Extracorporeal Shock Wave Therapy for Chronic Painful Heel Syndrome: A Prospective, Double Blind, Randomized Trial Assessing the Efficacy of a New Electromagnetic Shock Wave Device

Hans Gollwitzer, MD, CCRP,[1] Peter Diehl, MD,[2] Alexej von Korff, MD,[3] Volker W. Rahlfs, Dr, CStat, RSS,[4] and Ludger Gerdesmeyer, MD, PhD[5]

Published data describing the efficacy of extracorporeal shock wave therapy for the treatment of plantar heel pain provide conflicting results, and optimal treatment guidelines are yet to be determined. To assess the efficacy and safety of extracorporeal shockwave therapy compared with placebo in the treatment of chronic painful heel syndrome with a new electromagnetic device, we undertook a prospective, double-blind, randomized, placebo-controlled trial conducted among 40 participants who were randomly allocated to either active, focused extracorporeal shockwave therapy (0.25 mJ/mm^2) or sham shockwave therapy. Both groups received 3 applications of 2000 shockwave impulses, each session 1 week apart. The primary outcome was the change in composite heel pain (morning pain, pain with activities of daily living, and pain upon application of pressure with a focal force meter) as quantified using a visual analog pain scale at 12 weeks after completion of the interventions compared with baseline. Secondary endpoints included changes in morning pain, pain with activities of daily living, and pain upon application of pressure with a focal force meter, as measured on a visual analog pain scale, as well as the change in the Roles and Maudsley score, at 12 weeks after the baseline measurement. Active extracorporeal shockwave therapy resulted in a 73.2% reduction in composite heel pain, and this was a 32.7% greater reduction than that achieved with placebo. The difference was not statistically significant (1-tailed Wilcoxon Mann-Whitney U *test,* P *=.0302), but reached clinical relevance (Mann-Whitney effect size = 0.6737). In regard to the secondary outcomes, active extracorporeal shockwave therapy displayed relative superiority in comparison with the sham intervention. No relevant adverse events occurred in either intervention group. The results of the present study support the use of electromagnetically generated extracorporeal shockwave therapy for the treatment of refractory plantar heel pain.* (The Journal of Foot & Ankle Surgery 46(5):348–357, 2007)

Key words: calcaneal spur, ESWT, extracorporeal shockwave therapy, heel pain, lithotripsy, plantar fasciitis

Extracorporeal shockwave therapy (ESWT) has been used for the treatment of numerous musculoskeletal disorders, including calcified tendonitis of the shoulder, lateral epicondylitis, Achilles' and patellar tendinopathies, chronic plantar fasciitis, osteonecrosis of the femoral head, and delayed union and nonunion of fractures (1–6). The rationale for the use of ESWT for these conditions is based on stimulation of soft tissue healing by local hyperemia, neovascularization, reduction of calcification, inhibition of pain receptors and/or denervation to achieve pain relief and persistent healing of chronic inflammatory processes (7–9). In regard to recalcitrant plantar fasciitis, ESWT has become an alternative therapy that may, in some participants, alleviate symptoms and prevent the need for more invasive interventions (10, 11). Recently published level 1 clinical evidence has yielded contradictory results in regard to the efficacy of ESWT for the treatment of chronic plantar fasciitis, and the clinical relevance of the effect of ESWT compared with placebo remains controversial (12–19).

Address correspondence to: Hans Gollwitzer, MD, Trauma Center Murnau, Prof. Küntscher-Str. 8, 82418 Murnau, Germany. E-mail: hgollwitzer@bone-and-joint.org.

[1]Orthopaedic Resident, Trauma Center Murnau, Murnau, Germany, and Department of Orthopedic Surgery, Technical University, Munich, Germany.

[2]Attending Orthopaedic Surgeon, Department of Orthopedic Surgery, Technical University, Munich, Germany.

[3]Orthopaedic Resident, Department of Orthopedic Surgery, Technical University, Munich, Germany.

[4]Director, idv-Data Analysis and Study Planning, Gauting, Germany.

[5]Associate Attending Orthopaedic Surgeon, Assistant Professor of Orthopaedic Surgery, Department of Orthopedic Surgery, Technical University, Munich, Germany, and Department of Orthopedic Surgery and Traumatology, Mare Klinik, Kiel-Kronshagen, Germany.

1067-2516/07/4605-0005$32.00/0

doi:10.1053/j.jfas.2007.05.011

ESWT has been shown to be more effective if local or regional anesthesia is not used and, instead, if treatment is guided by participant feedback that is used to direct the application of the shockwave energy to the most tender location in the affected heel (17). Furthermore, treatment with higher total energies has been shown to result in a greater treatment effect in comparison with the application of lower energies (14).

Because of a lack of homogeneity between randomized controlled trials (RCTs) investigating the use of ESWT for the treatment of plantar heel pain, it is not possible to quantitatively combine the results of the level 1 studies in a meaningful meta-analysis. The lack of homogeneity between these studies is related to differences in study design, the method used for targeting the shockwave energy, the amount of shockwave energy delivered, the method of shockwave generation (electrohydraulic, electromagnetic, or piezoelectric), and the use of anesthesia and sedation.

A new, small, and mobile shockwave device, which can deliver both focused shockwaves as well as radial pressure waves, has been used in the current investigation. Radial pressure waves are generated ballistically by accelerating a bullet to hit an applicator, which finally transforms the kinetic energy into radially expanding pressure waves, affecting a large treatment area. Compared with these low-energy radial pressure waves, the focused shockwaves used in the present investigation were generated electromagnetically, and show deeper tissue penetration with significantly higher energies concentrated to a smaller and defined focus (medium to high energy). Furthermore, there are marked differences in physical characteristics, because radial pressure waves miss the typical steepening of focused shockwaves and therefore do not reach comparably high energy flux densities in the tissue. Shockwaves have been previously defined as low energy (~0.08 mJ/mm^2), medium energy (~0.28 mJ/mm^2), and high energy (~0.60 mJ/mm^2) (20).

The aim of the present study was to assess the efficacy and safety of focused ESWT delivered by a new electromagnetic device to apply high levels of shockwave energy, without local anesthesia, for the treatment of plantar fasciitis in a randomized, double blind, placebo-controlled investigation.

Material and Methods

Study Design

A double-blind (participant and observer), randomized, placebo-controlled trial with parallel group design was conducted at a university hospital in Munich, Germany, with a 12-month enrollment phase. Participants who were eligible and provided written, informed consent were randomized by permuted blocks of different length to receive either active treatment or placebo. Random allocation was guaranteed by consecutive sealed and nontransparent envelopes, which provided treatment allocation assigned by a computer-generated random list (Rancode; idv-Data Analysis and Study Planning, Gauting, Germany). In designing the trial, we adhered to the standardized guidelines of good clinical practice from the International Conference on Harmonization (21). The Institutional Ethics Review Committee of the Faculty of Medicine of the Technical University of Munich approved the study.

TABLE 1 Previous conservative treatments for painful heel syndrome

Nonpharmacological treatments	Pharmacological treatments
Physical therapy, eg, ice, heat, ultrasound, iontophoresis, electromyostimulation	External (topical) application of analgesic and/or antiinflammatory gels
Physiotherapy, eg, massage, stretching	Prescription analgesics and/or NSAIDs
Over-the-counter devices like orthosis, taping, heel pads	Local anesthetic injection
Prescribed orthosis	Local corticosteroid injection
Shoe modification like higher heels	
Cast/immobilization	
Night splints	

Both 2 non-pharmacological and 2 pharmacological treatments had to be unsuccessful before enrollment.
Abbreviation: NSAIDs, nonsteroidal antiinflammatory drugs.

Participants

To be eligible for the trial, participants had to have a history of at least 6 months of chronic plantar heel pain that proved resistant to conservative treatments. Diagnosis was based on clinical examination, and the point of maximum heel pain had to be localized to the medial tubercle of the tuberosity of the calcaneus. All of the participants were required to have a baseline pain level designated as ≥5, as measured on a 0 to 10 visual analog scale (VAS), and they had to display significant, functional limitations as determined by a Roles and Maudsley Score of 3 (fair) or 4 (poor) (22). Participants were eligible if they were aged 18 years or older and able to give written, informed consent. All participants had to have failed at least 4 conservative treatment modalities, including at least 2 nonpharmacological treatments and 2 pharmacological treatments (Table 1), respecting a sufficient washout phase between the last conservative intervention and enrollment. The washout phases were designated as at least 6 weeks since the last corticosteroid injection; 4 weeks since the last local anesthetic injection, iontophoresis, ultrasound, or electrotherapy; 1 week since

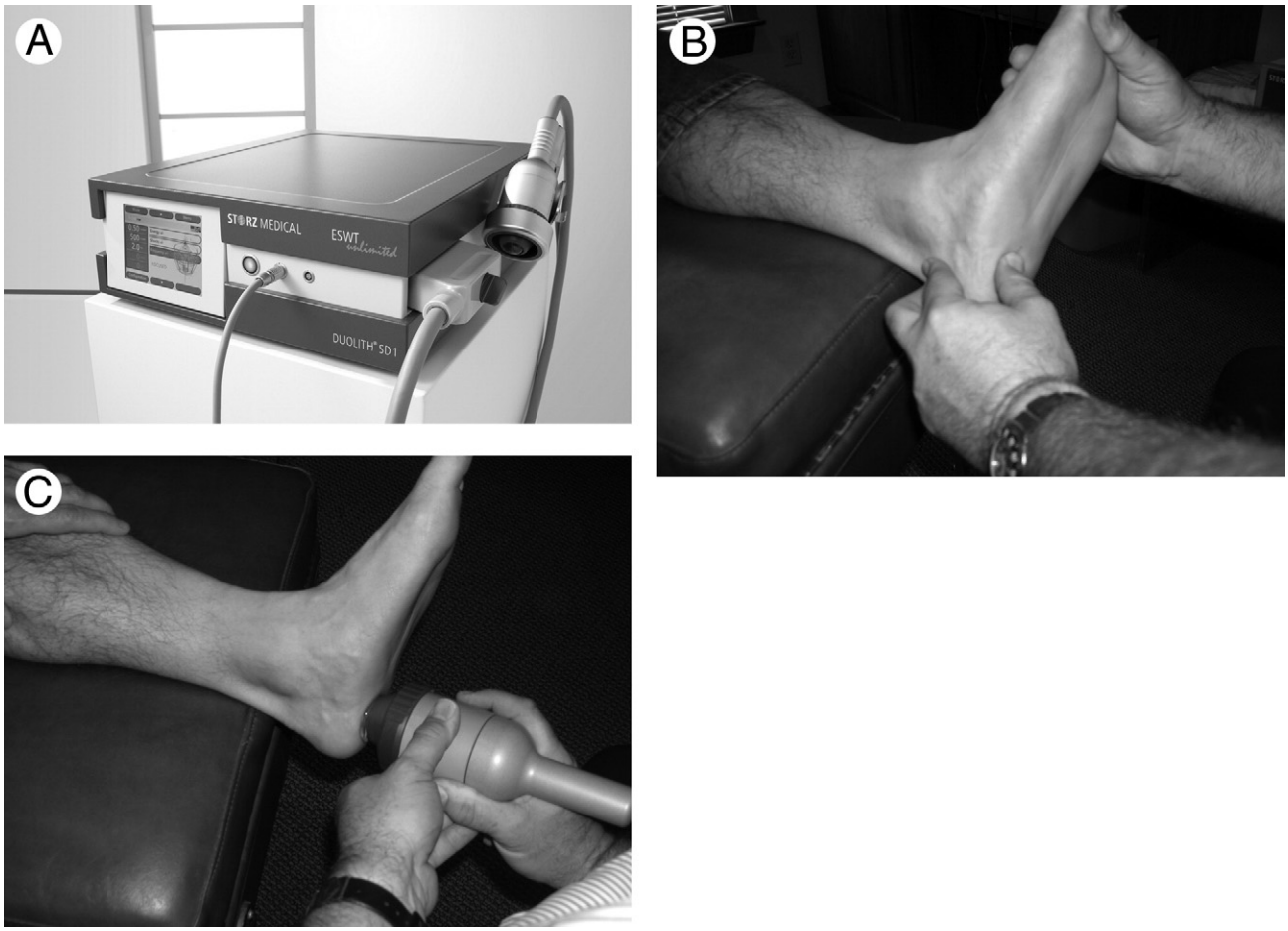

FIGURE 1 (*A*) Duolith SD1 shockwave device with handheld applicator for focused ESWT. (*B*) Palpation of the most tender spot of the proximal plantar fascia. (*C*) Shockwave treatment with the focused hand piece with correction of the treatment area by patient feedback.

the last intake of nonsteroidal antiinflammatory drugs; and at least 2 days since the last application of heat, ice, massage, stretching (active or passive night splinting), and/or change in the use of foot orthotics. Participants were excluded if any of the following conditions were present: rheumatic or other systemic inflammatory disease, inflammatory disorders of the upper and/or lower ankle, collagenosis, diabetes mellitus or other metabolic disease, tendon ruptures in the treatment area, neurological or vascular insufficiencies, nerve entrapment syndrome, hyperthyroidism, active malignant disease with or without metastases, Paget's disease, calcaneal fat pad atrophy, osteomyelitis or active infection or history of chronic infection in the treatment area, history of calcaneal fracture, immunosuppressive therapy, systemic long-term treatment with corticosteroids, severe cardiac or respiratory disease, disturbance of coagulation or ongoing anticoagulation therapy, worker's compensation or litigation associated with their heel pain, previous surgery for painful heel, unsuccessful prior ESWT, or bilateral heel pain.

Intervention and Blinding

Focused shockwaves were generated by a Duolith SD1 extracorporeal shockwave therapy system (Storz Medical, Tägerwilen, Switzerland), a mobile device with lightweight hand pieces providing either electromagnetic focused ESWT (0.01–0.55 mJ/mm^2) or radial pressure wave impulses with very consistent energy (Figure 1). The focus zone (>5 megapascals) of the focused ESWT hand piece is defined by an ellipsoid with a depth extension of 12 cm, and a 35-mm standoff was used in the present study. Participants were assigned randomly to receive either focused ESWT or an identical sham intervention. All of the participants, as well as the follow-up observer, were blinded to treatment allocation. After randomization to an intervention group, the participant was placed in supine position, and the physician clinically located the point of maximum tenderness. The therapy head was coupled to the identified area with ultrasound gel to avoid energy loss and to reduce superficial pain sensation due to rarefaction energy wave concentration at the skin surface.

Two-thousand shockwaves were applied at each ESWT session with an energy flux density of 0.25 mJ/mm^2. A total of 3 shockwave interventions were performed within weekly intervals, accounting for a total of 1.5 mJ/mm^2 administered.

Participants in the control group received identical placebo therapy. An air-chambered polyethylene foil was located between the coupling head and the participant, which absorbed all the acoustic energy. Thereby, setup and sound created by the shockwave device was identical in both groups; however, transmission of shockwaves was prevented in the placebo group.

The intervention was performed by locating the focus zone at the most tender point of the medial calcaneal tubercle. Proper placement was achieved by participant-directed feedback and adjusted during the intervention as necessary.

A standardized rescue medication was available throughout the entire study if pain became unbearable. Specifically, participants were administered up to 2 g of paracetamol per day for up to 14 days after the last intervention session, thereafter, up to 2 g of paracetamol per week as needed. No other therapies were allowed, and foot orthotics, if in use, were not to be modified until the 3-month follow-up.

Baseline and Outcome Measures

Baseline variables were recorded and included date of birth, sex, weight, height, duration of symptoms, previous treatments, affected side, and any coexisting conditions. Follow-up evaluations were performed at 6 weeks and 12 weeks after the last intervention session, and outcome measures were determined by measuring heel pain on a 10-cm VAS and by physical examination.

The primary endpoint was the change in composite heel pain (defined below) as quantified using a 10-cm visual analog pain scale, with 0 being no pain and 10 being maximal pain, at 12 weeks after completion of the intervention in comparison with the baseline measurement. The composite heel pain score was defined as the sum of three 10-cm VAS measurements: 1) heel pain when taking the first steps in the morning; 2) heel pain while doing daily activities, and 3) heel pain while applying a standardized pressure with the force meter (F-meter; Storz Medical). The blinded investigator used the F-meter to measure pressure sensitivity at the point of maximum tenderness on the participant's heel. Specifically, the pressure that just elicited unbearable pain was documented at baseline with the F-meter and the 10-cm VAS. At each follow-up visit, the same F-meter pressure was applied, and the subject was asked to score the pain on the VAS. Clinically significant improvement was defined as at least a 30% decrease in the VAS composite score compared with baseline, in accordance with the report from Farrar et al (23).

Secondary outcome measures included: 1) change in the Roles and Maudsley Score, 2) change in each individual VAS score (initial morning heel pain, pain during the activities of daily living, and pain upon focal pressure application with the F-meter), and 3) the overall success rate as determined by a percentage decrease in heel pain of at least 60% from baseline in at least 2 of the 3 heel pain VAS measurements. Functional outcome was assessed with the Roles and Maudsley score, which is a 4-point scale grading 1) "excellent" (no pain, full movement, and activity), 2) "good" (occasional discomfort, full movement, and activity), 3) "fair" (some discomfort after prolonged activity), and 4) "poor" (pain-limiting activities) (22). Although the Roles and Maudslay score has not been validated for foot disorders, it has been used extensively in similar studies and was therefore assessed to allow comparison of the results with other investigations. For the purposes of this investigation, Roles and Maudsley scores categorized as "excellent" and "good" were considered to be therapeutic success.

All adverse events related and unrelated to the intervention were assessed by the clinical investigator and recorded. Furthermore, 7 single items (pain during treatment, pain after treatment, skin redness, hematoma, petecchiae, swelling, and scar formation), all of which were considered most likely to be related to the intervention, were defined as adverse reactions (ARs) and assessed by a 5-point ordered categorical scale wherein 0 represented no signs and/or symptoms of an AR, and 4 represented severe signs and/or symptoms. The scores were combined into a summary AR composite score, the possible range for the composite score being 0 to 28.

Statistical Analyses

The study was planned to assess the specific treatment effect of focused ESWT compared with placebo, using both explanatory and descriptive statistical analyses. Superiority of one intervention compared with the other was statistically tested with the Wilcoxon Mann-Whitney U test and the Unconditional Exact Röhmel-Mansmann test. A P value $<$ .025 (1-sided) was considered statistically significant. For the secondary endpoints, descriptive statistics and 1-sided 97.5% confidence intervals were calculated. Missing data were replaced in accordance with the last observation carried forward technique, and an intention-to-treat analysis was performed.

Furthermore, with a relatively small number of participants (n = 40 in this investigation), effect sizes are particularly important in regard to the interpretation of the results. In an effort to identify differences in effect size between the different intervention groups, the Mann-Whitney (MW) effect size with predefined benchmarks was used to define the probability that a randomly selected participant from the test

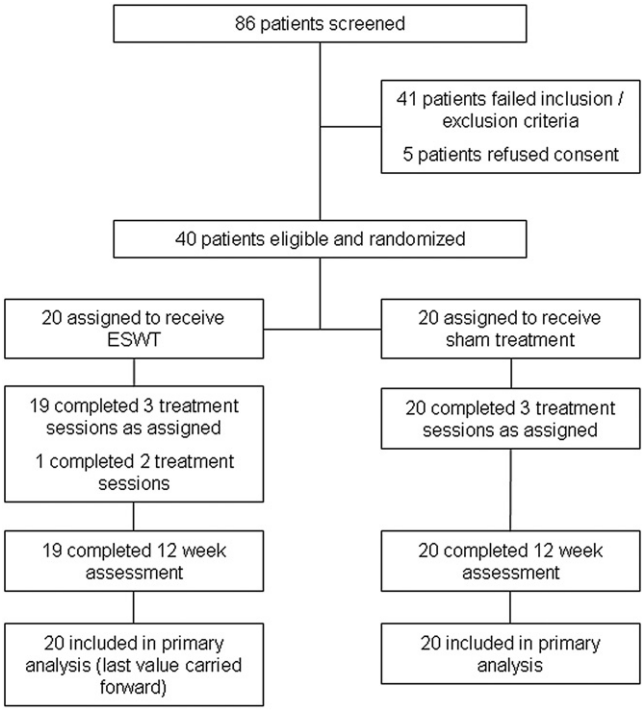

FIGURE 2 Flow of participants through the trial.

(active ESWT) group was better off than a randomly selected participant from the control (placebo) group. In accordance with Colditz et al (24), we used relevant benchmarks that corresponded to an MW effect size of 0.5 for equality (active therapy no better or worse than placebo); 0.44 or 0.56 for small-sized inferiority or superiority, respectively; 0.36 or 0.64 for medium-sized (clinically significant) inferiority or superiority, respectively; and 0.29 or 0.71 for large-sized inferiority or superiority, respectively. Furthermore, in accordance with the recommendations of the ICH E9 Biostatistics Guideline (25), statistical analyses were performed by an independent institute, idv-Data Analysis and Study Planning, using their Report, Testimate, and AE-Base software programs.

Results

Demographic and Baseline Values

A total of 40 participants with chronic plantar heel pain were randomly assigned, 20 to the ESWT group and 20 to the placebo group (Figure 2). One participant (2.5% of the total sample) from the active ESWT group (5% of the intervention group) withdrew from the trial after the second intervention, and all of the remaining participants completed the planned final evaluation at 12 weeks after the final intervention session. Demographic and baseline heel pain characteristics for all 40 study participants are shown in Table 2. There were 3 baseline characteristics that showed relevant group differences at baseline: gender (MW effect size = 0.3250, $P = .0484$), previous cortisone injection (MW effect size = 0.6500, $P = .1110$), and physical therapy (MW effect size = 0.3500, $P = .1053$). Stratified analyses showed that the influence of these baseline group differences, in regard to the composite heel pain VAS, showed no bias and was not relevant because the adjusted results of the stratified analysis were well comparable with the unadjusted results.

Outcome Measures

Follow-up investigations were performed at 6 weeks and 12 weeks after completion of the intervention sessions. The primary efficacy criterion was defined as the between-group difference in the composite heel pain VAS score (sum of the 3 pain measurements: heel pain when taking first steps of the day, heel pain while doing daily activities, and heel pain associated with pressure application using the F-meter). VAS pain measurements were made at 12 weeks after the last intervention and compared with the baseline measurements (Figure 3). The results of the statistical analyses are displayed in Table 3.

The final percent change from baseline in the composite heel pain VAS score was reduced by 73.2% in the ESWT group, and this was 32.7% greater than the reduction observed in the placebo group (Table 3). The between-group difference of ESWT to placebo was not statistically significant ($P = .0302$; 1-sided test, statistical significance was defined as = 0.025), but the MW effect size showed at least medium-sized (relevant) superiority for the ESWT group (MW = 0.6737).

Regarding the single VAS pain scales, in heel pain when taking first steps of the day, while doing daily activities, and during the application of the F-meter, the percent changes from baseline were not statistically significant, with $P = .0659$, $P = .0469$, and $P = .0472$ (all 1 sided), respectively. Thus, these results were all at least 20% greater for the ESWT group in comparison with the placebo group, and the observed superiority was relevant (MW effect size $\geq .6400$) (Table 3).

In regard to the success rates (percent change from baseline $\geq$ 60%), the effect sizes indicated small- to medium-sized superiority in the ESWT group (MW effect size estimates between 0.5500 and 0.6250). All of the success intervention rates were greater in the active ESWT group, in comparison with those observed for the placebo group (Table 3).

Therapeutic success (scores of "excellent" and "good") in regard to the functional outcome as assessed with the Roles and Maudsley score at 12 weeks after the final intervention session was 20 percentage points in favor of active ESWT

TABLE 2 Analysis of homogeneity of baseline characteristics, intention-to-treat population

	ESWT (N = 20)	Placebo (N = 20)	*P* value (2 sided)
Age, mean (SD, range), y	53.9 (12,5, 30–72)	58.9 (10.9, 35–76)	.2613
Women, no. (%)	9 (45)	16 (80)	.0484
Body mass index, mean (SD, range), kg/m^2	27.4 (4.6, 20–38)	27.9 (4.5, 23–39)	.6927
Heel pain duration, mean (SD, range), mo	11.3 (7.4, 6–28)	12.1 (8.0, 6–36)	.4314
Heel pain when taking first steps in the morning, mean (SD, range), VAS	7.5 (1.5, 5–10)	7.1 (1.7, 5–10)	.4485
Heel pain while doing daily activities, mean (SD, range), VAS	7.1 (1.9, 5–10)	6.5 (1.9, 3–10)	.4902
Heel pain after application of F-meter, mean (SD, range), VAS	7.7 (1.6, 5–10)	7.4 (2.3, 3–10)	.9508
Heel pain composite score, mean (SD, range)	22.2 (3.9, 15–30)	21.1 (4.4, 13–30)	.3420
Roles and Maudsley Score, mean (SD, range)	3.8 (0.4, 3–4)	3.9 (0.3, 3–4)	.6614

Abbreviations: SD, standard deviation; VAS, visual analog scale.

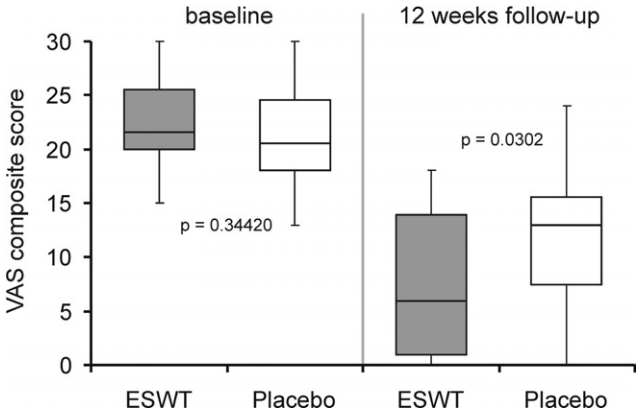

FIGURE 3 VAS composite score at baseline and at 12-week follow-up. *P* values describe between-group differences of ESWT and placebo.

(Table 3) and displayed relevant superiority in the active ESWT group (MW effect size = 0.6600).

Safety Criteria

The mean AR composite score in the ESWT group was 3.1, 2.7, and 3.0, respectively, for each of the first, second, and third intervention visits, with a maximum calculated score in the ESWT group of 5. In the placebo group, the mean AR composite score was 0.8, 0.9, and 1.2, respectively, for each of the first, second, and third intervention visits, and the maximum calculated score was 8. Concomitant analgesic therapy during the study period was documented for only 1 participant in the placebo group, and none in the active ESWT group used concomitant analgesia. No participant required local anesthesia during shockwave application.

Discussion

The present study was performed to investigate the efficacy of focused ESWT with a new electromagnetic shockwave device for the treatment of chronic, painful plantar heel syndrome (plantar fasciitis), thereby applying repeated sessions of shockwaves with an energy flux density that can still be tolerated without local anesthesia (0.25 mJ/mm^2).

Plantar fasciitis is a common and often disabling complaint and is estimated to account for 11% to 15% of all foot symptoms in adults requiring professional care (26). The etiology of plantar fasciitis is still unknown and probably multifactorial, although a degenerative process with inflammatory reaction, microscopic tears, and fibrosis may play an important role. A calcaneal bone spur is evident in 50% to 65% of patients with painful heel, but its influence with regard to clinical symptoms and prognosis was described to be of minor significance (27, 28), although single studies observed a negative influence on treatment outcome (14). The goals of treatment are pain relief and restoration of function. There are a vast number of treatment options including stretching, cryotherapy, heel cushions and shoe inserts, night splints, custom-made orthotics, antiinflammatory drugs, corticosteroid injection, and immobilization (29). Martin et al and Crawford et al reviewed numerous studies of nonsurgical treatment for plantar fasciitis and showed success rates ranging from 44% to 90% (30, 31), without providing more than limited evidence of efficacy, however (26, 30). Some of the treatment options are also associated with significant risks like plantar fascia rupture after steroid injection (32). For participants with chronic heel pain resistant to conservative treatment, surgical interventions like heel spur resection and fasciotomy have been proposed. However, surgical measures can be associated with prolonged healing (33), and surgery did not prove superior to ESWT (34), which has been proposed as a treatment alternative in recalcitrant plantar fasciitis.

Multiple studies have been published describing the treatment of painful heel syndrome by ESWT, but only a few publications were designed in a manner likely to produce unbiased conclusions. Furthermore, the published randomized and double-blinded trials provide controversial conclusions regarding effectiveness and clinical relevance of treatment effect of ESWT compared with placebo (11–16, 18).

TABLE 3 Statistical analysis of efficacy 12 weeks after final treatment for primary efficacy criterion (percentage change of VAS composite score) and secondary criteria, intention-to-treat population, lower bound of confidence interval, and last observation carried forward replacement of missing values

Outcome measure	ESWT (N = 20)		Placebo (N = 20)		Between-group differences		*P* value (1 sided)
	Absolute change: median	Percentage change: median	Absolute change: median	Percentage change: median	Percent change (in favor of ESWT)	MW effect size (1 sided 97.5% LB-CI) (24)	
Primary measure of efficacy							
VAS composite score	−15.5	−73.2	−7.5	−40.5	32.7	0.6737 (0.4985)	.0302
Secondary outcome measures							
First steps, VAS	−4.5	−64.6	−2.0	−41.4	23.2	0.6400 (0.4631)	.0659
Daily activities, VAS	−5.0	−65.7	−3.0	−33.0	32.7	0.6550 (0.4798)	.0469
F-Meter, VAS	−6.0	−75.0	−4.0	−52.8	22.2	0.6550 (0.4827)	.0472
	Success, no. (%)	No success, no. (%)	Success, no. (%)	No success, no. (%)	Difference in success rate, %	MW effect size (1 sided 97.5% LB-CI)	*P* value
Overall success rate (>60% decrease of VAS in ≥2 of 3 VAS)	11 (55)	9 (45)	8 (40)	12 (60)	15	0.5575 (0.4220)	.2148
Success rate first steps (>60% decrease of VAS)	11 (55)	9 (45)	6 (30)	14 (70)	25	0.6250 (0.4768)	.0648
Success rate daily activities (>60% decrease of VAS)	10 (50)	10 (50)	8 (40)	12 (60)	10	0.5500 (0.3966)	.3057
Success rate F-Meter (>60% decrease of VAS)	12 (60)	8 (40)	7 (35)	13 (65)	25	0.6250 (0.4752)	.0769
	Absolute change: mean	Success rate, no. (%)	Absolute change: mean	Success rate, no. (%)	Difference in success rate, %		
Roles and Maudsley Score	−1.8	12 (60)	−1.3	8 (40)	20	0.6600 (0.4932)	.0416

Abbreviations: ESWT, extracorporeal shockwave therapy; MW, Mann-Whitney; LB-CI, lower bound of confidence interval; VAS, visual analog scale.

These differences in outcomes are due to variations in study design, including differences in study populations, heterogeneity of treatment parameters such as focal energy, geometry of the shockwave focus, treatment regimens, and methods of shockwave generation. Further, the significant influence of blinding outcomes assessors is obvious when single-blinded and double-blinded studies are compared. Interestingly, placebo shockwave intervention demonstrated an average improvement in VAS heel pain scores of approximately 40% in double-blind studies (12, 15, 19), compared with 0% to 4% in single-blinded trials (11, 35). Therefore, blinding of both participants and evaluating investigators is a worthwhile undertaking that, in light of its bias-reducing influence, is likely to yield a valid assessment of group differences. Blinding of subjects and follow-up observers was carried out in the present study, although the blinding efficacy was not specifically assessed after treatment.

In spite of the different treatment methodologies applied, published RCTs support that the method of directing the shockwaves can be important in regard to the final outcome. Notably, some double-blind RCTs that failed to show the superiority of ESWT over placebo focused the acoustic energy at anatomical landmarks rather than at the point of greatest tenderness as defined by the participant, and local anesthesia was used in some of the investigations in an effort to blind the participants. Local anesthesia might thereby inhibit direct analgesic effects like modification of the release of pain mediators, hyperstimulation, and the gate-control mechanism (8). We believe that the use of local anesthesia in well-designed RCTs conducted by Buchbinder et al and Haake et al resulted in failure of these investigators to demonstrate the superiority of ESWT compared with placebo (12, 13). Similarly, we believe that ultrasonic guidance of the shockwaves to the thickest part of the plantar fascia, rather than toward the point of maximum pain as localized with participant-controlled feedback, has also resulted in an inability to demonstrate the therapeutic superiority of ESWT in comparison with placebo. In contrast, studies directing the shockwaves to the most tender point without using anesthesia have consistently demonstrated ESWT to be significantly more effective than placebo (14, 16, 17). These observations were further corroborated by Rompe et al, who demonstrated in an RCT that ESWT

applied without local anesthesia was significantly more effective than ESWT used with local anesthesia (17). Therefore, directing ESWT to the most tender point in the absence of local anesthesia appears to be a very important factor related to achieving a successful therapeutic outcome.

Another important factor appears to be the total energy applied to the affected heel. Although both high- and low-energy shockwaves have proven effective in treating painful heel syndrome (11, 15, 16, 19), the total energy applied significantly influences final outcome. Obviously, lower-energy flux densities can be partly compensated by higher impulse numbers and repeated treatment. The dose-dependent efficacy of ESWT was demonstrated by Malay et al in a recent Food and Drug Administration phase 3 RCT (14).

Because of the significant influences of the various treatment variables on treatment outcome, conclusions concerning the effectiveness of ESWT cannot be generalized at this time. This is particularly true in regard to efforts to pool data for quantitative meta-analyses and systematic reviews of RCTs investigating the use of ESWT for the treatment of chronic plantar fasciitis (12, 26).

Despite the availability of statistical evidence indicative of the effectiveness of ESWT for the treatment of chronic plantar fasciitis, the clinical relevance of the beneficial effects has been questioned (26). Farrar et al have analyzed the clinical importance of changes in chronic pain in a database of 2724 patients, independent of underlying disease (23). The 0-to-10-point numerical rating of pain intensity was found to be a consistent and valuable tool for the evaluation of changes in the subjective measurement of pain. In their experience, a reduction of 2 points on the 11-point scale, or approximately 30% of the pain scale, represented a clinically important difference (23). As a case in point, Theodore et al demonstrated a statistically significant superiority of ESWT in the reduction of morning pain, although the between-group difference, in comparison with placebo, reached only 0.7 points on the 10-cm VAS (19). The study from Ogden et al—conducted with ankle-block anesthesia—also showed a statistically significant difference in the success rates in favor of the active treatment. However, the clinical relevance of these results caused controversy because the maximum between-group difference, being just 16% in favor of ESWT for the "investigator's assessment of heel pain," was, for all of the other outcomes (morning heel pain, activity related heel pain, and use of pain medication), even smaller (15).

Based on these observations, we wondered if a protocol applying repeated ESWT (3 $\times$ 2000 impulses) with relatively high energy flux densities (0.25 mJ/mm^2) that can be tolerated without local anesthesia would demonstrate clinically relevant and optimized efficacy. A new, small electromagnetic shockwave device generating focused impulses (ESWT) with a light hand piece was available for use in this investigation. We conducted the present study to assess the clinically relevant treatment effect of this new ESWT regimen in comparison with placebo, rather than attempting to demonstrate a statistically significant intergroup difference. To study the overall improvement in heel pain, we assessed the VAS composite score for heel pain as the primary criterion of efficacy. The calculation of the composite scores for pain measurement is recommended by the ICH Biostatistics Guideline E9 (25). Furthermore, morning pain and heel pain after activity have been shown to be the symptoms that bother most with painful heel syndrome (12), and were therefore combined with standardized pressure measurement to form the VAS composite score.

Consistent with previous descriptions, we also observed a significant placebo effect with reduction of the VAS composite score by 40.5% compared with baseline (Table 3, Fig 2), underlining the importance of conducting ESWT trials in a double-blind, placebo-controlled design. The presented regimen of ESWT was followed by a reduction in the VAS composite score of 73.2% compared with baseline. In comparison with the placebo group, pain reduction was in favor of ESWT with a between-group difference of 32.7%, also exceeding the previously defined threshold of 30% for clinically relevant changes in chronic pain (23). Thus, ESWT not only demonstrated a more than 70% improvement relative to the baseline measurement, but also a clinically relevant superiority over placebo with an MW effect size of 0.6737 in favor of ESWT (0.6400 being the benchmark for medium-sized, clinically relevant superiority). Furthermore, all of the single VAS heel pain scales also showed a relevant effect size in favor of ESWT, with all of the MW effect sizes being $\geq$0.6400, and the between group differences being $>$2 points on the 10-cm VAS (Table 3). The final percent changes of the VAS composite score (primary criterion) further support the above-mentioned results as well as the results observed with the Roles and Maudsley Score. Both of these scores fell short of the conventional level of statistical significance ($P = .0302$ and $P = .0416$, 1-sided null hypothesis tests), and we believe that in the current investigation this was due to the relatively small sample size in our feasibility study. Furthermore, the results of this feasibility study are limited by a maximum follow-up of just 3 months, whereas previous studies have demonstrated the treatment effect of ESWT to improve over time and to persist for at least 1 year in chronic, painful heel syndrome (5, 14–16). Finally, replacement of missing values by the last observation carried forward technique biases results toward the null and might have precluded a statistically significant result, because most ESWT interventions require several weeks to effect clinically significant relief.

In regard to the safety criteria that were quantified with the AR composite score, with which we compared 7 symptoms that were most likely to be related to ESWT (pain during treatment, skin redness, hematoma, petechiae,

swelling, scars, continuing pain), the composite score of the ESWT group was comparably higher at all intervention visits compared with the placebo group. The score for both groups was situated at the lower end of the scale, and no complaints were reported during any follow-up evaluation and no other relevant side effects were observed.

In conclusion, ESWT with 3 repetitive applications of 2000 impulses of an electromagnetic shockwave device without local anesthesia appeared to be an effective, noninvasive treatment modality for proximal plantar fasciitis. This intervention was associated with negligible side effects. We believe that this treatment could be used to reduce the necessity for surgical intervention used in the treatment of proximal plantar fasciitis. Treatment effects observed in this investigation have shown between-group differences in pain reduction of more than 30% and more than 2 points on the 10-cm VAS scales (11-point rating scale from 0 = no pain to 10 = unbearable pain), thus demonstrating clinical relevance (23) and greater efficacy than most previously published investigations. The study also suggests that focusing the acoustic energy at the most tender point, as guided by participant feedback, with a small, handheld device seems to be an alternative that results in improved pain reduction compared with image-guided shockwave administration, with lower cost because of the lack of a need for an additional ultrasonic targeting device. However, a direct comparison of this speculation in a randomized trial should be realized. Our results support data from Rompe et al, who showed similar efficacy (11), and these findings refute the idea that electromagnetic ESWT devices are less potent and, therefore, less effective in comparison with ESWT devices that use other methods of shockwave generation (such as electrohydraulic or piezoelectric methods). Assessment of the published data clearly showed that the outcome is strongly dependent on the administered treatment protocol, and conclusions concerning the effectiveness of ESWT must not be generalized for different treatment setups. The current study advocates the application of ESWT with a handheld electromagnetic device for the treatment of chronic and refractory painful heel syndrome.

Acknowledgments

We would like to thank Richard T. Bouché, DPM, and Edward G. Blahous, Jr, DPM, of the Sports Medicine Clinic in Seattle, WA, for their thoughtful review and critiques of the article.

References

1. Furia JP. High-energy extracorporeal shock wave therapy as a treatment for insertional Achilles tendinopathy. Am J Sports Med 34:733–740, 2006.
2. Gerdesmeyer L, Wagenpfeil S, Haake M, Maier M, Loew M, Wortler K, Lampe R, Seil R, Handle G, Gassel S, Rompe JD. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. JAMA 290:2573–2580, 2003.
3. Gollwitzer H, Brandner H, Gloeck T. Extracorporeal shock wave therapy for bony non-union: evidence-based therapy—review of the literature and personal results. Trauma Berufskrankh 8:142–152, 2006.
4. Hsu RW, Hsu WH, Tai CL, Lee KF. Effect of shock-wave therapy on patellar tendinopathy in a rabbit model. J Orthop Res 22:221–227, 2004.
5. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. Clin Orthop 387:47–59, 2001.
6. Rompe JD, Hope C, Kullmer K, Heine J, Burger R. Analgesic effect of extracorporeal shock-wave therapy on chronic tennis elbow. J Bone Joint Surg Br 78:233–237, 1996.
7. Maier M, Milz S, Tischer T, Munzing W, Manthey N, Stabler A, Holzknecht N, Weiler C, Nerlich A, Refior HJ, Schmitz C. Influence of extracorporeal shock-wave application on normal bone in an animal model in vivo. Scintigraphy, MRI and histopathology J Bone Joint Surg Br 84:592–599, 2002.
8. Maier M, Milz S, Wirtz DC, Rompe JD, Schmitz C. Basic research of applying extracorporeal shockwaves on the musculoskeletal system. An assessment of current status Orthopade 31:667–677, 2002.
9. Wang CJ, Huang HY, Pai CH. Shock wave-enhanced neovascularization at the tendon-bone junction: an experiment in dogs. J Foot Ankle Surg 41:16–22, 2002.
10. Krischek O, Rompe JD, Herbsthofer B, Nafe B. Symptomatic low-energy shockwave therapy in heel pain and radiologically detected plantar heel spur. Z Orthop Ihre Grenzgeb 136:169–174, 1998.
11. Rompe JD, Schoellner C, Nafe B. Evaluation of low-energy extracorporeal shock-wave application for treatment of chronic plantar fasciitis. J Bone Joint Surg Am 84-A:335–341, 2002.
12. Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabaharan V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. JAMA 288:1364–1372, 2002.
13. Haake M, Buch M, Schoellner C, Goebel F, Vogel M, Mueller I, Hausdorf J, Zamzow K, Schade-Brittinger C, Mueller HH. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. BMJ 327:1982–1991, 2003.
14. Malay DS, Pressman MM, Assili A, Kline JT, York S, Buren B, Heyman ER, Borowsky P, Lemay C. 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.
15. Ogden JA, Alvarez R, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. J Bone Joint Surg 86-A:2216–2228, 2004.
16. Rompe JD, Decking J, Schoellner C, Nafe B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial Am J Sports Med 31:268–275, 2003.
17. 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.
18. Speed CA, Nichols D, Wies J, Humphreys H, Richards C, Burnet S, Hazleman BL. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial J Orthop Res 21:937–940, 2003.
19. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot Ankle Int 25:290–297, 2004.
20. Rompe JD, Küllmer K, Vogel J, Eckardt A, Wahlmann U, Eysel P,

Hopf C, Kirkpatrick CJ, Bürger R, Nafe B. Extrakorporale Stoßwellentherapie: Experimentelle Grundlagen, klinischer Einsatz. Orthopade 26:215–228, 1997.
21. European Medicines Agency. ICH Topic E6, Guideline for Good Clinical Practice. Available at: http://www.emea.eu.int/pdfs/human/ich/013595en.pdf. Accessed June 20, 2007.
22. Roles NC, Maudsley RH. Radial tunnel syndrome: resistant tennis elbow as a nerve entrapment. J Bone Joint Surg Br 54:499–508, 1972.
23. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 94:149–158, 2001.
24. Colditz GA, Miller JN, Mosteller F. Measuring gain in the evaluation of medical technology. The probability of a better outcome Int J Technol Assess Health Care 4:637–642, 1988.
25. European Medicines Agency. ICH Topic E9, Statistical Principles for Clinical Trials. http://www.emea.eu.int/pdfs/human/ich/036396en.pdf. Accessed June 20, 2007.
26. Buchbinder R. Clinical practice. Plantar fasciitis N Engl J Med 350: 2159–2166, 2004.
27. Lee GP, Ogden JA, Cross GL. Effect of extracorporeal shock waves on calcaneal bone spurs. Foot Ankle Int 24:927–930, 2003.
28. Schepsis AA, Leach RE, Gorzyca J. Plantar fasciitis. Etiology, treatment, surgical results, and review of the literature Clin Orthop 266: 185–196, 1991.
29. ACFAS Clinical Practice Guideline Heel Pain Panel. The diagnosis and treatment of heel pain. J Foot Ankle Surg 40:329–340, 2001.
30. Crawford F, Thomson C. Interventions for treating plantar heel pain. Cochrane Database Syst Rev CD000416, 2003.
31. Martin RL, Irrgang JJ, Conti SF. Outcome study of subjects with insertional plantar fasciitis. Foot Ankle Int 19:803–811, 1998.
32. Sellman JR. Plantar fascia rupture associated with corticosteroid injection. Foot Ankle Int 15:376–381, 1994.
33. Davies MS, Weiss GA, Saxby TS. Plantar fasciitis: how successful is surgical intervention? Foot Ankle Int 20:803–807, 1999.
34. Weil LS Jr, Roukis TS, Weil LS, Borrelli AH. Extracorporeal shock wave therapy for the treatment of chronic plantar fasciitis: indications, protocol, intermediate results, and a comparison of results to fasciotomy. J Foot Ankle Surg 41:166–172, 2002.
35. Cosentino R, Falsetti P, Manca S, De Stefano R, Frati E, Frediani B, Baldi F, Selvi E, Marcolongo R. Efficacy of extracorporeal shock wave treatment in calcaneal enthesophytosis. Ann Rheum Dis 60: 1064–1067, 2001.