

Long-term Results of Extracorporeal Shockwave Treatment for Plantar Fasciitis

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Background: Extracorporeal shockwave treatment has shown mixed short-term results for plantar fasciitis. However, the long-term results are not available.

Hypothesis: Long-term results of shockwave treatment are comparable with short-term results.

Study Design: Randomized controlled clinical trial; Level of evidence, 1.

Methods: This prospective study consisted of 149 patients (168 heels) with an established diagnosis of chronic plantar fasciitis, including 79 patients (85 heels) in the shockwave treatment group and 70 patients (83 heels) in the control group. In the shockwave group, patients received 1500 impulses of shockwaves at 16 kV to the affected heel in a single session. Patients in the control group received conservative treatment consisting of nonsteroidal anti-inflammatory drugs, orthotics, physical therapy, an exercise program, and/or a local cortisone injection. Patients were evaluated at 60 to 72 months (shockwave group) or 34 to 64 months (control group) with a 100-point scoring system including 70 points for pain and 30 points for function. The clinical outcomes were rated as excellent, good, fair, or poor.

Results: Before treatment, the groups showed no significant differences in the scores for pain and function. After treatment, the shockwave group showed significantly better pain and function scores as compared with the control group. The overall results were 69.1% excellent, 13.6% good, 6.2% fair, and 11.1% poor for the shockwave group; and 0% excellent, 55% good, 36% fair, and 9% poor for the control group ($P < .001$). The recurrence rate was 11% (9/81 heels) for the shockwave group versus 55% (43/78 heels) for the control group ($P < .001$). There were no systemic or local complications or device-related problems.

Conclusion: Extracorporeal shockwave treatment is effective and safe for patients with plantar fasciitis, with good long-term results.

Keywords: plantar fasciitis; shockwave treatment; long-term result

Plantar fasciitis is a common orthopaedic disorder of unknown origin, and the role of heel spurs in the causation of heel pain remains controversial.¹⁶ The goals of treatment are to alleviate pain and restore function. Nonoperative treatments, including nonsteroidal anti-inflammatory drugs (NSAIDs), orthotics, physical therapy, exercise, or local cortisone injection, are the initial choice. The results from such treatments vary considerably, and there is no consensus of opinion on the best method.^{5,23} Surgical treatment with either open or endoscopic release of the plantar fascia is

recommended in patients who fail to respond to nonoperative treatment.⁸ However, the results of surgery are inconsistent and unpredictable.^{8,16}

Extracorporeal shockwave treatment was recently introduced for the alleviation of pain due to plantar fasciitis, with mixed short-term results.^{1,2,4,7,9-15,18,19,22} However, the long-term results are lacking. The purpose of this study was to evaluate the result of shockwave treatment for plantar fasciitis, with 5- to 6-year follow-up.

PATIENTS AND METHODS

Inclusion criteria consisted of patients with diagnosed plantar fasciitis established by clinical examination and radiographs of the heel. The diagnosis was made by patient history and physical examination. Radiographic evidence of a heel spur was not required. Exclusion criteria consisted of patients with systemic or local infection, diabetes mellitus, obstructive peripheral vascular disease, metabolic

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TABLE 1
Patient Characteristics

	Shockwave Group	Control Group
No. of patients/heels	76/81	65/78
Gender, male/female	18/58	25/40
Affected side, right/left	39/42	44/34
Age (mean \pm SD [range]), y	53.2 \pm 11.0 [21-75]	51.6 \pm 9.8 [20-74]
Duration of disease (mean \pm SD [range]), mo	9.8 \pm 9.6 [6-36]	9.4 \pm 12.9 [6-38]
Follow-up time (mean \pm SD [range]), mo	64.1 \pm 4.3 [60-72]	39.8 \pm 9.9 [34-64]

disease such as gout, pregnancy, or patients younger than 18 years.

Between February 1998 and December 1999, 149 patients (168 heels) with an established diagnosis of plantar fasciitis were enrolled in this study, including 79 patients (85 heels) in the shockwave group and 70 patients (83 heels) in the control group. The diagnosis was made primarily based on patient history and physical examination, including heel pain and local tenderness over the plantar medial aspect of the calcaneal tuberosity near the insertion site of the plantar fascia. Radiographs showed the presence of a heel spur in approximately 75% of the cases. Patients were randomly divided to receive either shockwave or conservative treatment (control group) based on their medical record numbers; patients with odd chart numbers were assigned to the shockwave group, and patients with even chart numbers were assigned to the control group. Six patients in the shockwave group and 13 in the control group received treatment to both heels. Approximately one quarter of the patients in both groups were recreational athletes in running sports. Patient characteristics are summarized in Table 1.

In the shockwave group, patients received 1500 impulses of shockwaves at 16 kV (energy flux density, 0.32 mJ/mm²) to the affected heel as a 1-time treatment. The source of the shockwaves was an OssaTron Orthotripter (High Medical Technology, Kruezingen, Switzerland). Treatments were performed on an outpatient basis using local anesthesia with 2% xylocaine. The area of treatment was focused with a control guide on the machine, and surgical lubricant was placed on the skin in contact with the shockwave tube. The patient's vital signs and local discomfort were monitored throughout the course of treatment. The treated area was inspected for local swelling, ecchymosis, or hematoma immediately after the treatment. Patients were sent home with a nonnarcotic analgesic such as acetaminophen; NSAIDs were not prescribed. A second or third treatment was recommended to patients with inadequate response 30 to 45 days after the first treatment. Overall, 58 patients (60 heels) received only 1 treatment, 16 patients (19 heels) received 2 treatments, and 5 patients (6 heels) received 3 treatments.

Patients in the control group were treated with NSAIDs, orthotics, physical therapy, an exercise program, or a local cortisone injection. Patients were initially treated with a single modality (NSAIDs). Additional modalities such as physical therapy, orthotics, and an exercise program were subsequently prescribed, either singularly or in combination, if the initial modality failed to provide satisfactory

TABLE 2
100-Point Scoring System for Plantar Fasciitis

I. Pain score (70 points):	
1. Pain on maximal distance for level walking (0-45 points)	0 m, 0 points < 100 m, 15 points < 1000 m, 30 points > 1000 m, 45 points
2. Start-up pain (0-5 points)	Yes, 0 points No, 5 points
3. Pressure pain (0-20 points)	Severe pain, 0 points No pain, 20 points
II. Function score (30 points):	
1. Pain at work (0-10 points)	Severe restriction, 0 points No restriction, 10 points
2. Pain during free time/sports (0-10 points)	Severe restriction, 0 points No restriction, 10 points
3. Pain at night (0-10 points)	Severe restriction, 0 points No restriction, 10 points

results or if patients developed recurrence of symptoms. A local cortisone injection with 0.5 mL of betamethasone (7 mg/mL) and 1.0 mL of 2% xylocaine was given only to patients with severe heel pain.

Follow-up examinations were performed independently by one of the coauthors, who was blinded to patient treatment status. A 100-point scoring system including 70 points for pain and 30 points for function was used for evaluation (Table 2). Pain intensity was recorded on a 10-point visual analog scale, with 0 for no pain and 10 for severe pain. Radiographs of the heel were obtained before treatment and at the most recent follow-up examination. The clinical outcomes were rated as excellent, good, fair, or poor. An excellent result was defined as having no heel pain on all activities of daily living, including sports; a good result as having less than 50% of the original heel pain on certain activities, including sports; a fair result as having 50% to 75% of the original heel pain on certain activities; and a poor result as having 75% or more of the original heel pain.

TABLE 3
Pain Intensity Before and After Treatment

	Visual Analog Scale ^a Score		
	Mean	SD	Range
Shockwave group			
Before treatment (79 patients/85 heels)	4.0	1.3	2-8
After treatment (76 patients/81 heels)	0.2	0.7	0-4
Control group			
Before treatment (70 patients/83 heels)	4.1	1.1	2-8
After treatment (65 patients/78 heels)	4.2	1.7	2-8

^a10-point visual analog scale for pain intensity; 0 = no pain, 10 = severe pain.

^b $P < .001$.

^c $P = .478$.

^d $P = .179$.

Statistical Analysis

The scores for pain and function before and after treatment within the same group were compared statistically using a paired *t* test, and the data between the shockwave and control groups were compared statistically using the Mann-Whitney test, with statistical significance at $P < .05$.

RESULTS

Eight patients (9 heels) were excluded, including 3 patients (4 heels) in the shockwave group and 5 patients (5 heels) in the control group. In the shockwave group, 1 patient (2 heels) died of unrelated causes, and 2 patients (2 heels) were lost to follow-up. In the control group, 5 patients (5 heels) were lost to follow-up. Therefore, 76 patients (81 heels) in the shockwave group and 65 patients (78 heels) in the control group were included in the final analysis.

The changes in pain intensity before and after treatment are summarized in Table 3. Before treatment, the intensity of pain was comparable between the 2 groups ($P = .179$). After treatment, a statistically significant improvement in pain intensity was noticed in the shockwave group as compared with the control group ($P < .001$).

The pain and function scores before and after treatment are summarized in Table 4. Before treatment, the scores for pain and function were comparable between the 2 groups (pain scores before treatment, $P = .174$; function scores before treatment, $P = .165$). After treatment, statistically significant improvements in the pain and function scores were observed in the shockwave group, whereas the changes in the control group were not significant. The differences in the pain and function scores after treatment between the 2 groups were statistically significant (pain and function scores, $P < .001$).

Before treatment, 75% of patients showed heel spur on radiographs. Radiographs of the heel before and after treatment showed no discernible difference in the size and shape of the heel spur. There was no regression of the heel spur or formation of a new spur.

The overall results were 69.1% (56/81 heels) excellent, 13.6% (11 heels) good, 6.2% (5 heels) fair, and 11.1% (9 heels) poor for the shockwave group; and 0% excellent, 55% (43/78 heels) good, 36% (28 heels) fair, and 9% (7 heels) poor for the control group ($P < .001$). Most patients in the shockwave group improved within 2 weeks, with the most beneficial effects seen after 1 to 2 months. Approximately two thirds of the athletic patients were able to resume full activities, including running sports. Recurrence of symptoms occurred in 11% (9/81 heels) of the shockwave group and in 55% (43/78 heels) of the control group ($P < .001$). In the control group, the frequency of recurrent symptoms averaged 7.3 ± 5.8 times (range, 1-25 times), and the duration of recurrence averaged 5.4 ± 2.8 months (range, 1-12 months). In the shockwave group, 2 patients (2 heels) chose surgery, and 7 patients (7 heels) received alternative methods of treatment, including herbal medicine; these patients had been classified as poor results. The interim results of this group were good to excellent in 91%; their recurrence rate was 6%, with 6- to 12-month follow-up.^{18,19} There were no systemic or local complications or device-related problems.

DISCUSSION

The optimal nonoperative treatment for plantar fasciitis is unclear. Many studies documented good clinical results with different regimens of nonsurgical treatment.²³ In contrast, other studies reported that most of the conservative treatments were found to be unpredictable or minimally effective.⁵ The results of the current study showed that conservative treatments for plantar fasciitis achieved only 55% good or excellent results, with a recurrence rate of 55%. This result was in part because of the fact that the majority of our patients were initially treated elsewhere and subsequently referred to the tertiary hospital for further treatment after persistent or recurrent symptoms. Therefore, most patients were evaluated with symptoms of refractory plantar fasciitis before treatment.

Shockwaves are high-energy acoustic waves generated by an underwater high-voltage condenser spark discharge and

TABLE 4
Pain Scores and Function Scores Before and After Treatment

	Pain Score (70 points)		
	Mean	SD	Range
Shockwave group			
Before treatment	25.4	12.4	0-65
After treatment	69.3	4.0	45-70
Control group			
Before treatment	27.3	13.8	2-38
After treatment	28.1	14.0	2-40

	Function Score (30 points)		
	Mean	SD	Range
Shockwave group			
Before treatment	14.1	4.0	2-26
After treatment	29.6	1.9	18-30
Control group			
Before treatment	13.8	1.6	10-17
After treatment	14.0	1.63	10-17

^a*P* < .001.
^b*P* = .361.
^c*P* = .174.
^d*P* = .190.
^e*P* = .165.

then focused at the diseased area using an elliptical reflector. The pattern of shockwaves is monophasic, consisting of a high peak positive pressure of 100 MPa or 500 bars and a low negative tensile pressure of 10 MPa, with a broad frequency of 16 to 20 MHz. Shockwaves differ from ultrasound waves, which are typically biphasic and have a peak pressure of 0.5 bars. Therefore, the peak pressure of shockwaves is approximately 1000 times that of ultrasound waves. There are 2 basic effects of shockwaves, including the primary effect by direct mechanical forces that generate the beneficial pulse energy at the treatment site and the secondary effect by cavitation that may cause negative effects or damage to the tissue. In Europe, extracorporeal shockwaves have been used with success in the treatment of several musculoskeletal disorders, including nonunion of long-bone fracture, calcific tendinitis of the shoulder, lateral epicondylitis of the elbow, and plantar fasciitis, for more than 15 years.^{9,10,11,15-17} In the United States, the Federal Drug Administration (FDA) first approved shockwave therapy for proximal plantar fasciitis in October 2000. Currently, FDA-approved devices include HealthTronics OssaTron (for the heel in 2000 and for the elbow in 2003), Dornier Epos (for the heel in 2002), Siemens Sonocur (for the elbow in 2002), and Medispec Orthospec (for the heel in 2005).

Many studies have reported consistently good results for shockwaves in the treatment of plantar fasciitis in the short term.^{2,4,7,10,14,15,18,19} Some authors also reported that the results of shockwaves are comparable with those after surgical treatment, without the surgical risks and complications.^{15,22} Weil et al²² reported satisfactory results in 82% of

patients treated with shockwaves and 83% of those treated with percutaneous plantar fasciotomy in 46 feet treated for plantar fasciitis. The results of our previous studies showed that shockwave treatment yielded 91% satisfactory results, with a 6% recurrence rate for patients with plantar fasciitis with 6- to 12-month follow-up.^{18,19} The results of the current study showed that shockwave treatment provides 82.7% good to excellent results, with a 11% recurrence rate at 5- to 6-year follow-up. Despite the changes in efficacy and recurrence rate, the overall findings demonstrate that shockwave treatment is more effective with less recurrence than is conservative treatment for plantar fasciitis in the long term.

Few studies have reported negative effects of shockwaves in the treatment of plantar fasciitis.^{3,6,17} Buchbinder et al³ reported no beneficial effect on pain, function, and quality of life of low-energy shockwaves over placebo in patients with plantar fasciitis 6 and 12 weeks after treatment. Haake et al⁶ stated that extracorporeal shockwaves were ineffective in the treatment of chronic plantar fasciitis, with results comparable with those of placebo. The disparity of the results from such studies may be attributed to many factors, including the bias in selecting patients with a short duration of disease, the administration of low-dose shockwaves in the control study, the use of different shockwave devices with low energy levels, and the short 12- to 15-week follow-up.

Despite the success in clinical application, the mechanism of shockwaves remains unknown. It has been postulated that shockwaves induce hyperstimulation analgesia by

increasing the threshold of pain.¹⁰ Recently, Wang et al^{20,21} demonstrated that shockwaves induce neovascularization associated with increased expressions of angiogenic growth factors, including endothelial nitric oxide synthase (eNOS), vessel endothelial growth factor (VEGF), and proliferating cell nuclear antigen (PCNA) at the tendon-bone junction in rabbits. Neovascularization may play a role in the increase in blood supply that leads to repair of the tendon. The causes of plantar fasciitis are multifactorial and include inflammation, degenerative changes, and overuse injury associated with hypovascularity of the affected plantar fascia. We surmise that shockwaves relieve heel pain by increasing the threshold of pain and cause biological responses as well as improving blood supply to the heel.

The strengths of this study include adequate numbers of patients in the treatment and control groups with sufficient length of follow-up time. The weaknesses include lack of standardization in the control group, as most patients received various modalities of treatment, and lack of a sham procedure in the study design. Furthermore, there are many unanswered questions regarding musculoskeletal shockwaves. The definition of high- and low-energy shockwaves is poorly defined. At the present time, a high-energy shockwave is arbitrarily defined as having an energy flux density of 0.47 mJ/mm² or higher, whereas a low-energy shockwave has an energy flux density of 0.18 mJ/mm².

In conclusion, extracorporeal shockwave treatment is a new therapeutic modality that can safely and effectively treat patients with plantar fasciitis, with good long-term results.

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