up.

Table 4. Correlations between body mass index (BMI), outcomes at baseline, after treatment, and follow up

Outcome measure	BMI	VAS (baseline)	VAS (after treatment)	VAS (follow up)	RM (baseline)	RM (after treatment)
VAS (baseline)	0.45*					
VAS (after treatment)	0.35	0.21				
VAS (follow up)	0.12	0.22	0.51*			
RM (baseline)	0.23	0.38*	0.01	0.47*		
RM (after treatment)	0.04	-0.04	0.43*	0.52*	0.58*	
RM (follow up)	-0.034	-0.03	0.32	0.72*	0.32	0.40

* Spearman correlation coefficient is significant at $P<.05$

The second purpose of our study was to compare the results of our ESWT treatment group to a control group that received ice application and stretching exercises with the placebo shock wave. At the end of the treatment, participants in the placebo group did not have significant reduction in pain or functional improvement. However, at the short-term follow up after treatment, patients in the placebo group had significant reduction in pain and significant functional improvement. When comparing both groups, there were no significant differences in pain reduction and functional improvement neither at the end of treatment nor at follow up.

While there are multiple trials on the effect of ESWT on PF, outcomes vary. The results of this study are in agreement with those reported by many studies.[14,17,18] Speed et al.[18] studied the effect of ultrasound focused ESWT using electromagnetic generator compared to a placebo for 3 months on participants with PF. Assessing pain during the day, nocturnal pain and morning start up pain at baseline, before each treatment session and 1 and 3 months after the completion of treatment, their conclusion was that there was no significant treatment effect of moderate dose ESWT in participants with PF. Similarly, Haake et al.[14] randomized 272 patients to receive low-energy ESWT (3 times at 2-week intervals) or a placebo. Researchers concluded that this protocol was no more effective than a placebo, though patients reported excellent or good results for the RM score at 3 months (45.7%) and 1 year (80.5%) after intervention. Likewise, in a double blind study by Buchbinder et al.,[17] 166 randomly-assigned participants with PF received either ultrasound-guided low-energy ESWT or a placebo given weekly for 3 weeks. Although both groups demonstrated significant improvements, there was no evidence for the superiority of ESWT over placebo with regards to pain, function, or quality of life at 6 and 12 weeks after treatment.

In contrast with the findings above, there are multiple studies that reported positive results of ESWT for PF.[19-22] In a study by Rompe et al.,[21] 30 patients with PF were randomly assigned to receive 3 treatments of low-energy shock waves or a placebo at weekly intervals. A significant relief in pain and an improvement in function were noted

only in the ESWT group at 3 months follow up. Rompe et al.[20] also conducted a randomized trial of 45 running athletes with chronic PF of more than 12 months duration to either a treatment group receiving 3 treatments of low-energy shock wave therapy or a placebo. At both 6 and 12 month follow-ups, there was significant reduction of pain on the VAS of the treatment group. Similarly, Ogden et al.[19] investigated the efficacy of high-energy ESWT in 293 participants with PF. As with previous studies, positive results were reported with respect to start-up pain, pain-free activity and investigator-rated pain for the treatment group versus the placebo group, including at the 3 month follow-up.

The controversial results observed across these studies can be attributed to many factors. One factor is related to variations in the protocol of treatment used including the intensity of shock wave (low vs. moderate vs. high energy), the mechanism of energy production by shock wave generators (electrohydraulic vs. electromagnetic), the overall size and volume of the applied shock waves by different machines, and the total number of shockwave sessions. Another factor is the differences in placebo methods used. Moreover, the discrepancy in selecting patients may affect reported results. Lastly, the use of different outcome measures can also prevent direct comparisons between studies.

Limitations

One limitation of this study, as related to experimental design for the investigation of a treatment modality, was that these findings focus on the short term follow-up of participants. As such, our results cannot be extended to the long term effects of ESWT. Another limitation of this study was the small sample of participants involved.

CONCLUSIONS

The findings of our study demonstrated good effect for the use of ESWT in reducing pain and improving functional level in individuals with PF for short-term follow up. However, participants in control group demonstrated similar results especially in the follow up period. Therefore, future studies with larger number of patients are recommended to further investigate the short-term effect of using ESWT over placebo.

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التأثير قصير الأجل لاستعمال الموجات التصادمية في علاج اللفافة الأخمصية

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الملخص

الخلفية: التهاب اللفافة الأخمصية هي واحدة من أكثر مشاكل الجهاز العضلي الهيكلي شيوعا في العالم والتي يتم علاجها باستخدام جهاز الموجات التصادمية. كان الهدف من هذه الدراسة هو التعرّف إلى التأثير قصير الأجل لجهاز الموجات التصادمية في التخفيف من الألم وتحسين وظائف القدم عند مرضى اللفافة الأخمصية.

الطريقة: شارك في الدراسة عيّنة مكونة من 34 مريضا (21 منهم إناث). تم تقسيم المشاركين في الدراسة عشوائيا إلى مجموعة العلاج بجهاز الموجات التصادمية وعددهم 15 مريضا ومجموعة المراقبة وعددهم 19 مريضا. تلقى كل مريض جلسة واحدة أسبوعيا لمدة 3 أسابيع وتم وضع حاجز على كعب المرضى في مجموعة المراقبة. وقد تم قياس الألم والمستوى الوظيفي للقدم باستخدام أدوات ذات مصداقية عالية قبل البدء بالعلاج وبعد الانتهاء من العلاج مباشرة وبعد 3 أسابيع من انتهاء العلاج.

النتائج: أحرز المشاركون في مجموعة العلاج بجهاز الموجات التصادمية تحسناً كبيراً في التخفيف من الألم وتحسين وظائف القدم في نهاية العلاج وبعد 3 أسابيع من انتهاء العلاج. في حين أن المشاركين في مجموعة المراقبة لم يحرزوا تحسنا ملحوظا في التخفيف من الألم وتحسين وظائف القدم في نهاية العلاج لكنهم أحرزوا تحسناً كبيراً بعد 3 أسابيع من انتهاء العلاج. وعند مقارنة النتائج بين المجموعتين، كانت درجات الألم أعلى في مجموعة المراقبة بعد الانتهاء من العلاج مباشرة وبعد 3 أسابيع من انتهاء العلاج، ومع ذلك، لم تتم ملاحظة أي فروق ذات دلالة إحصائية بين المجموعتين في مقاييس النتائج.

الخلاصة: أظهر العلاج بجهاز الموجات التصادمية نجاحا في التخفيف من الألم وتحسين وظائف القدم عند مرضى اللفافة الأخمصية بعد فترة قصيرة من المتابعة.

الكلمات الدالة: التهاب اللفافة الأخمصية، العلاج بالموجات التصادمية، الألم.