0363-5465/103/3131-0268$02.00/0
THE AMERICAN JOURNAL OF SPORTS MEDICINE, Vol. 31, No. 2

Shock Wave Application for Chronic Plantar Fasciitis in Running Athletes

A Prospective, Randomized, Placebo-Controlled Trial

Jan D. Rompe,* MD, Jens Decking, MD, Carsten Schoellner, MD, and Bernhard Nafe, MD

From the Department of Orthopaedics, Johannes Gutenberg University School of Medicine, Mainz, Germany

Background: Recent articles have reported success with repeated low-energy shock wave application for treatment of chronic plantar fasciitis in runners.
Hypothesis: Shock wave treatment for chronic plantar fasciitis is safe and effective.
Study Design: Prospective, randomized, placebo-controlled trial.
Methods: Forty-five running athletes with intractable plantar heel pain for more than 12 months were enrolled; half were assigned to a treatment group that received three applications of 2100 impulses of low-energy shock waves, and half received sham treatment. Follow-up examinations were performed at 6 months and at 1 year by a blinded observer.
Results: After 6 months, self-assessment of pain on first walking in the morning was significantly reduced from an average of 6.9 to 2.1 points on a visual analog scale in the treatment group and from an average of 7.0 to 4.7 points in the sham group. The mean difference between groups was 2.6 points. After 12 months, there was a further reduction of pain in both groups, to an average 1.5 points in the treatment group, and to 4.4 points in the sham group.
Conclusion: Three treatments with 2100 impulses of low-energy shock waves were a safe and effective method for treatment of chronic plantar fasciitis in long-distance runners.

Chronic plantar fasciitis due to cumulative overload stress is one of the most common painful foot conditions observed in runners, both competitive athletes and those who run for basic conditioning.[12,22,45] The specific pathologic features of this clinical entity are not well understood; inflammation of the plantar fascia, thickening of the proximal fascia, decreased vascularity, peritendinous inflammation, loss of normal elasticity, and alteration of nociceptor physiology all may play roles in the onset and persistence of heel pain.[22,30] The pain is usually present when the patient first stands on his or her feet after awakening, and it persists or becomes worse with activities of daily living. The use of nonoperative methods such as rest, application of ice to the sore area, nonsteroidal antiinflammatory medication, or topical application of steroids will alleviate the condition in most patients,[14,33,37,39,42] and the performance of a stretching protocol is regarded as the mainstay of recommended treatment.[32] The use of shoes with shock-absorbing soles or shoes fitted with a standard orthopaedic device such as a rubber heel pad or taping of the foot into a specific position is also recommended. The recommendation of heel elevation to achieve reduction of loading of the plantar fascia is controversial.[19] Steroid injections into the painful area also have been used[27] but are associated with a significant risk of subsequent rupture of the plantar fascia.[23]

Usually, plantar fasciitis can be treated successfully by tailoring treatment to a patient's risk factors and preferences. When nonoperative treatment options are unsuccessful, physicians often resort to open or endoscopic release of a portion of the plantar fascial insertion onto the calcaneus. If there is suspicion of entrapment of the calcaneal branches of the tibial nerve, the nerves can be decompressed. As with any surgery, fascial release is not without substantial risk and may be associated with prolonged healing time and postoperative rehabilitation; an alteration of foot biomechanical integrity may also occur.[1,3,5,16,41,43]

* Address correspondence and reprint requests to Jan D. Rompe, MD, Department of Orthopaedics, Johannes Gutenberg University School of Medicine, Langenbeckstrasse 1, D-55131 Mainz, Germany.
One author has received financial benefit from research in this study.

Because of the recognized risks and delayed healing associated with surgery, alternative nonoperative therapeutic methods have been assessed. Since 1996, there have been reports of promising results from the use of extracorporeal shock wave application for plantar fasciitis, particularly in Europe.[7,9,20,26,30,31,34] Randomized, controlled studies on shock wave application and prospective observational trials on shock wave application have reported comparable treatment effects in 50% to 60% of patients.[2,10] The scientific value of some of the studies that examined the use of shock wave application for treatment of plantar fasciitis was seriously questioned recently.[6] Therefore, the current clinical study was planned as a prospective, randomized, single-blinded evaluation of the potential for low-energy electromagnetic application of extracorporeal shock waves to bring about pain relief for chronic plantar fasciitis in runners. Our hypothesis was that three applications of 2100 impulses were superior to three placebo applications at 6 months after treatment.

MATERIALS AND METHODS

The study was designed as a randomized, single-center, single-blinded parallel treatment study with an independent observer to determine the effectiveness of three applications of 2100 impulses of low-energy shock waves to the heels of long-distance runners with intractable plantar fasciitis. A sham treatment group was used for comparison.

Statistical Assumptions

On the basis of the results of a pilot study,[36] a difference of 3 points on the average pain rating on a visual analog scale ranging from 0 to 10 points was assumed to be a significant difference between the groups, with a common standard deviation of 3 points. A sample size of 17 patients per treatment group would have more than 80% of the power to detect the treatment difference with a two-sided significance level of 0.05. Accordingly, a sample size of 22 patients per treatment group, including an assumed 20% rate of patients lost to follow-up, was calculated to give sufficient statistical power. The sample size was also sufficient for the evaluation of the treatment differences in terms of the Ankle-Hindfoot Scale,[18] and in terms of the subjective four-step rating scale.

Participants

Over a period of 3 years, recreational athletes who ran more than 30 miles per week and were suffering from chronic plantar fasciitis for more than 12 months were screened and randomized to one of two treatment groups: active treatment or sham treatment.

Inclusion Criteria. For the current study, chronic heel pain was defined as symptoms of moderate-to-severe heel pain in the involved foot at the origin of the proximal plantar fascia on the medial calcaneal tuberosity. The pain must have persisted for at least 12 months before the study enrollment, in patients who ran at least 30 miles per week before symptoms occurred. Over a period of more than 6 months, at least three attempts of nonoperative treatment had failed to provide pain relief for all patients: this included at least two prior courses of intervention with physical therapy, the use of orthotic devices, and at least one prior course of pharmacologic treatment.

Exclusion Criteria. Exclusion criteria included dysfunction in the knee or ankle, local arthritis, generalized polyarthritis, rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, neurologic abnormalities, nerve entrapment syndrome, a history of previous plantar fascial surgery, age of less than 18 years, pregnancy, infections or tumors, a history of spontaneous or steroid-induced rupture of the plantar fascia, bilateral heel pain, participation in a workers' compensation program, or use of systemic therapeutic anticoagulants or nonsteroidal antiinflammatory drugs for any chronic condition. No other treatment was permitted until 6 weeks after shock wave application, with the exception of use of already-worn shoe inserts during the period of treatment. Patients were instructed to use the foot but to avoid painful stress.

Forty-nine patients qualified for the study, of whom 4 declined to be randomized, leaving 45 patients enrolled in the study (Fig. 1). Extracorporeal shock wave treatment was free of cost to all participants. No crossover between the two groups was offered. In case of failure of treatment, the patients were invited to undergo surgery of the heel. All patients had been treated unsuccessfully by their general practitioner, and 38 patients had also been treated by an orthopaedic practitioner. All patients had been given medication, mostly nonsteroidal antiinflammatory drugs, and had received shock-absorbing shoe inserts. All had performed some kind of stretching exercises on a regular basis; only 18 patients had used night splints. Eleven

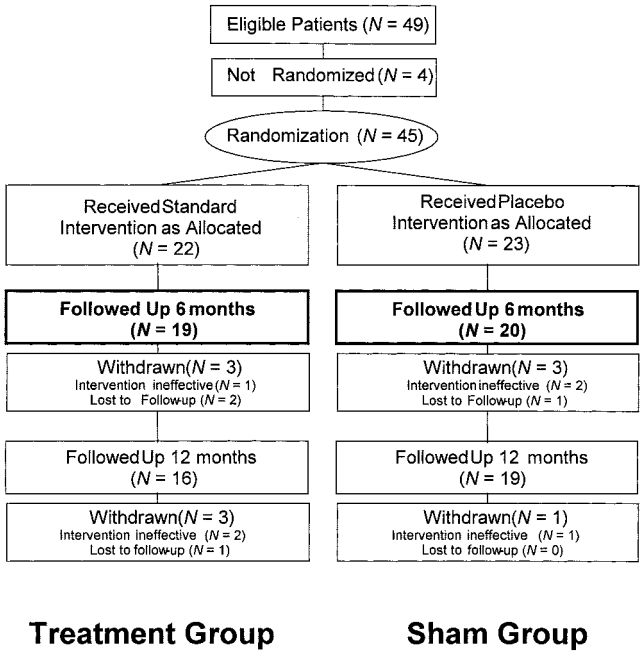

Figure 1. Profile of the randomized controlled trial.

patients had been immobilized in a cast for at least 2 weeks, and an average of 2.8 corticosteroid injections had been given (range, 1 to 5). An average of three different physical therapy treatment regimens had been used, such as icing, ultrasound, magnetic field, iontophoresis or phonophoresis, contrast baths, or radiation therapy (range, one to five different treatment regimens).

Randomization

After 4 weeks of no treatment at all and after giving informed consent, the patients were reevaluated regarding exclusion criteria and were then randomized into the two treatment groups by use of identical sealed envelopes. Patients in the two groups did not differ regarding weekly running distance, age, sex, duration of pain, weight, or body mass index. The first shock wave application started immediately after the identification of treatment group.

Shock Wave Treatment Group. The treatment group consisted of 10 women and 12 men, with a mean age of 43 years (range, 32 to 59) and a mean duration of pain of 20 months (range, 12 to 60).

Sham Treatment Group. The group receiving sham treatment consisted of 13 women and 10 men, with a mean age of 40 years (range, 30 to 61) and a mean duration of pain of 18 months (range, 12 to 72).

Method of Treatment

The extracorporeal shock wave therapy was applied by a mobile therapy unit especially designed for orthopaedic use (Sonocur Plus, Siemens AG, Erlangen, Germany), with the shock wave head suspended by an articulating arm for flexible movement of the head in three planes. The shock wave head was equipped with an electromagnetic shock wave emitter. Shock wave focus guidance was established by in-line integration of an ultrasound probe (a 7.5-MHz sector scanner) in the shock head. The physical output parameters of the device, measured with a laser hydrophone, are listed in Table 1.

Both groups were treated under the same conditions, and patients were treated singly to avoid influencing one another. Each study subject assigned to active treatment underwent shock wave application for a total of 6300 shocks in three treatment sessions, with a 1-week interval in between, at an energy flux density of 0.16 mJ/mm^2 and at a frequency of 4 Hz, without local anesthesia. Ultrasound coupling gel was used between the treatment head and the heel. The shock tube head was applied under in-line ultrasound control (Fig. 2); fine adjustment to the most tender region was performed by palpation and interaction with the patient. Treatment was started at the lowest energy level, 1, for 50 impulses and was then increased to energy level 2 for another 50 impulses. Then 2000 impulses of energy level 3 (energy flux density of 0.16 mJ/mm^2) were applied.

For those patients assigned to sham treatment, a sound-reflecting pad was interposed between the coupling membrane of the treatment head and the heel to absorb the shock waves through the presence of multiple air cavities. No coupling gel was used. A total of 6300 shocks was delivered in three treatment sessions, with a 1-week interval in between, effectively duplicating the duration and noise of active treatment.

Method of Evaluation

All patients were assessed before and after treatment. The actual study procedure was conducted by a physician who was aware of the treatment. However, this physician played no role in assessing the patients after treatment. Another physician, an independent treatment-blinded observer, examined the patients at 6 and at 12 months after the last application of the extracorporeal shock wave therapy.

Primary Outcome Measure

The primary outcome measure was prospectively defined as reduction of the subject's self-assessment of pain on first walking in the morning. On the visual analog scale, 10 points indicated unbearable pain and 0 points, no pain at all. The 6-month interval was selected because it was

TABLE 1
Output Parameters of the Shock Wave Device

Physical value		Unit	Energy level 1	Energy level 2	Energy level 3 (treatment level)
Peak positive pressure	P_+	Mpa	5.5	7.9	11
−6 dB focal extend in x, y, z direction	$f_{x(-6\ dB)}$	mm	6.0	5.7	5.5
	$f_{y(-6\ dB)}$	mm	6.0	5.7	5.5
	$f_{z(-6\ dB)}$	mm	58	57	56
5 MPa focal extent, lateral	$f_{x(5\ Mpa)}$	mm	2.2	3	5
	$f_{y(5\ Mpa)}$	mm	2.2	3	5
Positive energy flux density	ED_+	mJ/mm^2	0.016	0.04	0.07
Total energy flux density	ED	mJ/mm^2	0.04	0.09	0.16
Positive energy of −6 dB focus	$E_{+(-6\ dB)}$	mJ	0.38	0.7	1.1
Total energy of −6 dB focus	$E_{(-6\ dB)}$	mJ	1.1	2	3
Positive energy of 5 MPa focus	$E_{+(5\ Mpa)}$	mJ	0.5	0.7	1
Total energy of 5 MPa focus	$E_{(5\ Mpa)}$	mJ	1.8	2	3
Positive energy of 5-mm focal area	$E_{+(5\ mm)}$	mJ	0.24	0.5	0.9
Total energy of 5-mm focal area	$E_{(5\ mm)}$	mJ	0.63	1.3	2

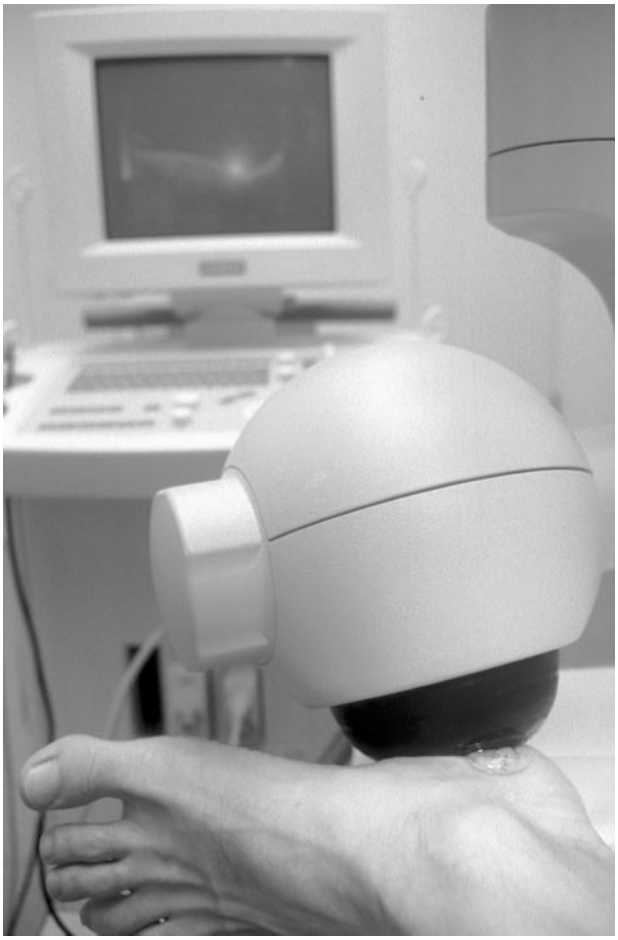

Figure 2. Ultrasound-guided adaptation of the shock wave head to the medioplantar aspect of the left heel.

expected that the healing process would likely be evident (although not necessarily complete) at this point in time.

Secondary Outcome Measures

Prospectively defined secondary outcome measures for clinical evaluation 6 and 12 months after treatment included at least a 50% reduction of a subject's self-assessment of pain on first walking in the morning, a visual analog scale rating of less than 4 of 10 points, and improvement from the baseline in the American Orthopaedic Foot and Ankle Society's Ankle-Hindfoot Scale.[18] This strictly clinical score has 100 possible points (pain, 40 points; function, 50 points; alignment, 10 points). In addition, patients had to show improvement from baseline on a subjective four-point rating scale and achievement of a rating less than or equal to two points at 6 months and at 12 months after shock wave application. On the scale, 1 point was defined as excellent, with the patient having no pain, satisfied with the treatment outcome, and able to perform unlimited walking free from pain. Two points was defined as good, with symptoms significantly improved and the patient satisfied with treatment outcome and able to walk free from pain for more than 1 hour. Three points was considered acceptable, with symptoms somewhat improved, pain at a more tolerable level than before treatment, and the patient slightly satisfied with the treatment outcome. Four points indicated a poor outcome, with symptoms identical or worse and the patient dissatisfied with the treatment outcome.

Statistical Analysis

The methods used for statistical analysis in this study were determined by the local Institute for Medical Statistics and Documentation before the study was begun and were performed by them when the study was completed. Wilcoxon's rank sum test was applied for comparison of the difference between the two groups for pseudocontinuous, not normally distributed variables, such as pain when first walking in the morning and scores on the Ankle-Hindfoot Scale.[24] The four-step scale, a categorical variable, was compared by means of Fisher's exact test and its extension to $2 \times N$ contingency tables. The level of significance was set at 95%. Tested comparisons with P values of less than 0.05 were considered to be significantly different. Multiple adjustments were not performed for secondary outcome measures, which were measured in an exploratory way. The primary outcome measure was tested in a confirmatory way.[28]

RESULTS

Follow-up

Twenty-two and 23 patients were randomized consecutively to each group. Two patients in the treatment group and one patient in the sham group were lost to follow-up. Thus, after 6 months, 19 patients in the treatment group and 20 in the sham group were evaluated (Fig. 1). One patient in the treatment group and two patients in the sham group refused further contact because of lack of success of the therapy.

At 12 months, the intervention had been ineffective for two patients, who refused to cooperate further, and one patient could not be contacted. Thus, 16 patients in the treatment group were available for examination. Nineteen patients in the sham group were evaluated at 12 months, and one additional patient refused to cooperate further because shock wave therapy had not improved his condition.

Outcomes

The primary outcome measure was prospectively defined as reduction of pain on first walking in the morning after 6 months of a subject's self-assessment. Results are presented in Table 2. The mean difference between groups was 2.6 points ($P = 0.0004$; 95% confidence interval, 1.3 to 3.9 points; power = 0.9)

After 6 months, 12 of 20 patients (60%) in the treatment group and 6 of 22 patients (27%) in the sham group reported more than a 50% improvement in pain on first

TABLE 2
Mean Reduction in Self-Assessment of Pain on First Walking in the Morning

Group	Initial rating	6 months	1 year
Treatment	6.9 ± 1.3	2.1 ± 2.0	1.5 ± 1.7
P value	0.8667	0.0004	<0.0001
Sham	7.0 ± 1.3	4.7 ± 1.9	4.4 ± 1.7

walking in the morning, with values of less than 4 points on the visual analog scale ($P = 0.0600$). These results included those of one patient in the treatment group and two patients in the sham group who reported via telephone an ineffectiveness of the intervention and refused further clinical evaluation; they were rated as treatment failures. After 12 months, 13 of 18 patients (72%) in the treatment group and 7 of 20 patients (35%) in the sham group reported more than a 50% improvement in pain on first walking in the morning ($P = 0.0051$). These results also included those of two patients in the treatment group and one patient in the sham group who reported by telephone an ineffectiveness of the intervention and refused further clinical evaluation; they were also rated as treatment failures.

After 6 months, an increase in the Ankle-Hindfoot Scale was observed in both groups, by 37.2 ± 15.2 points in the treatment group and by 19.4 ± 17.8 points in the sham group ($P = 0.0025$). The three patients who refused to participate further in the study because of ineffectiveness of treatment were not included in the computation of the score. Results are given in Table 3.

Before the extracorporeal shock wave therapy started, all patients rated their condition as "4" in the subjective four-step scale. There was no difference between the groups at this point in time. After 6 months, an improvement was seen in both groups on the four-step scale, by 1.9 ± 0.9 points in the treatment group and by 1.0 ± 1.0 point in the sham group ($P = 0.0112$). Results are given in Table 4.

Complications

Low-energy extracorporeal shock wave therapy was considered unpleasant by all patients, although not as unpleasant as the local infiltration all patients had had during the various and unsuccessful treatment regimens before the current study. No patient discontinued the shock wave procedure because of severe pain. No side effects were seen at either follow-up examination. There were no hematomas, infections, or abnormal neurologic findings.

TABLE 3
Mean Scores on the American Orthopaedic Foot and Ankle Society's Ankle-Hindfoot Scale

Group	Initial score	6 months	1 year
Treatment	52.7 ± 10.0	89.9 ± 8.6	90.4 ± 8.3
P value	0.1977	0.0025	0.0211
Sham	49.7 ± 10.1	69.1 ± 20.1	75.4 ± 17.3

TABLE 4
Subjective Scale Results

Group	Initial rating	6 months	1 year
Treatment	4.0 ± 0.0	2.1 ± 0.8	1.9 ± 0.6
P value	1.0000	0.0112	0.0445
Sham	4.0 ± 0.0	3.0 ± 1.0	2.7 ± 1.1

Concurrent Interventions

Numbers of concurrent interventions did not differ significantly between groups at follow-up. At 6 months, 3 of 19 patients (16%) in the treatment group and 6 of 20 patients (30%) in the sham group received further nonoperative therapy. At 12 months, 3 of 16 patients (19%) in the treatment group and 5 of 19 patients (26%) in the sham group received further nonoperative therapy. One patient in each group had undergone surgery (6% and 5%, respectively).

DISCUSSION

The clinical diagnosis of plantar fasciitis is relatively easy to make.[21] Radiographically, a heel spur on the inferior surface of the calcaneus frequently is evident but is not considered pathognomonic of the disorder.[37] Magnetic resonance imaging regularly shows edematous involvement of the calcaneal insertion of the plantar aponeurosis, with a marked thickening of the proximal segment of the central cord of the plantar fascia.[4,13,29,40] Although proximal plantar fasciitis is the most frequent cause of inferomedial heel pain, other pathologic conditions, such as seronegative arthropathies or nerve entrapment, may be causal in about 10% of cases. Two patient cohorts seem to have a particularly high incidence of plantar fasciitis: obese middle-aged women and young male runners.[26,30,37]

Most authors agree that subjects with insertional plantar fasciitis have a self-limiting disease and that most will attain good results without significant intervention. Therefore, the initial treatment should be nonoperative, with use of modalities such as physical therapy, especially fascial stretching, orthoses, night splints, shoe wear modifications, and nonsteroidal antiinflammatory drugs.[30] However, Martin et al.[27] reviewed numerous studies of nonsurgical treatment for plantar fasciitis and showed a wide variation of acceptable outcomes, ranging from 44% to 82% of patients obtaining complete relief of heel pain. In their metaanalysis, Crawford et al.[12] looked for randomized controlled trials on plantar fasciitis and found 11 studies on nonoperative treatment since 1966. However, these trials had low methodologic assessment scores; not a single one evaluated the effectiveness of surgical therapy. The metaanalysis showed there was limited evidence for the short-term effectiveness of topical corticosteroid administered by iontophoresis and for the effectiveness of use of dorsiflexion night splints. A preliminary study from our institution also showed limited evidence of the effectiveness of low-energy extracorporeal shock wave therapy.[34] This preliminary positive outcome has been confirmed in prospective clinical studies from various university hospitals.[20,31,38] The scientific value of these studies was seri-

ously questioned recently,[6] and the therapeutic mechanism involved remains a topic of speculation.[15,25] Ogden et al.[30] postulated that shock waves are directed at controlled microdisruption of internal fascial tissue, which initiates a more appropriate healing response within the fascia and a better long-term capacity to adapt to biologic and biomechanical demands. No evidence was presented.

There is no consensus so far concerning the (repeated) use of low-energy shock waves, requiring no local anesthesia,[34,36] versus the (single) use of high-energy shock waves, requiring local or regional anesthesia.[7,30] Indeed, there is no consensus so far as to how to differentiate low-energy from high-energy shock waves, because multiple physical parameters are involved (see Table 1). Although the clinical effect of both protocols appears to be comparable, as discussed later, there is clear evidence of increasing side effects with the application of increasing energy levels.[35] With the treatment regimen described in this article, deleterious side effects are extremely unlikely as compared with treatment regimens involving application of higher-energy flux densities. No local anesthesia was required, so related side effects are lacking. The only "disadvantage" is that, according to our experience, a repeated application is needed.

Maier et al.[26] recently reported good or excellent results on a subjective four-step score in 75% of 48 heels 29 months after low-energy shock waves were applied three times at weekly intervals without local anesthesia. The clinical outcome was not influenced by the length of follow-up. No negative side effects were reported. Wang et al.[43] reported 33 of 41 patients to be either free of pain or significantly better at 12 weeks after shock wave therapy. Ogden et al.[30] published results of a randomized placebo-controlled study with 119 patients in the treatment group and 116 patients in the placebo group. Twelve weeks after a single application of 1500 high-energy shock waves at 18 kV under regional anesthesia, success was observed in 47% of patients (56). After sham treatment, the success rate was only 30% (35 patients). The results of this study led to approval of shock wave therapy for painful heel by the United States Food and Drug Administration in 2000. Buch et al.[7] reported the results of another randomized placebo-controlled study for the Food and Drug Administration involving 150 patients. Therapy was applied once, with 3800 high-energy impulses under regional anesthesia. After 3 months, 61% of the patients (45 patients) in the treatment group and only 40% (29 patients) of the placebo group met the success criterion. Chen et al.[9] studied 80 patients treated with 1000 shock wave impulses at 14 kV. Fifty-four patients were evaluated at 6 months. There were no complaints from 32 patients (59.3%), and 15 patients (27.7%) were significantly improved.

More recently, we reported a randomized controlled trial of shock wave therapy in 112 patients.[36] Group 1 received 3 applications of 1000 impulses of a low-energy flux density, and group 2 received 3 applications of 10 impulses within 2 weeks. When the rates of good and excellent outcome on a four-step score were compared between the two groups, there was a significant difference of 47% in favor of group 1 treatment at 6 months. At 6 months, pressure pain had dropped for patients in group 1 from 77 points to 19 points on a visual analog scale. In group 2, the ratings did not decrease significantly, from 79 points to 77 points. In group 1, walking became completely free from pain for 25 of 50 patients, compared with none of 48 patients in group 2. By 5 years, when the rates of good or excellent outcomes in the four-step score were compared, the difference of only 11% in favor of group 1 was no longer significant; pressure pain was down to 9 points in group 1 and to 29 points in group 2. Meanwhile, 5 of 38 patients (13%) in group 1 had undergone surgery of the heel, compared with 23 of 40 patients (58%) in group 2.

Buchbinder et al.[8] included 166 patients in a double-blind, randomized, placebo-controlled trial. Patients were randomly assigned to receive either ultrasound-guided extracorporeal shock wave treatment given weekly for 3 weeks to a total dose of at least 1 J/mm^2 or an identical placebo to a total dose of 0.006 J/mm^2. After significant improvements in both groups (26.3 points in the treatment group, 25.7 points in the sham group), there was no evidence for superiority of extracorporeal shock wave treatment over placebo. The study by Buchbinder et al. is of excellent quality, but there are some points to be discussed. First, patients in the treatment group did not receive identical treatment (either 2000 or 2500 shock waves per treatment of energy levels varying between 0.02 mJ/mm^2 and 0.33 mJ/mm^2), in contrast with the current study. Second, the mean dose in the treatment group was 1407 mJ/mm^2, 500 mJ/mm^2 more than in the current study. In the experience of the authors of the current study, patients will not tolerate such a high dose unless the treatment area of maximal pain is missed. Accordingly, and third, Buchbinder et al. did not focus on the area of maximal pain as in the current study, but on the area of maximal thickness of the plantar fascia. Fourth, a potent analgesic drug was allowed for the duration of the study. Fifth, patients were enrolled with a pain history as short as 6 weeks, in contrast with the 12 months in the current study. Sixth, there was no real placebo group; sham therapy consisted of application of 100 shock waves of 0.02 mJ/mm^2.

In the current study, better results were observed 6 months after low-energy shock wave application of 2100 impulses compared with sham treatment, with a significant reduction of the subjects' self-assessment of pain on first walking in the morning by an average of 5 points in the treatment group (from 7 to 2 points) and by 2 points (from 7 to 5 points) in the sham group. Sixty percent of patients in the treatment group, versus 27% of the patients in the sham group, reported at least a 50% reduction and a visual analog scale rating of less than 4 of 10 points. After 12 months, 72% of the patients of the treatment group, versus 35% of the patients of the sham group, rated accordingly. Cointerventions remained on a comparable low level in both groups.

Because of the well-described natural history of proximal plantar fasciitis,[30] it was expected that symptoms of chronic heel pain could resolve with time, even in this selected treatment patient population in whom several previous nonoperative treatments had failed. Therefore,

the improvement in both groups between 6 months and 1 year after treatment probably reflects the self-limiting course of the disease. However, more patients in the treatment group improved during this period of follow-up than in the sham group. No side effects have been reported so far from low-energy extracorporeal shock wave application, compared with calcification after steroid injections or postoperative development of wound infections, hypertrophic sensitive scars, or calcaneal fractures.[5,11,37] In the current study, no negative side effects were recorded. This clinical experience is in accordance with those of histologic and MRI-based studies.[26,35] High-energy shock waves, also in use for the treatment of heel pain,[30,31,38] on the other hand, may produce side effects such as periosteal detachments and small fractures of the inner surface of the cortex.[17]

CONCLUSION

The results of the current study revealed beneficial effects of low-energy extracorporeal shock wave therapy in long-distance runners with chronic plantar fasciitis. In accordance with the results of other prospective randomized controlled trials,[7,30,36] shock wave therapy appeared to be a useful, noninvasive treatment method with negligible side effects. The level of evidence for success with this treatment concept is still limited,[6,12] but this is true also for other nonoperative procedures and especially true for surgical treatment, which bears a higher risk of complications. Therefore, we recommend shock wave therapy to any patient who has had unsuccessful conventional nonoperative treatment over a period of at least 6 months, before considering an operative intervention. Further prospective work is necessary to compare the effectiveness of repeated low-energy shock wave application without local anesthesia with the efficacy of single high-energy shock wave application with local or regional anesthesia.

REFERENCES

1. Barrett SL, Day SV: Endoscopic plantar fasciotomy for chronic plantar fasciitis/heel spur syndrome: Surgical technique—early clinical results. *J Foot Surg 30:* 568–570, 1991
2. Benson K, Hartz AJ: A comparison of observational studies and randomized, controlled trials. *N Engl J Med 342:* 1878–1886, 2000
3. Benton-Weil W, Borelli AH, Weil LS Jr, et al: Percutaneous plantar fasciotomy: A minimally invasive procedure for recalcitrant plantar fasciitis. *J Foot Ankle Surg 37:* 269–272, 1998
4. Berkowitz JF, Kier R, Rudicel S: Plantar fasciitis: MR imaging. *Radiology 179:* 665–667, 1991
5. Blanco CE, Leon HO, Guthrie TB: Endoscopic treatment of calcaneal spur syndrome: A comprehensive technique. *Arthroscopy 17:* 517–522, 2001
6. Böddeker R, Schäfer H, Haake M: Extracorporeal shockwave therapy (ESWT) in the treatment of plantar fasciitis—A biometrical review. *Clin Rheumatol 20:* 324–330, 2001
7. Buch M, Knorr U, Fleming L, et al: Extracorporeal shockwave therapy in plantar fasciitis—-3 months results of a multicentre prospective randomised double blind placebo controlled trial. *Orthopäde 31:* 637–644, 2002
8. Buchbinder R, Ptasznik R, Gordon J, et al: Ultrasound-guided extracorporal shock wave therapy for plantar fasciitis: A randomized controlled trial. *JAMA 288:* 1364–1372, 2002
9. Chen HS, Chen LM, Huang TW: Treatment of painful heel syndrome with shock waves. *Clin Orthop 387:* 41–46, 2001
10. Concato J, Shah N, Horwitz RI: Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med 342:* 1887–1892, 2000
11. Conti RJ, Shinder M: Soft tissue calcifications induced by local corticosteroid injection. *J Foot Surg 30:* 34–37, 1991
12. Crawford F, Atkins D, Edward J: Interventions for treating plantar heel pain (Cochrane Review), in *Cochrane Library, Issue 3.* Oxford, Update Software, 2000
13. Grasel RP, Schweitzer ME, Kovalovich AM, et al: MR imaging of plantar fasciitis: Edema, tears, and occult marrow abnormalities correlated with outcome. *AJR Am J Roentgenol 173:* 699–701, 1999
14. Gudeman SD, Eisele SA, Heidt RS Jr, et al: Treatment of plantar fasciitis by iontophoresis of 0.4% dexamethasone. A randomized, double-blind, placebo-controlled study. *Am J Sports Med 25:* 312–316, 1997
15. Heller KD, Niethard FU: Using extracorporeal shockwave therapy in orthopedics: A meta-analysis [in German]. *Z Orthop Ihre Grenzgeb 136:* 390–401, 1998
16. Henricson AS, Westlin NE: Chronic calcaneal pain in athletes: Entrapment of the calcaneal nerve? *Am J Sports Med 12:* 152–154, 1984
17. Ikeda K, Tomita K, Takayama K: Application of extracorporeal shock wave on bone: Preliminary report. *J Trauma 47:* 946–950, 1999
18. Kitaoka HB, Alexander IJ, Adelaar RS, et al: Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int 15:* 349–353, 1994
19. Kogler GF, Veer FB, Verhulst SJ, et al: The effect of heel elevation on strain within the plantar aponeurosis: In vitro study. *Foot Ankle Int 22:* 433–439, 2001
20. Krischek O, Rompe JD, Herbsthofer B, et al: Symptomatic low-energy shockwave therapy in heel pain and radiologically detected plantar heel spur. *Z Orthop Ihre Grenzgeb 136:* 169–174, 1998
21. Lapidus PW, Guidotti FP: Painful heel: Report of 323 patients with 364 painful heels. *Clin Orthop 39:* 178–186, 1965
22. Leach RE, DiIorio E, Harney RA: Pathologic hindfoot conditions in the athlete. *Clin Orthop 177:* 116–121, 1983
23. Leach RE, Jones R, Silva T: Rupture of the plantar fascia in athletes. *J Bone Joint Surg 60A:* 537–539, 1978
24. Lehmann EL: *Nonparametrics: Statistical Methods Based on Ranks.* San Francisco, Holden-Day, 1975
25. Loew M, Daecke W, Kusnierczak D, et al: Shock-wave therapy is effective for chronic calcifying tendinitis of the shoulder. *J Bone Joint Surg 81B:* 863–867, 1999
26. Maier M, Steinborn M, Schmitz C, et al: Extracorporeal shock wave application for chronic plantar fasciitis associated with heel spurs: Prediction of outcome by magnetic resonance imaging. *J Rheumatol 27:* 2455–2462, 2000
27. Martin RL, Irrgang JJ, Conti SF: Outcome study of subjects with insertional plantar fasciitis. *Foot Ankle Int 19:* 803–811, 1998
28. Maurer W, Hothorn LA, Lehmacher W: Multiple comparison in drug clinical trials and preclinic assays: A priori ordered hypotheses, in Vollmer J (ed): *Biometrie in der pharmazeutischen Industrie*. *Volume 6. Testing Principles in Clinical and Preclinical Trials.* Stuttgart, Fischer, 1995, pp 3–18
29. Narvaez JA, Narvaez J, Ortega R, et al: Painful heel: MR imaging findings. *Radiographics 20:* 333–352, 2000
30. Ogden JA, Alvarez R, Levitt R, et al: Shock wave therapy for chronic proximal plantar fasciitis. *Clin Orthop 387:* 47–59, 2001
31. Perlick L, Boxberg W, Giebel G: High-energy shock wave treatment of the painful heel spur [in German]. *Unfallchirurg 101:* 914–918, 1998
32. Pfeffer G, Bacchetti P, Deland J, et al: Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis. *Foot Ankle Int 20:* 214–221, 1999
33. Probe RA, Baca M, Adams R, et al: Night splint treatment for plantar fasciitis. A prospective randomized study. *Clin Orthop 368:* 190–195, 1999
34. Rompe JD, Hopf C, Nafe B, et al: Low-energy extracorporeal shock wave therapy for painful heel. A prospective controlled single-blind study. *Arch Orthop Trauma Surg 115:* 75–79, 1996
35. Rompe JD, Kirkpatrick CJ, Kullmer K, et al: Dose-related effects of shock waves on rabbit tendo Achillis. A sonographic and histological study. *J Bone Joint Surg 80B:* 546–552, 1998
36. Rompe JD, Schoellner C, Nafe B: Evaluation of low-energy extracorporeal shock-wave application and treatment of chronic plantar fasciitis. *J Bone Joint Surg 84A:* 335–341, 2002
37. Schepsis AA, Leach RE, Gorzyca J: Plantar fasciitis. Etiology, treatment, surgical results, and review of the literature. *Clin Orthop 266:* 185–196, 1991

38. Sistermann R, Katthagen BD: Five-year lithotripsy of plantar heel spur: Experiences and results. A follow-up study after 36.9 months [in German]. *Z Orthop Ihre Grenzgeb 136:* 402–406, 1998
39. Sobel E, Levitz SJ, Caselli MA: Orthoses in the treatment of rearfoot problems. *J Am Podiatr Med Assoc 89:* 220–233, 1999
40. Steinborn M, Heuck A, Maier M, et al: MRI of plantar fasciitis [in German]. *RoFo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr 170:* 41–46, 1999
41. Theodorou DJ, Theodorou SJ, Kakitsubata Y, et al: Plantar fasciitis and fascial rupture: MR imaging findings in 26 patients supplemented with anatomic data in cadavers. *Radiographics 20:* S181–S197, 2000
42. Tomczak RL, Haverstock BD: A retrospective comparison of endoscopic plantar fasciotomy to open plantar fasciotomy with heel spur resection for chronic plantar fasciitis/heel spur syndrome. *J Foot Ankle Surg 34:* 305–311, 1995
43. Wang CJ, Chen HS, Chen SW, et al: Treatment of painful heels using extracorporeal shock wave. *J Formos Med Assoc 99:* 580–583, 2000
44. Wapner KL, Sharkey PF: The use of night splints for treatment of recalcitrant plantar fasciitis. *Foot Ankle 12:* 135–137, 1991
45. Ward WG, Clippinger FW: Proximal medial longitudinal arch incision for plantar fascia release. *Foot Ankle 8:* 152–155, 1987
46. Young CC, Rutherford DS, Niedfeldt MW: Treatment of plantar fasciitis. *Am Fam Physician 63:* 467–478, 2001