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ELECTROHYDRAULIC HIGH-ENERGY SHOCK-WAVE TREATMENT FOR CHRONIC PLANTAR FASCIITIS

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Background: Plantar fasciitis is a common foot disorder that may be resistant to nonoperative treatment. This study evaluated the use of electrohydraulic high-energy shock waves in patients who failed to respond to a minimum of six months of antecedent nonoperative treatment.

Methods: A randomized, placebo-controlled, multiply blinded, crossover study was conducted. Phase 1 consisted of twenty patients who were nonrandomized to treatment with extracorporeal shock waves to assess the phase-2 study protocol. In phase 2, 293 patients were randomized and an additional seventy-one patients were nonrandomized. Following ankle-block anesthesia, each patient received 100 graded shocks starting at 0.12 to 0.22 mJ/mm^2, followed by 1400 shocks at 0.22 mJ/mm^2 with use of a high-energy electrohydraulic shock-wave device. Patients in the placebo group received minimal subcutaneous anesthetic injections and nontransmitted shock waves by the same protocol. Three months later, patients were given the opportunity to continue without further treatment or have an additional treatment. This allowed a patient in the active treatment arm to receive a second treatment and a patient who received the placebo to cross over to the active treatment arm. Patients were followed at least one year after the final treatment.

Results: Treatment was successful in seventeen of the twenty phase-1 patients at three months. This improved to nineteen (95%) of twenty patients at one year and was maintained at five years. In phase 2, three months after treatment, sixty-seven (47%) of the 144 actively treated patients had a completely successful result compared with forty-two (30%) of the 141 placebo-treated patients (p = 0.008). At one year, sixty-five of the sixty-seven actively treated, randomized patients maintained a successful result. Thirty-six (71%) of the remaining fifty-one nonrandomized patients had a successful result at three months. For all 289 patients who had one or more actual treatments, 222 (76.8%) had a good or excellent result. No patient was made worse by the procedure.

Conclusions: The application of electrohydraulic high-energy shock waves to the heel is a safe and effective noninvasive method to treat chronic plantar fasciitis, lasting up to and beyond one year.

Level of Evidence: Therapeutic study, <u>Level I-1a</u> (randomized controlled trial [significant difference]). See Instructions to Authors for a complete description of levels of evidence.

Extracorporeal shock waves have been applied since 1990, principally in Europe, for the treatment of numerous musculoskeletal disorders[1-4]. One of the initial treatment concepts was the noninvasive dissolution of a calcific mass in the rotator cuff, similar to the break-up of a kidney stone (lithotripsy)[5-7]. Several musculoskeletal entities that have been treated include calcific tendinitis of the shoulder, lateral epicondylitis, delayed union and nonunion of fractures, chronic plantar fasciitis, Achilles and patellar tendinopathies,

and osteonecrosis of the femoral head[1-9]. Basic-science studies increasingly are providing an understanding of the physiologic mechanisms of pain relief (often immediate) and the modification and repair of the target tissue, which usually requires weeks to months to occur[10-29].

Extracorporeal shock-wave treatments have been applied to patients with chronic plantar fasciitis who have failed to respond to multiple conservative pharmacologic and therapeutic interventions[29-38]. Recent randomized, controlled stud-

ies have been published but with varying results because of differences in study design, direction of the shock-wave delivery, energy levels, size (volume) of the focused energy ellipsoid (f_z) that is transcutaneously transmitted to the fascia, and method of forming the shock wave (electrohydraulic, electromagnetic, and piezoelectric)[32, 39-52]. One study found that satisfactory results were maintained five years following electromagnetic shock-wave treatment[43].

Randomized, placebo-controlled clinical trials for musculoskeletal applications of high-energy shock waves have been conducted in the United States[43,46]. One trial led to Food and Drug Administration approval of the use of electrohydraulic high-energy extracorporeal shock waves for the treatment of plantar fasciitis in October 2000[44,53].

The present study assessed both the short and long-term results of the application of high-energy electrohydraulic shock waves in the treatment of plantar fasciitis. We hypothesized that the likelihood of a successful result would be better in patients receiving active treatment than in patients receiving a placebo. We further hypothesized that nonrandomized patients would have an outcome equal to or greater than that for the treated randomized patients.

Methods

This study was conducted between 1996 and 2003. Phase-1 and phase-2 protocols were approved sequentially by the Food and Drug Administration. Study approvals were for a specific shock-wave generation device, the OssaTron (Health-Tronics Surgical Services, Marietta, Georgia, and High Medical Technologies, Lengwil, Switzerland). This device generates repetitive, high-energy shock waves by the electrohydraulic method and transmits them transcutaneously through the plantar skin into the target tissue. At all participating institutions, the study was conducted by members of the Department of Orthopaedics and was approved by the institutional review board.

Phase 1 involved the nonrandomized application of extracorporeal shock waves to patients with chronic plantar fasciitis to assess any procedural or safety risks, to judge the potential efficacy, and to assess the planned phase-2 study protocol. All phase-1 study patients received active shock-wave treatments. The phase-1 patients were allowed to receive a second treatment at three months if they were dissatisfied with the initial results, on the basis of the four outcome criteria proposed for phase 2.

Phase 2 involved a prospective, randomized, placebo-controlled, physician and patient-blinded, multicenter evaluation to determine both the safety and the effectiveness of this treatment method. Patients who received an actual treatment were given the opportunity to have a second treatment if they failed one or more of the four specific primary outcome parameters. Patients who received a placebo treatment similarly could choose to receive one or two actual treatments (cross over). All retreatment and crossover treatment decisions were made, according to protocol, three months after the initial treatment. Patients were not informed as to which study arm they were in

initially. An additional group of nonrandomized patients was treated to allow training of the physician investigators. These patients also were given the option of a second treatment at three months if they failed any of the outcome parameters. All of these nonrandomized patients in the training arm, who were comparable with phase-1 patients, were aware that they had an actual treatment.

A minimum of two physician investigators participated at each study site. One investigator served as the treatment-blinded evaluator, both for the baseline patient assessment (according to specific inclusion and exclusion criteria detailed in the Appendix) as well as for the follow-up evaluations. This physician was not allowed to observe patient treatment. The actual procedure was performed by a second trained physician who was aware of the specific treatment rendered (with use of a sealed randomization envelope), but who did *not* play any role in evaluating the patient before or after treatment.

Subjects were randomized with use of blocks stratified by study site. Randomization was done by a statistician (Stat-Tech Services) using numbered envelopes that were prepared at a central facility and subsequently distributed to each treatment facility. When a patient was to be treated, the study coordinator was contacted and randomly assigned a specific numbered envelope for the patient.

In both phases of the overall study, chronic heel-pain syndrome was defined as moderate-to-severe heel pain in the involved foot at the origin (enthesis) of the proximal plantar fascia at the medial calcaneal tuberosity that had persisted for at least six months.

There were three important criteria for inclusion in the study. (1) The patient had to have failed to respond after at least three attempts of interventional conservative treatment, which could include at least two prior courses of physical therapy (Achilles tendon and plantar fascia-stretching exercises) and the use of orthotic devices (heel cup, molded shoe insert, night splint, or cast) and at least one prior course of pharmacologic treatment (aspirin, acetaminophen, nonsteroidal anti-inflammatory drug, or corticosteroid injection). If the patient had a corticosteroid injection, extracorporeal shock waves were not administered unless at least four weeks had elapsed since the injection. (2) The objective assessment of pain in the proximal plantar fascia by an investigator, using a pain measurement pressure device (dolorimeter), was ≥5 cm on a 10-cm visual analog scale[54,55]. (3) The patient self-assessment of pain after the first five minutes of walking in the morning was ≥5 cm on the 10-cm visual analog scale.

All patients underwent monofilament sensory testing (10-g retractable monofilament; Smith and Nephew, Germantown, Wisconsin) according to Semmes-Weinstein criteria to screen for possible peripheral neuropathy[56-58]. Any patient who tested positive at two or more of ten sites was excluded from the study. Monofilament testing also was done at each posttreatment evaluation.

Patients with bilateral involvement were allowed to have treatment of only one foot. However, these patients were discouraged from participating during the enrollment evaluation

because of the possible pharmacologic treatment of the contralateral heel at or near the critical three-month evaluation point that might adversely affect one of the four primary outcome criteria. Any patient with pain in the contralateral heel of >4 on the visual analog scale was excluded from the study.

Patients filled out a Short Form-36 (SF-36) questionnaire[59] before treatment and at three months and twelve months after treatment. All patients also were given specific self-assessment questions regarding pain at rest, pain with activity throughout the day, level of participation in recreational activities, and the ability to work.

All patients had radiographs of the heel made in three views during the pretreatment evaluation, at three months after treatment, and at the final follow-up evaluation at one year. The presence or absence of a plantar heel spur was documented. The presence of intraosseous lesions, such as a calcaneal cyst or subtalar arthritis, was exclusionary.

The blinded investigator (evaluator) used a pressure sensor (dolorimeter) to document objectively the amount of pressure (lb/in^2) that, when applied to the site of maximum tenderness, elicited from the study subject a subjective baseline visual analog scale response duplicating maximum daily pain. At each subsequent posttreatment evaluation, the same baseline dolorimeter pressure was applied and the patient was asked to requantify the current amount of pain using the visual analog scale response. This method ensured consistency of the objective pressure evaluation, while allowing for the subjective evaluation, by the patient, of changes in the amount of pain perceived at the time of follow-up.

Patients were treated in an outpatient surgical center. Prior to ankle-block anesthesia, the point of maximum plantar surface tenderness was demarcated (targeted) with a surgical marking pen. The involved leg was draped from the direct view of the patient. Ear protection devices were used by the study subject and all involved personnel. Patients received either a complete ankle-block anesthesia with lidocaine (the treatment group) or three 1-mL subcutaneous injections of lidocaine (the placebo group) prior to the application of shock waves. The shock-wave treatments were applied with use of the OssaTron device. Standard ultrasound gel was applied to the heel for transcutaneous conduction of the shock waves from the OssaTron into the heel tissues. The device was adjusted to maximize the focused treatment wave (f$_2$) into the plantar fascia[60]. Each study subject assigned to active treatment received 100 graded shocks (14 to 18 kV; 0.12 to 0.22 mJ/mm^2) to assess the effectiveness of anesthesia, followed by 1400 shocks at 18 kV (0.22 mJ/mm^2) for a total of 1500 shocks, all of which were applied at two per second (2 Hz). The total energy delivered was 324.25 J. The treating physician continually manipulated the heel against the treatment head throughout the shock-wave applications. Shock waves thus were applied to the maximum pain site as well as an area in a 1-cm radius surrounding it.

For the patients assigned to placebo treatment, a styrofoam block was placed against the treatment head to absorb the shock waves by the presence of the multiple air cavities. In addition, a fluid-filled intravenous bag was placed between the styrofoam block and the subject's heel to mimic the water-filled treatment head. Patients who received a placebo treatment did not have any coupling gel (ultrasound gel) applied to the heel. Placebo patients also had 1500 shocks "delivered" according to the aforementioned gradation protocol, effectively duplicating the duration and noise of an active treatment. Patients who received the placebo treatment and patients who received the active treatment were kept apart in the recovery room to avoid any discussions and comparisons about what occurred in the surgical suite.

All patients underwent evaluations within forty-eight hours following treatment and at one, two, three, six, nine, and twelve months. In both phase 1 and phase 2, an initial success or failure status was assigned on the basis of the subjective and objective findings three months after the initial treatment. This three-month interval was selected on the basis of the expectation that some or all of the healing process most likely would be evident at that time. Subsequently, patients either were followed to one year without additional intervention or received additional treatment followed by periodic evaluations until one year following the additional treatment. Patients were encouraged to continue follow-up beyond one year.

At three and twelve months, patients were assigned a success or failure status according to each of four predetermined primary criteria. (1) On the investigator assessment of pain, the patient had to have a minimum improvement of 50% over the dolorimeter-induced baseline pain score, with a required score of ≤4 on the visual analog scale. (2) On the patient self-assessment of pain on first walking in the morning, success required a minimum improvement of 50% over the pretreatment baseline and a visual analog scale score of ≤4. (3) On the patient self-assessment of activity with regard to the distance and time that he or she was able to walk without heel pain, the patient had to demonstrate an improvement of ≥1 point on a 5-point scale or had to maintain a 0 or 1 baseline level (no pain or minimal pain). (4) With regard to the use of pain medications, prescription analgesics were not given after treatment. Self-treatment with over-the-counter analgesics or anti-inflammatory medications was documented with a medication log returned at each evaluation. Success required that the patient had not taken any such medication (even for a reason other than pain in the treated heel) between ten and twelve weeks after treatment.

Each patient in the randomized group unequivocally had to meet all four success criteria to attain an overall status assignment of success.

Patients who were assigned a failure status at three months were informed that they could (1) withdraw from the study to pursue alternative treatment modalities or (2) continue in the study by trying an additional active treatment as allowed by the study protocol. All evaluations of retreatment or crossover from placebo to active treatment were done according to the same protocol as for the primary treatment-placebo study arm.

The patients who elected to receive an additional treat-

ment or treatments were classified arbitrarily as having a failure of the initial treatment. All patients receiving additional treatment were followed according to the same protocol (with evaluations at one, two, three, six, nine, and twelve months) after the last applied shock-wave treatment.

If patients did not complete the twelve-month follow-up protocol, efforts were made to encourage compliance. Any patient who failed to respond to these efforts was classified as a failure in the outcome assessment.

Patient acceptance into the study, data collection, and analysis were further blinded. At each center, a research assistant collected questionnaire data (subject self-assessments and SF-36) independently of the evaluating physician. Individual centers were not allowed to communicate with each other. Data from all centers were sent to an independent organization, M² and Associates, for composite compilation and initial analyses. Final data sets and analyses were then sent to an outside statistician, Stat-Tech Services, to validate the results.

Univariate analyses were performed with use of the Pearson chi-square statistic. Multiple logistic regression was used to test jointly the explanatory variables that were significant in the univariate analyses. The adjusted odds ratios were presented with the respective 95% confidence intervals. Significance was considered at a two-tailed level of <0.05.

The study sample size was obtained on the basis of the need to collect sufficient safety information. The original efficacy sample size was calculated on the basis of an assumed response of 70% in the active treatment arm and 30% in the placebo arm, which was smaller than the sample size required for adequate safety information. Additional subjects were added after the study sample size was reached in order to allow continued patient access and obtain additional safety information.

The primary efficacy analysis was based on the success status at three months. The p value for the inferential evaluation of the null hypothesis of no treatment effect was obtained with use of a likelihood ratio test controlling for study site. The test statistic was obtained by evaluating the difference in log-likelihood for the logistic model including the study site and treatment and the logistic model including only the study site. The Pearson chi-square test also was used to evaluate the null hypothesis that there was no association between treatment and response at three months.

To investigate the durability of the response through six months and one year, the time-to-failure after the initial treatment was compared with use of Kaplan-Meier methodology, and inference was based on the log-rank statistic. Substantially more follow-up data were available to support this analysis than were available for the three-month analysis at the time of the initial Food and Drug Administration submission. The proportion of six-month and one-year responders was compared, with use of a Pearson chi-square test, for all subjects who had six months of follow-up data. A two-tailed Fisher exact test was used to compare the distribution of successful outcomes at three months for the patients who had retreatment with electrohydraulic shock waves and the patients who initially had the placebo treatment. Secondary efficacy measures

of the visual analog scale scores for pain were summarized at each visit through six months. The six-month and one-year time-points included only subjects who were responders at three months. The hypothesis of no treatment difference in the mean percentage change from baseline was evaluated with use of a t test assuming equal variance.

Selected demographic and baseline characteristics were assessed for homogeneity in the subject population across sites and treatment groups. The assessment of homogeneity was used to assist in the interpretation of the efficacy and safety analyses. For categorical variables, a logistic modeling approach was used. For continuous variables, a general linear modeling approach was used and inference was based on p values associated with the type-III sums of squares.

Deviations from planned analyses included use of an additional Pearson chi-square test to compare the proportion of subjects with a successful outcome at six months. No further confidence intervals were calculated, except for the 95% confidence interval of the relative risk for success at three months. Testing comparing the visual analog scale scores for the patients who had retreatment with electrohydraulic shock waves and the patients who were initially treated with placebo was not performed.

Results

Twenty patients were enrolled in the phase-1 study (Fig. 1). The treating and evaluating physician was the same individual, and all patients knew that they received active extracorporeal shock-wave treatment. Seventeen patients (85%) had substantial improvement or complete relief of pretreatment symptoms at three months. Three patients were not satisfied with the results at three months and chose a second treatment. Two of the three had symptomatic improvement, whereas one continued to have no improvement. All twenty patients were followed to one year, with a good-to-excellent result maintained at one year in nineteen[54]. These nineteen patients reported continued relief of symptoms for sixty-five to sixty-eight months later, and none had a recurrence of symptoms. The single patient who had no symptomatic improvement continued to have chronic pain.

Phase 2 involved 344 patients, comprising 293 randomized and fifty-one nonrandomized study subjects (Figs. 2 and 3). This patient population was predominantly female (66.3%). The mean age of the subjects at the time of enrollment was 48.6 years (range, nineteen to seventy-nine years; median [and standard deviation], 49 ± 11.3 years). Age was not significantly associated with the three-month outcome (p = 0.138). Gender, ethnicity, and pretreatment osteoarthritis in other joints, such as the knee or the hip, were not significantly associated with success or failure.

Of the 148 randomized patients who had an active treatment initially, 144 returned for all evaluations up to three months and eighty-nine continued to twelve months. Of the 145 randomized patients who initially received a placebo, 141 returned for evaluations at three months and sixty-four continued to twelve months. Of the fifty-one nonrandomized pa-

tients, forty-seven returned for evaluations at three months and thirty-six continued to twelve months. Altogether 189 phase-2 patients (55%) cooperated in follow-up to at least one year following the initial treatment.

Duration of Symptoms
All patient groups were similar with respect to the mean duration of symptoms prior to shock-wave or placebo treatment. The duration of symptoms was significantly associated with
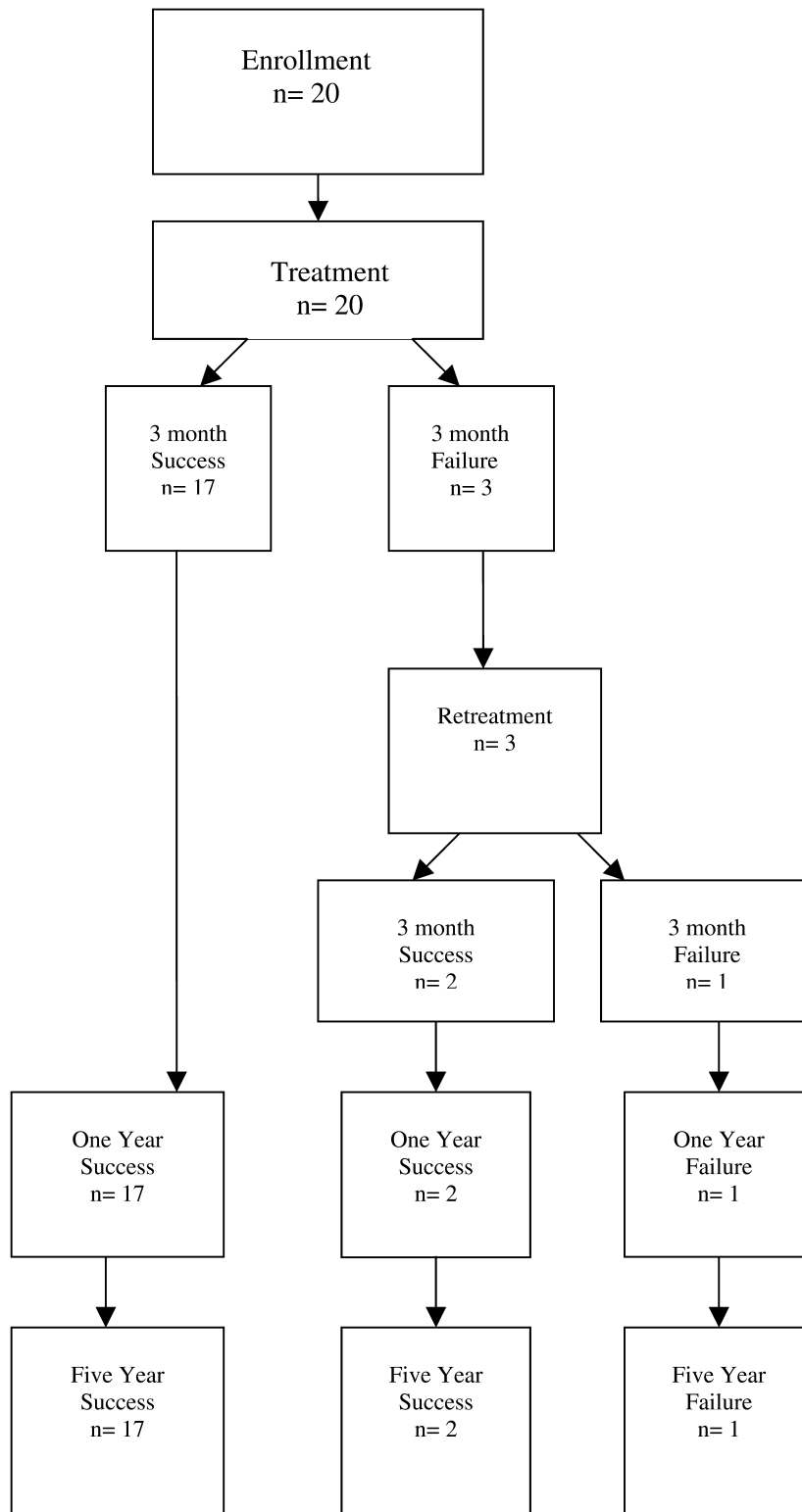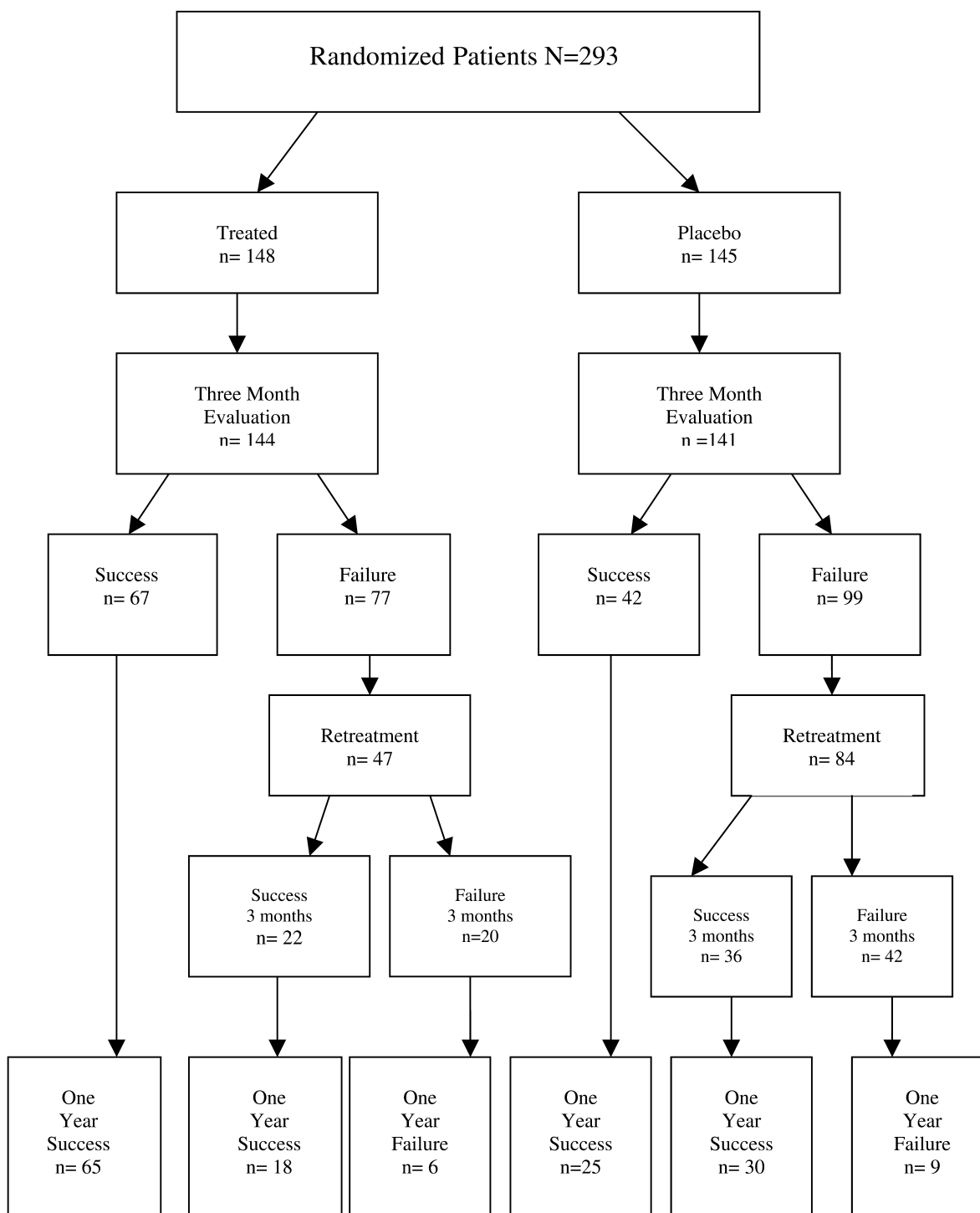
Fig. 1
Flowchart of phase-1 patients.

Fig. 2

Flowchart of randomized phase-2 patients.

success (p = 0.001). Adjusting for the duration of symptoms affected the overall significance of the association between treatment and success (p = 0.004). The analysis divided the population into patients with a shorter duration of pain (less than or equal to the median duration) and those with a greater duration of pain (more than the median duration). Patients with a shorter duration of symptoms had higher response rates, and the absolute difference in the success rates

between the two patient groups was similar in magnitude. The difference in treatment success rates was 13% (52% for the active treatment group compared with 39% for the placebo group) for the patients with a shorter duration of pain and 20% (40% for the active treatment group compared with 20% for the placebo group) for the patients with a longer duration.

Investigator Heel-Pain Assessment
All treatment groups had comparable baseline pain scores (Table I). Evaluation of the investigator assessment of heel pain at four, eight, and twelve weeks indicated significant treatment effects as early as the four-week visit. The percent-

age change (improvement) in investigator assessment of heel pain at four, eight, and twelve weeks was 41%, 49%, and 59%, respectively, for active treatment subjects compared with 27%, 32%, and 43%, respectively, for placebo treatment subjects. The p values for the comparisons of active treatment versus placebo at these visits were 0.018, 0.001, and 0.002, respectively. This dolorimeter-based visual analog scale measurement at three months was the most sensitive measure comparing patients who had received active treatment with those who had been randomized to treatment with a placebo (p = 0.002). This sensitivity was maintained at twelve months (p = 0.005).

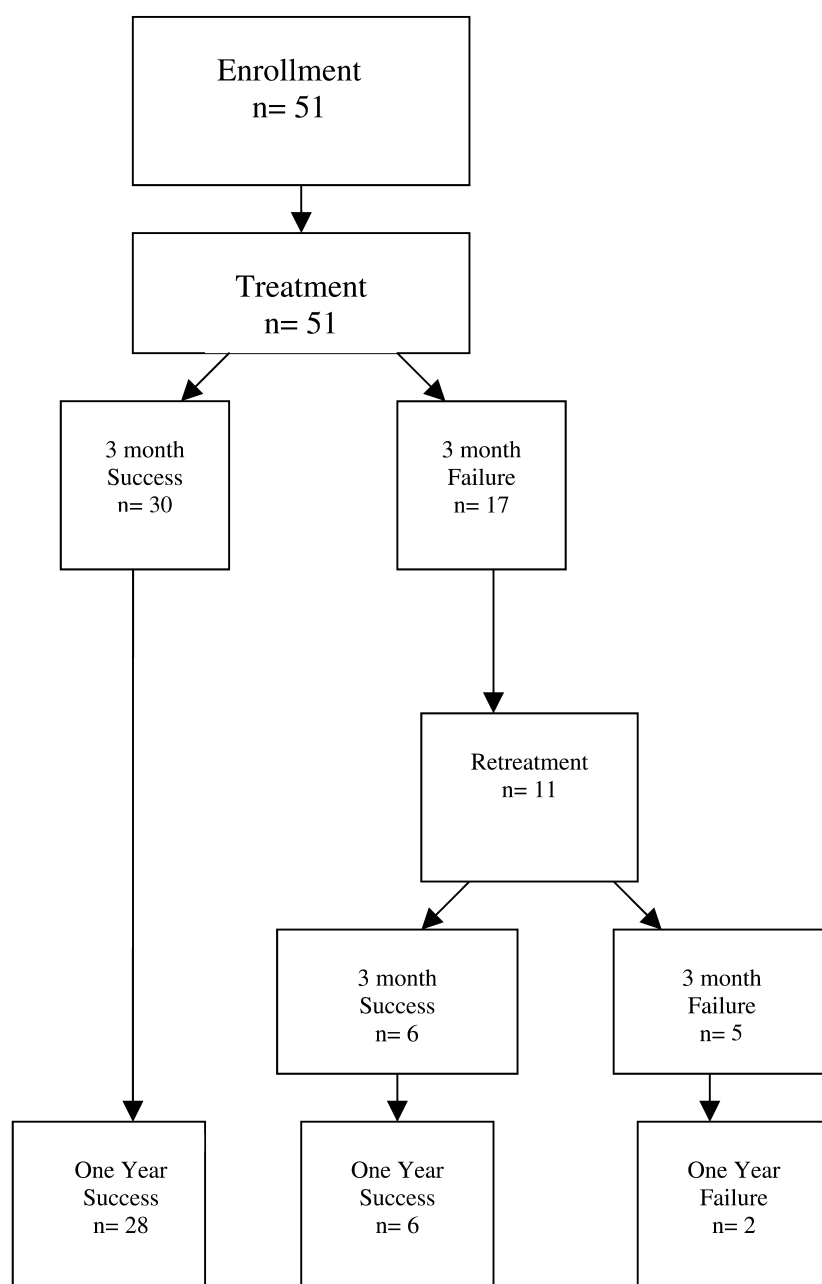Fig. 3
Flowchart of nonrandomized phase-2 patients.

TABLE I Physician Assessment of Heel Pain*					
		Phase 2			
	Phase 1	Treated	Placebo (No Cross Over)	Placebo (Cross Over)	Nonrandomized
Baseline (n = 364)	7.95	7.80	7.99	7.67	7.83
12 weeks (n = 352)	2.95	3.23	4.52	2.50	2.01
1 year (n = 209)	1.67	1.87	5.13	1.73	1.39
*The values are given as the mean score on the visual analog scale.					

TABLE II Patient Self-Assessment of Morning Heel Pain*				
		Phase 2		
	Phase 1	Treated	Placebo	Nonrandomized
Baseline (n = 364)	7.83	8.08	8.14	6.85
12 weeks (n = 352)	3.17	3.43	4.28	2.36
1 year (n = 209)	1.34	1.41	3.54	1.27
*The values are given as the mean score on the visual analog scale.				

Subject Self-Assessment of Morning Heel Pain
Baseline values were comparable (Table II). For the patient self-assessment of morning heel pain, the mean score at four, eight, and twelve weeks improved 45%, 50%, and 58%, respectively, for the subjects who had active treatment and 31%, 39%, and 47%, respectively, for the subjects who had placebo treatment. The p values for the comparisons of active treatment and placebo effects at these visits were 0.002, 0.021, and 0.014, respectively. At twelve months, this difference was maintained (p = 0.015).

Subject Self-Assessment of Activity-Related Pain
Baseline values were comparable (Table III). For the patient self-assessment of pain with activity, the mean score at four, eight, and twelve weeks improved 40%, 53%, and 51%, respectively, for patients who had active treatment and 29%, 32%, and 47%, respectively, for subjects who had placebo treatment. The p values for the comparisons of active treatment and placebo effects at these visits were 0.024, 0.077, and 0.059, respectively. By twelve months, however, no difference in subjective self-assessment of activity-related pain persisted between the two groups.

Use of Pain Medications
This parameter had the least sensitivity to differentiate between actively treated patients and those who received the placebo as success levels in both groups were nearly identical. Furthermore, over 70% of the patients took medications for pain in another body region than the treated heel.

Repeat Procedures
In phase 2, forty-seven (61%) of the seventy-seven patients who had active treatment and were assigned to a failure status at twelve weeks chose to have retreatment, whereas eighty-four (85%) of ninety-nine placebo-treated patients with a failure status at twelve weeks chose to undergo an active extracorporeal shock-wave treatment and nineteen had a second active treatment. In the nonrandomized cohort, eleven (23%) of forty-seven patients chose a second treatment. A total of 370 active extracorporeal shock-wave treatments were performed in randomized and nonrandomized subjects. The difference between the randomized, actively treated patients and the placebo-treated patients with respect to the selection of a second treatment was significant (p = 0.003).

At three months, twenty-two of forty-two patients who were initially actively treated and received a second active treatment attained success. This success was maintained in eighteen of the twenty-two patients at one year. Three months after seventy-eight placebo-treated patients had crossover treatment, thirty-six attained success. At one year, thirty-nine patients were lost to follow-up. Of the remaining thirty-six patients, thirty had a successful outcome. Three months after a repeat procedure, six of eleven nonrandomized subjects had a successful outcome and six of eight had a successful outcome at one year.

Complications
There were no complications in the phase-1 patients. The most frequent phase-2-related complications in all groups were pain after treatment and mild neurologic symptoms (numbness or dysesthesia) principally related to the ankle-block anesthesia. All patients had complete resolution of the post-treatment neurologic symptoms by the three-month evaluation, and no patient had neurologic complaints at one year.

Rates of Treatment Success for Randomized Patients
Of the 144 phase-2 patients who were randomized to active treatment, 47% met all four success criteria at three months

TABLE III Patient Self-Assessment of Pain During Activity*

	Phase 1	Phase 2		
		Treated	Placebo	Nonrandomized
Baseline (n = 364)	3.18	3.49	3.53	2.63
12 weeks (n = 352)	0.91	1.72	1.88	0.85
1 year (n = 209)	0.61	0.83	1.56	0.63

*The values are given as the mean score on the visual analog scale.

TABLE IV Summary of Data on 289 Patients Treated During the Food and Drug Administration Clinical Trial

	Outcome*			
	Excellent	Good	Fair	Poor
Phase 1	19	—	1	—
Phase-2 treated	67	37	21	19
Phase-2 crossover treated	36	24	8	10
Phase-2 nonrandomized	25	14	5	3
Total†	147	75	35	32

*The outcome was evaluated according to the criteria described by Roles and Maudsley[61], with an excellent outcome indicating that all four criteria for success were met; good, that two or three of the four criteria were met; fair, that one of the four criteria was met; and poor, that none of the four criteria was met. †A total of 222 patients had a good or excellent result, and sixty-seven patients had a fair or poor result.

compared with 30% of the 141 subjects who received placebo treatment (p = 0.008). Of the fifty-one nonrandomized patients, 67% met all four success criteria. Of the eighty-four patients who had been randomized to placebo treatment, failed to meet the four success criteria, and subsequently elected to have an active treatment, 43% subsequently achieved a success at three months. The time to treatment failure was evaluated starting at three months and followed through to twelve months. A significant difference was found when patients who had one or more treatments (including crossover treatments) with success were compared with patients (actively treated and placebo-treated) who were rated as having a failure (log-rank test, chi-square = 9.68; p = 0.0019).

The primary efficacy comparison for success of all four components of efficacy at three months indicated a robust treatment effect (p = 0.003). Accordingly, the relative risk for success at three months (active treatment relative to placebo) was 1.56 (95% confidence interval, 1.15 to 2.13), implying a >50% increase in the chance of success at three months with active treatment compared with placebo.

In the phase-2 patients, the rate of success maintained at twelve months was 93% for those initially treated actively, 83% for those who crossed over from initial placebo treatment, and 93% for those who were not randomized. In contrast, only twenty-five (18%) of the 141 patients who received the placebo and chose no subsequent treatment at three months had a success at twelve months. At twelve months, the differences between the actively treated patients and the placebo-treated patients showed a continuing significance (p = 0.002). Thirty-four patients subsequently were followed between twelve and

twenty-seven months, and all maintained the successful results. The overall maintenance of a successful outcome was found to be significant (Fisher exact test, p = 0.040).

Analysis of All Treated Patients
Although only the randomized patients were used for the initial three-month and final one-year statistical analyses submitted to the Food and Drug Administration, the results in all patients were subsequently assessed in a clinically relevant manner with use of a grading system similar to one commonly used in most published European musculoskeletal shock-wave outcome studies[61]. Patients who had initial visual analog scale scores (in the first three outcome assessment categories) of >8 frequently met the criterion of 50% improvement, but they failed to have a visual analog scale score of ≤4. All 289 phase-1 and 2 patients who received one or two actual shock-wave treatments were grouped together and were rated as having an excellent result if all four success criteria were met, a good result if two or three of the four success criteria were met, a fair result if one of the four success criteria were met, or a poor result if none of the four success criteria were met.

With use of this grading system, 147 (50.9%) of 289 patients had an excellent result and seventy-five (26%) had a good result (Table IV), for a combined total of 222 patients (76.8%) in whom the result was considered a success, even when pain relief was not complete in one of the outcome categories.

Discussion

Chronic heel pain that adversely affects employment or lifestyle is a common complaint. A heel spur is evident in

50% to 60% of patients having a diagnosis of heel pain. In one study, electrohydraulic shock waves delivered at the energy level used for plantar fasciitis (18 to 20 kV; 0.22 to 0.27 mJ/mm^2) caused no change in the heel spur when one was present nor did the presence or absence of an inferior heel spur affect the likelihood of a positive response[62].

The initial treatment of proximal plantar fasciitis should be conservative (nonsurgical), an approach that may be successful in as many as 90% of patients by providing substantial, if not complete, relief of the symptoms[63]. However, there is no consensus for a specific treatment protocol, particularly when symptoms last for more than three months.

Evaluations of the nonoperative methods for treating chronic plantar fasciitis have been difficult to assess statistically, since many protocols have included multiple and variable nonoperative regimens within the same study, and few nonoperative treatments have been analyzed with randomized controlled studies[63]. Martin et al. reviewed numerous studies on nonoperative treatment and showed a wide variation in acceptable outcomes, ranging from 44% to 82% (average, 60.3%) of patients who had complete relief of heel pain[64]. Interestingly, in that study, only 51% of the patients were completely asymptomatic following treatment, whereas 82% were satisfied with the final outcome relative to the amount of residual pain[64]. We found similar outcome perceptions and satisfaction levels by the patients who received shock-wave treatment; complete pain relief was not needed for patient satisfaction with the eventual outcome.

Of interest was the lower than expected rate of retreatment in the active treatment arm of study. The study was designed on the assumption that the majority of subjects who failed to respond to the primary treatment would elect to have a second treatment. However, forty-seven (61%) of the seventy-seven treated subjects who failed to meet all four success criteria chose retreatment compared with eighty-four (85%) of the ninety-nine patients who failed the placebo treatment. This observation suggests that many subjects who were assigned a final "fail" status (less than four of the four criteria for success were met) may have been sufficiently satisfied with the outcome that they did not want a second treatment.

When such noninvasive methods fail to achieve relief in a reasonable period of time, surgery frequently is recommended. A recent study found that patients undergoing electrohydraulic high-energy shock-wave application and patients undergoing percutaneous partial fasciotomy had comparable outcomes[65]. However, the former group (patients who had extracorporeal shock waves) had a more rapid return to the activities of work and daily living.

The technology of applying shock waves to the heel is similar to that used for lithotripsy. Several devices have been designed specifically for the treatment of musculoskeletal conditions. This is necessary since the energy levels, the focused volume of the energy ellipsoid (f$_2$), the central size of the maximum energy level within the ellipsoid, and the depth of penetration used in lithotripsy are different from those considered safe and effective for musculoskeletal tissues that are not as deeply situated as the kidneys and ureters. These musculoskeletal devices generate and focus the shock waves by one of three basic methods—electrohydraulic, electromagnetic, or piezoelectric[60]. The differences in shock-wave energy to the target tissue relate specifically to the method of generation of the shock wave, the size and volume of the f$_2$ ellipsoid, and the depth of energy penetration. These factors may result in significant differences in the potential clinical efficacy[2,60]. Comparison studies with lithotriptors (for renal stones only) have described the electrohydraulic method as being more clinically effective in stone fragmentation compared with electromagnetic or piezoelectric devices[66]. The machine used for the current musculoskeletal studies employed electrohydraulic shock-wave generation and was the first shock-wave device approved by the Food and Drug Administration for any musculoskeletal indications[53]. Since direct comparison studies of machines have not been done, there is no information concerning the relative efficacy of one method of shock-wave generation over any other for specific musculoskeletal tissue applications[60].

Electrohydraulic application is based on one treatment in most patients, whereas electromagnetic and piezoelectric devices, as described in most European-based publications, routinely use multiple (three to six) treatments[1,2]. Buchbinder et al. assessed a low-energy electromagnetic device in a randomized, double-blind, placebo-controlled study with use of three treatments[49]. They found no differences between the patients who received active treatment and those who received the placebo. This observation suggested that the overall efficacy of low-energy, multiple shock-wave treatments for musculoskeletal applications was questionable. However, such a generalization was inappropriate because of limitations of that particular study (the patients were treated as early as six weeks after symptom onset, actual shock waves were delivered to placebo-treated patients, and variable numbers of shocks [mJ/mm^2 and total energy (Joules)] per patient were used) compared with other studies. Furthermore, patients received no specific physical examinations before and after treatment, and no orthopaedist was involved in the study. A "trained technician" delivered the treatment after a radiologist focused the device with use of ultrasound. In the current study, patients had to have had symptoms for a minimum of six months, all patients received exactly the same energy levels, shock waves were not delivered to placebo patients, and trained orthopaedists actively participated in the evaluation and treatment of the patients. When the Food and Drug Administration approved the OssaTron device, one stipulation was that treatment should be administered only by an appropriately trained and certified physician or podiatrist.

Other studies on low-energy electromagnetic shock waves in which patients received the same dosage and those treated with a placebo received no shock waves, with delivery in a transverse direction, also showed no effective difference between the actively treated patients and the patients who received the placebo[50,51]. Those studies (compared with the present study on high-energy electrohydraulic shock waves) sug-

gested that there are different tissue responses to shock waves contingent upon the method of generation (electrohydraulic or electromagnetic), the level of energy applied, or the direction of delivery (perpendicular to the plantar surface or transverse).

Low-energy electromagnetic and piezoelectric devices have an adjunct ultrasound device that must be used to focus f_2 because the low-energy shock waves are delivered in a medial-to-lateral direction, rather than perpendicular to the plantar surface. This technique delivers shock waves to the thinnest portion of the fascia, which is done to minimize shock-wave impaction against the calcaneus, thus avoiding pain stimulation and the need for anesthesia. This technique requires additional expertise in ultrasound imaging by the treating physician. With transverse delivery, the foot is held in a fixed position. Accordingly, only a small section of the fascia is impacted by the shock waves. In contrast, the electrohydraulic shock waves are administered through the plantar surface (a wider surface area), targeting the point of maximal pain, and the foot is continually manipulated to treat an area 2 cm in diameter around the predetermined focal point of maximal pain. Some of the shock waves strike the calcaneus and bone and are reflected back into the involved fascia, potentially increasing the total effect of each shock wave.

One study stated that the low-energy treatment was considered "unpleasant by all patients."[32] Treatment with high-energy shock waves, particularly those generated electrohydraulically, requires some type of anesthetic agent. In our study, patients receiving the actual high-energy shock waves were administered an ankle block. Since the approval of the device by the Food and Drug Administration, we have also used conscious sedation. This anesthetic technique also allows the treatment of both heels when appropriate levels of chronic fascial pain are present bilaterally[67].

Rompe et al. performed several studies on the treatment of plantar fasciitis with shock waves[4,32,39,43]. Those studies all used electromagnetically generated shock waves, involved multiple treatments, and varied considerably with respect to the treatment protocols. All outcome evaluations emphasized subjective improvement, rather than complete relief of heel pain, and used outcome criteria that were much less restrictive than those used in our study. In one study, Rompe et al. recently reported on patients who had a successful outcome five years after treatment with low-energy extracorporeal shock waves[43]. Hammer et al. reported on forty-four patients with chronic plantar fasciitis who were treated with piezoelectric shock-wave generation[42]. There were no control patients. In twenty-four of forty-four patients (55%), the visual analog scale improved; however, only thirteen patients (30%) rated the outcome as completely successful.

The mechanism of shock-wave action in soft tissues (tendon and fascia) is still under investigation. Rompe et al. showed no tendon cellular damage in a rabbit model with use of energy levels normally applied clinically for the treatment of plantar fasciitis[10,11]. They demonstrated neovascular proliferation as did Wang et al.[14,22]. When shock waves are applied to bone (at a much greater energy level and number of shocks),

microfractures and osteocyte damage occur, followed by a proliferation of osteoblasts and elaboration of bone[1,2,4,17,20,23-26]. A similar microdisruption of the thickened plantar fascial origin probably occurs, resulting in an inflammatory and soft-tissue reparative response[2,10,14].

This study presents robust evidence of a treatment effect. The primary efficacy end point of success at three months and the analysis of sustained response were both highly significant ($p < 0.01$). Analyses of the long-term (one-year) response supported a continuing treatment difference. Hence, there is ample evidence that electrohydraulically generated high-energy transcutaneous shock-wave treatment is an effective treatment of heel pain due to chronic plantar fasciitis when compared with placebo. We believe that our data support the use of electrohydraulic high-energy shock-wave treatment before consideration of any open or endoscopic surgical treatment.

Appendix

(eA) A table showing the complete inclusion-exclusion criteria is available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ∎

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