Extracorporeal Shock Wave Therapy for the Treatment of Plantar Fasciitis

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ABSTRACT

One hundred fifty patients were enrolled in a multicenter, randomized, placebo-controlled, prospective, double-blind study to assess the clinical safety and effectiveness of extracorporeal shock wave therapy (ESWT) using the Dornier Epos Ultra for the treatment of plantar fasciitis. The Active Group was treated with electromagnetically generated shocks using ultrasound guidance during a single therapy session. The Control Group received a sham treatment under similar clinical conditions. The groups were demographically similar with respect to age, height, and weight. The average duration of symptoms was nearly 2 years in both groups. All patients were evaluated by the visual analog scale for pain, American Orthopaedic Foot and Ankle Society scores, Roles and Maudsley Score, SF-12 health status questionnaire, and physical examination. The Active Group reported 56% success at 3 months and 94% success at 12 months posttreatment. The Control Group reported 47% success at 3 months posttreatment. Twelve-month data were not collected for the Control Group as they were unblinded at 3 months and offered treatment. ESWT represents a safe treatment option for chronic proximal plantar fasciitis.

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INTRODUCTION

Plantar fasciitis is a common foot disorder in which symptoms may become chronic and functionally disabling. Various predisposing factors have been suggested for plantar fasciitis, including minor trauma, foot pronation, improper fitting shoes, obesity, and jobs that require prolonged standing.[5,7,10,13,21,30] This condition likely involves a traction degeneration of the plantar fascia band at its origin in the medial calcaneal tuberosity.[27] Many treatments have been employed, including stretching exercises, shoe inserts, cortisone injections, physical therapy, night splints, and surgery, with variable success.[7,15,19,20,26,31]

Extracorporeal shock wave therapy (ESWT) is evolving as a treatment option for this disorder. Preliminary studies[3,9,17,22,23,24] have reported success rates between 48% and 81% in eliminating heel pain. Both low- and high-energy protocols have been utilized.[9,17,22,24] The purpose of this study was to evaluate further the clinical effectiveness of high-energy shock wave therapy for the treatment of plantar fasciitis during a single therapeutic session.

MATERIALS AND METHODS

A total of 150 patients with chronic plantar fasciitis were enrolled in a randomized, 1:1 allocated, placebo-controlled, prospective, double-blind study at six clinical sites. Seventy-six patients were enrolled in the Active Group, which received ESWT, and 74 patients were enrolled in the Control Group, which received a sham treatment. All patients were screened for eligibility into the study by meeting the inclusion and exclusion criteria (Table 1).

The study group consisted of 109 women and 41 men. The mean age was 50 years (range, 26–69) for the

Table 1: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
• Greater than 18 years of age • Unilateral single-site plantar medial heel pain • Symptoms greater than 6 months • Participation in a prescribed stretching program within the last 6 months • Pain with local pressure over the medial calcaneal tuberosity with passive dorsiflexion of the foot • Visual analog scale (VAS) score >5 (0- to 10-cm scale) for pain during the first few minutes of walking in the morning • Roles and Maudsley Score of 3 or 4 (fair, poor) • History of 6 months of unsuccessful therapy to include NSAIDs and at least two other therapies (physical therapy, orthotics, stretching exercises, cortisone injection, and casting) • Willingness to forgo any other concomitant therapies for the duration of the study	• Previous surgery or shock wave treatment for plantar fasciitis • Corticosteroid injection within 1 month of treatment • History of documented autoimmune or systemic inflammatory disorder • Coagulation abnormalities • Peripheral vascular disease • Diabetes • Local tumor • Calcaneal stress fracture • Infections • Pregnancy • Peripheral neuropathy • Loss of ankle/foot sensation as assessed by Semmes-Weinstein 10-g monofilament wire system • Presence of cardiac pacemaker • Sensitivity or allergy to xylocaine • Bilateral symptoms • Anticoagulant therapy within 7 days of treatment • Bleeding disorder or hemophilia • Clubfoot • Reflex sympathetic dystrophy • Nonpalpable posterior tibial and dorsalis pedis pulses • Abnormal capillary refill • Previous conservative treatment within 2 weeks of treatment • Inability to understand or complete the outcome forms or follow the protocol

Active Group and 53 years (range, 31–72) for the Control Group. The mean duration of symptoms was 22 months (range, 6–120) for the Active Group and 24 months (range, 6–99) for the Control Group. Variables such as height, weight, affected foot, participation in weekly exercises, and time required to stand were comparable between the two groups (Table 2).

All study patients, including the Control Group, were given a medial calcaneal nerve block using 5 mL of 1% xylocaine 15–20 minutes prior to the procedure. All patients were placed in the prone position and ultrasound visualization of the proximal plantar fascia origin was performed. The Active Group received 3800 shocks (3500 at 0.36 mJ/mm^2) for a total of 1300 mJ/mm^2. The Control Group went through the identical process but had a thin air cushion placed on the therapy head to prevent shock wave penetration into the foot.

The air cushion was placed prior to the patient entering the treatment room to further ensure blinding.

Shock waves were generated using the Epos Ultra device (Dornier MedTech America, Inc., Atlanta, GA). The Dornier Epos Ultra is an electromagnetic system, which uses an electromagnetic coil and an opposing metal membrane to produce a magnetic field that compresses the surrounding fluid medium to generate a shock wave. An isocentric ultrasound is included in the Epos Ultra system to allow precise shock wave delivery to the tissues.

The position of the shock wave source was modified during the treatment using the ultrasound image and patient feedback to ensure that the shock wave focus was directed precisely into the pain epicenter. Pain intensity during treatment and immediately posttreatment was recorded for all patients, as well as any adverse effects.

Table 2: Patient demographics

Characteristic	Active Group (n = 76)	Control Group (n = 74)	p Value[a]
Age (years)			NS
Mean	50	53	
Range	26–69	31–72	
Gender			
Male	14 (18.0%)	27 (36.5%)	NS
Female	62 (81.6%)	47 (63.5%)	.0156
Height (inches)			
Mean	66	68	.0131
Range	6.4–77.0	56.0–79.5	
Weight (lbs)			
Mean	180	186	NS
Range	12.0–294.0	115.0–39.0	
Affected Foot			
Right	46%	55%	NS
Left	54%	45%	NS
Required to stand	55%	68%	NS
Participation in weekly exercise	55%	60%	NS
Duration of symptoms (months)			
Mean	22	24.1	NS
Range	6–120	3.0–99.0	

[a]p-value associated with two-way analysis of variance (ANOVA) for continuous parameters and Cochran-Mantel Haenszel for categorical variables.

All patients were evaluated at pretreatment and at 3–5 days, 6 weeks, 3 months, 6 months, and 12 months posttreatment. Patients were assessed by means of the visual analog scale (VAS) for pain during the first few minutes of walking in the morning, pain with normal activity during the day, pain with leisure time/sport-related physical activity, and pain prior to going to bed for the evening. A Roles and Maudsley Score, SF-12 health status questionnaire, American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scoring System questionnaire, and physical examination, including pressure threshold measurement (PTM, Pain Diagnostics and Thermography, Great Neck, NY) were also used. Evaluations were performed at each center by an independent physician who was blinded to the treatment status of the patients (Table 3).

The study patients were unblinded at 3 months posttreatment. Those patients in the Control Group who had not experienced improvement were offered active ESWT. These patients constituted the "Crossover Group."

The primary outcome measure of pain while walking for the first few minutes in the morning (VAS score) was used to determine an appropriate sample size for the clinical investigation. The sample size was created based on effect size, which was calculated from expected differences in changes in VAS scores at 3 months. Clinical success was defined as 60% improvement for the Active Group and 35% improvement for the Control Group. Additional assumptions were as follows: significance level of .05, 80% power, a two-sided t test method, and a projected 15% dropout rate. The calculation was determined by using Statistical Solutions nQuery Advisor® Release 3. Using this software, the sample size per treatment group was thought to be adequate to detect significant differences between the two groups.

RESULTS

Primary and secondary efficacy end points were defined. The primary efficacy end point of the change from baseline in the VAS pain score while walking for the first few minutes in the morning was analyzed to determine the difference between Active and Control groups by using a repeated measures analysis of covariance. Covariates included in the model were baseline pain score, body weight, and duration of symptoms. In addition, the proportion of patients achieving at least a 60% improvement in pain while

Table 3: Baseline values for primary and secondary end points

Parameter	Active Group (*n* = 76)	Control Group (*n* = 74)	*p* Value (*n* = 150)
VAS pain: 1° End point (0–10)			
Mean	7.7	7.7	.9644
Range	5.0–1.0	4.7–1.0	
Mean AOFAS pain	13.4	12.2	.4746
Severe = 0			
Moderate = 20			
Mild = 30			
None = 40			
Mean Roles & Maudsley Score	3.8	3.8	.3217
Excellent = 1			
Good = 2			
Fair = 3			
Poor = 4			
Mean SF-12 (Mental)	53	52	.2410
Mean SF-12 (Physical)	39	38	.4733
Mean AOFAS ROM-Sagittal	7.4	7.0	.0710
Normal/Mild = 8			
Moderate = 4			
Severe = 0			
Mean AOFAS ROM-Hindfoot	5.5	5.5	.6954
Normal/Mild = 6			
Moderate = 3			
Marked = 0			
Pain on palpation (kg)			
Mean	5.8	5.6	.4533
Range	1.1–15.9	1.3–13.3	

walking for the first few minutes in the morning was compared between the two groups at 3 months.

In the Active Group, the mean pain score decreased from 7.7 ± 1.4 at baseline to 3.4 ± 2.8 at 3 months posttreatment ($p = .0001$), resulting in a mean percent improvement of 57%. In the Control Group, the mean score decreased from 7.7 ± 1.5 at baseline to 4.1 ± 3.1 at 3 months posttreatment ($p = .0001$), resulting in a mean percent improvement of 47%. Comparison between groups in change from baseline, at 3 months, via an analysis of covariance with fixed effects for treatment site and covariates of baseline VAS, body weight, and duration of symptoms, resulted in a significant treatment effect ($p = .0435$) (Table 4). The treatment difference through 3 months in the change from baseline in VAS pain was statistically significant using a repeated measures analysis of covariance ($p = .0149$) on completed patients. Follow-up compliance at 3 months was 96% in the Active Group and 99% in the Control Group. Three patients in the Active Group and one patient in the Control Group discontinued the study prior to the 3-month follow-up visit. At 12 months

posttreatment, the Active Group (50/76) had a 91% improvement from baseline (Table 5).

The proportion of patients achieving at least a 60% improvement (clinical success) in pain during the first few minutes of walking in morning was compared between the two groups at 3 months. In the Active Group, 56% (41/73) of the patients achieved a 60% reduction in their VAS pain score compared to 45% (33/73) in the Control Group. The difference between the groups, with the numbers available, did not reach statistical significance ($p = .1885$).

The clinical data showed that, on average, patients with a higher baseline VAS score, a longer duration of symptoms, or a greater body weight had a greater improvement in VAS pain score. In addition, for patients who had symptoms for >12 months, those in the Active Group had a significantly greater reduction in pain (−5.1 change on average), as compared to the Control Group, (−3.7 change on average), $p = .0309$. This significant treatment effect in this subgroup was supported by the comparability between treatment groups in symptom duration at baseline.

Table 4: VAS scores for active and control groups — baseline through 3 months posttreatment

Group	Baseline	3–5 Days	6 Weeks	3 Months	Change From Baseline[a]	p Value[b]
Active Group						
N	76	74	72	73	—	.0001
Mean	7.7	5.0	4.6	3.4	−4.4	
SD	1.4	2.8	3.1	2.7	2.8	
Control Group						
N	74	74	71	73	—	.0001
Mean	7.7	5.7	5.0	4.1	−3.6	
SD	1.5	2.8	3.0	3.1	3.1	

[a]Comparison between treatments in change from baseline, via an analysis of covariance with fixed effects for treatment and site and covariates of baseline VAS, body weight, and duration of symptoms, resulted in a significant treatment effect at $p = .0435$.
[b]Paired t test

Table 5: VAS (first few minutes of walking in the morning)

Group	Baseline	3–5 Days	6 Weeks	3 Months	6 Months	12 Months	% Change From Baseline
Active Group							
N	76	74	72	73	58	50	91.3%
Mean	7.7	5.0	4.6	3.4	2.2	.6	
SD	1.4	2.8	3.1	2.7	2.6	1.2	
Control Group[a]							
N	74	74	71	73	—	—	—
Mean	7.7	5.7	5.0	4.1	—		
SD	1.5	2.8	3.0	3.1			

[a]Control Group was unblinded at 3 months which is why no data are shown for 6 and 12 months.

The secondary efficacy end points included the Roles and Maudsley Score, which is a four-point patient self-assessment of pain and limitations of activity. At 3 months posttreatment, the Active Group had 62% (45/73) of the patients change from a fair/poor response at baseline to an excellent/good assessment, compared to 40% (29/73) for the Control Group (Table 6). This comparison was statistically significant ($p = .0327$).

Other secondary end points, including AOFAS Ankle-Hindfoot scale and SF-12 health status questionnaire, did not show statistically significant differences between the two groups. Numerical trends in favor of the Active Group, though not statistically significant, were observed in the AOFAS pain score and the SF-12 physical component score.

Adverse events were evaluated by the type, nature, severity, and intensity during treatment and at each follow-up visit (Table 7). The most common adverse events observed were pain during the treatment and pain at 3–5 days posttreatment. These events all resolved within a week of the treatment. One patient withdrew from the study before resolution of paresthesia. This adverse event was coded as permanent as no additional follow-up was obtainable after withdrawal. The adverse event was moderate in intensity and was coded by the investigator as anticipated/not serious. There were no other long-term complications.

DISCUSSION

When plantar fasciitis fails to respond to multiple nonsurgical treatments over an extended period of time, surgical fasciotomy is often recommended.[2,15,19,25,26] Surgery may be associated with variable success, complications, prolonged recovery time, and loss of time from work.[4,6,12,14,29] Many patients and physicians

Table 6: Roles & Maudsley through 12 months posttreatment

Time Period	Excellent to Good (Score of 1 or 2)		Fair to Poor (Score of 3 or 4)		p Value
	Active Group	Control Group[a]	Active Group	Control Group[a]	
Baseline	1/76 (1.3%)	1/73 (1.4%)	75/76 (98.7%)	72/73 (98.6%)	.3217
6 weeks	25/72 (35.7%)	23/71 (32.4%)	47/72 (65.3%)	48/71 (67.6%)	.9343
3 months	45/73 (61.6%)	29/73 (39.7%)	28/73 (38.4%)	44/73 (6.3%)	.0327
6 months	39/58 (67.2%)	—	18/58 (31.0%)	—	—
12 months	48/51 (94.1%)	—	3/51 (5.9%)	—	—

Roles and Maudsley not evaluated at 3–5 days posttreatment.
[a]Control Group was unblinded at 3 months which is why no data are shown for 6 and 12 months.

Table 7: Adverse events treatment through 3-month follow-up

Adverse Event	Active Group (n = 76)			Control Group (n = 74)			p Value
	Number of Patients[a]	Number of Occurrences	% of Patients	Number of Patients[a]	Number of Occurrences	% of Patients	–
Pain during treatment[b]	55	55	73%	5	5	7%	<.001
Pain post-treatment[c]	28	31	37%	24	26	32%	1.0000
Edema	5	5	7%	6	7	8%	.3655
Ecchymosis	5	5	7%	4	4	5%	1.0000
Petechiae	0	0	0%	1	1	1%	.4933
Rash	1	1	1%	0	0	0%	1.0000
Hypesthesia	2	3	3%	6	6	8%	1.0000
Neuralgia	1	1	1%	0	0	0%	1.0000
Paresthesia	3	3	4%	3	4	4%	1.0000
Total events		104			53		—

[a]Number of patients experiencing at least one occurrence.
[b]Pain during shock wave application: statistical significance with p value < .0001 by Fischer's Exact test.
[c]Pain experienced immediately after treatment through 3-month follow-up.

will often discount the surgical option entirely because of uncertain results, therefore leading to acceptance of chronic pain and loss of function.

As an alternative to surgery, ESWT has several advantages. First, it is a noninvasive technology without the obvious potential complications associated with surgery. Second, it has a relatively limited recovery time during which the patient may return to employment and normal activities the day following treatment.[18] Third, it demonstrates a success rate comparable to surgery and even to other conventional therapies for this disorder.[4,15] Finally, it has the potential to be utilized earlier in the course of this disease, which may limit patient suffering and healthcare costs.

The exact mechanism of extracorporeal shock wave therapy remains undefined. There may be an effect on local pain receptors leading to hyperstimulation of axons and a reflex analgesic effect.[1,16] Other investigators have shown an inflammatory response at the area of healing with cellular changes, including release of nitrous oxide and growth factors.[28] It is also apparent that higher energy shock waves ($0.28–0.6 \text{ mJ/mm}^2$) initiate a more effective and quicker clinical response than low-energy waves (0.08 mJ/mm^2).[11,18]

This study utilized an ultrasound-mediated electromagnetic system, Epos Ultra, to deliver shock waves to the epicenter of pain during a single therapeutic session using high-energy density levels. This study

demonstrated a 57% improvement in VAS scores at 3 months (before unblinding) and a 94% success rate at 12 months posttreatment in the Active Group. Other secondary end points, such as Roles and Maudsley, indicated similar rates of improvement. These results were similar to other investigations.[8,9,22,23]

It should be noted that based on all available data, patients in the Crossover Group experienced a change from baseline VAS score, which was established using the original 3-month data, of 53% at 3 months ($p = $ $<.0001$, $n = 38$) and 76% at 12 months ($p = <.0001$, $n = 30$). Based on all available data, 78% (28/36) of the Crossover Group reported a good to excellent response at 3 months and 93.1% (27/29) at 12 months, compared to 22% (8/36) who reported a fair to poor response at 3 months and 6.9% (2/29) at 12 months.

AOFAS scores between the two groups in this study were found to have no statistical significance, primarily because patients with chronic plantar fasciitis did not demonstrate significant range-of-motion deficits either at baseline or posttreatment. Similarly, the SF-12 scores showed no significant difference because functional improvements are modest for this disorder in relatively normal patients, and the study was not designed with sufficient patients to observe statistically significant differences for these secondary outcomes.

The 47% improvement in VAS score from baseline in the Control Group deserves explanation. First, it is not unusual to observe 30% placebo improvement in chronic conditions. Second, although the mean duration of symptoms in this Control Group was 24 months, plantar fasciitis is considered a self-limited condition and these patients simply may have improved with time.[15] It should be noted that change from baseline VAS score was found to be statistically significant between groups ($p = .0309$) in patients who preoperatively presented with symptoms greater than 12 months.

In conclusion, extracorporeal shock wave therapy has emerged as a safe treatment option for chronic plantar fasciitis. This study demonstrates that electromagnetically generated, high-energy shock waves administered with ultrasound guidance during a single therapeutic session can safely produce clinical improvement by 3 months posttreatment.

ACKNOWLEDGMENTS

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