Ultrasound-Guided Extracorporeal Shock Wave Therapy for Plantar Fasciitis

A Randomized Controlled Trial

Rachelle Buchbinder, MBBS, MSc
Ronnie Ptasznik, MBBS, FRANZCR
Jeanine Gordon, BAppSci
Joylene Buchanan, DipAppSci
Vasuki Prabaharan, BSc, MAppSci
Andrew Forbes, PhD

Context Extracorporeal shock wave therapy (ESWT) is increasingly used for plantar fasciitis, but limited evidence supports its use.

Objective To determine whether ultrasound-guided ESWT reduces pain and improves function in patients with plantar fasciitis.

Design Double-blind, randomized, placebo-controlled trial conducted between April 1999 and June 2001.

Setting Participants were recruited from the community-based referring physicians (primary care physicians, rheumatologists, orthopedic surgeons, and sports physicians) of a radiology group in Melbourne, Australia.

Participants We screened 178 patients and enrolled 166; 160 completed the 15-week protocol. Entry criteria included age at least 18 years with plantar fasciitis, defined as heel pain maximal over the plantar aspect of the foot of at least 6 weeks' duration, and an ultrasound-confirmed lesion, defined as thickening of the origin of the plantar fascia of at least 4 mm, hypoechogenicity, and alterations in the normal fibrillary pattern.

Interventions Patients were randomly assigned to receive either ultrasound-guided ESWT given weekly for 3 weeks to a total dose of at least 1000 mJ/mm^2 (n=81), or identical placebo to a total dose of 6.0 mJ/mm^2 (n=85).

Main Outcome Measures Overall, morning, and activity pain, measured on a visual analog scale; Maryland Foot Score; walking ability; Short-Form–36 Health Survey (SF-36) score; and Problem Elicitation Technique score, measured at 6 and 12 weeks after treatment completion.

Results At 6 and 12 weeks, there were significant improvements in overall pain in both the active group and placebo group (mean [SD] improvement, 18.1 [30.6] and 19.8 [33.7] at 6 weeks [P=.74 for between-group difference], and 26.3 [34.8] and 25.7 [34.9] at 12 weeks [P=.99], respectively). Similar improvements in both groups were also observed for morning and activity pain, walking ability, Maryland Foot Score, Problem Elicitation Technique, and SF-36. There were no statistically significant differences in the degree of improvement between treatment groups for any measured outcomes.

Conclusion We found no evidence to support a beneficial effect on pain, function, and quality of life of ultrasound-guided ESWT over placebo in patients with ultrasound-proven plantar fasciitis 6 and 12 weeks following treatment.

JAMA. 2002;288:1364-1372 www.jama.com

PLANTAR FASCIITIS, OR PAINFUL heel, is a common musculoskeletal problem estimated to affect 10% of runners at some time and to occur in a similar proportion of the general population in their lifetime.[1] It denotes a clinical condition of pain in the plantar aspect of the heel, characteristically worse on arising in the morning and after periods of prolonged sitting.[2] There is maximal tenderness at the plantar fascial origin on the medial process of the calcaneal tuberosity, and pain increases with passive stretching of the plantar fascia. The etiology of plantar fasciitis is unknown and probably multifactorial. Excessive loading may result in inflammation, degeneration, microtears, and/or fibrosis at the plantar fascia origin. A calcaneal spur may be present in 50% of patients with painful heel,[3] but has been reported in 10% to 27% of asymptomatic patients.[3,4] Plantar fasciitis is most commonly a disorder of middle age[3,5] and men and women are affected equally. Other risk factors include obesity[3,5-8] and spending prolonged periods standing or walking,[3,5] particularly on hard floors.[5] Symptoms may be bilateral in over 10% of

Author Affiliations: Department of Clinical Epidemiology, Cabrini Hospital, and Cabrini Medical Centre, Malvern, Victoria, Australia (Dr Buchbinder); Department of Epidemiology and Preventive Medicine, Monash University (Drs Buchbinder and Forbes and Ms Prabaharan); Radiology Department, Latrobe University Medical Centre (Dr Ptasznik); and Mayne Health Diagnostic Imaging, Epworth Hospital (Mss Gordon and Buchanan), Melbourne, Australia.
Corresponding Author and Reprints: Rachelle Buchbinder, MBBS, MSc, FRACP, Department of Clinical Epidemiology, Suite 41, Cabrini Medical Centre, 183 Wattletree Rd, Malvern, Victoria, Australia 3144 (e-mail: rachelle.buchbinder@med.monash.edu.au).

cases.[3] Plantar heel pain is generally a self-limiting condition, and more than 80% of those who present for medical attention have resolution of the problem within 12 months of onset of symptoms.[9,10]

Treatments advocated for plantar fasciitis have included rest, ice, stretches, nonsteroidal anti-inflammatory drugs,[2,10] corticosteroid injection,[2,6] iontophoresis of dexamethasone,[11] various orthotics including heel cushions, low-profile plastic heel cups,[5,12] Tuli heel cups,[13] night splints,[8] heat, ultrasound,[14] below-the-knee non–weight-bearing casts,[5] and short-leg walking casts.[15] A small number of patients undergo surgery, including spur resection and release of all or part of the fascial band.[16] However, evidence of the effectiveness of all these treatment modalities is limited due to the lack of well-designed and conducted comparative studies, as documented in a Cochrane systematic review performed by Atkins et al.[17,18]

Recently, extracorporeal shock wave therapy (ESWT) has been advocated for treatment of this condition.[18-28] Since 1976, ESWT in the form of lithotripsy has been used to disintegrate renal and biliary calculi.[29] Shock waves are single-pulse acoustic waves (sound waves) that propagate rapidly in 3-dimensional space and cause a sudden rise in pressure at the wave front.[30,31] They dissipate mechanical energy at the interface of 2 substances with differing acoustic impedance, resulting in disintegration of calculi. From the early 1990s there have been published descriptions of its use in Germany in a variety of musculoskeletal disorders including pseudoarthroses, calcific tendinitis of the shoulder, lateral and medial epicondylitis, and painful heel.[19,21,30,32,33]

Medical shock waves are usually generated through a fluid medium (eg, water) and a coupling gel to facilitate transmission into biological tissues.[31] There are 3 main techniques for generating shock waves—electrohydraulic, electromagnetic, and piezoelectric[31]—and all 3 have been used to treat plantar fasciitis. The first generation of orthopedic shock wave machines used a spark plug to generate the shock wave (electrohydraulic technique).[31] In October 2000 the US Food and Drug Administration (FDA) approved an electrohydraulic device for use in the treatment of chronic proximal plantar fasciitis (heel spurs) in the United States.[34] Subsequently, an electromagnetic device, which generates the shock wave by passing an electric current through a coil to produce a strong magnetic field, has also been approved.[35] Piezoelectrically generated shock waves are produced by piezocrystals that are mounted on the inside of a sphere. These receive a rapid electrical discharge, resulting in deformation of the crystals to induce the shock wave.[31]

While all 5 placebo-controlled trials of ESWT in chronic plantar fasciitis have reported benefit of variable magnitude,[19,20,22,23,35] methodological limitations may have influenced their outcome. Participants were unblinded in 3 trials,[19,20,23] and none of the 5 trials described their method of randomization, allocation concealment, or sample size calculation. One double-blind trial, performed by Ogden et al,[22] evaluated success of therapy by combining 4 outcomes into a composite outcome. While the overall proportion of participants who met the predetermined criterion of success at 12 weeks was significantly higher in the actively treated group (47.1% vs 30.2%; $P=.008$), the superiority of the active treatment compared with placebo treatment was only statistically significant for investigator assessment of heel pain (62.2% of the active group vs 44% of the placebo group met success criteria; $P=.005$).[36] The second double-blind trial found a small but statistically significant difference favoring the active group in their primary end point (difference in improvement in morning pain between the active and placebo groups measured at 12 weeks post-treatment: 0.7 cm on a 10-cm visual analog scale [VAS]; $P=.01$).[35] The determination of the presence of plantar fasciitis was made solely on clinical grounds in both double-blind trials.

To further clarify the value of ESWT for this condition we performed a double-blind, randomized, placebo-controlled trial in patients with ultrasound-proven plantar fasciitis. The aim of our study was to determine whether ultrasound-guided ESWT, given weekly for 3 weeks, reduces pain and improves function at 6 and 12 weeks after completion of treatment.

METHODS

Study Design

A double-blind, randomized, placebo-controlled trial was conducted between April 1999 and June 2001. Patients who fulfilled inclusion criteria and provided written informed consent were randomized and stratified by treatment center (3 treatment sites) in blocks of 4 to receive either active treatment or placebo regimens according to a computer-generated random-numbers list created by the study biostatistician. Both the patients and a single outcome assessor were blinded to the therapy received.

Patients

Patients were recruited from the community-based referring physicians (primary care physicians, rheumatologists, orthopedic surgeons, and sports physicians) of Mayne Health Diagnostic Imaging (formerly Melbourne Diagnostic Imaging Group) in Melbourne, Australia. Radiologists evaluated all referred patients to ascertain eligibility criteria. The radiologists who ascertained eligibility had no other involvement in the study. Patients were included if they were 18 years or older, described heel pain felt maximally over the plantar aspect for at least 6 weeks, and had an ultrasound-confirmed lesion. The latter was defined as thickening of the origin of the plantar fascia (greater than or equal to 4 mm) as well as hypoechogenicity and alterations in the normal fibrillary pattern. When symptoms were bilateral, the more symptomatic side was studied. Patients were excluded if any of the following were present: generalized inflammatory arthritis, including anky-

losing spondylitis, Reiter syndrome, rheumatoid arthritis, or psoriatic arthritis; any wound or skin lesion; pregnancy; severe infection; known malignancy; bleeding disorder; pacemaker; previous surgery to the heel; previous ESWT to any site (because of the risk of unblinding); oral and/or topical nonsteroidal anti-inflammatory medication in the previous 2 weeks; local corticosteroid injection in the previous month; oral glucocorticosteroids within the previous 6 weeks; lack of informed consent; or any other reason thought likely to result in inability to complete the trial, such as uncertainty about being able to attend for follow-up assessment and poor English skills thought likely to affect ability to complete outcome assessment.

Description of Interventions

All treatments were given by a single extracorporeal shock wave (ESW) therapist who was informed of treatment allocation (by central telephone) just prior to commencement of treatment according to the participant's identification number. An ESW therapist is a qualified health professional who has undergone training in the delivery of ESWT. The ESW therapist was not involved in any other part of the study and interacted with study participants in a standardized way irrespective of treatment allocation. Care was taken to ensure that study participants did not meet, and individual study participants were asked to wait in separate waiting areas.

All treatments were given according to a standardized protocol using the Dornier MedTech EPOS (Extracorporeal Pain therapy and Orthopaedic System) Ultra (Dornier MedTech America Inc, Kennesaw, Ga).[35] All patients were positioned sitting in a chair with the affected foot resting on a foam support and footstool. Ultrasound gel was placed on a water cushion and the ultrasound transducer. The water cushion and transducer were placed over the heel and positioned so that the origin of the plantar fascia adjacent to the calcaneum was visible. The cross hair, which is used to indicate the position of the shock wave focus, was positioned within the plantar fascia adjacent to the calcaneum, in the thickest portion of the plantar fascia.

Each patient in both the placebo and experimental groups received a total of 3 treatments given at weekly intervals. For the placebo group this consisted of 100 shock waves per treatment, of energy 0.02 mJ/mm^2 (energy level 1). The frequency of these pulses was set at 60 per minute. The total dose received by the placebo group was 6.0 mJ/mm^2. The experimental group received either 2000 or 2500 shock waves per treatment of energy levels varying between 0.02 mJ/mm^2 and 0.33 mJ/mm^2 (ie, within levels 1-9). The frequency of these pulses was gradually increased to 240 per minute. Treatment began on level 1 and was gradually increased through to the highest tolerable level of pain for each participant. Thus the total calculated dose for each participant was different. In general, a total dose of 1000 mJ/mm^2 or more was the treatment goal. The mean (SD) dose of ESWT in the experimental group was 1406.73 (390.58) mJ/mm^2.

Participants were able to continue to wear orthotics/splints as prescribed, but no new orthopedic devices were allowed. Apart from paracetamol, no other therapies (including massage, chiropractic, laser, night splints, acupuncture, or oral, topical, or locally injected corticosteroids) were allowed for the duration of the study.

Ethical approval was obtained from the Epworth Hospital Ethics Committee.

Baseline and Outcome Assessment

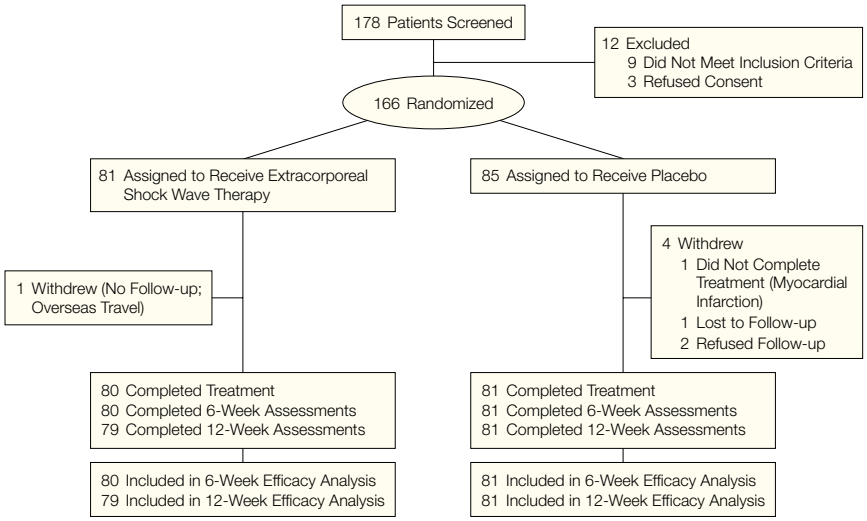
Baseline variables that were recorded included date of birth, sex, weight, height, years of formal education, marital status, duration of symptoms, history of trauma, previous episodes, medication, previous treatments including orthotics, results of radiological investigations, any coexisting condition(s), approximate hours of weight bearing per day, and the type of flooring used for the majority of the day.

The presence or absence of a heel spur on plain anteroposterior/lateral radiograph if already obtained was noted, but plain radiographs were not performed routinely. All participants had a diagnostic ultrasound.

Follow-up evaluations were performed at 6 and 12 weeks following completion of the 3-week course of treatment. Seven outcomes were measured: (1) Overall, morning, and activity pain were each measured on a vertical 100-mm VAS with descriptors at either end of 0 (no pain) to 100 (maximal pain). Overall pain at 12 weeks was the primary end point of the study for the determination of efficacy and sample size. (2) Walking ability without need for a rest to relieve painful heel,[19] measured using a 6-point rating scale (0 = <5 minutes, 1 = 5-14 minutes, 2 = 15-29 minutes, 3 = 30-44 minutes, 4 = 45-59 minutes, and 5 = ≥60 minutes). (3) The Maryland Foot Score[37] is a disability index that derives a score from 0 to 100 points, taking into account pain and function of the foot. Interpretation of the score has been suggested as 100 graded as normal, 90 to 100 as excellent, 75 through 89 as good, 60 through 74 as fair, and less than 60 as poor. While its clinimetric properties have not been formally studied, it has been shown to correlate with the severity of foot injuries[37] and has also been used in a clinical trial of plantar fasciitis in which it appeared to be responsive to change.[11] (4) The Problem Elicitation Technique[38] is an interviewer-administered patient-preference disability measure in which the individual is asked to identify his/her own problems related to the condition under study that he/she would most like to see improve as a result of therapy. The importance and magnitude of each identified problem are elicited by Likert scales (importance: 0 ["not at all important"] to 10 ["most important"]; magnitude: 0 ["without any difficulty"] to 7 ["unable to do"]). The score for each problem is obtained by multiplying the importance of the problem by the magnitude of the problem (level of difficulty, frequency, or degree of severity). A higher score indicates a higher degree of per-

ceived disability and/or importance. The Problem Elicitation Technique score is obtained by adding the scores for all volunteered problems. (5) The Short-Form–36 Health Survey (SF-36)[39] is a self-administered 36-item generic indicator of health status that consists of 8 subscales representing 8 dimensions of quality of life: physical function, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and general mental health. Each of the 8 subscales is rescaled from 0 to 100; higher scores represent better health. (6) All reported adverse effects were recorded. (7) Success of blinding was assessed at the conclusion of the study by asking participants to indicate which treatment they believed they had received.

Figure. Flow of Participants Through the Trial



Sample Size

The sample-size calculation was based on the comparison of ESWT and placebo groups with respect to the principal outcome measure of pain (on a 0- to 100-mm VAS scale) at the 12-week follow-up assessment. Pilot data collected in 121 participants indicated that the between-subject SD was approximately 25 mm and the baseline/6-week correlation was approximately 0.5. The baseline/12-week correlation can be extrapolated from this value to be 0.25. Using these parameters, a sample size of 60 patients per group would have 80% power ($P = .05$, 2-sided) to detect a difference of 13 mm in mean pain level between the groups at 12-week follow-up using an analysis of covariance adjusting for baseline pain level.

Data Analysis

All analyses were planned on an intention-to-treat principle using all randomized patients who provided any postbaseline data. Demographic characteristics of the ESWT and placebo groups were summarized by descriptive statistics. Changes from baseline to 6 and 12 weeks for outcomes measured using essentially continuous scales (pain, Problem Elicitation Technique, Maryland Foot Score, and SF-36 components) were compared between ESWT and placebo groups using *t* tests, or Mann-Whitney U tests where required. Additional supportive analyses using adjustment for baseline values of the outcome variables and characteristics exhibiting at least slight imbalance at baseline were performed using multiple linear regression. The estimates of between-group differences in means with and without such adjustments exhibited only minor differences, and therefore only the unadjusted between-group differences are presented, together with 95% confidence intervals (CIs). For simplicity of presentation, all results are presented as improvements from baseline (for example, reduction of 20 units on a VAS scale is represented by an improvement of 20 units). Consistency of results across a priori–specified subgroups (thickness of lesion and unilateral vs bilateral symptoms) was assessed including relevant interaction terms in regression models. In addition, consistency of results across total doses of ESWT (as greater or less than 1000 mJ/mm^2) was also assessed by multiple regression.

Walking ability was measured on an ordinal scale and was compared between groups at 6 and 12 weeks using an ordinal logistic regression model. This regression produces odds ratios (ORs) comparing the likelihood of higher scores on the scale for ESWT compared with placebo. For example, an OR of 0.80 indicates that the odds of a high (as opposed to low) score in patients receiving ESWT are 20% less than the odds in the placebo group. Therefore, for ordinal scales where higher scores indicate greater functionality, an OR less than 1 indicates poorer performance in patients receiving ESWT than in patients receiving placebo. Baseline values of the relevant outcome were accounted for in these models as covariates; similarly, additional adjustment for coefficients imbalanced at baseline was performed by adding appropriate regression terms. All analyses were performed using Stata v7.0 (Stata Corp, College Station, Tex).

RESULTS

There were 166 study participants randomly assigned (81 to the ESWT group and 85 to the placebo group) (FIGURE). Five participants withdrew from the trial prior to the first follow-up visit at 6 weeks. One participant in the placebo group withdrew after the first week of treatment because of a myocardial infarction (unrelated to the trial). Four

participants (1 active and 3 placebo) completed treatment but did not return for the 6-week follow-up (2 refused, 1 was lost to follow-up, and 1 traveled overseas). As there were no follow-up data for these participants, they were excluded from the efficacy analysis. Another participant (active group) withdrew prior to the 12-week follow-up and was excluded from the 12-week efficacy analysis. This approach provided the same estimated between-group differences as imputing the mean change from baseline for the active group for that patient.

Table 1. Demographic and Clinical Characteristics and Baseline Outcome Measurements of Trial Participants According to Treatment Group*

Characteristic	ESWT (n = 80)	Placebo (n = 81)	Dropouts (n = 5)
Age, mean (SD), y	52.2 (12.81)	54.2 (12.05)	55.8 (14.5)
Women, No. (%)	46 (57.5)	47 (58.0)	4 (80)
Height, mean (SD), cm	169.23 (10.57)	168.56 (9.71)	170 (7.6)
Weight, mean (SD), kg	84.19 (15.83)	81.68 (16.36)	78.2 (10.5)
Duration of symptoms, median (range), wk	36 (8-600)	43 (8-980)	52 (28-78)
Weight bearing per day, mean (SD), h	9.21 (3.67)	8.47 (4.09)	8.8 (3.0)
Hard flooring majority of day, No. (%)	50 (62.5)	53 (65.4)	4 (80)
Plantar thickness, mean (SD), mm	6.04 (1.34)	5.80 (1.26)	5.7 (1.3)
Plantar spur, No. (%)	21/27 (77.8)	16/23 (69.6)	1/1 (100)
Affected heel, No. (%)			
Left	47 (59.5)	37 (45.7)	2 (40)
Right	28 (35.0)	32 (39.5)	2 (40)
Bilateral	5 (6.3)	12 (14.8)	1 (20)
History of heel trauma, No. (%)	3 (3.8)	7 (8.6)	0 (0)
Previous same-sided heel pain, No. (%)	7 (8.9)	11 (13.6)	1 (20)
Previous treatment, No. (%)			
NSAIDs	39 (49.4)	42 (51.8)	3 (60)
Orthotics	43 (53.8)	47 (58.0)	3 (60)
Cortisone injections	28 (35.0)	23 (28.4)	3 (60)
1	15 (19.0)	8 (9.9)	1 (20)
≥2	13 (16.3)	15 (18.5)	2 (40)
Physiotherapy	7 (8.9)	14 (17.3)	1 (20)
Massage	6 (7.5)	11 (13.6)	1 (20)
Pain, mean (SD)			
Overall	71.5 (21.7)	68.6 (23.3)	65.6 (23.7)
Morning	72.8 (24.8)	67.9 (31.9)	49.2 (22.8)
Activity	73.6 (21.1)	73.8 (23.6)	58 (32.9)
Walking ability, No. (%), min			
<5	6 (7.5)	5 (6.2)	0 (0)
5-14	21 (26.3)	15 (18.5)	2 (40)
15-29	17 (21.3)	25 (30.9)	2 (40)
30-44	10 (12.5)	15 (18.5)	0 (0)
45-59	7 (8.8)	7 (8.6)	1 (20)
≥60	19 (23.8)	14 (17.3)	0 (0)
Problem Elicitation Technique score, mean (SD)	128 (69.4)	141.4 (71.1)	143.3 (68.8)
Maryland Foot Score, mean (SD)	54.8 (16.0)	53.4 (17.0)	55.2 (15.1)
SF-36 score, mean (SD)			
Physical function	60.2 (21.8)	55.6 (23.4)	46 (23.3)
Role limitation (physical)	43.1 (39.8)	33.3 (36.9)	15 (22.4)
Bodily pain	45.1 (21.3)	43.2 (18.6)	35.6 (16.3)
General health	69.1 (20.5)	67.6 (21.2)	71.6 (19.0)
Vitality	57.6 (20.2)	53.8 (18.7)	36 (26.5)
Social function	74.5 (26.0)	69.8 (24.8)	62.5 (29.3)
Role limitation (emotional)	66.3 (41.3)	56.0 (43.1)	46.7 (38.0)
Mental health	74.8 (16.8)	71.3 (17.5)	54.4 (21.7)

*ESWT indicates extracorporeal shock wave therapy; SF-36, Short-Form–36 Health Survey; and NSAID, nonsteroidal anti-inflammatory drug.

The demographic and clinical characteristics of the 161 study participants who provided postbaseline data are presented in TABLE 1. There were no baseline differences of clinical importance between the 2 groups for any of the examined baseline demographic or clinical characteristics. The baseline demographic and clinical characteristics of the 5 participants who withdrew prior to the initial follow-up assessment, also shown in Table 1, were similar to the study population as a whole.

Both treatment groups improved over time (TABLE 2 and TABLE 3). There were no statistically significant differences in outcome between the active and placebo groups for any of the measured outcome variables at 6 or 12 weeks (apart from the social function dimension of the SF-36 at 6 weeks, which favored the placebo group). Furthermore, the 95% CIs indicated that the range of plausible differences between the groups did not include differences of any practical importance.

Analyses adjusted for duration of symptoms yielded similar results (data not shown). The results were also consistent across subgroups, including thickness of lesion, unilateral vs bilateral symptoms, and total dose of ESWT received (n=68 for ≥1000 mJ/mm^2; n=13 for <1000 mJ/mm^2), with all-interaction $P>.10$ for all outcome measures.

Few adverse effects were reported in either group. Pain for 1 week after the treatment was reported by 1 participant from each group, heat and numbness by 1 participant from the active group, a burning sensation in heel and ankle by 1 participant from the placebo group, and bruising after the first treatment by 1 participant from the active group.

TABLE 4 displays problems identified at baseline (using the Problem Elicitation Technique) as those that 5 or more participants would most like to see

Table 2. Mean Changes in Pain Measures and Scores From Baseline at 6 and 12 Weeks*

	6 Weeks				12 Weeks			
	Mean (SD) Change†				Mean (SD) Change†			
Outcome Measure	ESWT (n = 80)	Placebo (n = 81)	Between-Group Difference (95% CI)‡	*P* Value	ESWT (n = 79)	Placebo (n = 81)	Between-Group Difference (95% CI)‡	*P* Value
Overall pain	17.9 (30.5)	19.8 (33.7)	−1.9 (−11.9 to 8.1)	.74	26.3 (34.8)	25.7 (34.9)	0.6 (−10.3 to 11.5)	.99
Morning pain	20.0 (34.6)	20.6 (39.5)	−0.6 (−12.1 to 11.0)	.99	23.7 (40.7)	23.5 (42.2)	0.2 (−12.7 to 13.1)	.92
Activity pain	16.4 (32.0)	22.1 (33.8)	−5.7 (−15.9 to 4.5)	.32	25.1 (37.4)	26.6 (35.8)	−1.5 (−13.0 to 9.9)	.68
Problem Elicitation Technique	23.9 (51.3)	37.5 (67.1)	−13.6 (−32.3 to 5.1)	.15	38.9 (65.1)	47.2 (79.8)	−8.4 (−31.1 to 14.4)	.38
Maryland Foot Score	10.8 (14.9)	13.2 (19.6)	−2.4 (−7.8 to 3.1)	.40	15.0 (20.6)	13.9 (20.5)	1.2 (−7.6 to 5.3)	.85
SF-36								
Physical function	4.1 (20.2)	9.8 (24.5)	−5.0 (−11.6 to 1.7)	.12	7.5 (21.6)	9.8 (26.7)	−2.3 (−9.9 to 5.3)	.49
Role limitation (physical)	12.2 (48.8)	21.9 (41.7)	−9.7 (−23.9 to 4.4)	.24	17.4 (43.6)	16.4 (41.3)	1.1 (−12.2 to 14.3)	.79
Bodily pain	6.4 (22.0)	9.8 (24.5)	−3.4 (−10.7 to 3.8)	.35	11.2 (26.8)	9.3 (21.7)	1.9 (−5.7 to 9.5)	.72
General health	−0.6 (21.5)	0.3 (16.9)	−0.9 (−6.9 to 5.1)	.67	−2.4 (24.7)	−3.0 (18.4)	0.6 (−6.2 to 7.4)	.89
Vitality	−1.9 (16.0)	2.0 (17.2)	−3.9 (−9.0 to 1.3)	.17	0.4 (18.2)	0.8 (16.6)	−0.4 (−5.8 to 5.1)	.83
Social function	0.2 (22.3)	8.6 (23.7)	−8.5 (−15.7 to −1.3)	.03	3.2 (28.5)	5.1 (25.8)	−1.9 (−10.4 to 6.6)	.45
Role limitation (emotional)	3.3 (39.6)	19.3 (65.8)	−16.0 (−32.9 to 0.9)	.05	9.3 (41.0)	7.4 (43.1)	1.9 (−11.3 to 15.0)	.95
Mental health	0.7 (13.1)	1.1 (16.3)	−0.5 (−5.1 to 4.1)	.98	0.3 (14.5)	0.5 (16.1)	−0.2 (−5.0 to 4.6)	.99

*ESWT indicates extracorporeal shock wave therapy; CI, confidence interval; and SF-36, Short-Form–36 Health Survey.
†Positive change indicates improvement, negative change indicates worsening.
‡Positive difference in mean change indicates ESWT group improved more than placebo group. Because of rounding, some between-group differences may differ from values obtained by subtracting mean change (placebo) from mean change (ESWT).

improve as a result of treatment. The most commonly identified problems were walking after getting out of bed in the morning (88/160 [55%]), standing after sitting for a prolonged period (71/160 [44.4%]), and walking or standing for long periods (61/160 [38.1%] and 46/160 [28.8%], respectively).

Nineteen participants (24.4%) in the active group correctly identified their treatment group, compared with 29 participants (36.2%) in the placebo group. Twenty-nine participants (35.8%) in the active group were uncertain which treatment they had received, compared with 36 participants (45.0%) in the placebo group. An index to assess the success of blinding was computed[40] to be 0.68 (bootstrap 95% CI, 0.61-0.75). This index takes the value 1 for complete blinding and 0 for complete lack of blinding. The value of 0.68 can be interpreted as moderate to high degree of blindedness, and represents a statistically significant amount of blinding beyond that expected by chance (the value of the blinding index equals 0.5 for random guessing).

Table 3. Walking Ability at 6 and 12 Weeks*

	6 Weeks				12 Weeks			
	No. (%)				No. (%)			
Walking Ability, min	ESWT (n = 80)	Placebo (n = 81)	OR (95% CI)	*P* Value	ESWT (n = 79)	Placebo (n = 81)	OR (95% CI)	*P* Value
<5	4 (5.0)	0 (0)	0.8 (0.5-1.4)	.49	3 (3.8)	3 (3.7)	1.1 (0.6-1.9)	.72
5-14	18 (22.5)	14 (17.3)			15 (19.0)	13 (16.1)		
15-29	20 (25.0)	24 (29.6)			16 (20.3)	20 (24.7)		
30-44	7 (8.8)	15 (18.5)			13 (16.5)	18 (22.2)		
45-59	10 (12.5)	9 (11.1)			10 (12.7)	8 (9.9)		
≥60	21 (26.3)	19 (23.5)			22 (27.9)	19 (23.5)		

*ESWT indicates extracorporeal shock wave therapy; OR, odds ratio; and CI, confidence interval.

COMMENT

We failed to find any evidence of benefit of ultrasound-guided ESWT using our treatment parameters over placebo for ultrasound-confirmed plantar fasciitis at 6 and 12 weeks after completion of treatment. Over this time, participants in both study groups improved with respect to overall pain by almost 20 mm (6 weeks) and greater than 25 mm (12 weeks) on a 100-mm VAS scale, with similar improvements for morning- and activity-related pain. This was accompanied by similar improvements in function as determined by walking ability, the Problem Elicitation Technique, and the Maryland Foot Score, as well as the physical function, role limitation (physical), and bodily pain components of the SF-36.

These observed treatment effects might be explained by placebo effects related to participating in a trial or by the self-limiting natural history of the condition. In a systematic review of 11 randomized trials studying treatments for heel pain it was observed that, with the exception of a cross-over study of night splints,[41] all trials reported some improvement in patients' mean scores in both the treated and nontreated populations.[17] The authors postulated that the observed treatment effects could be explained on the basis of placebo effects in view of the relatively short treatment period in some trials and the long duration of some participants' symptoms. The median duration of participants' symp-

Table 4. Problem Elicitation Technique: Problems Identified by 5 or More Participants at Baseline (n = 160)

Problem Related to Heel Pain	No. (%)
Walking after getting out of bed in the morning	88 (55.0)
Standing after sitting for a prolonged period	71 (44.4)
Walking for long periods	61 (38.1)
Standing for long periods	46 (28.8)
Participation in sport or leisure activities	34 (21.3)
Participation in nonleisure activities	21 (13.1)
Frustration	21 (13.1)
Walking around the neighborhood	20 (12.5)
Wearing footwear of choice	15 (9.4)
Lying in bed comfortably	15 (9.4)
Performing minor maintenance outside the house	11 (6.9)
Working for wages outside the home	11 (6.9)
Driving a car	10 (6.3)
Sleeping through the night	9 (5.6)
Walking with a limp	7 (4.4)
Unable to lose weight	7 (4.4)
Unable to run	5 (3.1)
Depressed	5 (3.1)

toms in our trial (36 and 43 weeks in the treatment and placebo groups, respectively) was similar to those in the studies included in the systematic review.

Despite our study exhibiting greater between-subject variability than was initially planned, we still believe there was adequate statistical power to detect important treatment effects if they had been present, and to precisely estimate the magnitude of between-group differences. The increased variability was offset to a large degree by the recruitment of 160 patients rather than the initially planned 120 patients. With these updated design parameters, the study had 80% power to detect a difference of 15 mm on a 100-mm VAS scale for overall pain at 12 weeks. More important, the fairly narrow width of the resulting 95% CIs was sufficient to rule out differences of practical importance.

Our findings of a lack of benefit of ESWT using our treatment parameters for plantar fasciitis are inconsistent with the findings of previous placebo-controlled trials.[19,20,22,23,35] We used a technique similar to that used by Rompe et al[19,20] to deliver a mean (SD) dose of shock wave in the experimental group of 1406.73 (390.58) mJ/mm^2. Rompe et al performed a single-blind trial in 30 patients comparing 3 weekly treatments of 1000 impulses of 0.06mJ/mm^2 ESWT with simulated treatment (same procedure but no contact with the foot).[19] Inclusion criteria included pain for more than 12 months, positive bone scan, and the presence of a calcaneal spur. Significant alleviation of pain was noted at 3- and 6-week follow-ups in the treatment group compared with the placebo group. A second trial by the same investigators included a larger study population of 119 patients with painful heel lasting more than 6 months and compared 1000 impulses with 10 impulses given at weekly intervals for 3 weeks.[20] A significant reduction in pain was also demonstrated in this study at 12 weeks. The authors also noted a favorable outcome at 52 weeks; while not explicitly referenced, it appears that a recently published study by the same authors also report favorable 6-month and 5-year outcomes from the same trial.[42] The results after 12 weeks need to be viewed cautiously because of the potential confounding effect of additional treatments (including corticosteroid infiltrations and surgery) that unresponsive patients in both treatment groups could receive after this time.[18] Cosentino et al[23] performed a single-blind randomized trial of 6 treatments of an electrohydraulically generated shock wave (maximum dose, 2880 mJ/mm^2) or placebo in 60 patients with heel pain associated with a heel spur. While they also reported significant differences favoring the actively treated group, the lack of blinding of participants in all of these studies may have led to an overestimation of the treatment effects.

Ogden et al[22] performed a multicenter double-blind placebo-controlled trial of a single administration of electrohydraulically generated ESWT, using ankle-block anaesthetic, in 302 patients with chronic plantar fasciitis. Although the mode of ESWT delivery was different from that in our trial, the total dose of ESWT delivered to the active groups was similar in the 2 studies (1300 mJ/mm^2 in the trial by Ogden et al compared to a mean dose of 1406.76 mJ/mm^2 in our trial). Inclusion criteria included pain for greater than 6 months, failure to respond to at least 3 attempts at conservative treatment, investigator assessment of pain (≥5 cm on a 10-cm VAS), and subject self-assessment of pain (≥5 cm on a 10-cm VAS) after the first 5 minutes of walking in the morning. In contrast to our study, which required ultrasound confirmation of plantar fasciitis, the presence of plantar fasciitis was determined solely on clinical grounds. The study population also differed from ours in that the median duration of symptoms was much longer (19 months vs 6-7 months), there was a higher proportion of women (65.9%), mean age was younger (49.6 years), and mean morning pain was higher (8.03 and 8.14 in the active and placebo groups, respectively).[36] It is uncertain whether the 2 groups in their trial were comparable at baseline, as no baseline data separated by treatment group were reported.

Ogden et al defined overall success of treatment at 12 weeks if all 4 of the following criteria were fulfilled: minimum 50% improvement over baseline in investigator assessment of pain (by dolorimeter), with a VAS score of 4 cm or greater; minimum 50% improvement over pretreatment baseline in subject's self-assessment of pain on first walking in the morning and VAS score of 4 cm or greater; minimum 1 point or greater improvement on a 5-point scale of distance walked without heel pain, or maintenance of baseline assessment of no pain or minimal pain; and no prescription analgesics for heel pain in the treated heel between 10 and 12 weeks after treatment. While success in the 3 criteria other than investigator assessment of pain also favored the active treatment, none was statistically significant (subject's self-assessment of pain criterion: 59.7% in ESWT group vs 48.2% in placebo group, $P = .08$; subject's self-assessment of activity level: 71.4% in ESWT group vs 67.2% in placebo group, $P = .49$; and use of pain medications: 69.7% in ESWT group vs 67% in placebo group, $P = .41$).[36]

Our trial design and results also differ from the trial that was sponsored by

Dornier MedTech Inc,[35] that was presented to the FDA to gain approval for the electromagnetic device used in our study in the United States. The FDA study was a multicenter, double-blind, randomized, placebo-controlled trial of a single administration of electromagnetically generated ESWT, using ankle-block anesthetic, that enrolled 150 patients at 6 clinical centers. The total dose of ESWT delivered to the active group was 1300 mJ/mm^2. Inclusion criteria included symptoms present for greater than 6 months, and a VAS score of greater than 5 for pain during the first few minutes of walking in the morning. Like the trial by Ogden et al,[22] the presence of plantar fasciitis was determined solely using clinical criteria. While the duration of symptoms was again longer than in our trial (mean [range] duration of symptoms: 22 [6-120] months and 24.1 [3.0-99.0] months) in the active treatment and placebo groups, respectively), the mean baseline morning pain scores were similar (7.7 [0-10 scale] in both treatment groups compared with 73 and 68 [0-100 scale] in the active treatment and placebo groups in our trial, respectively).

While a statistically significant difference favoring the active group in improvement in morning pain (P=.01) was reported to be evidence of efficacy of ESWT,[35] it could be argued that a difference of 0.7 on a 10-cm VAS pain scale may not be clinically significant. There was no statistically significant difference between groups in the proportion of participants with at least 60% improvement in morning pain, AOFAS (American Orthopaedic Foot and Ankle Society) Ankle-Hindfoot Score, and SF-12 Health Status Questionnaire at 12 weeks, although the proportion of participants reporting excellent and good results favored the active group (61.6% vs 39.7%, P=.03).

It is unlikely that the negative results we observed in our study were due to inclusion of participants who were not likely to benefit from ESWT treatment. We failed to find any evidence that ESWT was more beneficial than placebo in certain subgroups according to duration of symptoms, thickness of the lesion, the presence of unilateral vs bilateral symptoms, and to the total dose of ESWT greater or less than 1000 mJ/mm^2. Helbig et al[43] have suggested that patients with chronic symptoms are more likely to have a positive effect from ESWT, since in their study longer duration of symptoms correlated with greater success of therapy. They postulated that this difference in response is related to fragmentation of the relatively avascular, sclerotic, biomechanically abnormal reparative tissue, which encourages more effective healing in those with chronic symptoms, whereas there is not the degree of interstitial tissue change in acute disease that is conducive to the effects of shock waves. On the other hand, a recent study by Maier et al[44] found that the presence of calcaneal bone marrow edema on magnetic resonance imaging was highly predictive of satisfactory outcome, suggesting that greater inflammation and vascularity may be more responsive to the effects of ESWT. The latter view is supported by further analyses from the trial by Ogden et al,[36] which showed that a shorter duration of symptoms was significantly associated with success of therapy (P=.005).

One possible explanation for our failure to detect a difference in benefit between the active and placebo groups in our trial is that the small shock wave dose delivered to the placebo group (6 mJ/mm^2) had a therapeutic effect. While we cannot rule out this possibility we believe it is unlikely. We chose to deliver a small dose of shock wave to the placebo group in preference to sham therapy in order to limit the likelihood that participants would determine their treatment allocation. This was similar to one of the 2 trials by Rompe et al,[20] in which a small shock wave dose (1.8 mJ/mm^2) was delivered to the placebo group. In the trials by Ogden et al and Dornier MedTech Inc, both treatment groups received ankle-block anesthesia, making it possible to use true sham ESWT. We delivered ESWT over 3 weeks, assuming that the effect is cumulative over time. It may be that a single larger treatment is more beneficial. It is also possible that we did not detect a treatment effect because our follow-up was too short, although we measured outcome at time points similar to those used in previous trials. Finally, the different modes of delivery of ESWT (generation of the shock wave, single high-energy shock waves with ankle anesthesia vs repeated lower-energy waves without anesthesia, and different dosages) may also influence the outcome of therapy.

We included participants with a clinical history compatible with plantar fasciitis as well as ultrasound criteria of thickening of the origin of the plantar fascia (≥4 mm), hypoechogenicity, and alterations in the normal fibrillary pattern. These ultrasound criteria are in keeping with changes previously reported for plantar fasciitis on ultrasound examination.[45-51] Previous ESWT trials have either relied on clinical criteria alone[22,35] or required the presence of a calcaneal spur and positive bone scan.[19,20]

Also, we used ultrasound to position the shock wave focus to the thickest portion of the plantar fascia adjacent to the calcaneum. The direction of the shock wave may also affect treatment outcome. Cosentino et al[23] have reported a significant reduction in the grade of enthesitis 1 month after electrohydraulically generated shock wave therapy aimed at the enthesophytosis identified during ultrasound examination. Unfortunately we did not perform repeat ultrasounds following treatment in our study.

The use of a patient preference questionnaire (ie, the Problem Elicitation Technique) in our trial verified that the most common problems encountered by patients with plantar fasciitis are pain, typically worse on arising in the morning and after periods of prolonged sitting, and limitation of activities related to walking. As we could not find any disability questionnaires that have been specifically developed for plantar fasciitis, we used it in our study to complement the Maryland Foot Score (a fixed-item foot-specific disability index) and a generic quality-of-life instrument (ie, the SF-36). Our results provide evidence that

the Problem Elicitation Technique is a valid measure for this disorder. The Problem Elicitation Technique score, Maryland Foot Score, walking ability without need for a rest to relieve painful heel, and the physical function, role limitation (physical), and bodily pain components of the SF-36 all improved over time commensurate with improvement in the pain indices, suggesting that they are all sensitive to change in plantar fasciitis. More study to further define their clinimetric properties in this disorder is needed.

In conclusion, ESWT as applied in our randomized double-blind trial was no better than placebo in the treatment of ultrasound-proven plantar fasciitis. Six and 12 weeks after completion of ultrasound-guided ESWT given weekly for 3 weeks, we detected no difference with respect to pain or function compared with a placebo control.

Author Contributions: *Study concept and design:* Buchbinder, Ptasznik, Gordon, Forbes.
Acquisition of data: Buchbinder, Ptasznik, Gordon, Buchanan.
Analysis and interpretation of data: Buchbinder, Prabaharan, Forbes.
Drafting of the manuscript: Buchbinder, Forbes.
Critical revision of the manuscript for important intellectual content: Buchbinder, Ptasznik, Gordon, Buchanan, Prabaharan, Forbes.
Statistical expertise: Prabaharan, Forbes.
Administrative, technical, or material support: Buchbinder, Ptasznik, Gordon, Buchanan.
Study supervision: Buchbinder, Ptasznik.
Funding/Support: Melbourne Diagnostic Imaging Group and Mayne Health Diagnostic Imaging funded this study.
Acknowledgment: We gratefully acknowledge the support of the partnership of the Melbourne Diagnostic Imaging Group and research assistants Suzanne Gregory, BAppSci, Jenny Gmehling, DipAppSci, and Naomi Zalcman, and the cooperation and assistance of Dornier MedTech Inc and Mayne Health Diagnostic Imaging.

REFERENCES

1. Kibler W, Goldberg C, Chandler T. Functional biomechanical deficits in running athletes with plantar fasciitis. *Am J Sports Med.* 1991;19:66-71.
2. Furey J. Plantar fasciitis. *J Bone Joint Surg Am*. 1975; 57:672-673.
3. Lapidus P, Guidotti F. Painful heel: report of 323 patients with 364 painful heels. *Clin Orthop.* 1965; 39:178-186.
4. Rubin G, Witten M. Plantar calcaneal spurs. *Am J Orthop.* 1963;3:38-40.
5. Gill L, Kiebzak G. Outcome of nonsurgical treatment for plantar fasciitis. *Foot Ankle Int.* 1996;17: 527-532.
6. Blockey N. The painful heel: a controlled trial of the value of hydrocortisone. *BMJ.* 1956;1:1277-1278.
7. Hill J, Cutting P. Heel pain and body weight. *Foot Ankle.* 1989;9:254-256.
8. Wapner K, Sharkey P. The use of night splints for treatment of recalcitrant plantar fasciitis. *Foot Ankle.* 1991;12:135-137.
9. Davis PF, Severud E, Baxter DE. Painful heel syndrome: results of nonoperative treatment. *Foot Ankle Int.* 1994;15:531-535.
10. Wolgin M, Cook C, Graham C, Mauldin D. Conservative treatment of plantar heel pain: long-term follow-up. *Foot Ankle Int.* 1994;15:97-102.
11. Gudeman SD, Eisele SA, Heidt RS, Colosimo AJ, Stroupe AL. Treatment of plantar fasciitis by iontophoresis of 0.4% dexamethasone: a randomized, double-blind, placebo-controlled study. *Am J Sports Med*. 1997;25:312-316.
12. Snook GA, Chrisman OD. The management of subcalcaneal pain. *Clin Orthop.* 1972;82:163-168.
13. Schepsis AA, Leach RE, Gorzyca J. Plantar fasciitis: etiology, treatment, surgical results, and review of the literature. *Clin Orthop.* 1991;266:185-196.
14. Crawford F, Snaith M. How effective is therapeutic ultrasound in the treatment of heel pain? *Ann Rheum Dis.* 1996;55:265-267.
15. Tisdel CL, Harper MC. Chronic plantar heel pain: treatment with a short leg walking cast. *Foot Ankle Int.* 1996;17:41-42.
16. Daly PJ, Kitaoka HB, Chao EY. Plantar fasciotomy for intractable plantar fasciitis: clinical results and biomechanical evaluation. *Foot Ankle.* 1992;13: 188-195.
17. Atkins D, Crawford F, Edwards J, Lambert M. A systematic review of treatments for the painful heel. *Rheumatology (Oxford).* 1999;38:968-973.
18. Crawford F, Atkins D, Edwards J. Interventions for treating plantar heel pain [Cochrane Review on CD-ROM]. Oxford, England: Cochrane Library, Update Software; 2002; issue 2.
19. Rompe JD, Hopf C, Nafe B, Burger R. Low-energy extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study. *Arch Orthop Trauma Surg.* 1996;115:75-79.
20. Rompe JD, Kullmer K, Riehle HM, et al. Effectiveness of low energy extracorporeal shock waves for chronic plantar fasciitis. *Foot Ankle Surg*. 1996;2:215-221.
21. Heller K, Niethard. Der Einsatz der extrakorporalen Stoßwellentherapie in der Orthopädie: eine Metaanalyse. *Z Orthop.* 1998;136:390-401.
22. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. *Clin Orthop.* 2001;387:47-59.
23. Cosentino R, Falsetti P, Manca S, et al. Efficacy of extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study. *Ann Rheum Dis*. 2001;60:1064-1067.
24. Chen HS, Chen LM, Huang TW. Treatment of painful heel syndrome with shock waves. *Clin Orthop.* 2001;387:41-46.
25. Hammer D, Rupp S, Kreutz A, Pape D, Kohn D, Seil R. Extracorporeal shock wave therapy (ESWT) in patients with chronic proximal plantar fasciitis. *Foot Ankle Int.* 2002;23:309-313.
26. Wang CJ, Chen HS, Huang TW. Shockwave therapy for patients with plantar fasciitis: a one-year follow-up study. *Foot Ankle Int.* 2002;23:204-207.
27. Alvarez R. Preliminary results on the safety and efficacy of the OssaTron for treatment of plantar fasciitis. *Foot Ankle Int.* 2002;23:197-203.
28. Ogden J, Alvarez R, Marlow M. Shockwave therapy for chronic proximal plantar fasciitis: a meta-analysis. *Foot Ankle Int.* 2002;23:301-308.
29. Chaussy C, Eisenberger F, Wanner K, et al. The use of shock waves for the destruction of renal calculi without direct contact. *Urol Res.* 1976;4:175.
30. Loew M, Jurgowski W, Mau HC, Thomsen M. Treatment of calcifying tendinitis of rotator cuff by extracorporeal shock waves: a preliminary report. *J Shoulder Elbow Surg*. 1995;4:101-106.
31. Ogden J, Tóth-Kischkat A, Shultheiss R. Principles of shock wave therapy. *Clin Orthop.* 2001;387:8-17.
32. Rompe JD, Hopf C, Küllmer K, Heine J, Bürger R, Nafe B. Analgesic effect of extracorporeal shock-wave therapy on chronic tennis elbow. *J Bone Joint Surg Br.* 1996;78:233-237.
33. Valchanou VD, Michailov P. High energy shock waves in the treatment of delayed and nonunion of fractures. *Int Orthop.* 1991;15:181-184.
34. US Food and Drug Administration. FDA approves shock wave device for severe heel pain. Rockville, Md: US Dept of Health and Human Services; 2000. Available at: http://www.fda.gov/bbs/topics/ANSWERS/ANS01045.html. Accessibility verified August 13, 2002.
35. Dornier MedTech Inc. *Dornier Epos™ Ultra: Summary of Safety and Effectiveness Data*. Kennesaw, Ga: Dornier MedTech Inc; 2002.
36. US Food and Drug Administration. *HealthTronics OssaTron™: Summary of Safety and Effectiveness Data*. Rockville, Md: US Dept of Health and Human Services; 2000. Available at: http://www.fda.gov/cdrh/pdf/p990086b.pdf. Accessibility verified August 13, 2002.
37. Myerson MS, Fisher RT, Burgess AR, Kenzora JE. Fracture dislocations of the tarsometatarsal joints: end results correlated with pathology and treatment. *Foot Ankle.* 1986;6:225-242.
38. Buchbinder R, Bombardier C, Yeung M, Tugwell P. Which outcome measures should be used in rheumatoid arthritis clinical trials? clinical and quality-of-life measures' responsiveness to treatment in a randomized controlled trial. *Arthritis Rheum.* 1995;38: 1568-1580.
39. Ware J, Sherbourne C. The MOS 36-item short-form health survey (SF-36), I: conceptual framework and item selection. *Med Care.* 1992;30:473-483.
40. James D, Bloch D, Lee K, Kraemer H, Fuller R. An index for assessing blindness in a multi-centre clinical trial: disulfiram for alcohol cessation—a VA cooperative study. *Stat Med.* 1996;15:1421-1434.
41. Powell M, Post WR, Keener J, Wearden S. Effective treatment of chronic plantar fasciitis with dorsiflexion night splints: a crossover prospective randomized outcome study. *Foot Ankle Int.* 1998;19:10-18.
42. Rompe J, Schoellner C, Nafe B. Evaluation of low-energy extracorporeal shock-wave application for treatment of chronic plantar fasciitis. *J Bone Joint Surg Br.* 2002;84:335-341.
43. Helbig K, Herbert C, Schostok T, Brown M, Thiele R. Correlations between the duration of pain and the success of shock wave therapy. *Clin Orthop.* 2001; 387:68-71.
44. 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.* 2000;27:2455-2462.
45. Gibbon W, Long G. Ultrasound of the plantar aponeurosis (fascia). *Skeletal Radiol.* 1999;28:21-26.
46. Kamel M, Kotob H. High frequency ultrasonographic findings in plantar fasciitis and assessment of local steroid injection. *J Rheumatol.* 2000;27:2139-2141.
47. Kane D, Greaney T, Bresnihan B, Gibney R, FitzGerald O. Ultrasound guided injection of recalcitrant plantar fasciitis. *Ann Rheum Dis.* 1998;57:383-384.
48. Tsai WC, Chiu MF, Wang CL, Tang FT, Wong MK. Ultrasound evaluation of plantar fasciitis. *Scand J Rheumatol.* 2000;29:255-259.
49. O'Duffy EK, Clunie GP, Gacinovic S, Edwards JC, Bomanji JB, Ell PJ. Foot pain: specific indications for scintigraphy. *Br J Rheumatol.* 1998;37:442-447.
50. Cardinal E, Chhem RK, Beauregard CG, Aubin B, Pelletier M. Plantar fasciitis: sonographic evaluation. *Radiology.* 1996;201:257-259.
51. Groshar D, Alperson M, Toubi A, Gorenberg M, Liberson A, Bar-Meir E. Plantar fasciitis: detection with ultrasonography versus bone scintigraphy. *Foot.* 2000; 10:164-168.

