Randomized, Placebo-Controlled, Double-Blind Clinical Trial Evaluating the Treatment of Plantar Fasciitis with an Extracorporeal Shockwave Therapy (ESWT) Device: A North American Confirmatory Study

Patricia Kudo,[1] Katie Dainty,[1] Michael Clarfield,[2] Larry Coughlin,[3] Pauline Lavoie,[4] Constance Lebrun[1]

[1]Fowler Kennedy Sport Medicine Clinic, 3M Centre University of Western Ontario, London, Ontario N6A 3K7, Canada

[2]The Sports Medicine Specialists, 150 Eglinton Avenue East, Toronto, Ontario M4P 1E8, Canada

[3]West Island Orthopedic & Sports Medicine Center, 3881 Boulevard St-Jean Dollard-des-Ormeaux, Quebec H9G 2V1, Canada

[4]Action Sport Physio, 1451 rue Montarville, St-Bruno, Quebec J3V 3T6, Canada

Received 2 December 2004; accepted 16 May 2005

Published online 18 November 2005 in Wiley InterScience (www.interscience.wiley.com). DOI 10.1002/jor.20008

ABSTRACT: Despite numerous publications and clinical trials, the results of treatment of recalcitrant chronic plantar fasciitis with extracorporeal shockwave therapy (ESWT) still remain equivocal as to whether or not this treatment provides relief from the pain associated with this condition. The objective of this study was to determine whether extracorporeal shock wave therapy can safely and effectively relieve the pain associated with chronic plantar fasciitis compared to placebo treatment, as demonstrated by pain with walking in the morning. This was set in a multicenter, randomized, placebo-controlled, double-blind, confirmatory clinical study undertaken in four outpatient orthopedic clinics. The patients, 114 adult subjects with chronic plantar fasciitis, recalcitrant to conservative therapies for at least 6 months, were randomized to two groups. Treatment consisted of approximately 3,800 total shock waves (±10) reaching an approximated total energy delivery of 1,300 mJ/mm^2 (ED+) in a single session versus placebo treatment. This study demonstrated a statistically significant difference between treatment groups in the change from baseline to 3 months in the primary efficacy outcome of pain during the first few minutes of walking measured by a visual analog scale. There was also a statistically significant difference between treatments in the number of participants whose changes in Visual Analog Scale scores met the study definition of success at both 6 weeks and 3 months posttreatment; and between treatment groups in the change from baseline to 3 months posttreatment in the Roles and Maudsley Score. The results of this study confirm that ESWT administered with the Dornier Epos Ultra is a safe and effective treatment for recalcitrant plantar fasciitis. © 2005 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res 24:115–123, 2006

Keywords: plantar fasciitis; shock wave therapy; heel pain; ESWT

INTRODUCTION

In the past 20 years extracorporeal shock waves have been used to safely and effectively treat a number of medical conditions. Shock wave lithotripsy (ESWL) has been well established for over 20 years for the treatment of urologic conditions,[1] and more recently, there has been significant interest in orthopedic applications such as nonunion fractures and several types of tendonopathies. Despite numerous publications and clinical trials, one orthopedic application of ESWT, which still remains highly equivocal, is the treatment of chronic plantar fasciitis.

Correspondence to: Katie Dainty (Telephone: 416-480-6100, ext. 7227; E-mail: katie.dainty@sw.ca)

Plantar fasciitis is defined as a tensile overload of the plantar fascia at its origin on the medial tubercle of the calcaneus.[15] The plantar fascia is a thick fibrous tissue on the bottom of the foot that protects sensitive plantar structures such as nerves, vessels, muscles, and tendons, and in addition, is responsible for maintaining the plantar arch. The symptoms usually start as a dull intermittent pain that most often progresses to a sharp persistent pain. The patient typically suffers pain with the first steps in the morning or after period of prolonged sitting. This pain is aggravated by continuous weight bearing, and becomes progressively more severe. Its onset is insidious, and not always associated with a specific incident or trauma. Standard care at present is conservative treatment, but about 10% of patients fail to respond or heal spontaneously.[3] This extremely painful condition has been reported to effect up to 20% of the general population over their lifetime,[4] and is responsible for approximately 1 million patient visits per year in the United States.[5]

In a review of the current published literature on the use of shockwave therapy for the treatment of plantar fasciitis, several clinical trials were found. Among a plethora of nonrandomized publications, there are only six placebo-controlled trials.[6–11] all of which have reported extremely variable results. A meta-analysis done by Ogden et al. in 2002[12] found that those published studies that fulfilled the criteria for acceptable methodology with sufficient duration did show that directed application of shockwaves to the origin of the plantar fascia is a safe and effective nonsurgical method for treating chronic, recalcitrant heel pain syndrome.[4] However, recent studies such as those by Buchbinder et al.,[7] Haake et al.,[8] and Speed et al.[10] have reported no statistically significant differences in the degree of improvement between groups on measured outcomes.

Of those trials that reported a positive outcome, shock wave therapy for the treatment of plantar fasciitis was shown to be most efficacious with a single therapy session. A pivotal study approved by the Food and Drug Administration in 2002, showed that the Dornier Epos Ultra shockwave device could safely produce clinical improvement in chronic plantar fasciitis using a single therapeutic session.[11] The Active treatment group in this trial reported 56% success and the control group reported 47% success at 3 months posttreatment. Other publications from all over the world have shown success rates as high as 88%.[12]

Two ESWT devices have now gained approval from the Food and Drug Administration for the treatment of recalcitrant plantar fasciitis in the United States; however, the evidence is still divergent. The significant differences in the results of the various studies may be explained by a number of factors including technical differences (machine design, shock intensity and frequency, and the use of different forms of placebo treatment), as well as differences in subject populations, severity of disease, and study design. This highlights the need for further investigation using solid randomized prospective and confirmatory clinical trials. To further enhance the results shown in the first study using the Dornier Epos Ultra, the present study was designed as a confirmatory evidence trial to assess the safety and effectiveness of the Dornier Epos Ultra in the treatment of pain associated with chronic plantar fasciitis.

MATERIALS AND METHODS

This was a multicenter, randomized, placebo-controlled, prospective, double-blind, confirmatory clinical study with two groups: one group receiving ESWT with the Epos Ultra (Active group) and a Control group receiving placebo treatment. The objective of the study was to determine whether ESWT could safely and effectively relieve the pain associated with chronic plantar fasciitis compared to placebo treatment with a single high-energy treatment, as demonstrated by relief of pain with the first few minutes of walking in the morning.

The initial sample size calculation was based on the primary efficacy outcome, defined as the difference between the Active Epos treatment and the Placebo treatment measured by the change from baseline to 3 months in the Visual Analog Scale (VAS) score for pain while walking for the first few minutes in the morning ($p = 0.05$). The expected effect size of the primary outcome was estimated from the treatment difference and standard deviation of 1.4 and 3.0, respectively, found in the original pivotal U.S. clinical study[11] should be #13. The calculation was done using Statistical Solutions *nQuery Advisor*® Release 3.0 software, and was adjusted by 15% to account for attrition rates. Secondary efficacy outcomes included change scores for the American Orthopedic Foot and Ankle Society (AOFAS) ankle–hindfoot scale score[16] (pain and range of motion domains), the Roles and Maudsley Score[2] (a four-point patient self-assessment of pain and limitations of activity), the SF 12 Global Health Rating Scale,[14] and pain on palpation (point of tenderness) as measured with a pressure threshold meter (PTM, Pain Diagnostics and Thermography, Great Neck, NY). A

primary safety analysis was also done comparing the incidence of adverse events between groups at the time of treatment, and during follow-up. All follow-up data was measured by independent research investigators at each site, all of whom were blinded to the randomization assignment.

Recruitment

The study was conducted at four centers throughout Canada. Each site obtained approval from an institutional ethics review board review board prior to beginning the study. An Investigational Testing Authorization from the Therapeutic Products Programme Division of Health Canada was also granted. Subjects were recruited through outpatient clinics at each of the study sites. All coinvestigators were primary care, sport medicine physicians or orthopedic specialists and were trained on treatment with the Dornier Epos Ultra extracorporeal shockwave system prior to the study. All potential subjects were assessed according to the inclusion and exclusion criteria (Fig. 1) in the study protocol and signed informed consent prior to their baseline evaluation. Absence of a calcaneal fracture, bony abnormality, or other pathology (i.e., tumors) was confirmed with a lateral radiograph prior to treatment.

Randomization

The randomization scheme was generated by Biostat International, Inc., Tampa, Florida. Sealed, opaque, tamper-proof envelopes containing individual randomization assignments were provided to each investigational site prior to the beginning of the study. Subjects were randomized by the treating investigator just prior to the beginning of treatment. The first subject was randomized in November 2000, and the last subject was randomized in December 2002.

Treatment

All procedures were performed in outpatient settings using a single treatment method with the Dornier Epos Ultra extracorporeal shockwave therapy system (Dornier MedTech Systems, GmbH, Germany). The subjects were placed either prone (44.7% of subjects) or on their side (55.3% of subjects) on the examination table

Inclusion Criteria

- Greater than 18 years old and symptoms present for greater than 6 months
- Compliance with a physician prescribed stretching program for plantar fasciitis within the last 6 months
- A single site of tenderness and pain with local pressure over the medial calcaneal tuberosity on passive dorsiflexion of the foot
- Visual Analog Scale (VAS) score of >5 for pain during the first few minutes of walking in the morning
- History of 6 months of unsuccessful conservative therapy to include any NSAIDS AND at least two of the following therapies (rest, heel cushions, heat, ice, ultrasound, massage, orthotics, heelcups, steroid injection, casting, taping, shoe modifications, nightsplinting)
- Willingness to forgo any other concomitant therapy for the duration of the study
- Willingness to use adequate contraceptive measures to prevent pregnancy for 4 months after enrollment into study (for female subjects of child bearing capacity)
- Baseline Roles and Maudsley Score of 3 or 4
- Signed informed consent

Exclusion Criteria

- Previous treatment with anti-inflammatory medications, rest, stretching, heat, ice, ultrasound, massage, orthotics or other aids, casting, taping, or nightsplinting, within two (2) weeks of treatment
- Previous treatment with corticosteroid injection within one (1) month of treatment
- Previous surgery for plantar fasciitis or unresolved infection in the treatment area
- History or documented evidence of autoimmune or peripheral vascular disease
- Nonpalpable posterior tibial AND dorsalis pedis pulses or abnormal capillary refill
- History or documented evidence of Type I or Type II diabetes mellitus or peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.
- History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, etc.
- History or documented evidence of a worker's compensation/litigation
- History or documented evidence of loss of ankle/foot sensation as measured by Semmes-Weinstein 10-g monofilament wire system
- Pregnancy
- Reflex sympathetic dystrophy or Clubfoot
- History or documented evidence of bleeding disorder or hemophilia or use of Anticoagulant therapy (including aspirin) within 7 days of treatment
- History or documented evidence of generalized tumor(s) or tumor in the area
- Cardiac pacemaker
- Bilateral symptoms
- Calcaneal stress fracture as evidenced by positive squeeze test
- Known sensitivity or allergy to Xylocaine

Figure 1. Study inclusion/exclusion criteria.

with the study foot placed in a supported position. Choice of position was based on patient comfort. Prior to shock wave exposure, the area of pain was marked with an X on the skin to assist in focusing the delivery of the shock waves, and all study subjects, including the Placebo group, were given a medial calcaneal nerve block using 5 mL of 1% Xylocaine, 15–20 min prior to the procedure. The therapy head was coupled tangentially on the medial aspect of the foot, and ultrasound localization was used for positioning of the focal area.

The Active treatment session was performed using the energy levels indicated in Table 1. The energy parameter was 0.36 mJ/mm^2 (ED+), which is equivalent to 0.64 mJ/mm^2 (ED). Shock wave frequency began at 60 shocks/min, and was increased in increments of 30 shocks/min. During treatment, the frequency of release of the shock waves began at 60 shocks/min at level 1, and was increased by one level of 30 shocks/min at each energy level until 240 shocks/min were reached at level 7. Fifty (±10) shocks were delivered at levels 1–6 as the frequency was being increased. Approximately 3,500 (±10) shock waves were administered at level 7 to reach an approximated total energy delivery of 1,300 mJ/mm^2 (ED+) or 2,330 mJ/mm^2 (ED) (3,800 total shocks).

The Placebo group received the identical treatment procedure; however, shock waves were prevented from entering the subject's foot by a thin foam cushion placed on the therapy head with an application of ultrasound gel. The cushion was put in place prior to the subject's arrival in the treatment room to maintain blinding. A new cushion was used with each treatment session.

All treatments were performed according to instructions in the Epos Ultra Operating Manual. Pain intensity during treatment and immediately posttreatment were recorded, as well as any adverse events resulting during the treatment session. After treatment and at each follow-up visit, blinding was assessed by asking subjects to identify which treatment they believed they received. All subjects were instructed to eliminate athletic activities and pain medication posttherapy until the 6 week follow-up evaluation.

Follow-up

All subjects were evaluated by an independent (blinded) investigator at 3–5 days, 6 weeks, and 3 months posttreatment. Unblinding occurred at the 3-month visit. Subjects who received Active treatment continued in the study and were evaluated at 6 and 12 months posttreatment. Subjects who originally received placebo treatment and whose symptoms were still significant according to specified inclusion criteria were offered to "crossover," and receive Active treatment with the Epos Ultra after their 3 month follow-up visit. Subjects originally randomized to the Placebo group who elected not to cross over at 3 months were discontinued from study follow-up. All subjects were given a pain medication diary with instructions during screening and at each follow-up visit. Entries were made by the subject for any alternative medication taken between follow-up visits (i.e., Tylenol for a headache). All subjects underwent a physical examination including a pressure threshold measurement and were asked to assess their pain using a VAS for various activities of daily living, and complete the Roles and Maudsley Pain questionnaire, the AOFAS ankle–hindfoot scale, and the SF-12 Global Health Rating Scale before treatment and at follow-up visits. Adverse events were evaluated by the type, nature, severity, and intensity during treatment and at each follow-up visit. The last follow-up visit for the primary efficacy endpoint occurred in March 2003.

Statistical Analysis

All statistical analyses were performed using the SAS® System (Cary, NC), with a significance level of 0.05 and on an intention-to-treat basis. The primary analysis method was a two-sample *t*-test comparing treatment groups in the changes from baseline to 3 months posttreatment. Statistical testing also included a repeated measures analysis of the changes from baseline, testing for treatment and time main effects, and treatment by interaction effects, with relevant covariates, such as baseline VAS score, included in the model. The effect of missing data on efficacy results was determined prior to analysis. All follow-up, evaluations were included in the analysis out to 3 months, prior to treatment unblinding. Investigational site effects on the changes in pain score at 3 months were tested for significance in a two-way analysis of variance. To reduce the size of the residual error term used in making inferences on treatment

Table 1. Energy Levels Utilized for the Study

Energy Level	Positive Energy-Flux Density (ED+) (mJ/mm^2)	Total Energy-Flux Density (ED) (mJ/mm^2)	No. of Shock Waves	Frequency
1	0.03	0.13	50 (±10)	60 shocks/minute
2	0.06	0.17	50 (±10)	90 shocks/minute
3	0.08	0.22	50 (±10)	120 shocks/minute
4	0.15	0.32	50 (±10)	150 shocks/minute
5	0.21	0.43	50 (±10)	180 shocks/minute
6	0.29	0.53	50 (±10)	210 shocks/minute
7	0.36	0.64	3500 (±10)	240 shocks/minute

effect at 3 months, analysis of covariance was employed to investigate linear effects of baseline characteristics, for example, pain, age, or weight. In addition to evaluating the actual changes in pain score, the proportion of subjects achieving at least 60% improvement in pain was compared between treatment groups at 3 months using a chi-square test. Proportions of subjects experiencing adverse events were also compared between treatment groups via Fisher's Exact tests, whereby the column totals (denominators) were the total number of subjects treated in each group.

RESULTS

One hundred fourteen study participants were randomly assigned to either the Active treatment group (58) or the Placebo control group (56). Two participants in the Active group and two participants in the Placebo group withdrew after the follow-up visit at 3–5 days. Two subjects in the Active group withdrew from the study after the visit at 6 weeks and one subject in the Placebo group missed the 6-week visit. One subject in the Active group and two subjects in the Placebo group missed the 3-month follow-up visit. Reasons for withdrawal are included in Figure 2. At 3 months, 53 of the 58 subjects from the Active treatment group and 52 of the 56 subjects from the Placebo group were evaluated (92%).

The groups were found to be similar with respect to baseline demographics such as age, gender, height, weight, duration of symptoms, pain on VAS, and characteristics of physical inspection (Table 2). There were no significant differences between groups in the baseline data for previous therapies tried.

Significant differences were found between groups on outcomes measured during treatment including pain and verification of blinding. Forty-six of the 58 participants in the Active group reported pain during treatment compared to five in the Placebo group ($p < 0.0001$). There was no significant difference between groups with regard to pain reported immediately after treatment.

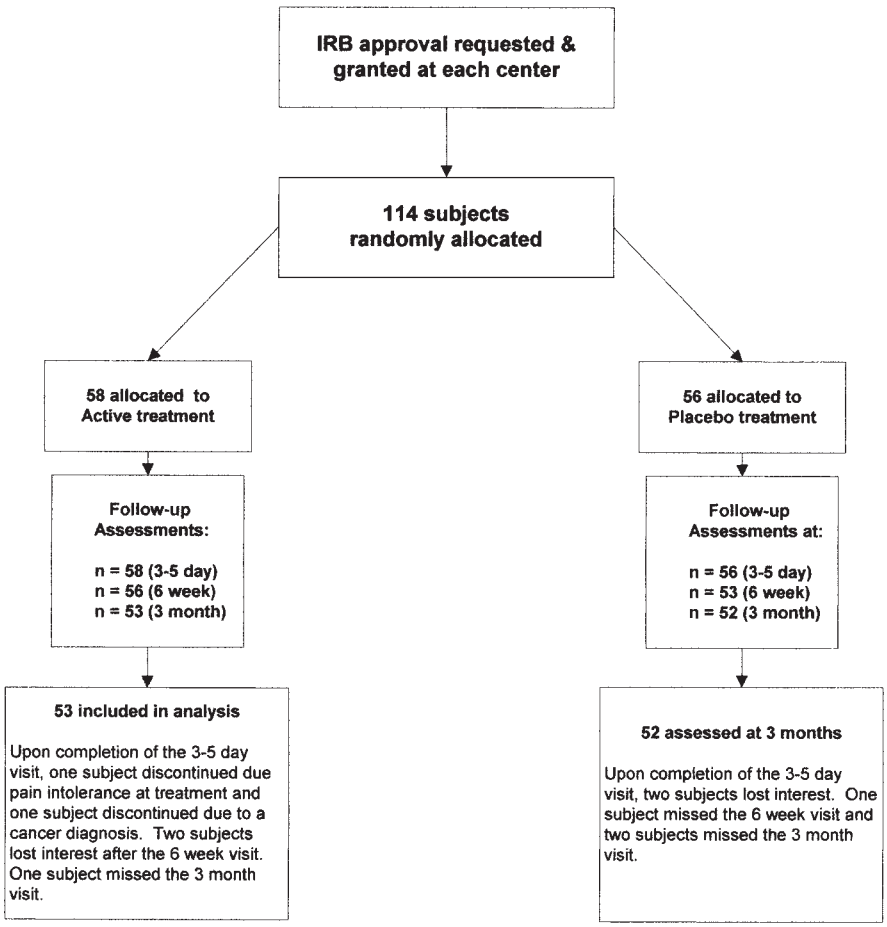

Figure 2. Study flow diagram.

Table 2. Baseline Characteristics of Subjects

Characteristics at Baseline	Active Treatment Group ($n = 58$)	Placebo Group ($n = 56$)	p-Value
Patients enrolled at each site			
London, Ontario	19	19	
Toronto, Ontario	10	9	
St. Bruno, Quebec	7	8	
Montreal, Quebec	22	22	
Gender (No. of subjects)			
Male/Female	18/40	23/33	0.2533
Affected foot (No. of pts)			
Right/Left	25/33	33/23	0.0955
Mean (SD) Age (years)	51.1 (10.6)	48.8 (9.8)	0.3936
Mean (SD) Body Weight (lb)	179.2 (34.8)	186.8 (38.6)	0.3558
Mean (SD) Height (in)	66.3 (3.6)	67.1 (4.2)	0.1363
Mean (SD) history of heel pain (months)	31.3 (32.5)	27.1 (23.5)	0.4092
Participate in weekly exercise (No. of pts)	35 (60.3%)	25 (44.6)%	0.0937
Required to stand	35 (60.3%)	37 (66.1%)	0.5725

When comparing verification of blinding data, 34 participants in the Active group believed they had received the ESWT treatment when questioned immediately posttreatment versus only 13 in the Placebo group ($p = 0.0007$). Twenty-two participants in the Active group (37.9%) and 33 (58.9%) in the Placebo group reported they did not know whether they had received the treatment or not. This was not statistically significant.

With regard to the primary outcome measure, a statistically significant difference ($p = 0.0124$) was found in the change from baseline to 3 months in the VAS scores of the treated versus Placebo group (Table 3). In the Active treatment group, the mean pain score decreased from 7.5 to 3.9 at 3 months ($p < 0.0001$), resulting in a mean percentage improvement of 49.1%. In the Placebo group, the mean pain score decreased from 7.9 to 5.3 at 3 months ($p < 0.0001$), a mean percentage improvement of 33.3%.

Clinical success was defined as >60% improvement from baseline in VAS scores for pain during the first few minutes of walking. Table 3 shows that at 3 months after treatment, there was a statistically significant difference between the percentage of Active treatment and Placebo treatment subjects that met the above definition of a success. In the Active group, 47% (25 of 53) of the subjects achieved greater than 60% improvement in pain, and in the Placebo group only 23% (12 of 52) met the same criteria ($p = 0.0099$). Although both Placebo and Active groups also reported significant improvement in their pain with normal activity, leisure/sport activity, and prior to bed, the improvements in the Active group were consistently numerically superior to placebo with marginal statistical significance ($p < 0.10$) between treatments in these clinical outcomes. Success, defined as a score of none or mild on the pain portion of the AOFAS ankle–hindfoot scale was also numerically superior to placebo with marginal statistical significance at 3 months posttreatment.

In terms of the Secondary Outcomes measures, no significant difference between groups was found with the numbers available in any of the AOFAS ankle–hindfoot indices (Table 3) or the SF-12 Global Health Rating Scale. However, a significant difference between groups was determined on the Roles and Maudsley scores ($p = 0.0121$) using a Cochran–Mantel–Haenszel mean score test and the pain measurement on palpation ($p = 0.0027$) using a two-way ANOVA F-test for group effect at 3 months posttreatment (Table 3).

Adverse events (other than pain) reported during treatment or in the first 3–5 days after treatment were relatively few, and there was no significant difference in number of side effects reported between groups through 3 months. The adverse events reported were primarily anticipated and included ecchymosis, edema, pain, and transient parasthesias. There was one report of low back pain in the Active group and one of pruritis in the Placebo group. Both were deemed unrelated to the study intervention.

After 3–5 days and through 3 months posttreatment, one participant in the Placebo group sustained an accidental injury, which led to increased pain in the study foot, and one had generalized spasms in the study foot following activity.

Table 3. Results for Primary and Secondary Outcome Measures

	Active Treatment Group $n = 53$	Placebo Treatment Group $n = 52$	p-Value
Primary outcome measure			
Pain during the first few minutes of walking scored on VAS			
Baseline [score (SD)]	7.5 (1.5)	7.9 (1.5)	
3 month [score (SD)]	3.9 (3.2)	5.3 (2.7)	<0.0001
Clinical Success [No. of subjects (%)]			
Defined by >60% improvement on the primary outcome measure	25/53 (47%)	12/52 (23%)	0.0099
VAS pain during normal daily activity			
Baseline [score (SD)]	6.2 (2.0)	6.0 (2.0)	
3 month [score (SD)]	3.7 (3.1)	4.4 (2.5)	0.0524
VAS pain during leisure/sport activity			
Baseline [score (SD)]	7.4 (2.4)	7.7 (2.1)	
3 month [score (SD)]	3.9 (3.5)	5.2 (2.9)	0.0904
VAS pain prior to bed			
Baseline [score (SD)]	6.2 (2.4)	6.5 (2.5)	
3 month [score (SD)]	3.9 (3.3)	4.9 (2.6)	0.0793
AOFAS ankle hindfoot scale at 3 months			
Total score [% change (SD)]	30.3 (33.3)	25.8 (34.2)	0.2927
Success[a] (No. of subjects)	27/53	18/52	0.0913
SF-12 global health score at 3 months			
Mental health [% change (SD)]	6.8 (29.4)	2.0 (19.1)	0.7812
Physical health (% change (SD))	14.2 (25.5)	9.1 (33.8)	0.2229
Roles and maudsley score			
Baseline (No. of subjects)			
Excellent to good	0/58	0/56	0.3528[b]
Fair to poor	58/58	56/56	
3 months (No. of subjects)			
Excellent to good	23/53	16/52	0.0121[b]
Fair to poor	30/53	36/52	
Pain on palpation			
Baseline [score (SD)]	5.7 (2.0)	6.2 (2.5)	
3 month [score (SD)]	7.2 (2.5)	6.3 (2.3)	0.0027
Adverse events through 3 months			
Pain *during* treatment (% Incidence)	79.3	8.9	0.0000
Edema (% Incidence)	3.5	1.8	1.0000
Generalized spasm (% Incidence)	0.0	1.8	0.4911
Pain (% Incidence)	14	27.3	0.1035
Paresthesia (% Incidence)	1.8	0.0	1.0000
Back pain (% Incidence)	1.8	0.0	1.0000
Accidental injury (% Incidence)	0.0	1.8	0.4911
Peripheral neuritis (% Incidence)	1.8	0.0	1.0000

[a]Defined as score of none or mild on the pain domain.
[b]Cochran-Mantel-Haenszel mean score test.

The onset of pain and edema during this period were comparable between treatment groups. One subject in the Active Group experienced tingling in the affected foot at the 6-week follow-up visit. The event was coded as anticipated/not serious and resolved by the 3-month visit. One subject in the Active Group experienced peripheral neuritis at the 6-week visit. The event was coded as anticipated/not serious and resolved prior to the 3 month visit (Table 3). Statistical analysis is pending for the 6- and 12-month follow-up (Active group) and Crossover safety and efficacy data.

DISCUSSION

This study demonstrated a statistically significant difference between groups in the primary outcome measure of change from baseline to

3 months after treatment in VAS pain scores in the first few minutes of walking (49.1% vs. 33.3%; $p = 0.0124$). Although improvement was noted in the Placebo group, this phenomenon could simply reflect the spontaneous remission or natural history of plantar fasciitis as a self-limiting condition or a sustained placebo effect. Standard treatment for plantar fasciitis is conservative, but about 10% of patients fail to respond or heal spontaeously.[3] Because this represents a significant number of people, we consider our findings about the effect of ESWT as an alternative treatment are quite relevant and useful. There were also statistically significant differences between treatments in the number of participants whose changes in VAS scores met the study definition of success and in the distribution of Roles and Maudsley pain and activity self-assessment scores. This provides further evidence that ESWT does offer an additional benefit with regard to pain and activity levels to at least 3 months posttreatment. The Roles and Maudsley score is considered to be clinically significant for providing patient self-assessment information,[2] which in many cases is more important than other clinical outcomes. Unfortunately, the study was not powered to show significant difference in the SF-12 scale, as this would have required an unfeasible amount of patients.

The significant difference in blinding verification between the groups deserves explanation. This most likely was influenced by the subject's judgment about the presence or absence of pain during treatment, which incidentally was also statistically significant. The presence or absence of pain during treatment in either group could be due to several variables such as differences in subject's pain tolerance or inconsistent adequacy of the anaesthetic block.

To truly compare a clinical intervention to placebo, as the comparative clinical trials in the past have claimed to do, blinding of subjects and assessment of the efficacy of the blinding are necessary to attemp to control the placebo effect. Many previous trials of ESWT for plantar fasciitis did not include blinding or assessment of blinding, so it is difficult to compare our results in this area to others in the literature. It should be noted that our assessment of the subjects' blindness to the type of treatment is of interest only for evaluating our method of blinding, and we can safely conclude that our method of blinding worked as well as possible.

There have been a number of randomized controlled trials published recently with varying results. Our results are only valid for the therapeutic variables used in this study. It is difficult to compare studies, which use different patient populations, energy sources, and treatment protocols. It is unclear if the negative results of other studies are due to insufficient energy levels, possible over treatment, which can produce a lack of/or negative biologic effect, or inclusion of subjects who might not benefit from ESWT. The results presented here confirm those of the previous randomized controlled trial performed as part of the initial study in which some of the same authors participated.[11]

ESWT has several advantages and should be considered an effective and safe tool in the treatment of chronic plantar fasciitis. As an alternative to surgery, it is a noninvasive technology, which has considerably less complications. It has a relatively short recovery time during which the patient can continue with most employment and activities of daily living, as soon as the day following treatment. Finally, because ESWT can be used utilized earlier in the course of this disease, it can aid in reducing patient suffering, loss of time at work, and health care costs associated with prolonged treatments and surgery.

CONCLUSION

Present conservative treatments for plantar fasciitis include rest, physical therapy, heel cushions, nonsteroidal anti-inflammatory drugs, corticosteroid injections, taping, orthotics, shoe modifications, nightsplinting, and casting. ESWT is proposed as an additional conservative treatment to be used to avoid surgery, when other available conservative methods have failed. Relief from pain can be recognized with a single session compared to traditional conservative therapies that require multiple applications and for which clear benefits have not been established. Shock wave therapy is minimally invasive, has a short recuperation period, and reports only minor, transient side effects. Also, shock wave therapy may circumvent the need for surgical intervention and the associated costs, lost time from work, and complications associated with surgery.

The results of this study confirm that high-energy ESWT, administered with the Dornier Epos Ultra is a safe and effective treatment for patients who have failed previous conservative nonsurgical treatments for chronic plantar fasciitis. The future of our research of ESWT will include

further study of optimal dosing, frequency, and treatment regimens.

ACKNOWLEDGMENTS

All clinical sites received research grant funding from Dornier MedTech America, Inc., Atlanta, GA. We gratefully acknowledge the following investigators for their dedication and participation in the clinical trial: Joyce Johansson, MD, Alain Scheldeman, B.Sc. PT., CAT(c), Rory Mullin MSc, ATC, CAT (c), Dac., and Susanne Pare, Bsc.PT. A special thank you to the many other colleagues and especially the Research Coordinators, who could not all be named but without whom the study could not have been completed.

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