

Chronic Plantar Fasciitis Treated with Two Sessions of Radial Extracorporeal Shock Wave Therapy

Mahmoud I. Ibrahim, MSc, DSc, PhD, PT; Robert A. Donatelli, PhD, OCS, PT; Christoph Schmitz, MD; Madeleine A. Hellman, MHM, Ed.D, PT; Frederick Buxbaum, DPM
Brooklyn, NY

ABSTRACT

Background: Radial extracorporeal shock wave therapy (RSWT) has been previously demonstrated as an efficient treatment option for chronic plantar fasciitis (PF) when administered in three sessions. The present study tested the hypothesis that chronic PF can also be treated successfully with RSWT when only two treatment sessions are performed. **Materials and Methods:** A total of 50 patients with unilateral, chronic PF were randomly assigned to either RSWT ($n = 25$) or placebo treatment ($n = 25$). RSWT was applied in two sessions 1 week apart (2,000 impulses with energy flux density = 0.16 mJ/mm^2 per session). Placebo treatment was performed with a clasp on the heel. Endpoints were changes in the Visual Analog Scale (VAS) score and the modified Roles & Maudsley (RM) score from baseline to 4 weeks, 12 weeks and 24 weeks followup. **Results:** Mean VAS scores were reduced after RSWT from 8.5 ± 0.3 (mean \pm SEM) at baseline to 0.6 ± 1.5 at 4 weeks, 1.1 ± 0.3 at 12 weeks and 0.5 ± 0.1 at 24 weeks from baseline. Similar changes were found for mean RM scores from baseline after RSWT but were not observed after placebo treatment. Statistical analysis demonstrated that RSWT resulted in significantly reduced mean VAS scores and mean RM scores at all followup intervals compared to placebo treatment (each with $p < 0.001$). No serious adverse events of RSWT were observed. **Conclusion:** RSWT was successful in the treatment of chronic PF even when only two sessions with 2,000 impulses each were performed 1 week apart.

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Corresponding Author:

Mahmoud I. Ibrahim, MSc, DSc, PhD, PT
Rocky Mountain University of Health Professions
Orthopaedic
8415 10th Ave.
Brooklyn, NY 11228
E-mail: msrt78@aol.com
For information on pricings and availability of reprints, call 410-494-4994, x232.

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INTRODUCTION

Plantar fasciitis (PF), the most common cause of heel pain, accounts for approximately 11% to 15% of foot symptoms presenting to physicians. In the United States, more than two million individuals are treated for PF on an annual basis.²³ 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'.²³ Details about etiology, pathogenesis, risk factors, diagnosis and general treatment strategies for PF have been provided in a series of comprehensive reviews recently.^{5,22,23,24} Briefly, both athletes and the elderly commonly present to physicians with PF, and the diagnosis of PF is usually based on the patient's history and clinical examination. It has been recommended to start treatment of PF with conservative treatment modalities, including physical therapy, stretching, inserts/orthotics etc.²³ For patients not responding to conservative treatment for 6 months (between 10% and 20% of all patients) extracorporeal shock wave therapy (ESWT) can be considered.²³ In case a patient does not benefit from ESWT either, surgical intervention can be considered.²³

Several randomized, controlled trials of ESWT with focused shock waves for chronic PF have been published^{5,23,24}, demonstrating favorable results in the range of 50% to 70% of patients after a followup period of 3 months after treatment. Besides this, a recent study demonstrated safety and efficacy of radial extracorporeal shock wave therapy (RSWT) for chronic PF.⁸ Specifically, Gerdesmeyer et al.⁸ administered RSWT or placebo treatment in three sessions, each 2 weeks (± 4 days) apart and evaluated the treatment outcome at 12 weeks and 12 months after the

first session. The authors found a significant difference in the reduction of the mean Visual Analog Scale composite score between the patients treated with RSWT and the placebo-treated patients both at 12 weeks and 12 months from baseline.

To further evaluate the potential of RSWT to become a routine therapeutic modality in the treatment of chronic PF, we identified the following questions not addressed in the study by Gerdesmeyer et al.⁸ First, it is unknown whether treatment success can also be reached by two RSWT sessions 1 week apart, rather than by three RSWT sessions each 2 weeks apart as applied by Gerdesmeyer et al.⁸ Anecdotal reports by colleagues in Europe indicated that this could indeed be the case. Second, immediate return to normal daily activities (including sports activities) and normal daily footwear indicates that patients suffering from chronic PF and treated with RSWT experience profound pain relief much earlier than 3 months after the first RSWT session, applied as first followup in the study by Gerdesmeyer et al.⁸

Therefore we tested the hypothesis in the present prospective, randomized, double-blind, placebo-controlled study that treatment of chronic PF with two RSWT sessions 1 week apart will result in better pain relief than placebo treatment 4 weeks after the first RSWT treatment, lasting for at least 6 months.

MATERIALS & METHODS

Patients

A total of 55 patients with unilateral, chronic PF were enrolled in the present study between October 2007 and November 2008. Patients were diagnosed by primary care physicians who had chronic PF primarily based on the patient's history and physical examination, including heel pain and local tenderness over the plantar-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 two corticosteroid injections and 12 physical therapy sessions. Patients were then referred to the office of the principal investigator and considered for participation in the present study according to the inclusion and exclusion criteria summarized in Table 1. Before randomization, two patients chose to withdraw, and another three 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, they were randomly assigned by an independent treatment center in blocks of two to receive either RSWT ($n = 25$) or placebo treatment ($n = 25$). Randomization was performed by a computerized random number generator created by an independent bio-statistician to draw up groups' allocation. An

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:

1. Pain in the morning or after sitting a long time
2. Local pain where the fascia attaches to the heel
3. Increasing pain with extended walking or standing for more than 15 minutes

History of 6 months of unsuccessful conservative treatment

Therapy free period of 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

Table 2: Demographic Characteristics

Variable	RSWT	Placebo	Statistical analysis
Sex: female; male	18; 7	14; 11	Two-sided Chi-square test; $X^2 = 1.389$; $p = 0.239$
Age [years]: mean \pm SEM (range)	56.6 \pm 2.71 (26–87)	49.1 \pm 2.55 (28–78)	Unpaired two-tailed Student's <i>T</i> test; $t = 2.008$; $p = 0.050$
Body weight [kg]: mean \pm SEM (range)	90.3 \pm 3.67 (57.5–125)	84.2 \pm 2.82 (60–110)	Unpaired two-tailed Student's <i>T</i> test; $t = 1.322$; $p = 0.192$
Affected side: left; right	11; 14	12; 13	Two-sided Chi-square test; $X^2 = 0.081$; $p = 0.777$
Types of jobs: sedentary; light; medium-heavy; heavy	0; 6; 14; 5	3; 3; 15; 4	Two-sided Chi-square test; $X^2 = 4.146$; $p = 0.246$

SEM, standard error of the mean.

administrative assistant distributed interventions via opaque, sealed envelopes, containing information about the individual allocation schedule. Both patients and the study investigators were blinded for the entire duration of the study. Specifically, the study investigators did not have access to the patients' treatment records, including patient allocation or the allocation sequence, until all patients had completed the 24-weeks of followup. No patient dropped out from the study after randomization. Ethical approval was obtained from the Institutional Review Board before starting the study. The study was carried out in accordance with the World Medical Association Declaration of Helsinki.⁶

With the numbers available, the patients treated with RSWT were not significantly different from the patients treated with placebo with respect to the sex distribution, mean age, mean body weight, affected side and types of job (Table 2).

Treatment

RSWT was performed by the principal investigator with the EMS Swiss Dolorclast[®] (EMS Electro Medical Systems Corporation; Dallas, TX) approved by the U.S. Food and Drug Administration (FDA) to treat heel pain associated with chronic proximal plantar fasciitis. Each patient received two sessions of RSWT 1 week apart, with 2,000 impulses per session (air pressure of the device set at 3.5 bar [EFD = 0.16 mJ/mm²]; impulses applied with the 15 mm applicator at frequency of 8 Hz; Figure 1A). Placebo treatment was performed identically but with a clasp on the heel that prevented 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-blinded studies on ESWT for chronic PF by, e.g., Haake et al.¹⁰, Kudo et al.¹⁴ and Malay et al.¹⁹ The patients were not aware whether they received RSWT or placebo treatment.

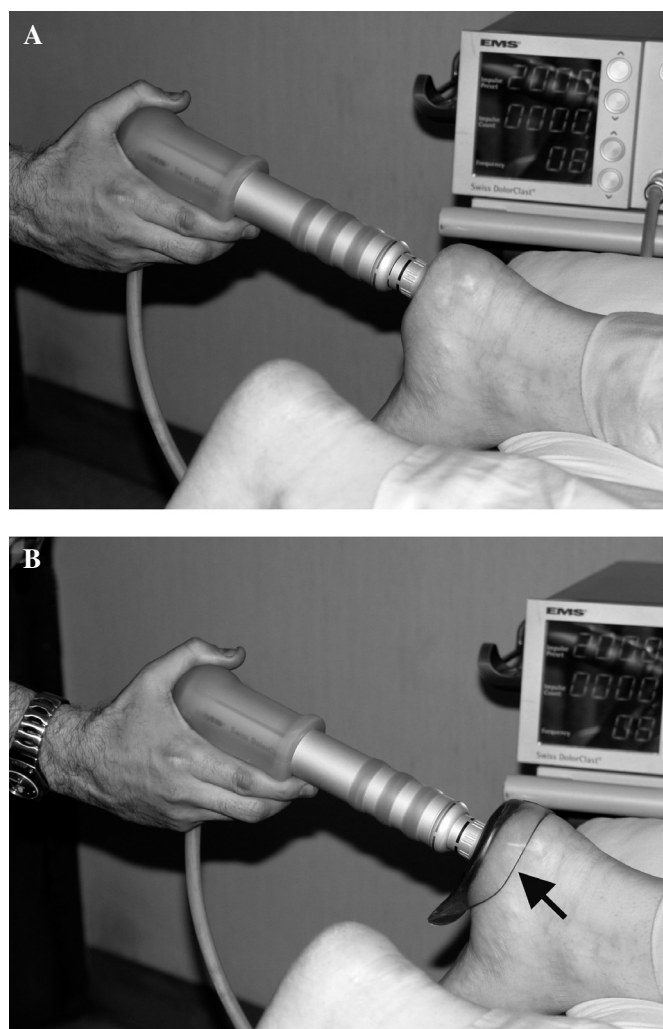


Fig. 1: Delivering RSWT (A) or placebo treatment (B) for chronic plantar fasciopathy. Placebo treatment was performed with a clasp on the patient's heel (arrow in B).

The principal investigator who applied the treatments was not blinded and interacted with study participants strictly in a standardized way irrespective of treatment allocation, preventing any behavior that could have indicated to the patients whether they received RSWT or placebo treatment. 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 ten minutes. Local anesthesia was not applied. No other conservative treatments were allowed during the study.⁸

Evaluation

Patients were requested to assess pain and quality of life before (i.e., at baseline) as well as 4, 12, and 24 weeks after RSWT or placebo treatment, respectively. To this end, both the Visual Analog Scale score and the modified Roles & Maudsley score were used. The clinical outcome was assessed by observers blinded to treatment allocation.

The Visual Analog Scale (VAS) was 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 5 or greater on the Visual Analog Scale at baseline.

The modified Roles & Maudsley (RM) score was used to evaluate the patients' pain in relation to normal daily activities. RM Score 1 represented excellent quality of life (i.e., no symptoms; unlimited walking ability without pain; patient satisfied with the treatment outcome [when assessed after RSWT or placebo]), RM score 2 represented good quality of life (i.e., ability to walk more than one hour without pain; symptoms substantially decreased after treatment; patient satisfied with the treatment outcome), RM score 3 acceptable quality of life (i.e., inability to walk more than one hour without pain; symptoms somewhat better and pain more tolerable than before treatment; patient slightly satisfied with the treatment outcome), and RM score 4 poor quality of life (i.e., inability to walk without severe pain; symptoms not better or even worse after treatment; patient not satisfied with the treatment outcome). Only 2% (1/50) of all patients reported a RM score of 2 at baseline, 18% (9/50) a RM score of 3 at baseline, and 80% of the patients a RM score of 4 at baseline. Accordingly, 98% of the patients were not able to walk more than one hour without pain at baseline, and 80% of the patients could not walk at all without severe pain at baseline.

Pain and/or discomfort was noted by 3 patients who received RSWT and 2 patients who received placebo treatment. However, all patients were able to complete their treatments without any anesthesia. Besides this, one patient

reported minor skin reddening for a brief period following treatment. No other adverse events were observed.

Statistical methods

Mean and SEM of the VAS scores and the RM scores were calculated for each investigated time point (i.e., at baseline as well as at 4, 12, and 24 weeks after baseline, respectively). Comparisons between RSWT and placebo treatment were performed using two-way Repeated Measured (RM) analyses of variance (ANOVA), followed by Bonferroni post-tests 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% from baseline at 4 weeks (short-term success) and 24 weeks (long-term success) from baseline. In this regard, comparisons between patients treated with RSWT and those treated with placebo were performed with two-sided Chi-square tests. 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 16.0.0 for Windows; SPSS, Chicago, IL) and GraphPad Prism (Version 5.01 for Windows; GraphPad Software, San Diego, CA). The investigators did not have access to the patients' allocation to either RSWT or placebo treatment until all patients had completed the 24-week followup evaluation.

RESULTS

All patients enrolled in the present study finished the corresponding treatment. Accordingly, there was no crossover and no drop-out, and, thus, the randomization to the treatment groups was not broken.^{12,15}

RSWT had a profound and lasting impact on the mean VAS and RM scores of the patients. The mean VAS scores were reduced after RSWT from 8.5 ± 0.3 (mean \pm SEM) at baseline to 0.6 ± 1.5 at 4 weeks (-92.5%), 1.1 ± 0.3 at 12 weeks (-87.3%) and 0.5 ± 0.1 at 24 weeks (-93.9%) from baseline (Figure 2A). Likewise the mean RM scores were changed after RSWT from 3.8 ± 0.1 at baseline to 1.2 ± 0.1 at 4 weeks (-68.1%), 1.4 ± 0.2 at 12 weeks (-61.7%) and 1.3 ± 0.1 at 24 weeks (-64.9%) from baseline (Figure 2B).

These changes in mean VAS and RM scores were not observed after placebo treatment. The mean VAS scores of the placebo-treated patients were 8.9 ± 0.2 at baseline, 7.6 ± 0.4 at 4 weeks (-15.2%), 7.7 ± 0.2 at 12 weeks (-13.5%) and 7.4 ± 0.5 at 24 weeks (-17.0%) from baseline (Figure 2A). Likewise the mean RM scores of the placebo-treated patients were 3.8 ± 0.1 at baseline, 3.6 ± 0.1 at 4 weeks (-6.3%), 3.2 ± 0.2 at 12 weeks (-15.8%) and 3.2 ± 0.2 at 24 weeks (-16.8%) from baseline (Figure 2B).

With the numbers available, two-way RM ANOVA showed for both the mean VAS scores and the mean RM scores statistically significant effects for the variables

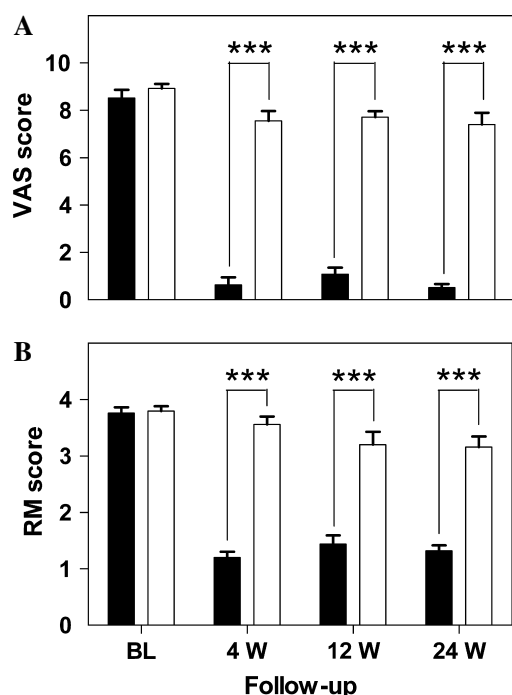


Fig. 2: Mean and standard error of the mean of Visual Analog Scale (VAS) scores (A) and modified Roles & Maudsley (RM) scores (B) of patients with chronic plantar fasciitis after treatment with radial extracorporeal shock waves (RSWT; $n = 25$; closed bars) or placebo treatment ($n = 25$; open bars) at baseline (BL) as well as 4 weeks (4 W), 12 weeks (12 W) and 24 weeks (24 W) after the first RSWT or placebo treatment, respectively. ***; $p < 0.001$.

Group (VAS scores: $F_{[1]} [one\ degree\ of\ freedom] = 480.3$, RM scores: $F_{[1]} = 125.5$; each with $p < 0.001$) and Followup Interval (VAS scores: $F_{[3]} = 106.3$; RM scores: $F_{[3]} = 66.4$; $p < 0.001$ each time) as well as the interaction between these variables (VAS scores: $F_{[3]} = 52.1$; RM scores: $F_{[3]} = 31.2$; each with $p < 0.001$). Post-hoc Bonferroni tests demonstrated statistically significant differences in the mean VAS scores and the mean RM scores between the RSW-treated patients and the placebo-treated patients at 4 weeks (VAS score: $t = 14.55$; RM score: $t = 8.814$; each with $p < 0.001$), 12 weeks (VAS score: $t = 13.97$; RM score: $t = 6.573$; $p < 0.001$ each time) and 24 weeks (VAS score: $t = 14.47$; RM score: $t = 6.872$; each with $p < 0.001$) from baseline, but not at baseline itself (VAS score: $t = 0.841$; RM score: $t = 0.149$; each with $p > 0.05$).

With respect to the treatment success, 92% (23/25) of the RSW-treated patients but only 4% (1/25) of the placebo-treated patients reported a percentage decrease in the VAS score larger than 60% from baseline at 4 weeks after the first session ($p < 0.001$). At 24 weeks after the first session, the corresponding numbers were 100% (25/25) for the patients treated with RSWT and 16% (4/25) for the patients treated with placebo ($p < 0.001$).

DISCUSSION

These results demonstrate that RSWT for chronic PF resulted in profound and lasting reduction in pain as well as improvement of the patients' quality of life, with short-term treatment success of 92% and long-term treatment success of 100% compared to only 4% short-term and 16% long-term treatment success in the group of patients treated with placebo. The present study fulfilled all criteria set out by Harris et al.¹¹ and Jadad et al.¹³ with respect to the quality of reports of randomized clinical trials.

The results of the present study are in agreement with the results reported by Gerdesmeyer et al.⁸ The primary difference in outcome between these studies was the smaller placebo effect in the present study (reductions in mean VAS scores by 13.5% at 12 weeks and 17.0% at 24 weeks from baseline, respectively) compared to the study of Gerdesmeyer et al.⁸ (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 think about partial unblinding of the patients since the principal investigator who administered the treatments was not blinded to explain the smaller placebo effect in the present study. This, however, was prevented by having the principal investigator interact with the study participants in a standardized way irrespective of treatment allocation,^{2,10,14,19}. In addition, the treatment success rates in the study of Gerdesmeyer et al.⁸ were smaller in the group of patients treated with RSWT (61.0% at 3 months and 63.4% at 12 months from baseline, respectively) and larger in the group of patients treated with placebo (42.2% at 3 months and 44.0% at 12 months from baseline, respectively) than 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 different size of the studies (a total of 50 patients in the present study compared to a total of 245 patients in the study by Gerdesmeyer et al.⁸) and slight differences in the VAS scores used. Specifically, 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 do not impair the overall observation that the study of Gerdesmeyer et al.⁸ and the present study came to the same result, i.e., that RSWT is a safe and effective treatment for patients with chronic PF, especially in cases of failed nonsurgical treatment.

RSWT of chronic PF was also evaluated by others^{3,20,9} Chow and Cheing³ treated patients suffering from chronic PF for at least 3 months either with fixed EFD (Group A; three sessions of RSWT each 1 week apart; 1,000 impulses per

session; EFD = 0.11 mJ/mm²) or increasing EFD (Group B; EFD = 0.12 mJ/mm², 0.15 mJ/mm² and 0.17 mJ/mm², 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/mm² per session. These data are in line with the results of the present study as well as the study by Gerdesmeyer et al.⁸

Marks et al.²⁰ treated patients with three sessions of RSWT each 3 days apart (500 impulses in the first session and 2,000 impulses in the second and third session, respectively; EFD = 0.16 mJ/mm²). The authors found no statistically significant differences in treatment success (defined as reduction in the VAS score greater than 50%) at 6 months from baseline between RSW-treated patients (56.2%; i.e., nine out of 16 patients) and placebo-treated patients (44.4%; i.e., four out of nine patients) ($p > 0.05$). However, Marks et al.²⁰ investigated very low numbers of patients suffering from either acute or chronic PF, and at least some of the placebo-treated patients were almost pain-free at baseline.

Very recently, Greve et al.⁹ subjected 16 patients with chronic PF to RSWT (three sessions each 7 days apart; 2,000 impulses per session; EFD = 0.14 mJ/mm²), and another 16 patients with chronic PF to conventional physiotherapy (ten sessions of ultrasound; two sessions per week; plus exercises after ultrasound application to stretch all posterior leg muscles and strengthen the tibialis anterior muscle). Patients suffered from painful symptoms for at least 3 months before being enrolled in the study. Patients in both groups reported reduced VAS scores at 3 months from baseline, with no statistically significant differences between 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 (treatment success was not calculated as in the present study and by Gerdesmeyer et al.⁸). However, the authors noted that the effects of RSWT occurred sooner than the effects of physiotherapy after the onset of treatment.

The results of the present study as well as others^{3,8,9} raise the question about the significance of RSWT in the treatment of chronic PF compared to ESWT with focused shock waves. Compared with radial shock waves, focused shock waves 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.²⁴ characterized studies by Buch et al.¹, Haake et al.,¹⁰ Kudo et al.¹⁴ and Malay et al.¹⁹ as well-designed. Buch et al.¹, Kudo et al.¹⁴ and Malay et al.¹⁹ found treatment success over placebo with different therapy protocols at 12 weeks from baseline, whereas Haake et al.¹⁰ did not. However, fewer than half of the patients enrolled by Haake et al.¹⁰ received minimal conservative care such as stretching exercises, casting or night splinting before inclusion in their study,²¹ and treatment was performed

with very low energy settings (EFD = 0.08 mJ/mm²). In summary, chronic PF can be treated successfully with focused shock waves. In contrast to RSWT, however, long-term (more than 12 weeks) treatment success for chronic PF has not been demonstrated yet for focused shock waves.

In the present study treatment success for chronic PF was achieved with two RSWT sessions compared to three RSWT sessions applied in the study by Gerdesmeyer et al.⁸ This could substantially increase the attractiveness of RSWT for chronic PF to both patients suffering from the disease and health care providers. However, it should be kept in mind that the sample size in the present study was relatively small compared to the sample size in the study by Gerdesmeyer et al.⁸ (129 versus 122). Thus, the question of whether two or three RSWT sessions in the treatment of chronic PF is necessary should be addressed in further research, comparing both strategies to one another in the same study.

The RSW-treated patients in the present study were on average 13% (or 7.5 years) older than the placebo-treated ones. In this regard a recent study indicated that older patients might experience better response than younger patients to ESWT for chronic PF.⁴ This was concluded from a statistically significant ($p < 0.05$) difference of merely 4% in mean age between patients treated either 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 by Kudo et al.¹⁴ This might raise the question whether in the present study the difference in mean age between the RSW-treated patients and the placebo-treated ones might have influenced the study outcome. Though we cannot completely discount age as a factor, all RSW-treated patients in the present study responded positively at 24 weeks regardless of age.

Finally it should be mentioned that RSWT has several advantages over surgery in the treatment of chronic PF, including minimally-invasive percutaneous radio frequency nerve ablation (RFNA).¹⁶ Specifically, 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 for many months. In contrast to surgery, either open or endoscopic, RSWT does not require that patients avoid weight bearing or a prolonged time for return to work. Rather, RSWT allows patients to return to activities of daily living within 1 or 2 days with immediate return to most jobs and normal daily footwear. Most importantly, to the best of our knowledge there are no published controlled trials of surgery for PF,²³ including RFNA.¹⁶

CONCLUSION

RSWT was a safe, effective and easy treatment for patients with chronic PF. RSWT can be considered in the treatment of every patient who has had unsuccessful conventional

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

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