Successful treatment of chronic plantar fasciitis with two sessions of radial extracorporeal shock wave therapy (RSWT®)

Mahmoud Ibrahim Ibrahim[1,2,3], Robert A. Donatelli[1], Christoph Schmitz[4], Madeleine Hellman[1], Frederick Buxbaum[1]

[1]Rocky Mountain University of Health Professions, Provo, UT 84601, USA
2Department of Orthopaedic Physical Therapy, Cairo University, Cairo, Egypt
[3]8415 10th Ave., Brooklyn, NY 11228, USA
[4]EMS Electro Medical Systems S.A., Ch. de la Vuarpilliere 31, 1260 Nyon, Switzerland

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, each two weeks apart. The present study tested the hypothesis that chronic PF can also be treated with RSWT when only two treatment sessions are performed one week apart. *Materials and Methods:* A total of n=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 one week apart (2,000 impulses 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 score from baseline to four weeks, 12 weeks and 24 weeks followup. *Results:* Mean VAS scores were reduced after RSWT from 8.52 ± 0.34 (mean ± SEM) at baseline to 0.64 ± 1.52 at 4 weeks, 1.08 ± 0.28 at 12 weeks and 0.52 ± 0.14 at 24 weeks after treatment. Similar changes were found for mean RM scores 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 is efficient in the treatment of chronic PF even when only two sessions with 2,000 impulses each are performed one week apart.

Level of Evidence: Level 1 (prospective, randomized, double-blinded, controlled therapeutic study).

Keywords: Extracorporeal shock wave therapy (ESWT); Painful heel; Plantar fasciitis; Radial extracorporeal shock wave therapy (RSWT)

Corresponding Author: Dr. Mahmoud Ibrahim Ibrahim, 8415 10th Ave., Brooklyn, NY, 11228, USA. Phone: +1-718-4144382; Fax: +1-718-2380316; E-mail: msrt78@aol.com.

Dr. Schmitz is employee of EMS Electro Medical Systems S.A. (Nyon, Switzerland), the manufacturer and distributor of the EMS Swiss Dolorclast® radial shock wave device used in the present study. Dr. Schmitz was not involved in the planning of the present study, recruitment, randomization, clinical examination, treatment and followup of the patients enrolled in the present study. He became involved after all data were generated and was substantially involved in writing the manuscript, based on his great experience in the field of extracorporeal shock wave therapy (ESWT) (Dr. Schmitz authored 20 papers in the field of ESWT in the international peer-reviewed literature). Nevertheless, Dr. Schmitz assumes full responsibility for the content of the manuscript.

No benefits in any form have been received or will be received by Drs. Ibrahim, Donatelli, Hellman and Buxbaum from EMS or any other commercial party related directly or indirectly to the subject of this article.

INTRODUCTION

Plantar fasciitis (PF), the most common cause of heel pain, accounts for approximately 11-15% of foot symptoms presenting to physicians. In the United States, more than two million individuals are treated for PF on an annual basis.[20] 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', as heel pain is associated with degenerative changes in the fascia and with atrophy of the abductor minimi muscle (for a detailed review see Rompe[20]) and is not an inflammatory condition.[22] Details about etiology, pathogenesis, risk factors, diagnosis and general treatment strategies for PF have been provided in a series of comprehensive reviews recently[3, 19, 20, 22] Briefly, (i) both athletes and the elderly commonly present to physicians with PF; (ii) the diagnosis of PF is usually based on the patient's history

and clinical examination; (iii) imaging is generally not helpful in diagnosing PF but should be considered to rule out other causes of heel pain or to establish the diagnosis of PF when in doubt; and (iv) the treatment of PF should start with conservative treatment modalities, including rest, physical therapy, stretching, exercises, shoe inserts/orthotics, night splints, non-steroidal anti-inflammatory drugs and local corticosteroid injections. Patients not responding to conservative treatment for 6 months (between 10% and 20% of all patients) should then be prescribed extracorporeal shock wave therapy (ESWT) as their next course of treatment. In case a patient does not benefit from ESWT either, she/he shall be treated with botulinum toxin and finally, surgery.[20]

Several controlled trials of ESWT for chronic PF have been published.[3, 20, 22] A meta-analysis by Rompe et al.[22] revealed a preponderance of well-designed studies showing favourable results in the range of 50% to 70% after a followup period of at least three months after ESWT. Recently, Gerdesmeyer et al.[6] demonstrated safety and efficacy of radial extracorporeal shock wave therapy (RSWT®) for chronic PF in a prospective, randomized, double-blinded, placebo-controlled international multicenter study. Radial shock waves are generated ballistically by accelerating a bullet to strike an applicator, which transforms the kinetic energy of the bullet into radially expanding shock waves.[5] Compared with these radial shock waves, focussed shock waves show deeper tissue penetration with substantially higher energies concentrated to a smaller focus.[5, 15] Gerdesmeyer et al.[6] administered RSWT or placebo treatment in three sessions, each two weeks (±4 days) apart (2,000 impulses per session, energy flux density [EFD] = 0.16 mJ/mm^2, eight impulses per second) and evaluated the treatment outcome 12 weeks and 12 months after the first session. 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 (-56.0 ± 39.3%) and the placebo-treated patients (-44.1 ± 41.8%) at 12 weeks, and even more pronounced superiority of RSWT (-61.9 ± 43.6%) over placebo (-46.5 ± 45.5%) at 12 months. Gerdesmeyer et al.[6] concluded that RSWT can be strongly recommended in cases of failed nonsurgical treatment.

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.[6] First, it is unknown whether treatment success can also be reached by two RSWT sessions one week apart, rather than by three RSWT sessions each two weeks apart as applied by Gerdesmeyer et al.[6] Anecdotal reports by colleagues in Europe indicated that this could indeed be the case. Second, immediate return to normal daily life activities (including sports activities) and normal daily shoe wear indicates that patients suffering from chronic PF and treated with RSWT experience profound pain relief already much earlier than three months after the first RSWT session, applied as first followup in the study by Gerdesmeyer et al.[6]

We therefore hypothesized that treatment of chronic PF with two RSWT sessions one week apart will result in profound pain relieve compared to placebo treatment already 4 weeks after the first RSWT treatment, lasting for at least 6 months. In the present prospective, randomized, double-blinded, placebo-controlled study we tested this hypothesis on a total of n=50 patients suffering from chronic PF. Our results might substantially increase the attractiveness of treatment with RSWT for chronic PF to both patients suffering from the disease and health care providers.

MATERIALS & METHODS

Patients

A total of n=55 patients with unilateral, chronic PF were enrolled in the present study between October 2007 and May 2009. The flow of participants through the study is displayed in Fig. 1. 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 plantar fasciitis for at least six 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 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; however, protected populations were not included. After having obtained written informed consent from each patient, they were randomly assigned by an independent treatment center affiliated with Rocky Mountain University (RMU) of Health Professions at Brooklyn, NY, USA 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 administrative assistant distributed interventions via opaque, sealed envelopes, containing information about the individual allocation schedule. Both patients and the study investigators at RMU 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 followup re-evaluation. No patient dropped out from the study after randomization.

Ethical approval was obtained from the Institutional Review Board of the Rocky Mountain University of Health Professions (Provo, UT, USA) before starting the

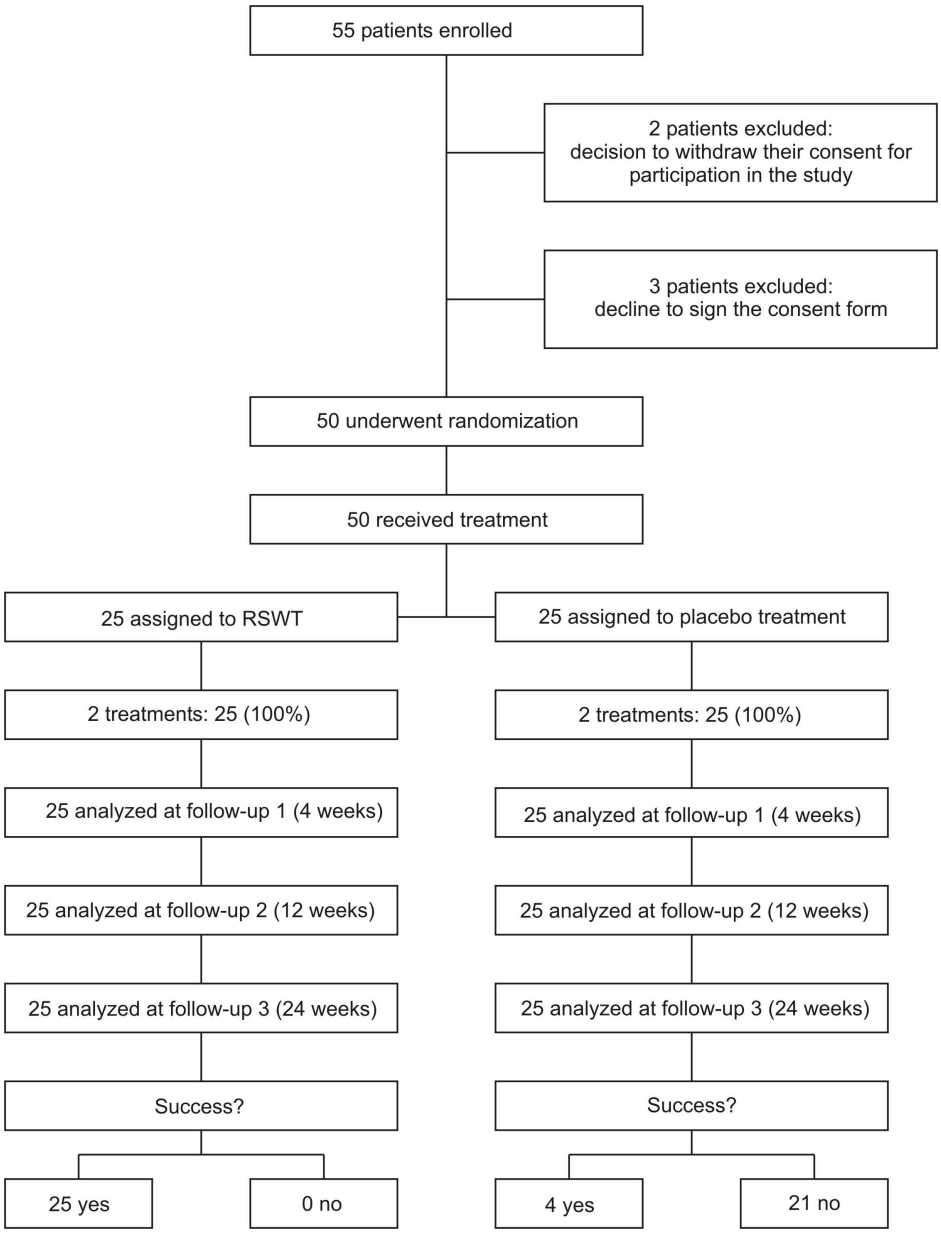

Figure 1: Flow of participants through the study.

study. The study was carried out in accordance with the World Medical Association Declaration of Helsinki.[4]

With the numbers available, the patients treated with RSWT were not statistically different from the patients treated with placebo in respect of (i) the sex distribution (RSWT: 18 females and seven males; placebo: 14 females and 11 males; two-sided Chi-square test: $X^2 = 1.389$; $p = 0.239$); (ii) the mean age (RSTW: 56.6 ± 2.71 years [mean ± standard error of the mean; SEM]; placebo: 49.1 ± 2.55 years; unpaired two-tailed Student's t test: $t = 2.008$; $p = 0.050$); (iii) the mean body weight (RSWT: 90.3 ± 3.67 kg; placebo: 84.2 ± 2.82 kg; unpaired two-tailed Student's t test: $t = 1.322$; $p = 0.192$); (iv) the affected side (RSWT: 11 left feet and 14 right feet; placebo: 12 left feet and 13 right feet (two-sided Chi-square test: $X^2 = 0.081$; $p = 0.777$); and (v) the types of job (RSWT: no patient with sedentary job, six patients with light jobs, 14 patients with medium-heavy jobs and five patients with heavy jobs; placebo: three patients with sedentary jobs, three patients with light jobs, 15 patients with medium-heavy jobs and four patients with heavy jobs; two-sided Chi-square test: $X^2 = 4.146$; $p = 0.246$).

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 six months of unsuccessful conservative treatment
Therapy free period of at least four 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 treatments of the heel spur
Hemorrhagic disorders and anticoagulant therapy
Pregnancy
Diabetes

Treatment

RSWT was performed by the principal investigator with the EMS Swiss Dolorclast® (EMS Electro Medical Systems Corporation; Dallas, TX, USA; shown in Fig. 2) approved by the U.S. Food and Drug Administration (FDA) to treat heel pain associated with chronic proximal plantar fasciitis (FDA pre-market approval [PMA] no. P050004 issued on May 8, 2007). Each patient received two sessions of RSWT one week apart, with 2,000 impulses per session (air pressure of the device set at 3.5 bar [EFD = 0.16 mJ/mm^2]; impulses applied with the 15 mm applicator at frequency of 8 Hz; Fig. 3). 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. The patients were not made aware as to whether they received RSWT or placebo treatment. The principal investigator who applied the treatments prevented any behavior that could have indicated to the patients whether they received RSWT or placebo treatment. Specifically, (i) he did not address this issue to the patients; (ii) no patient knew how placebo treatment was actually achieved; (iii) the sound, look and handling of the RSWT device were identical in both RSWT and placebo treatments; and (iv) all RSWT or placebo treatment sessions took approximately ten minutes. Thus, the patients could not determine whether they received RSWT or placebo treatment, even if discussion transpired between groups. Local anaesthesia was not applied. No other (conservative) treatments were allowed during the length of the study (as in the study of Gerdesmeyer et al.[6]).

Evaluation of treatment success

Patients were requested to assess pain and quality of life before (i.e., at baseline) as well as 4 weeks, 12 weeks 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. Again, the principal investigator in whose office these evaluations were performed prevented any behavior that could have indicated to the patients whether they had received RSWT or placebo treatment. The staff in the office of the principal investigator were blinded to the patients' treatments.

The Visual Analog Scale (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 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 life’s 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

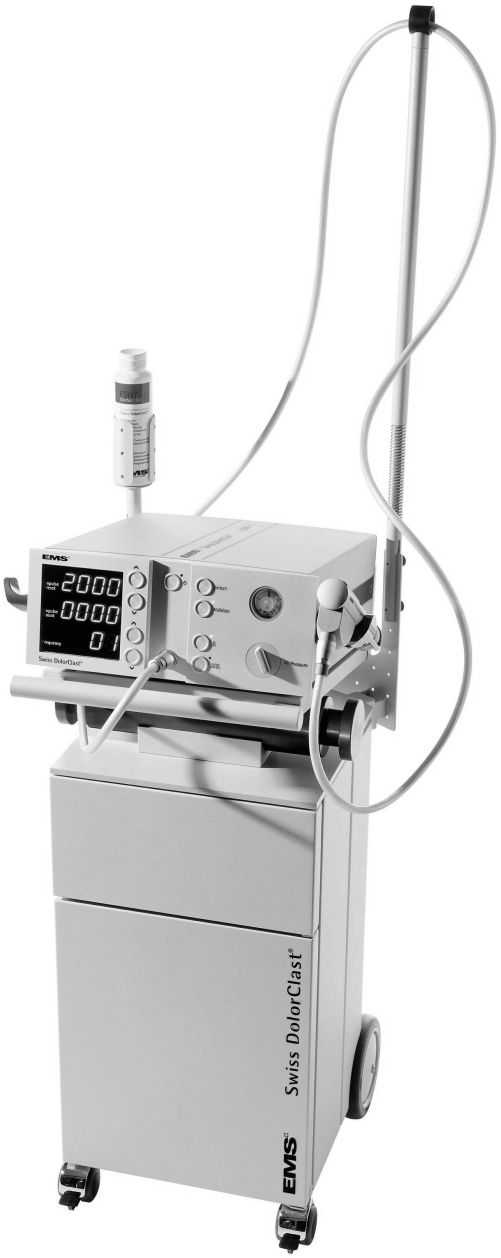

Figure 2: The RSWT device.

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 base line (i.e., 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).

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. Besides this, one 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.

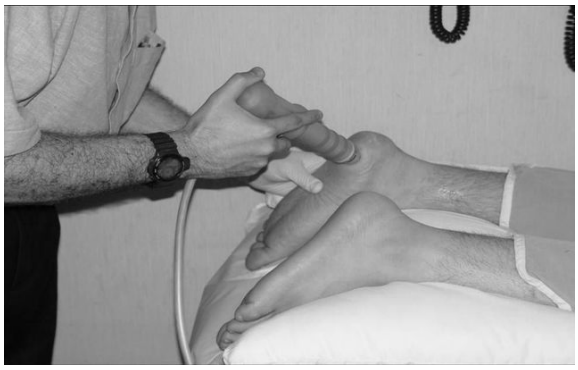

Figure 3: Delivering RSWT over the treatment area.

Statistical methods

For the patients who received RSWT as well as for those who received placebo treatment, 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 four weeks, 12 weeks and 24 weeks after RSWT or placebo treatment, 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 four weeks (short-term success) and 24 weeks (long-term success) after the first session. 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, USA) and GraphPad Prism (Version 5.01 for Windows; GraphPad Software, San Diego, CA, USA). Codes were not broken (i.e., 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 (RSWT or placebo, respectively). Accordingly, there was no crossover and no drop-out, and, thus, the randomization to the treatment groups was not broken. In other words, all patients were analyzed as randomized.[10, 13]

RSWT had a profound and lasting impact on the mean VAS and RM scores of the patients. Specifically, the mean VAS scores were reduced after RSWT from 8.52 ± 0.34 (mean ± SEM) at baseline to 0.64 ± 1.52 at four weeks (-92.5%), 1.08 ± 0.28 at 12 weeks (-87.3%) and 0.52 ± 0.14 at 24 weeks (-93.9%) after treatment (Fig. 4A). Likewise the mean RM scores were changed after RSWT from 3.76 ± 0.11 at baseline to 1.20 ± 0.10 at four weeks (-68.1%), 1.44 ± 0.15 at 12 weeks (-61.7%) and 1.32 ± 0.10 at 24 weeks (-64.9%) after treatment (Fig. 4B).

These changes in mean VAS and RM scores were not observed after placebo treatment. Specifically, the mean VAS scores of the placebo-treated patients were 8.92 ± 0.19 at baseline, 7.56 ± 0.42 at four weeks (-15.2%), 7.72 ± 0.24 at 12 weeks (-13.5%) and 7.40 ± 0.49 at 24 weeks (-17.0%) after placebo treatment (Fig. 4A). Likewise the mean RM scores of the placebo-treated patients were 3.80 ± 0.08 at baseline, 3.56 ± 0.14 at four weeks (-6.3%), 3.20 ± 0.23 at 12 weeks (-15.8%) and 3.16 ± 0.19 at 24 weeks (-16.8%) after placebo treatment (Fig. 4B).

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 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 four 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 $p < 0.001$) after RSWT or placebo treatment, respectively, but not at baseline (VAS score: $t = 0.841$; RM score: $t = 0.149$; each with $p > 0.05$).

The changes in individual VAS scores and RM scores over time were different for patients treated with RSWT and placebo-treated patients (shown for VAS scores in Fig. 5; individual RM scores not shown). Specifically, all patients treated with RSWT reported VAS scores of 0, 1 or 2 respectively at 24 weeks after the first RSWT session. In contrast, only two placebo-treated patiens reached a VAS score of 2 at 24 weeks after the first placebo treatment, and another two placebo-treated patients reached a VAS score of 3 at this time point (Fig. 5). In addition, particularly the placebo-treated patients reported quite heterogeneous VAS scores at four weeks after the first placebo treatment (Fig. 5). With respect to the treatment success, 92% (23/25) of the patients treated with RSWT but only 4% (1/25) of the patients treated with placebo reported a percentage decrease in the VAS score larger than 60% from baseline at four 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 ($p<0.001$).

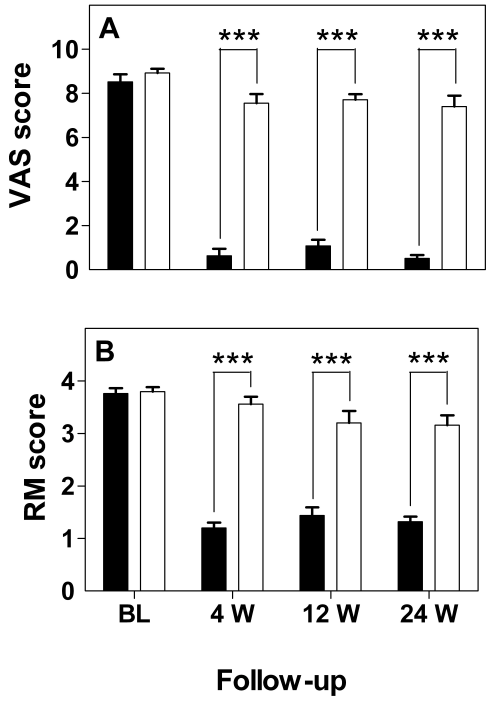

Figure 4: Mean and standard error of the mean of Visual Analog Scale (VAS) scores (A) and modified Roles & Maudsley (RM) scores (B) of patients with chronic plantar fasciitis after treatment with radial extracorporeal shock waves (RSWT; n=25; closed bars) or placebo treatment (n=25; open bars) at baseline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

DISCUSSION

The results of the present study 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 the criteria set out by Harris et al.[9] and Jadad et al.[11] and with respect

to the quality of reports of randomized clinical trials, i.e., (i) the generation of the randomization sequence was described; (ii) the method of allocation concealment was described; (iii) an Intention to Treat analysis was performed; (iv) no patients were lost to followup; (v) the outcome assessment was done blinded; and (vi) the patients were blind to treatment allocation.

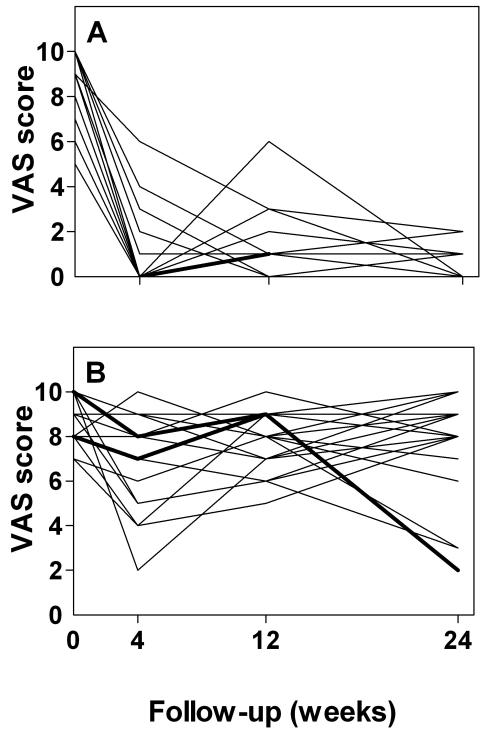

Figure 5: Individual Visual Analog Scale (VAS) scores of patients with chronic plantar fasciitis treated with radial extracorporeal shock waves (RSWT; n=25) (A) or placebo treatment (n=25) (B) at baseline (0 weeks) as well as four weeks, 12 weeks and 24 weeks after the first RSWT or placebo treatment, respectively. Each line represents the values of a single patient (or more than one patient in case of identical values) over time. For example, n=7 patients treated with RSWT reported a slight increase in the VAS score from 0 to 1 between four weeks and 12 weeks after the first RSWT treatment, represented by a single line in A (bold line between four weeks and 12 weeks). All patients treated with RSWT reported VAS scores of 0, 1 or 2 respectively at 24 weeks after the first RSWT treatment. In contrast, only two placebo treated patients reached a VAS score of 2 at 24 weeks after the first placebo treatment (bold lines in B) and another two placebo-treated patients reached a VAS score of 3 at this time point.

The results of the present study are in agreement with the results reported by Gerdesmeyer et al.[6] (the latter study also fulfilled the aforementioned criteria by Jadad et al.[11]). 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, respectively) compared to the study of Gerdesmeyer et al.[6] (reductions in mean VAS composite scores by 44.7% at 12 weeks and 43.2% at 12 months, respectively). In addition, the treatment success rates in the study of Gerdesmeyer et al.[6] were smaller in the group of patients treated with RSWT (61.0% after three months and 63.4% after 12 months, respectively) and larger in the group of patients treated with placebo (42.2% after three months and 44.0% after 12 months, respectively) than found in the present study, although the definition of treatment success was identical (percentage decrease in the VAS score larger than 60% from baseline). The reason for this discrepancy is not known. Possible causes are the different size of the studies (a total of n=50 patients in the present study compared to a total of n=245 patients in the study by Gerdesmeyer et al.[6] and slight differences in the VAS scores used. Specifically, Gerdesmeyer et al.[6] reported sum VAS scores of (i) heel pain when taking first steps of the day, (ii) heel pain when performing daily activities, and (iii) heel pain 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.[6] and the present study came to the same result, i.e., that RSWT is a safe, effective and easy treatment for patients with chronic PF, especially in cases of failed nonsurgical treatment. The results of the present study suggest that Gerdesmeyer et al.[6] would likely have also found substantial pain relief in the patients treated with RSWT at earlier time points than 12 weeks after the first treatment session.

RSWT of chronic PF was also evaluated in studies by Chow and Cheing,[2] Marks et al.[17] and Greve et al.[7] Chow and Cheing[2] randomly assigned a total of n=57 patients suffering from chronic PF for at least three months to three groups (information about conservative treatment before RSWT was not provided). Patients in Group A (n=19; 17 patients completed the trial) received three sessions of RSWT each one week apart (1,000 impulses per session, EFD = 0.11 mJ/mm^2, three impulses per second). Patients in Group B (n=19; 18 patients completed the trial) were treated in the same manner but with increasing energy flux densities (first week: EFD = 0.12 mJ/mm^2; second week: EFD = 0.15 mJ/mm^2; third week: EFD = 0.17 mJ/mm^2), whereas patients in Group C served as control (n=19; 14 patients completed the trial; three sessions of RSWT each one week apart, 30 impulses per session, EFD = 0.03 mJ/mm^2, three impulses per second). Six weeks after the first RSWT session patients in Groups A and B showed (among other variables) statistically

significant ($p < 0.05$) reductions in mean VAS scores by respectively 37% (Group A) and 83% (Group B) compared to baseline, whereas patients in Group C showed no changes in mean VAS scores compared to baseline. The results of the patients in Group B of the study by Chow and Cheing[2] are consistent with the results reported in the present study as well as by Gerdesmeyer et al.,[6] indicating that the energy flux density of the radial shock waves applied must exceed a certain level in order to cause a therapeutic effect. The lack of a placebo effect in the study by Chow and Cheing[2] could be explained by the very low number of applied impulses on the patients in Group C (30 impulses per session) and the resulting very short treatment time (10 sec). These patients could have realized that they were not treated with RSWT effectively.

Marks et al.[17] enrolled 25 adult patients who suffered from PF in their study. The authors randomly assigned n=16 patients to RSWT (three sessions each three days apart; 500 impulses in the first session and 2,000 impulses in the second and third session, respectively; EFD = 0.16 mJ/mm^2; frequency of the impulses not provided). Another n=9 patients were placebo treated (i.e., in the same manner as the patients subjected to RSWT but with the energy flux density of the radial shock waves reduced to almost zero). 56.2% (9/16) of the patients treated with RSWT and 44.4% (4/9) of the patients treated with placebo reported - compared to baseline - a reduction in the VAS score greater than 50% six months after the first session (defined as treatment success by Marks et al.).[17] This difference was not statistically significant ($p > 0.05$). However, the mean VAS score of the patients treated with RSWT was reduced by 54.1% at six months followup, but the mean VAS score of the patients treated with placebo only by 3.9%. Nevertheless, Marks et al.[17] concluded that there appeared to be a profound placebo effect in patients with heel pain, as well as a lack of evidence for the efficacy of RSWT in treating PF compared to sham therapy. Unfortunately, the paper by Marks et al.[17] suffers from some serious shortcomings: (i) in the main text, the authors described an average duration of heel pain of 28.3 months before RSWT or sham treatment. On the other hand, the duration of symptoms was reported in Table 1 of the same paper as follows: 35.6 ± 43.2 days (mean ± standard deviation) (range: one to 180 days) for the patients treated with RSWT, and 21.0 ± 16.4 days (range: one to 60 days) for the patients treated with placebo. Presumably the data provided in Table 1 in the paper by Marks et al.[17] are correct, whereas the description in the main text was a typo. In this case, however, Marks et al.[17] investigated mixed groups of patients suffering from either acute or chronic PF, and apparently a few patients were enrolled in the study immediately after the first experience of heel pain. Since more than 80% of PF patients experience resolution within 12 months, regardless of management,[20] the approach by Marks et al.[17] should be considered an inadequate selection of PF patients for RSWT rather than reflecting inefficacy of RSWT treatment of this disease. (ii) This is further corroborated by the notion that at least one patient treated with placebo had a VAS score of 6 (with a maximum VAS score of 100) in the study by Marks et al.,[17] which would translate into a VAS score of 0.6 in the studies by Chow and Cheing,[2] Gerdesmeyer et al.[6] and the present study. It remains unknown why such, almost pain-free patients were enrolled in the study by Marks et al.[17]

Very recently, Greve et al.[7] subjected n=16 patients with chronic PF to RSWT (three sessions each seven days apart; 2,000 impulses per session; EFD = 0.14 mJ/mm^2; six impulses per second; Group A), and another n=16 patients with chronic PF to conventional physiotherapy (10 sessions of ultrasound at a frequency of "1.0 Hz" [most likely a typo] and intensity of 1.2 watts/cm^2, two sessions per week; plus exercises after ultrasound application to stretch all posterior leg muscles and strengthen the tibialis anterior muscle; Group B). Patients suffered from painful symptoms for at least three months before being enrolled in the study. At baseline, n=1 patient in Group A had a VAS score (morning pain) between 2 and 5, and n=15 patients VAS scores between 6 and 10. Three months after the first RSWT treatment, n=9 patients in Group A had a VAS score of 0 or 1, n=5 patients a VAS score between 2 and 5, and n=2 patients a VAS score between 6 and 10. Very similar distributions were found for the patients in Group B (at baseline: n=1 patient with VAS score between 0 and 1, n=3 patients with VAS scores between 2 and 5, and n=12 patients with VAS scores between 6 and 10; three months after the first physiotherapy session: n=10 patients with VAS scores between 0 and 1, n=4 patients with VAS scores between 2 and 5, and n=2 patients with VAS scores between 6 and 10). There was no statistically significant difference between the groups ($p > 0.05$). From these and several other outcome measurements Greve et al.[7] 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 studies by Gerdesmeyer et al.,[6] Marks et al.[17] and the present study). In addition, the authors noted that the effects of RSWT occurred sooner than physiotherapy after the onset of treatment. The latter aspect is in line with the results of the present study, demonstrating treatment success already four weeks after the first treatment of chronic PF with RSWT. The similarity in outcome between RSWT and conventional physiotherapy in the study by Greve et al.[7] does not speak against the value of RSWT in the treatment of chronic PF, on the contrary: (i) Greve et al.[7] did not follow up with patients longer than 3 months after the first treatment session. Thus, it is not known whether the physiotherapy approach applied in their study would have also resulted in long-term therapy success of chronic PF as demonstrated by Gerdesmeyer et al.[6] (12-month followup) and in the present study (6-month followup). (ii) Rompe et al.[23, 24] treated chronic midportion Achilles tendinopathy with RSWT. When comparing RSWT with eccentric calf muscle training (eccentric loading), Rompe et al.[23] observed that both

treatment modalities resulted in comparable success at 4-month followup, whereas a wait-and-see strategy was ineffective for the management of chronic midportion Achilles tendinopathy. When combining RSWT with eccentric loading, however, Rompe et al.[24] found that at 4-month followup, eccentric loading alone was less effective when compared with a combination of eccentric loading and repetitive RSWT. Thus, it is reasonable to hypothesize that in future studies, the combination of RSWT with physical therapy in the treatment of chronic PF will also be more effective than either of these treatment modalities alone.

The results of the present study as well as those reported by Chow and Cheing,[2] Gerdesmeyer et al.[6] and Greve et al.[7] raise the question about the significance of RSWT in the treatment of chronic PF compared to focussed ESWT of this indication (the latter was addressed in at least 17 clinical trials).[20] Rompe et al.[22] characterized the studies by Buch et al.[1] (data presented also by Theodore et al.[25]), Haake et al.,[8] Kudo et al.[12] and Malay et al.[16] as well-designed (the study by Weil et al.,[26] also characterized as well-designed by Rompe et al.,[22] was a pre-description of the results obtained by Gerdesmeyer et al.[6]). Haake et al.[8] treated a total of n=272 patients with three sessions of 4,000 focused shock waves with EFD = 0.08 mJ/mm^2 under local anesthesia or placebo, at weekly intervals. After 12 weeks, the success rate was 34% in the ESWT group and 30% in the placebo group; the difference was not statistically significant ($p > 0.05$). This study was criticized as flawed[18] because fewer than half of the patients enrolled by Haake et al.[8] received minimal conservative care such as stretching exercises, casting or night splinting before inclusion in the study. In addition, the lack of treatment success in the ESWT group in the study by Haake et al.[8] can be explained by the low energy flux density of the applied shock waves (as shown by Chow and Cheing[2] for RSWT) as well as by the fact that Haake et al.[8] applied shock waves under local anesthesia. The negative influence of local anesthesia on the success of treating chronic PF with low-energy focussed shock waves was shown by Rompe et al.[21] Buch et al.[1] and Kudo et al.[12] achieved treatment success of chronic PF by applying high-energy focussed shock waves (single sessions of 3,800 impulses with EFD = 0.36 mJ/mm^2) or placebo treatment under local anaesthesia but did not follow up with the patients longer than 12 weeks after the treatment. Good or excellent outcome was reported by respectively 62%[1] and 43%[12] of the patients treated with focussed shock waves, and by respectively 40%[1] and 30%[12] of the placebo treated patients (differences statistically significant in both studies; $p < 0.05$). Malay et al.[16] treated a total of n=172 patients with a single session of 3,800 shock waves or placebo, without local anesthesia. The energy flux density of the applied shock waves was continuously increased from 0.08 mJ/mm^2 (lowest energy level of the used device) to 0.33 mJ/mm^2 (highest energy level of the used device). At 12 weeks, 43% of the patients treated with shock waves and 20% of the patients treated with placebo reported a 50% decrease of pain from baseline. In summary, chronic PF can be treated successfully with high-energy focussed shock waves, but long-term (> 12 weeks) treatment success has not been demonstrated yet for this treatment modality, as has been established for RSWT.

The fact that in the present study treatment success was achieved with two RSWT sessions compared to three RSWT sessions applied in the study of Gerdesmeyer et al.[6] 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 (25 vs. 25) was relatively small compared to the sample size in the study by Gerdesmeyer et al.[6] (129 vs. 122). Thus, the question "Two or three RSWT sessions in the treatment of chronic PF?" should be re-addressed in further research, comparing both strategies to one another in the same study.

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) propagated recently.[14] 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 over 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 life within one or two days with immediate return to most jobs and normal daily shoe wear. Most importantly, to the best of our knowledge there are no published controlled trials of surgery for PF.[20]

CONCLUSION

RSWT is a safe, effective and easy treatment for patients with chronic PF. RSWT should be offered to every patient who has had unsuccessful conventional treatment of PF, before considering any surgical treatment.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Rocco DePace for his support and contributions to this paper, and Samaa Lail for assistance with data collection.

REFERENCES

1. **Buch, M; Knorr, U; Fleming, L; et al.:** Extrakorporale Stosswellentherapie beim symptomatischen Fersensporn. Eine Übersicht [Extracorporeal shockwave therapy in symptomatic heel spurs. An overview]. Orthopade **31**:637-644; 2002.
2. **Chow, IH; Cheing, GL:** Comparison of different energy densities of extracorporeal shock wave therapy (ESWT) for the management of chronic heel pain. Clin Rehabil. **21**:131-141; 2007.
3. **Furia, JP; Rompe, JD:** Extracorporeal shock wave

therapy in the treatment of chronic plantar fasciitis and Achilles tendinopathy. Curr Opin Orthop. **18**:102-111; 2007.
4. **Fuson, RL; Sherman, M; Van Vleet, J; Wendt, T:** The conduct of orthopaedic clinical trials. J Bone Joint Surg Am. **79**:1089-1098; 1997.
5. **Gerdesmeyer, L; Maier, M; Haake, M; Schmitz, C:** Physikalisch-technische Grundlagen der extrakorporalen Stosswellentherapie (ESWT) [Physical-technical principles of extracorporeal shockwave therapy (ESWT)]. Orthopade **31**:610-617; 2002.
6. **Gerdesmeyer, L; Frey, C; Vester, J; et al.:** Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. Am J Sports Med. **36**:2100-2109; 2008.
7. **Greve, JM; Grecco, MV; Santos-Silva, PR:** Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. Clinics. **64**:97-103; 2009.
8. **Haake, M; Buch, M; Schoellner, C; et al.:** Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. Brit Med J. **327**:75; 2003.
9. **Harris, RP; Helfand, M; Woolf, SH; et al.:** Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med. **20** (3 Suppl):21-35; 2001.
10. **Hollis, S; Campbell, F:** What is meant by intention to treat analysis? Survey of published randomised controlled trials. Brit Med J. **319**:670-674; 1999.
11. **Jadad, AR; Moore, RA; Carroll, D; et al.:** Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials. **17**:1-12; 1996.
12. **Kudo, P; Dainty, K; Clarfield, M; et al.:** Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracoporeal shockwave therapy (ESWT) device: a North American confirmatory study. J Orthop Res. **24**:115-123; 2006.
13. **Lachin, JM:** Statistical considerations in the intent-to-treat principle. Control Clin Trials. **21**:167-189; 2000.
14. **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 Foot Ankle Surg. Epub ahead of print 5 July 2009.
15. **Maier, M; Milz, S; Wirtz, DC; Rompe, JD; Schmitz, C:** Grundlagenforschung zur Applikation extrakorporaler Stosswellen am Stutz- und Bewegungsapparat. Eine Standortbestimmung [Basic research of applying extracorporeal shockwaves on the musculoskeletal system. An assessment of current status]. Orthopade **31**:667-677; 2002.
16. **Malay, DS; Pressman, MM; Assili, A; et al.:** Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. J Foot Ankle Surg. **45**:196-210; 2006.
17. **Marks, W; Jackiewicz, A; Witkowski, Z; et al.:** Extracorporeal shock-wave therapy (ESWT) with a new-generation pneumatic device in the treatment of heel pain. A double blind randomised controlled trial. Acta Orthop Belg. **74**:98-101; 2008.
18. **Michelson, J:** Study of plantar fasciitis treatment is flawed. Brit Med J. **327**:870; 2003.
19. **Neufeld, SK; Cerrato, R:** Plantar fasciitis: evaluation and treatment. J Am Acad Orthop Surg. **16**:338-346; 2008.
20. **Rompe; JD:** Plantar fasciopathy. Sports Med Arthrosc. **17**:100-104; 2009.
21. **Rompe, JD; Meurer, A; Nafe, B; Hofmann, A; Gerdesmeyer, L:** Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis. J Orthop Res. **23**:931-941; 2005.
22. **Rompe, JD; Furia, J; Weil, L; Maffulli, N:** Shock wave therapy for chronic plantar fasciopathy. Br Med Bull. **81-82**:183-208; 2007.
23. **Rompe, JD; Nafe, B; Furia, JP; Maffulli, N:** Eccentric loading, shock-wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis: a randomized controlled trial. Am J Sports Med. **35**:374-383; 2007.
24. **Rompe, JD; Furia, J; Maffulli, N:** Eccentric loading versus eccentric loading plus shock-wave treatment for midportion achilles tendinopathy: a randomized controlled trial. Am J Sports Med. **37**:463-470; 2009.
25. **Theodore, GH; Buch, M; Amendola, A; et al.:** Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot Ankle Int. **25**:290-297; 2004.
26. **Weil, LS Jr.:** Continuing education: What you should know about shockwave therapy. Podiatry Today **17**:60-66; 2004.