Efficacy of Radial Extracorporeal Shockwave Therapy in Chronic Plantar Fasciitis

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Abstract

Background: Radial extracorporeal shockwave therapy (RSWT) has been previously demonstrated as an efficient treatment option for chronic plantar fasciitis (PF) when applied in 3 sessions.
Objective: The present study tested the hypothesis that chronic PF can also be treated successfully with only 2 RSWT applications.
Materials and Methods: A total of n=104 patients with unilateral, chronic PF were randomly assigned to either RSWT (n=52) or placebo treatment (n=52). The RSWT was applied in 2 sessions, 1 week apart (2,000 impulses with energy flux density = 0.16 mJ/mm2 each session). Placebo treatment was performed with a clasp on the heel. Pain measured by Visual Analog Scale (VAS) score and quality of life measured by the modified Roles and Maudsley (R&M) score were assessed at baseline, 4 weeks, 12 weeks and 24 weeks later.
Results: Statistical analysis demonstrated that RSWT had significantly ($p < 0.001$) reduced the mean VAS and R&M scores at all follow-up intervals compared to placebo treatment. Mean VAS scores were reduced after RSWT from 8.58 ± 0.32 (mean ± SEM) at baseline to 0.62 ± 0.21 at 4 weeks, 1.04 ± 0.18 at 12 weeks,, and 0.50 ± 0.09 at 24 weeks from baseline. Likewise, mean R&M scores were reduced after RSWT from 3.76 ± 0.07 at baseline to 1.20 ± 0.07 at 4 weeks, 1.42 ± 0.10 at 12 weeks, and 1.32 ± 0.06 at 24 weeks from baseline. No similar comparative changes were observed after the placebo treatment. No serious adverse events of RSWT occurred.
Conclusion: RSWT is a safe and efficient treatment for chronic PF even when only 2 applications, 1 week apart, with 2,000 impulses each are administered.
Level of Evidence: Level 1 (prospective, randomized, double-blind, placebo-controlled clinical study).

Keywords: *Extracorporeal shockwave therapy (ESWT); Painful heel; Plantar fasciitis; Radial extracorporeal shockwave therapy (RSWT)*

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INTRODUCTION

Plantar fasciitis (PF), the most common cause of heel pain, accounts for approximately 11-15% of foot symptoms presenting to physical therapists.[1,2] In the United States, more than 2 million individuals are treated for PF on an annual basis.[3,4] The term plantar fasciitis implies an inflammatory condition by the suffix 'itis'. However, various lines of evidence indicate that this disorder is better classified as "fasciosis" or "fasciopathy".[4-6]

Details about etiology, pathogenesis, risk factors, diagnosis and general treatment strategies for PF have been recently provided in a series of comprehensive reviews.[7] Briefly, both athletes and the elderly commonly present to physical therapists with PF, and the diagnosis of PF is usually based on the patient's history and clinical examination.[2,8] It has been recommended in the literature to start treatment of PF with conservative treatment, including physical therapy, stretching, and inserts/orthotics.[3,8,9]For patients not responding to conservative treatment for 6 months (between 10-20% of all patients) extracorporeal shockwave therapy (ESWT) should be considered.[7,8]

Therapeutic extracorporeal shockwaves are either focused or radial.[6,8]Focused shockwaves have high tissue penetration power (10 cm) and impact force (0.08Y,0.28 mJ/mm2).[2] They can be generated using electrohydraulic, electromagnetic, and piezoelectric methods.[6]

InElectrohydraulictechnique, shockwaves are generated by high voltage discharging to a spark plug in the underwater source.[2,6] Shockwavesare delivered to the treatment area througha rubber contact membrane.[2,6] The energy is dispersedover a treatment area that is large enough that

theintensity of the shockwaves reaches therapeutic levels.[2]

The electromagnetic shockwave system usesan electromagnetic coil and an opposing metalmembrane to produce a magnetic field that compressesthe surrounding fluid medium to generate a shockwave.[2,6]

In piezoelectricgenerator, piezo elements are arranged on a spherical surface and are synchronously excited by an electrical pulse to emit a pressure wave in the direction of the center of the spherical surface.This preciselyfocused energy literally passes through thebody's undamaged tissues without effect and is thenconcentrated on the pathologic tissue.[2,4]

On the other hand, radial shockwaves are pneumaticwaves generated by an air compressor.[6]Theyrepresent an alternative approach to therapeutic focused shockwaves, allowing for broader application.[2]The waves are generated ballistically by acceleratinga bullet to strike an applicator, which transforms the kinetic energy of the bullet into a radially expanding pressure wave.[6]The generated shockwavesare transmitted radially, with lower penetration (3 cm) and less impact (0.02Y, 0.06 mJ/mm2).[2,6]

To date, 6 ESWT devices have gained approval from the United States (U.S.) Food and Drug Administration (FDA) for the treatment of recalcitrant plantar fasciitis.[6]

The safety and efficacy of ESWT for chronic PF has been assessed in a variety of randomized clinical trials (RCTs). Rompeet al.[19]have already reviewed the results of using focused shockwave therapy to treat chronic PF. Since then, 5 RCTs[3,7-9,17] have assessed the safety and efficacy of RSWT for chronic PF.[6] Recently, Dizon et al.[2]reviewed the results of using both ESWT and RSWT for chronic PF.

The vast majority of published papers on the efficacy of ESWT in patients with plantar fasciitishave come up with rather controversial results.[2,6,7,19]The significant differences in theresults of the various studies may be explainedby a number of factors including technical differences (machine design, shockwavetype, intensity and frequency, and the use of different forms of placebo treatment), as well as differences in subjectpopulations, severity of disease, outcome measures, follow-up time, and study design.[2,6]

This highlights the need for further investigation using a rigorous scientific research leading to a concrete evidence.[2,6,7,19]To confirm the resultsreported in the previous studies,[7,8] using theEMS Swiss DolorClast RSWT device, our prospective, randomized, double-blind, placebo-controlled, clinicaltrial was designed to determine the efficacy of RSWT in patients with chronic PF.

METHODS

Participants

Sample Size

The sample size calculation was based on the comparison of the difference between RSWT and placebo groups with respect to the changes in the principal outcome measure (pain measured on a 0 to 10 cm VAS scale) at the 24-week follow-up assessment. Pilot data collected in 50 participants indicated that the between-subject standard deviation was approximately 2.5 cm and the baseline/12-week correlation was approximately 0.5. The baseline/24-week correlation can be extrapolated from this value to be 0.25.

Using these parameters, a sample size of 50 participants per group would have 80% power (P = .05, 2-sided) to detect a difference of 1.3 cm in mean pain VAS scores between the 2 groups at 24-week follow-up using an analysis of covariance adjusting for baseline pain scores. Using nQuery Advisor 3.0 (Statistical Solutions Ltd., Cork, Ireland), the sample size of 50 participants per treatment group was thought to be adequate to detect any significant differences between the two groups. Accordingly, a total sample size of 100 participants was targeted. However, we conservatively recruited 109 patients, bearing in mind that there might be participants' dropoutduring treatment or loss during the follow up.

A total of n=109 patients with unilateral, chronic PF were enrolled in the present study between October 2009 and November 2012.

Patients were diagnosed by primary care physicians with chronic PF primarily based on the patient's history and physical examination, including heel pain and local tenderness over the plantar's medial aspect of the calcaneal tuberosity near the plantar fascia insertion. Radiographs showed the presence of a heel spur in 77% of the patients.

All patients suffered from PF for at least 6 months and had undergone various conservative treatments, including at least 2 corticosteroid injections and 12 physical therapy sessions. Patients were then referred to the office of the principal investigator in Brooklyn, NY, USA and considered for participation in the present study according to the inclusion and exclusion criteria summarized in Table 1.

Before randomization, n=2 patients chose to withdraw their consent for participation in the study, and another n=3 patients declined to sign the consent form. Patients of any gender, race and ethnicity were eligible to participate in the present study.

After having obtained written informed consent from each patient, patients were randomly assigned by an independent treatment center affiliated with Rocky Mountain University of Health Professions (RMU) at Provo, UT, USA in blocks of 2 to receive either RSWT (n=52) or placebo treatment (n=52). Randomization was performed by a computerized random number generator created by an independent bio-statistician to draw up groups' allocation. An administrative assistant distributed interventions via opaque, sealed envelopes, containing information about the individual allocation schedule. Both patients and the study outcome assessors were blinded for the entire duration of the study. The study investigators, other than the principle investigator who administered the true or sham treatment, did not have access to the patients' treatment records, including patient allocation or the allocation sequence, until all patients had completed the 24-weeks follow-up re-evaluation. No patient dropped out from the study after randomization.

Table 1. Inclusion and exclusion criteria of patients with chronic plantar fasciitis enrolled in the present study.

Inclusion criteria
Adults over the age of 18 years
Diagnosis of painful heel syndrome by clinical examination, with the following positive clinical signs: • Pain in the morning or after sitting a long time • Local pain where the fascia attaches to the heel • Increasing pain with extended walking or standing for more than 15 minutes
History of 6 months of unsuccessful conservative treatment
No therapy for at least 4 weeks before referral
Signed informed consent
Exclusion criteria
Bilateral plantar fasciitis
Dysfunction of foot or ankle (for example, instability)
Arthrosis or arthritis of the foot
Infections or tumors of the lower extremity
Neurological abnormalities, nerve entrapment (for example, tarsal tunnel syndrome)
Vascular abnormality (for example, severe varicosities, chronic ischemia)
Operative treatment of the heel spur
Hemorrhagic disorders and anticoagulant therapy
Pregnancy
Diabetes

Ethical approval was obtained from the Institutional Review Board of RMU before starting the study. The study was carried out in accordance with the World Medical Association Declaration of Helsinki.[6]

There was no statistically significant difference between the patients treated with RSWT and those treated with placebo in respect of sex distribution, mean age, mean body weight, affected side and types of job.

Treatment

The RSWT was applied by the principal investigator with the EMS Swiss Dolorclast® (EMS Electro Medical Systems Corporation; Dallas, TX, USA) approved by the U.S. FDA to treat heel pain associated with chronic proximal plantar fasciitis. Each patient received 2 applications of RSWT, 1 week apart,[3,9] with 2,000 impulses per session.[8,9,17] The air pressure of the device was set at 3.5 bars, energy flux density (EFD) = 0.16 mJ/mm^2, and the impulses were applied with a 15 mm applicator at a frequency of 8 Hz (Figure 1A). Placebo treatment was identically applied but with a clasp on the heel to prevent the transmission of the impulses from the applicator to the skin at the treatment site (Figure 1B).

This was similar to the placebo treatments applied in double-blind studies on ESWT for chronic PF by other investigators.[10-12] The patients were not made aware as to whether they received RSWT or placebo treatment. But, as in the studies by Haake et al.,[10] Kudo et al.,[11] and Malay et al.,[12] the principal investigator who applied the treatments was not blinded. However, the principal investigator interacted with the present study participants strictly in a standardized way irrespective of their treatment allocation, preventing any behavior that could have indicated to them whether they received RSWT or placebo treatment.

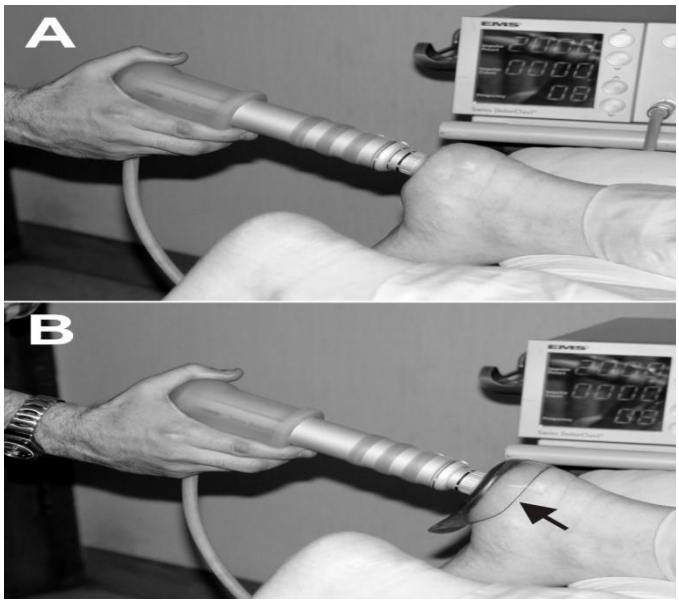

Figure 1. Delivering Radial extracorporeal shockwave therapy (RSWT) (A) or placebo treatment (B) for chronic plantar fasciitis. Placebo treatment was performed with a clasp on the patient's heel (arrow in B).

In addition, all the measures described in another double-blind study on RSWT for chronic PF by Ibrahim et al.[7] were applied. Specifically, (i) no patient knew how placebo treatment was actually achieved; (ii) the sound, look and handling of the RSWT device were identical in both RSWT and placebo treatments, and (iii) all RSWT or placebo treatment sessions took approximately 10 minutes.

Similar to the study reported by Ibrahim et al.,[7] local anesthesia was not used during the application of the true or sham RSWT and no other conservative treatments were allowed during the entire time of this study.

Evaluation of treatment success

The Visual Analog Scale (VAS) score and the modified Roles &Maudsley (R&M) score were used to quantify patients' pain and quality of life at baseline as well as at 4 weeks, 12 weeks, and 24 weeks from baseline. These 2 outcome measures are widely used and commonly reported in the relevant ESWT efficacy studies.[7,8] The clinical outcome was assessed by observers blinded to treatment allocation.

The VAS is a horizontal, 10 cm-long line with the phrase "no pain" on the left side (score: 0) and the phrase "pain as bad as it could be" on the right side of the line (score: 10). Patients were asked to place a hatch mark on the line that corresponded to their current level of pain. The distance between the phrase

"no pain" and the hatch mark was used as linear measure of the VAS score. All patients scored substantial pain of at least 7 or above on the VAS at baseline.

The R&M score was used to quantify the patients' quality of life as expressed by presence or absence of pain in relation to timed walking ability, presence or absence of symptoms, and satisfaction with the treatment outcome. Score 1 (*excellent* quality of life) representedunlimited walking ability without pain, no symptoms, patient satisfied with the treatment outcome. Score 2 (*good* quality of life) represented ability to walk more than 1 hour without pain, symptoms substantially decreased after treatment, patient satisfied with the treatment outcome. Score 3 (*acceptable* quality of life) represented inability to walk more than 1 hour without pain, symptoms somewhat better and pain more tolerable than before treatment, patient slightly satisfied with the treatment outcome. Score 4 (*poor* quality of life) represented inability to walk without severe pain, symptoms not better or even worse after treatment, patient not satisfied with the treatment outcome. All patients reported a R&M score higher than 3 at baseline. Accordingly, all the patients were at least not able to walk more than 1 hour without pain at baseline.

There were only a few adverse events associated with RSWT or placebo treatment in the present study such as pain and/or discomfort during treatment. This was noted by n=3 patients who received RSWT and n=2 patients receiving placebo treatment. However, all patients were able to complete their treatments without any anesthesia. In addition, 1 patient reported minor skin reddening for a brief period following treatment. No other adverse events (such as those that can result from any type of surgical fascial release, with or without heel spur resection) were observed.

Statistical methods

For the patients who received RSWT as well as for those whoreceived placebo treatment, mean and SEM of the VAS and the R&M scores were calculated for each investigated time point, i.e., at baseline as well as at 4 weeks, 12 weeks and 24 weeks from baseline, respectively.

Comparisons between RSWT and placebo treatment were performed using two-way repeated measures analyses of variance (ANOVA), followed by Bonferroni post-test to compare replicate means by the investigated time points.

In addition, the treatment (RSWT or placebo) was considered successful when a patient reported a percentage decrease in the VAS score larger than 60%[8] at 4 weeks (short-term success) and 24 weeks (long-term success) from baseline. Comparisons between RSWT and placebo treatment success, as defined by a reduction in mean VAS scores larger than 60%, were performed with two-sided Chi-square test.

In all analyses an effect was considered statistically significant if its associated p-value was smaller than 0.05. Calculations were performed using SPSS (Version 22.0 for Windows; SPSS, Chicago, IL, USA) and GraphPad Prism (Version 6.01 for Windows; GraphPad Software, San Diego, CA, USA).

Codes were not broken since the investigators other than the principle one did not have access to the patients' group allocation until all patients had completed the 24-week follow-up assessment.

RESULTS

All the patients included in the present study finished the corresponding treatment (RSWT or placebo, respectively).There was no crossover and no drop-out and accordingly the randomization to the treatment groups was not broken. Hence, all patients were analysed as randomized.[13,14]

The RSWT had a significant ($P < 0.001$) and lasting (at least for 6months) impact on the mean VAS and R&M scores of the treated patients. Specifically, the mean VAS scores were reduced after RSWT from 8.58 ± 0.32 (mean ± SEM) at baseline to 0.62 ± 0.21 at 4 weeks, 1.04 ± 0.18 at 12 weeks, and 0.50 ± 0.09 at 24 weeks from baseline (Table 2, Figure 2A). Likewise, the mean R&M scores were reduced after RSWT from 3.76 ± 0.07 at baseline to 1.20 ± 0.07 at 4 weeks, 1.42 ± 0.10 at 12 weeks, and 1.32 ± 0.06 at 24 weeks from baseline (Table 3, Figure 2B).

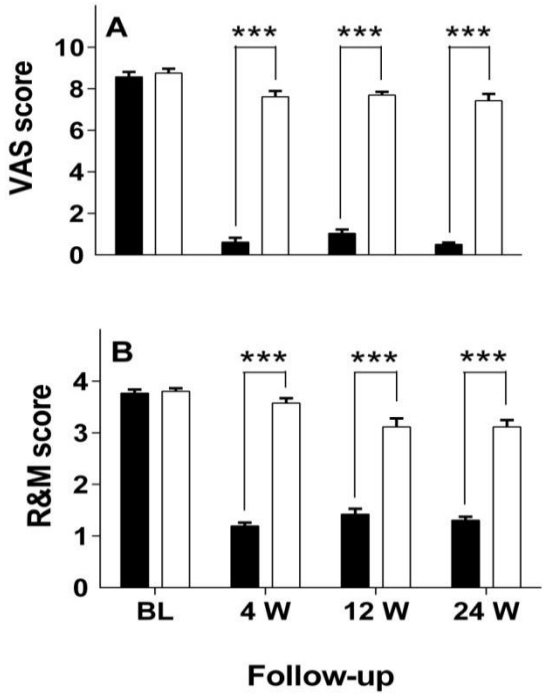

Figure 2. Mean and standard error of the mean of Visual Analog Scale (VAS) scores (A) and modified Roles &Maudsley (R&M) scores (B) of patients with chronic plantar fasciitis after treatment with radial extracorporeal shockwave (RSWT; n=52; closed bars) or placebo treatment (n=52; open bars) at baseline (BL) as well as 4 weeks (4 W), 12 weeks (12W) and 24 weeks (24 W) from baseline. ***; $p < 0.001$.

Table 2. VAS Scores [points] Mean ± SD (n = 52 per group)

	RSWT Group Mean ± SD	Placebo Group Mean ± SD	Difference	95% CI of diff.	t	*P* value
Initial	8.58± 1.68	8.92 ± 0.92	0.17	-0.62 to 0.97	0.54	P =0.57
4 Weeks	0.61± 1.48	7.61± 2.04	7.00	6.20 to 7.79	22.00	P <0.001
12Weeks	1.04± 1.89	7.69± 1.18	6.65	5.86 to 7.45	20.91	P <0.001
24 Weeks	0.50± 0.70	7.42± 2.39	6.92	6.12 to 7.72	21.76	P <0.001

SD: Standard Deviation; CI: Confidence Interval; VAS: Visual Analog Score; RSWT: Radial extracorporeal shockwave therapy

Table 3. The modified Roles and Maudsley (R&M) Scores [points] Mean ± SD (n = 52 per group)

	RSWT Group Mean ± SD	Placebo Group Mean ± SD	Difference	95% CI of diff.	t	*P* value
Initial	3.77 ± 0.51	3.81 ± 0.39	0.04	-0.32 to 0.39	0.27	P =0.67
4 Weeks	1.19 ± 0.49	3.58± 0.69	2.38	2.03 to 2.74	16.69	P <0.001
12Weeks	1.42 ± 0.75	3.11± 1.19	1.69	1.33 to 2.05	11.85	P<0.001
24 Weeks	1.31± 0.47	3.11± 0.94	1.81	1.45 to 2.17	12.65	P<0.001

SD: Standard Deviation; CI: Confidence Interval; R&M: The modified Roles and Maudsley questionnaire; RSWT: Radial extracorporeal shockwave therapy

Similar changes in mean VAS and R&M scores were not observed after placebo treatment. Specifically, the mean VAS scores of the placebo-treated patients were 8.75 ± 0.21 at baseline, 7.62 ± 0.28 at 4 weeks, 7.69 ± 0.16 at 12 weeks, and 7.42 ± 0.33 at 24 weeks from baseline (Table 2, Figure 2A). The mean R&M scores of the placebo-treated patients were 3.80 ± 0.05 at baseline, 3.58 ± 0.09 at 4 weeks, 3.11 ± 0.17 at 12 weeks, and 3.11 ± 0.13 at 24 weeks from baseline (Table 3, Figure 2B).

The two-way repeated measures ANOVA showed that RSWT had a statistically significant effects on the mean VAS and R&M scores (VAS scores: $F_{[1]}$ [1 degree of freedom] = 480.3, R&M scores: $F_{[1]}$ = 125.5; each with $p < 0.001$) and at follow-up interval (VAS scores: $F_{[3]}$ = 106.3; R&M scores: $F_{[3]}$ = 66.4; $p < 0.001$ each time) as well as on the interaction between these variables (VAS scores: $F_{[3]}$ = 52.1; R&M scores: $F_{[3]}$ = 31.2; each with $p < 0.001$).

Post-hoc Bonferroni test demonstrated statistically significant differences in the mean VAS and the R&M scores between the RSWT-treated patients and the placebo-treated ones at 4 weeks (VAS score: t = 22.00; R&M score: t = 16.64; each with $p < 0.001$), 12 weeks (VAS score: t = 20.91; R&M score: t = 11.85; each with $p < 0.001$), and 24 weeks (VAS score: t = 21.76; R&M score: t = 12.65; each with $p < 0.001$) frombaseline, but there was no difference at the baseline itself (VAS score: t = 0.54; R&M score: t = 0.27; each with $p > 0.05$)(Table 2,3).

DISCUSSION

The present study demonstrated that RSWT for chronic PF resulted in significant (P <0.001) and lasting (for at least 6 months) reduction in pain as well as improvement of thepatients' quality of life, with short-term treatment success of 94% and long-term treatment success of 100% compared to only 7% short-term and 18% long-term treatment success in the placebo treated group. The present study fulfilled all criteria set out by Harris et al.[15] and Jadad et al.[16] with respect to the quality of reports of randomized clinical trials.

Gerdesmeyer et al.[8] demonstrated the safety and efficacy of RSWT for chronic PF by administering RSWT or placebo treatment in 3 sessions, each 2 weeks (±4 days) apart and evaluated the treatment outcome at 12 weeks and 12 months from baseline. The authors found a statistically significant ($p < 0.05$) difference in the reduction of the mean Visual Analog Scale composite score between the patients treated with RSWT and the placebo-treated ones both at 12 weeks and 12 months from baseline.

The results of the present study are generally in agreement with the results reported by Gerdesmeyer et al.[8] The primary difference was the smaller placebo effect in the present study(reductions in mean VAS scores by 14.3% at 12 weeks and 18.6% at 24 weeks from baseline, respectively) compared to Gerdesmeyer et al.[8] study (reductions in mean VAS composite scores by 44.7% at 12 weeks and 43.2% at 12 months from baseline, respectively).

In general, one could blame the possible partial unblinding of the patients (because the principal investigator who administered the treatments was not blinded) in an attempt to explain the smaller placebo effect in the present study.This, however, was prevented by interacting with the study participants strictly in a standardized way irrespective of

treatment allocation, a routine procedure in randomized, placebo-controlled, double-blind clinical trials of ESWT for chronic PF when the shockwave applicators are not blinded.[2,7,10,12] In addition, the treatment success rates in the study of Gerdesmeyer et al.[8] were also smaller in the group of patients treated with RSWT (61.0% at 12 weeks and 63.4% at 12 months from baseline, respectively) than the treatment success found in the present study, although the definition of treatment success was identical.

The reason for this discrepancy is not known. Possible causes are the differences in the study sample size (a total of n=104 patients in the present study compared to a total of n=245 patients in the study by Gerdesmeyeret al.[8]) and in the pain assessment methodology.

Gerdesmeyer et al.[8] reported sum VAS scores of heel pain (i) when taking first steps of the day, (ii) when performing daily activities, and (iii) after application of a Dolormeter (EMS), i.e., a device that subjects the skin to a standardized local pressure in order to quantify local pressure pain. In contrast, patients enrolled in the present study were not asked to report different VAS scores for heel pain when taking first steps of the day and heel pain when doing daily activities, and a Dolormeter was not used. However, these differences would presumably not affect the way the results are interpreted and could not challenge the fact that both studies came to a final matching conclusion about the efficacy of RSWT.

The first successful treatment of patients with chronic PF by only 2 applications of RSWT was reported by Ibrahim et al.[7] They concluded at the end of their small sample size (a total of n=50 patients), otherwise well-designed RCT, that RSWT is an efficient treatment for chronic PF. However, they also acknowledged the need for future study with a larger sample size to confirm their results; the present study was meant to serve that purpose.

The effects of RSWT on chronic PF were also evaluated in the studies by Chow and Cheing,[3] Marks et al.,[17] and Greve et al.[9]

Chow and Cheing[3] treated patients suffering from chronic PF for at least 3 months either with fixed EFD (Group A: 3 sessions of RSWT, each 1 week apart, 1,000 impulses per session, EFD = 0.11 mJ/mm^2) or increasing EFD (Group B: EFD = 0.12 mJ/mm^2, 0.15 mJ/mm^2 and 0.17 mJ/mm^2, respectively in the first, second and third week). The authors found statistically significant ($p < 0.05$) reductions in mean VAS scores by respectively 37% (Group A) and 83% (Group B) at 6 weeks from baseline, but not for a control group treated with only 30 impulses with EFD = 0.03 mJ/mm^2 per session. These data are in line with the results of the present study as well as the studies by Gerdesmeyer et al.,[8] and Ibrahim et al.[7]

Marks et al.[17] treated patients with 3 applications of RSWT, each 3 days apart (500 impulses in the first session and 2,000 impulses in the second and third sessions, respectively, EFD = 0.16 mJ/mm^2). The authors found no statistically significant differences ($p > 0.05$) in treatment success (defined as reduction in the VAS score greater than 50%) at 6 months from baseline between RSWT-treated patients (56.2%) and placebo-treated ones (44.4%). These results could be attributed to the fact that Marks et al.[17] investigated very low number of patients suffering from either acute or chronic PF, and at least some of the placebo-treated patients were almost pain-free at baseline.

Greve et al.[9] subjected 1 group of patients n=16 with chronic PF to RSWT (3 applications, each 1 week apart, with 2,000 impulses per session, EFD = 0.14 mJ/mm^2), and another group of patients n=16 with chronic PF received conventional physical therapy (10 sessions of ultrasound followed by exercises to stretch all posterior leg muscles and strengthen the tibialis anterior muscle, twice a week). Included patients suffered from painful symptoms for at least 3 months before being enrolled in their study. Patients in both groups reported reduced VAS scores at 3 months from baseline, with no statistically significant differences between the 2 groups ($p > 0.05$). Greve et al.[9] concluded that both treatments were effective for pain reduction and improving the functional abilities of patients with PF, however, the authors noted that the effects of RSWT occurred sooner than the effects of physical therapy after the onset of treatment. In their study, treatment success was not calculated as in the present study and in the studies by Gerdesmeyer et al.,[8] and Ibrahim et al.[7]

The results of the present study as well as those reported by Chow and Cheing,[3] Gerdesmeyer et al.,[8] Ibrahim et al.,[7] and Greve et al.[9] raise the question about the significance of radial compared to focused extracorporeal shockwave therapy in treating chronic PF.

Compared with radial shockwaves, focused shockwaves show deeper tissue penetration with substantially higher energies concentrated to a smaller focus.[7,18] From the 17 clinical trials performed with focused ESWT for chronic PF so far, Rompe et al.[19] characterized studies by Buch et al.[1], Haake et al..[10] Kudo et al.,[11] and Malay et al.[12] as well-designed.

Buch et al.,[1] Kudo et al.,[11] and Malay et al.[12] found treatment success over placebo with different therapy protocols at 12 weeks from baseline, whereas Haake et al.[10] did not. But, this could be explained by the fact that fewer than half of the patients in Haake et al.[10] study received minimal conservative care such as stretching exercises, casting or night splinting before their inclusion,[20] and treatment was performed with very low energy settings (EFD = 0.08 mJ/mm^2).[19]

Rompeet al.[19] concluded that chronic PF can be treated successfully with focused shockwaves. However, in contrast to RSWT, long-term (> 12 weeks) focused shockwavetherapysuccess in treating chronic PF has not yet been demonstrated. [19]

In the present study as well as in Ibrahim et al.[7] study, treatment success for chronic PF was achieved with 2 RSWT applications compared to 3 applied in the study by Gerdesmeyer et al.[8] This could substantially increase the attractiveness of RSWT as a treatment of chronic PF to both the patients suffering from the disease and the health care providers. Nevertheless, the question whether 2 or 3 RSWT applications are considered as an effective treatment of chronic PF remains and should be re-addressed in further research, comparing both strategies to one another in the same study.

The RSWT-treated patients in the present study were on average 10% (or 5.5 years) older than the placebo-treated

ones. In this regard, a recent study reported by Chuckpaiwonget al.[4] indicated that older patients with chronic PF might experience better response than younger ones to ESWT. This was concluded from a statistically significant ($p < 0.05$) difference between patients treated successfully (mean age: 49 ± 10 years, mean ± standard deviation) or unsuccessfully (mean age: 47 ± 10 years) with focused ESWT, applied in the same manner as done by Kudo et al.[11] This might raise the question whether the difference in mean age between the RSWT-treated patients and the placebo-treated ones in the present study might have influenced the study outcome. This, however, appears unlikely because all RSWT-treated patients (52/52) reported treatment success at 24 weeks from baseline, regardless of how old or young each patient was.

Also, the study by Chuckpaiwong et al.[4] was an unblinded observational study without a control group, performed with focused shockwaves and a treatment protocol that differed substantially from the treatment protocol applied in the present study. In addition, their study did not take into account important potential outcome predictors for the success of ESWT with focused shockwaves for chronic PF, such as the patients' pain levels at baseline and the presence of a calcaneal bone marrow edema.[21]

Thus, the question whether older patients with chronic PF might experience better response than younger ones to RSWT cannot be definitely answered and should be addressed in future studies.

The beneficial effects of shockwave therapy can be attributed to a controlled microdisruption of the plantar fascia, while preserving the gross structural integrity and biomechanics of the foot.[1,11,12] The RSWT also stimulates the initiation of a healing response and adaptation of tissue biology.[7,8] Inflammatory mediated process and induction of physiological healing process as a result of RSWT is reported.[5,17-19]

The RSWT stimulates local metabolism, microcirculation, neovascularisation, induction of growth factors and tissue regeneration.[8,18,19] The RSWT induces a neovascularisation process with an early release of angiogenesis-related markers (vascular endothelial growth factor) at the tendon-bone junction.[5,8,18] Low energy RSWT promotes tendon healing (cell proliferation and tissue regeneration) by inducing the transforming growth factor (TGF)-ß1 and insulin growth factor-1.[8,22] Increased expression of proliferating cell nuclear antigens and activation of endothelial nitrogen oxide syntase was also registered.[17-19] The RSWT pain-relieving effect is attributed to a gate-control mechanism, damage to the neuron cell, degeneration of sensory nerve fibers, and changes in substance *P*.[22]

According to the study done by Chow and Cheing,[3] shockwaves aredefined as low intensity if the energy level is lessthan 0.1 mJ/mm2, moderate or medium intensity ifenergy level is higher than 0.1 mJ/mm2 but lowerthan 0.2 mJ/mm2, and high intensity if the energyused is higher than 0.2 mJ/mm2, regardless of howthe shockwaves are produced.[3]

There is no consensus on the appropriate RSWT dosage and treatment parameters remain empirical.[1,7] An emphasis is placed upon the use of a feasible regime with minimal side effects. Although the technique is widely reported to be safe,hemorrhage and local soft tissue damage through cavitation might potentially occur.[2,8]This appears to be more likely with the high intensities.[5,7] For this reason, a moderate intensity was chosen in our study, which in our opinion eliminated the need for the administration of local anesthetic to apply the RSWT and/or significant post- treatment rest.

In agreement with other reports,[7,8]significant adverse effects were not noted in our study, and the results indicated that RSWT of moderate intensity had significant beneficial effects over placebo.

Finally it should be mentioned that RSWT has several advantages over surgery in the treatment of chronic PF, including the recently propagated minimally-invasive percutaneous radio frequency nerve ablation (RFNA).[23]Surgery has risks such as transient swelling of the heel pad, calcaneal fracture, injury of the posterior tibial nerve or its branches, and flattening of the longitudinal arch with resultant midtarsal pain, which may delay recovery over months.In contrast to surgery, either open or endoscopic, RSWT does not require avoidance of weight bearing or a prolonged time for patients to return to their work.[7,8] Rather, RSWT allows patients to return to activities of daily life within 1 or 2 days, with immediate return to most jobs and normal daily shoe wear.[8] Most importantly, to the best of our knowledge there are no published controlled trials of surgery for PF,[24] including RFNA.[23,25]

CONCLUSION

The RSWT is a safe and effective treatment for patients with chronic PF. Itshould be considered in the treatment of every patient who has had unsuccessful conventional treatment of chronic PF, before considering any surgical procedure.

The fact that treatment success for chronic PF can be achieved with just 2 RSWT applications could increase the attractiveness of RSWT as a treatment of chronic PF to both the patients suffering from the disease and the health care providers.

Funding: None declared.

Ethical approval:This study was approved by Institutional Review Board ofRocky Mountain University of Health Professions, USA.

Conflict of interest: The authors declare there are no conflicts of interest in the undertaking of the study and preparation of this manuscript.

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الملخص العربي

فاعلية العلاج بالموجات ذات الصدمات العالية الشعاعية المتولدة خارج الجسم فى حالات التهاب اللفافة الأخمصية

خلفية البحث:- اثبت العلاج بالموجات ذات الصدمات العالية المتولدة خارج الجسم كفاءة علاجية لحالات التهاب اللفافة الأخمصية المزمن بواسطة ثلاث جلسات علاجية واجريت الدراسة الحالية لتختبر الفرضية القائلة بأنه يمكن تحقيق نجاح مماثل بهذا النوع من العلاج من خلال جلستين فقط. **مواد وطرق البحث:-** وزعت عينة كلية مكونة من 104 مريض بالتهاب اللفافة الأخمصية المزمن بإحدى القدمين بطريقة عشوائية غير انتقائية على مجموعتين . تم علاج احداها (52 مريض) بجلستين من الموجات ذات الصدمات العالية بينهما أسبوع والأخرى (52 مريض) تلقت علاجاً وهمياً بمنع وصول الموجات ذات الصدمات العالية إلى قدم المريض بوضع حاجز مطاطى سميك بين الكعب والجهاز. وتم استخدام 2000 نبضة بكثافة تدفق طاقة = 16. ميلى جول / مم ^{2}فى كل جلسة. وتم قياس حدوث اى تغيير فى شكوى كل مريض من الألم أو فى قدرته الوظيفية عند المتابعة الدورية بعد 4 و 12 و 24 اسبوع من القياس المبدئى لمستوى الألم والقدرة الوظيفية قبل تلقى العلاج. ولم يطلع اى من المرضى ومن قام بالقياسات طوال مدة البحث على حقيقة العلاج المعطى أفعلى أم وهمى. **النتائج:-** اثبت التحليل الأحصائى وجود انخفاض ملحوظ فى مستوى الألم وارتفاع ملحوظ فى مستوى القدرة الوظيفية للمرضى الذين تلقوا العلاج الفعلى بالموجات ذات الصدمات العالية بالمقارنة بمن تلقى العلاج الوهمى. ولم يلاحظ حدوث اى اثار سلبية خطيرة جراء استخدام هذا النوع من العلاج والذى يعد آمناً. **الخلاصة:-** ويخلص من هذا البحث ان جلستين فقط من العلاج بالموجات ذات الصدمات العالية بينهما اسبوع ذات كفاءة علاجية لحالات التهاب اللفافة الأخمصية المزمن عند اعطائها بواسطة 2000 نبضة تدفقية. ويعتبر هذا العلاج الحل الأمثل فى حالة فشل جميع العلاجات الدوائية والعلاج الطبيعى ويعد بديلاً أحسن واوفر اقتصادياً من اجراء التدخلات الجراحية. **مستوى الإثبات العلمى للدراسة:-** تعد الدراسة بتصميمها السريرى المزدوج التعمية المقارن بتحكم بين علاج فعلى ووهمى من اعلى مستويات الدليل الإثباتي العلمى .

مفتاح كلمات البحث:- الموجات ذات الصدمات العالية المتولدة خارج الجسم ، كعب مؤلم ، التهاب اللفافة الأخمصية ، الموجات ذات الصدمات العالية الشعاعية المتولدة خارج الجسم.