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Treatment of Plantar Fasciitis With Radial Soundwave "Early" Is Better Than After 6 Months: A Pilot Study

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ABSTRACT

Extracorporeal shock wave therapy/radial soundwave therapy has been predominantly used for chronic or recalcitrant plantar fasciitis with strong scientific evidence of reliable outcomes. Most of the studies included patients with plantar fasciitis with symptoms >6 months in duration. Only 2 known studies have investigated acute plantar fasciitis, which is <6 weeks in duration. They both found suboptimal results for the use of extracorporeal shock wave therapy. To the best of our knowledge, no studies have investigated radial soundwave therapy for the subacute stage or early stage of plantar fasciitis. Data were prospectively collected from 28 eligible patients who underwent radial soundwave therapy (RSWT) during a 9-month period in 2014. Of the 28 subjects, 14 were enrolled in the "early group" with a symptom duration of <3 months and 14 in the "standard/control" group with a symptom duration of >6 months. The pretreatment and posttreatment visual analog scale scores, Roles-Maudlsey scores, and activity level were recorded and compared. The early implementation of RSWT yielded comparable outcomes when compared with the standard group. RSWT is a valid treatment modality that can be implemented soon after the initial treatment options or first-phase treatment options have failed. Early treatment is more likely to allow for maintenance of patients' activity level. Also, waiting 6 months to treat plantar fasciitis with RSWT results in delays and inferior results. Early treatment is better for active and athletic patients.

Plantar fasciitis is often debilitating and becomes chronic in many cases. Typical treatment algorithms for plantar fasciitis include stretching, night splints, ice, inserts, shoe and activity modification, and nonsteroidal antiinflammatory drugs (NSAIDs) as initial treatment. After this first "phase" of treatment, the next recommendation is to consider corticosteroid injection, custom insoles, immobilization, and physical therapy (1). In addition, radiography, magnetic resonance imaging, and laboratory studies can be considered (2). These "phase 2" treatments and tests all have significant costs associated with their implementation. Saxena and Fullem (3) reported on the "conservative" treatment costs (through a survey of 12 orthopedic and podiatric practices). These costs were >$2500 to treat plantar fasciitis before consideration of using forms of "shockwave therapy." These charges included the initial office visit plus 2 follow-up visits, physical therapy, over-the-counter inserts, custom orthotics, night splints, NSAIDs, corticosteroid injections, and imaging studies (3). Some investigators distinguish between plantar fasciitis and plantar fasciosis; however, the latter was originally described in patients with chronic "fasciitis" who had undergone heel spur surgery. Signs of classic inflammation were not found in biopsy specimens from these patients (4). However, the distinction of when "fasciitis" becomes "fasciosis" is unclear. Therefore, for the purposes of consistency, fasciitis has been used to designate the condition associated with plantar fascia-related heel pain at the origin of the calcaneus in the present report.

When all reasonable treatments for plantar fasciitis are refractory, extracorporeal shockwave therapy (ESWT)/radial soundwave therapy (RSWT) can be considered, typically before surgery. ESWT/RSWT creates shock or pressure waves into pathologic tissues creating

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microtrauma and releasing the neuropeptide substance P. The release and subsequent depletion of substance P leads to a local inflammatory response to the region, resulting in increased vascularity, and can promote multiplication of the stem cells required for repair (5,6). Other "nonoperative" treatments such as platelet-rich plasma, radiofrequency, ultrasound "ablation," amnionic membrane injections, and needling are often "out-of-pocket" and have low to medium levels of evidence (7–10).

The purpose of the present study was to evaluate "early" implementation of RSWT in the treatment algorithm. We performed a pilot study to compare patients who had had plantar fasciitis for ≤3 months and had undergone RSWT with a control ("standard") group who had had plantar fasciitis symptoms and received other treatments for >6 months. An evaluation was performed to determine whether the early group had outcome scores that were the same or better than those of the standard group. The hypothesis was that early use of RSWT would result in better outcomes for patients with plantar fasciitis.

Patients and Methods

The institutional review board approved the present study for treating patients with shockwave therapy (i.e., ESWT/RSWT) for heel pain. The patients provided informed consent and were serially enrolled for treatment with a radial soundwave device (EnPuls; Zimmer MedizinSysteme, Neu-Ulm, Germany) during a 9-month period in 2014. The inclusion criteria were RSWT for symptoms associated with planta fasciitis and follow-up data available for a minimum of 1 year after RSWT. The exclusion criteria were patient withdrawal during the study period, lack of response to 3 follow-up telephone calls, the use of injection or surgery, and/or the presence of comorbidities such as neuropathy, chronic pain syndrome, radiculopathy, inflammatory arthropathy, and so forth. The patients were evaluated by the lead investigator (A.S., 27 years of clinical practice) to confirm the diagnosis of plantar fasciitis, including pain at the medial tubercle of the calcaneus associated with the plantar fascia origin without neuritic symptoms or signs of stress fracture. The duration of symptoms, pretreatment visual analog scale (VAS) and Roles-Maudsley (RM) scores and activity level were recorded. These have been validated as assessment tools for patients with heel pain (11,12). The patients were given the option to receive RSWT. No compensation for the study was given to the subjects or investigators. Patients who had had symptoms for ≤3 months were placed in the "early" group; those with ≥6 months of symptoms were placed in the "standard/control" group.

The early group underwent RSWT to the affected heel at 160 mJ (approximately 4.0 Bar) for 2500 pulses (with a 500-pulse "ramp-up") at 10 Hz for 3 sessions at approximately weekly intervals. After treatment, the patients were allowed to continue their activities as tolerated, including sports. They were advised to continue with appropriate shoe gear, inserts, stretching and ice and to avoid the use of NSAIDs and participating in any new activity that could aggravate their condition.

The patients were reevaluated at 3 and ≥12 months by a research fellow (A.Y.) in person or via a telephone interview to assess their VAS and RM scores. This individual was not involved in the actual treatment of the patient at RSWT application.

Statistical analysis included Student's t test and Fisher's exact test to assess improvement, with significance set at $p \leq .05$ using Excel™ (Microsoft Corp., Everett, WA). The number of patients who withdrew, received injections, underwent surgery, and did not improve (VAS score ≥4, RM score ≤3) were also recorded to determine the absolute "success" rate. The decreased desired activity (DDA) level was also recorded and compared between the 2 groups.

Results

A total of 42 patients were treated during the study period. Of these 42 patients, 10 did not respond to telephone follow-up and did not return for follow-up appointments. One patient (2.4%) opted for surgery 5 months after treatment. Three withdrew, preferring to discontinue RSWT and receive a corticosteroid injection, leaving 28 patients, with 14 each in the early treatment and standard treatment groups. (No patient had had symptoms for >3 but <6 months.)

The average age of the entire cohort was 50.5 ± 12.0 years. No difference was found in patient age between the 2 groups. The average pretreatment VAS score was 6.2 ± 1.7 for the entire cohort. This had significantly decreased at both 3 and 12 months (3.5 ± 2.4 and 0.9 ± 1.9, respectively; $p < .000001$). The VAS score for the early group decreased from 5.6 ± 2.0 initially to 3.1 ± 2.3 and 0.8 ± 1.6 at 3 and 12 months after treatment, respectively. The VAS score for the standard group decreased from 6.8 ± 1.8 initially to 3.8 ± 2.3 and 1.1 ± 1.6 at 3 and 12 months, respectively. All the VAS scores had significantly improved ($p < .000001$). Although the VAS scores were better for the early group, the difference in the VAS score between the 2 groups was not statistically significant ($p = .06$; Table 1).

Similar results were noted in the RM scores. The pretreatment RM score was 3.3 ± 0.6 for the entire cohort. At 3 and 12 months, the RM score had improved to 2.1 ± 1.2 and 1.4 ± 0.9, respectively; the differences for both were significant ($p < .000001$). The pretreatment RM score for the early group was 3.0 ± 0.6. This had improved to 1.8 ± 1.1 and 1.2 ± 0.6 at 3 and 12 months after RSWT, and the differences were statistically significant ($p < .000001$). The pretreatment RM score for the standard group was 3.6 ± 0.6. The posttreatment RM scores for the standard group had similarly improved at 3 and 12 months to 2.5 ± 1.1 and 1.6 ± 0.6, respectively; the differences were also statistically significant ($p < .000001$). The difference in the pretreatment RM scores between the 2 groups was statistically significant ($p = .0003$); however, the differences in the RM scores after treatment between the 2 groups were not ($p = .29$; Table 2).

Across all parameters using the VAS and RM scores, the early group scored better than did the standard group. If one calculates improvement as success in the study cohort (26 of 28), the success

Table 1
Early group

Pt. No.	Age (y)	Sex	DOS (mo)	VAS Score			RM Score		
				Baseline	3 mo	1 y	Baseline	3 mo	1 y
1	58	M	1	8	3	0	3	1	1
2	56	M	1	8	6	1	3	1	1
3	33	M	1	6	3	0	3	1	1
4	57	M	1.5	4	1	0	3	1	1
5	40	M	2	4	4	0	3	3	1
6	55	F	2	9	7	0	4	4	1
7	71	F	2	8	4	0	4	2	1
8	49	F	3	4	3	0	3	2	1
9	49	M	3	6	3	2	3	1	1
10	66	M	3	4	4	0.5	3	3	1
11	76	M	3	3	0	0	2	1	1
12	36	M	3	3	0	1	2	1	2
13	44	M	3	6	6	6	3	3	3
14	40	M	3	5	0	0	3	1	1
Mean ± SD	52.1 ± 13	NA	NA	5.6 ± 2.0	3.1 ± 2.3	0.8 ± 1.6	3.0 ± 0.6	1.8 ± 1.1	1.2 ± 0.6

Abbreviations: DOS, duration of symptoms; F, female; M, male; NA, not applicable; Pt. No., patient number; RM, Roles-Maudsley; SD, standard deviation; VAS, visual analog scale.