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Bilateral Chronic Proximal Plantar Fasciopathy: Treatment With Electrohydraulic Orthotripsy

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ABSTRACT

***Background*: Patients presenting for treatment of chronic plantar fasciopathy often have bilateral involvement. When various nonoperative treatments fail, subsequent intervention may be problematic, especially since bilateral surgery (bilateral fascial release) may not be realistic because of variable, frequently restrictive postoperative weightbearing limitations. *Methods*: Twenty-three patients (46 heels) were treated with electrohydraulic high-energy orthotripsy to the plantar entheses of both feet while under the same anesthesia (conscious sedation). Following orthotripsy, all patients immediately were fully weightbearing and resumed normal activities of daily living and work, usually within 24 hours. Progressive return to athletic activities was allowed. Patients were assessed by three outcome parameters: (1) pain measured objectively by a dolorimeter combined with the patient's subjective evaluation of the level of pain; (2) pain after 5 minutes of walking upon arising; and (3) pain with daily activities. All pain measurements were done by the visual analog scale. *Results*: Patients initially experienced varied pain relief responses. This included earlier pain relief in one heel compared to the other, as well as better pain relief in one heel than the other at the 6- and 12-week evaluations, but with much less variance at the 1-year evaluation. By 3 months following orthotripsy, 28 heels (61%) had good or excellent results. These results were maintained or improved at 1 year. In 18 heels (39%), the outcome was fair or poor. Nineteen heels received a second orthotripsy application; one patient requested a second orthotripsy treatment of only one heel, while nine patients requested a second treatment of both heels. The outcome showed further improvement following the second application of orthotripsy. At 1 year after one or two orthotripsy applications, 19 patients (38 heels) were satisfied with the results in both heels (83%), while four patients (eight heels) still had an unsatisfactory outcome (17%). *Conclusion*: Electrohydraulic high-energy orthotripsy is a reasonable nonincisional method for treating patients with bilateral chronic proximal plantar fasciopathy under a single anesthetic without the prolonged nonweightbearing status often recommended for patients following unilateral open or endoscopic fascial release.**

Key Words: Heel Pain; Plantar Fascia; Shock Wave

INTRODUCTION

Chronic plantar fasciopathy is an extremely common problem presenting to physicians who concentrate on disorders of the foot and ankle. Many patients have variably symptomatic bilateral complaints that may benefit from concomitant treatment.[22] The extent of bilateral involvement has been minimally addressed in studies.[9] Patient factors that increase susceptibility to bilateral involvement include obesity and heel pad atrophy.[7,17]

Patients with bilateral plantar fasciopathy that has failed to respond to multiple nonoperative medical, therapeutic, and orthotic interventions after 6 months or longer become a major challenge.[10] Surgery may be considered after such treatment failures.[2,3,15,25] The outcome is varied, with some studies reporting only 50–60% successful outcomes.[6,8] The recommendation that the patient be nonweightbearing or limited in full weightbearing for 3–4 weeks following unilateral

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open or endoscopic partial fascial release effectively precludes surgical treatment of the contralateral side under the same anesthesia.

Orthotripsy for the nonincisional treatment of chronic plantar fasciopathy has been used since 1990 in Europe and Asia.[1,4,12,18–21,23,24] In a previously reported study, patients were allowed to undergo orthotripsy of only a single heel.[11] As part of data acquisition for the Food and Drug Adminstration (FDA) evaluation of the orthotripsy, patients were questioned regarding bilateral symptoms. Of the patients enrolled in this particular study for unilateral orthotripsy, 199 of 314 (63%) patients had mild involvement of the contralateral side [visual analog scale (VAS) <4 when tested with the dolorimeter].[11] None of the studies described in a meta-analysis of treatment of plantar fasciopathy with orthotripsy discussed simultaneous treatment of both feet under the same anesthesia.[13]

Since FDA device approval of orthotripsy for chronic proximal plantar fasciopathy (February 2000), we have instituted bilateral treatment of chronic plantar fasciopathy under the same anesthesia to effectively allow a patient to return to normal work and activities of daily living as quickly as possible. The specific purpose of this study was to review the results of bilateral treatment of chronic plantar fasciopathy with high-energy electrohydraulic shock wave orthotripsy. Since symptom severity was usually different in each foot, we also assessed the pattern of pain development and the response to orthotripsy in each foot.

MATERIALS AND METHODS

The device used in this study, the OssaTron™ (HealthTronics Surgical Services, Marietta, GA; and High Medical Technologies, Lengwil, Switzerland), was approved by the FDA in October 2000 for the treatment of chronic proximal plantar fasciitis with high-energy electrohydraulic shock wave. All bilaterally involved patients were evaluated initially using criteria similar to the FDA study conducted previously in our office.[11] Patients had to have symptoms for a minimum of 6 months with failure of at least three nonoperative treatments on each side.

Of the initial 51 patients seeking treatment, 27 patients (54 heels) had major bilateral involvement, defined as moderate to severe pain by VAS. However, four patients failed to complete the study to 1 year. Accordingly, only 23 patients (46 heels) were assessed for outcome at 3, 6, and 12 months.

There were 15 men and eight women. The age range was 20–37 years (average, 29 years). Twenty-two patients were quite active athletically (distance running, 11; tennis, 9; squash, 1; golf, 1), and all felt the heel pain was interfering with their athletic activities. No patient had systemic disease.

All patients had at least one course of nonsteroidal antiinflammatory drugs. Seventeen patients had a unilateral cortisone injection, while eight patients had received bilateral injections (although at different times). Only three patients had consented to a repeat injection on the same side. Twenty-one patients had modified their normal or athletic shoes with either prefabricated or customized orthoses. All patients had undergone stretching regimens, but none had undergone referral specifically for physical therapy. Seven had worn night splints. None had been casted. Because of bilaterality of pain no patient had been placed on crutches. None of the patients had exactly the same antecedent treatment regimen prior to orthotripsy.

No patient with bilateral symptoms had developed simultaneous (synchronous) onset of the heel pain. The pain had been present in the initially symptomatic side for 11–39 months (average, 19 months) prior to orthotripsy. The onset of moderate to severe pain in the opposite heel ranged from 4 to 17 months (average, 11.3 months) after onset of pain on the initially presenting side. In no patient was the pain described as ''equal'' in severity. All patients felt the second side became symptomatic because of altered patterns of ambulation or during running or sports activity caused by first side pain. In 12 patients, the pretreatment pain was severe on both sides. In seven patients, the pain was severe on one side and moderate on the contralateral side. In four patients, the pain was moderate on both sides. The average pretreatment dolorimeter-induced heel pain VAS (46 heels) was 7.8 (range, 6.3–10).

Each heel was assessed individually. Evaluation included pressure dolorimeter and Semmes-Weinstein monofilament (Smith and Nephew, Germantown, PA; 10 g, 5.07 filament size) testing. The dolorimeter (Innovation and Development Corp, Victoria, BC, Canada), a hand-held pressure measurement device, was applied to the heel under increasing amounts of pressure from 0 to 50 psi. The dolorimeter was applied to the point of maximal tenderness and applied pressure (pounds per square inch) that duplicated the patient's perception of maximum pain was recorded as the reference baseline in follow-up studies. The patient also was asked to grade this degree of dolorimeter-induced pain on a 10-cm VAS. Using a daily log sheet, the patient was asked to utilize the same VAS to quantify pain in each heel after the first 5 minutes of walking in the morning, as well as pain in each heel during daily activities. All VAS scores were recorded in centimeters. No patient was given a prescription for controlled substance pain medication either before or after treatments.

In each VAS category, a pain rating was assigned. Severe indicated a VAS pain rating greater than 7 cm.

A moderate pain rating indicated a VAS greater than 4 cm but less than 7 cm. No patient with a VAS < 4 cm involving at least one heel was accepted in the study, as they would not qualify for bilateral orthotripsy.

All patients were reevaluated in the preanesthesia holding area, during which time the point of maximum tenderness at the plantar enthesis was verified and demarcated by a surgical marking pen. A longitudinal line was drawn through this point on the plantar suface. A perpendicular line was drawn, also through the point of maximal tenderness. These were perpendicular lines drawn through the point of maximal tenderness that were adjusted to similar lines on the device treatment head to determine the transcutaneous penetration site of the focus of maximum shock wave energy. Patients were brought into the treatment room and were given varied intravenous sedation at the discretion of the anesthesiologist (no patient requested bilateral ankle blocks). Following this each patient received 2000 shocks at 20 kV (0.27 mJ/mm^2; total energy 540 J) and 4 Hz. A total of 1500 shocks were delivered through the plantar surface and 500 shocks were delivered in a medial to lateral direction. Each foot was treated by this protocol while the patient was under the same anesthesia. The foot was manipulated by the treating physician, in and around the predetermined point of maximum tenderness over an area approximately 2 cm in diameter to cover a broad area of the plantar enthesis to ensure application of the shock waves to the point of maximum tenderness and its contiguous areas, covering a 2-cm diameter circular area around the point of maximum tenderness on the plantar surface.

Following treatment, patients were evaluated in the recovery room before discharge, at 48 hours by telephone, and in the office at 6 weeks, 12 weeks, 6 months, and 12 months. Heel pain was assessed during each visit using the dolorimeter, Semmes-Weinstein testing, and VAS ratings. The dolorimeter was applied at the previously determined pretreatment level. The patient provided a VAS evaluation of the amount of pain.

The outcome data were assessed in two ways: (1) the individual outcomes for each heel, and (2) the difference in outcome of each side. The final analysis only included the 23 patients who completed the study to 1 year.

A satisfactory result required at least a 50% reduction from the baseline VAS in a given outcome category. This meant the patient could still have residual pain, although considerably less than the pretreatment baseline. Each patient received an outcome grade in each of the three criteria. The total number of criteria achieved was the patient's score (range, 0–3). The grading method was as follows: excellent (3/3 outcome criteria satisfactorily achieved), good (2/3), fair (1/3), and poor (0/3).[16]

Patients were discouraged from repetitive athletic activities such as racquet sports or distance running that were likely to provoke the plantar fascia until their first posttreatment examination at 6 weeks. No statistical analysis or placebo studies were done.

RESULTS

Semmes-Weinstein monofilament testing did not show any sensory deficit in the foot. Before orthotripsy, the average heel pain VAS after 5 minutes of walking in the morning was 8.3 (range, 7.6–10). The average heel pain VAS with activities of daily living was 8.1 (range 7.4 to 10). The side-to-side pretreatment differences in the VAS measurements in the untreated 23 patients were as follows: (1) the average heel pain score difference was 2.3 (range, 1.2–3.7), (2) the average heel pain score difference after 5 minutes of walking in the morning was 2.4 (range, 1.7–3.4), and (3) the average heel pain score difference with activities of daily living was 2.9 (range, 2.1–3.5).

All patients were ambulatory immediately following orthotripsy and all returned to either work or normal activities of daily living within 24 hours. Following orthotripsy, outcome results at 3 months showed that 28 heels (61%) had a good or excellent resolution of pretreatment pain symptoms (Table 1). Twenty heels (43%) had a VAS rating of 0 in all three categories (excellent outcome) at 3 months following treatment. This was maintained in all patients in this outcome category at 1 year.

Eight heels (17%) had a good result. In seven of the eight heels, morning pain was 0. Most of these heels either had minimal pain with ambulation or with activities of daily living. Seven of these heels did not receive a second treatment; at 1 year, two of these heels were

Table 1: Results at 3 months following initial bilateral orthotripsy application

Heel–Heel Outcome	Number of Patients	Number of Heels			
		E	G	F	P
E–E	7	14	—	—	—
E–G	4	4	4	—	—
E–P	2	2	—	—	2 (2)
G–G	1	—	2	—	—
G–F	2	—	2 (1)	2 (2)	—
F–F	3	—	—	6 (6)	—
F–P	2	—	—	2 (2)	2 (2)
P–P	2	—	—	—	4 (4)
Totals	23	20	8 (1)	10 (10)	8 (8)

E, excellent; G, good; F, fair; P, poor
Number in parentheses represents the number of heels receiving a second orthotripsy application.

rated excellent and four good. One heel received a second treatment. At 1 year, the result was excellent.

Ten heels (22%) had unacceptable (fair) pain relief at 3 months. All 10 heels received a second orthotripsy treatment. In this group, five heels subsequently had complete or nearly complete resolution of pain (excellent, 3; good, 2), while the other five had no change (remained fair). There was no change in these ratings at 1 year.

Eight heels (17%) had unacceptable (poor) results at 3 months. This was defined as less than 50% improvement in two or more outcome categories. All were treated a second time. Following retreatment, the results at 3 months were excellent (1), good (3), fair (1), and poor (3). There were no subsequent outcome changes at 1 year.

Thus, at the evaluation 3 months after one treatment, the results when analyzed by ''individual heel'' were 20 excellent (43%), 8 good (17%), 10 fair (23%), and 8 poor or no response (17%). Nineteen heels (41%) received a second treatment.

One patient underwent a repeat treatment in one foot, while nine patients underwent a repeat treatment in both feet. Table 2 shows the results 1 year after either one or two orthotripsy applications.

Combining the outcomes 1 year following the first or second orthotripsy application there were 28 (60%) excellent, 10 (22%) good, 4 (9%) fair, and 4 (9%) poor (no response). No patient experienced worsening of symptoms. Accordingly, the results at 1 year showed patient satisfaction in 38 heels (83%) and patient dissatisfaction in 8 heels (17%).

No patient who had any symptomatic improvement in one heel experienced the same rate of improved symptoms in the other side during the initial posttreatment course (first 6 weeks). The rate of improvement thus was asynchronous relative to the initial rate of pain relief. Similarly, no patient who had any symptomatic improvement in one heel experienced the same amount of pain relief in the other heel during the first 6 weeks after treatment. However, by 3 months, 12 patients had good to excellent results in both feet (similar response in 8, dissimilar in 4). Four patients had a good response in one foot and a fair or poor response in the other foot, and seven patients had fair to poor results in both feet (Table 1).

Table 2: Results at 1 year following one or two orthotripsy applications (bilaterally treated patients)

Heel–Heel Outcome	Number of Patients	Number of Heels			
		E	G	F	P
E–E	13	26	—	—	—
E–G	2	2	2	—	—
G–G	4	—	8	—	—
F–F	1	—	—	2	—
F–P	2	—	—	2	2
P–P	1	—	—	—	2
Totals	23	28	10	4	4

E, excellent; G, good; F, fair; P, poor

The results, whether excellent to poor, in 96% of the patients were maintained at 1 year. The exception was a long-distance runner who had had mild return of heel pain while running. However, this was considerably less than pretreatment and did not cause him to alter training activities, as did the pretreatment pain.

DISCUSSION

The results demonstrate that patients with bilateral plantar fasciitis may be successfully treated during the same oupatient surgical and anesthesia session using high-energy electrohydraulic shock wave generation. The initial pattern of response is asymmetric. However, by 3 months, most patients have a response that is essentially symmetric, and is maintained at 1 year.

The current results demonstrate that orthotripsy, which has a treatment outcome success rate equal to or greater than partial surgical release of the fascia, gives the patient with bilateral involvement a useful treatment alternative.[25] Such a patient may have both heels treated by application of high-energy electrohydraulic shock waves while under the same anesthesia. The patient is fully ambulatory immediately after recovery from anesthesia, and may return to work and normal activities of daily living. The primary restriction is temporary nonparticipation in evocative sports.

In a study of 40 patients who had a single treatment of electrohydraulic orthotripsy, the successful outcome with orthotripsy (82%) compared favorably with that from percutaneous fasciotomy (85%) and allowed a more rapid return to work and activities of daily living.[25]

None of the current study patients described their presenting bilateral pain as comparable, side to side, in severity. Potential subjects with a contralateral VAS ≤ 4 (tested with dolorimeter) were discouraged from participation in or rejected from the current study.

Recent studies have stated that low-energy electromagnetic shock wave treatment, when given multiple time (three to six applications) in an office setting without anesthesia (even though patients experienced pain during treatment), may not be effective.[5] The first two shock wave devices, specifically designed for musculoskeletal applications, were approved by

the FDA following studies using a single high-energy treatment with administration of anesthesia.[11] There are substantial differences in the amount and area of energy delivered to the target tissue (fascia) by the methods used in these two FDA studies.[4,11,14] One generated shock waves electrohydraulically,[11] while the other generated the shock waves electromagnetically.[13] The overall outcome and the percentage difference were better in treated patients versus placebo patients in the electrohydraulic study compared to the electromagnetic study.[4,11]

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