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Original Research

Extracorporeal Shockwave Therapy Plus Rehabilitation for Patients With Chronic Plantar Fasciitis Might Reduce Pain and Improve Function but Still Not Lead to Increased Activity: A Case-Series Study With **Multiple Outcome Measures**

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ABSTRACT

Plantar fasciitis is a common cause of plantar-aspect heel pain. Although many patients will improve, a proportion will have ongoing and sometimes debilitating symptoms. Evidence from randomized controlled trials has shown that extracorporeal shockwave therapy (ESWT) results in benefits in treating pain. However, uncertainties remain whether these benefits translate to improvements in overall function. The present prospective case series examined the results from 35 patients with chronic plantar fasciitis who had undergone a course of ESWT in addition to a graded rehabilitation program. Of the 35 subjects, 34% were male, and the median age was 50.9 years. The duration of symptoms before ESWT was 24 months. The results of the present case series demonstrated statistically significant improvements in measures of self-reported "average pain" from a median of 7.0 of 10 at baseline to 5.0 of 10 at 3 months (p < .001) and of "worst pain" from 9.0 of 10 at baseline to 7.0 of 10 at 3 months (p < .001). In addition, significant improvements were found in several validated patient-rated outcome measures of local foot/ankle function but not in overall markers of health, anxiety/ depression scores, or activity levels, despite the improvements in pain. No statistically significant correlations were found between gender, age, or chronicity of symptoms and the improvements seen. No significant side effects occurred in the present study. The results of our series support the use of ESWT for patients with chronic plantar fasciitis for local pain symptoms; however, uncertainties remain regarding global benefits to health.

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Plantar fasciitis is a common condition causing plantar aspect heel pain. It most commonly affects people in their fourth and fifth decades, affecting sedentary and active populations (1–3). This represents an overuse or underrecovery issue, with histologically a myxoid degeneration, rather than an inflammatory process, affecting the plantar fascia (3,4). Although most patients with plantar fasciitis will experience improvement within 9 to 12 months, approximately 10% will develop persisting symptoms. A number of different treatments are available (5).

The plantar fascia is a tough band of connective tissue in the sole of the foot originating at the medial process of the tuberosity of the calcaneus and inserting in slips to the proximal phalanges. This supports the longitudinal arch of the foot but also has a role in proprioception and peripheral motor coordination (6). The plantar fascia, arising from the undersurface of the calcaneus, can be seen as the functional endpoint of the Achilles tendon, which attaches to the posterior margin of the calcaneus. Increasing tension in the Achilles tendon increases the strain through the plantar fascia. This could be one of the contributing factors to the development of plantar fasciitis, although evidence remains unclear (7,8). Although anatomically plantar fasciitis is not strictly a tendinopathy, its function and insertion into the calcaneus is very similar to that of an insertional tendinopathy, or enthesopathy, and the treatment strategies used for plantar fasciitis are very similar to those used for recalcitrant tendinopathies.

A wide variety of conservative therapies can be used to treat patients with plantar fasciitis (2). Low-risk conservative therapies for

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which some evidence might exist include rest or activity modification, stretches, tension night splints, taping, and orthotics (5,9-14). Corticosteroid and local anesthetic injections are often used in patients with plantar fasciitis, and a variety of differing techniques and broad outcome data for success rates have been reported. However, some studies have reported a plantar fascia rupture rate of \leq 10%, indicating that some caution might be needed (15–18). If these measures prove unsuccessful, several further options remain possible.

Surgery has been performed for plantar fasciitis resistant to conservative treatments, with a number of different surgical techniques reported, and success reported for 75% to 90% of cases, although success has been defined differently in different studies (19–21). Novel injection therapies, including autologous blood injections, have been used for a range of tendinopathies and for patients with plantar fasciitis. Evidence from several case series has suggested benefit; however, benefit has not yet been proved with more rigorous study designs (22–24).

Extracorporeal shockwave therapy (ESWT) might have a role in treating patients with chronic plantar fasciitis before consideration of more invasive procedures. ESWT is the use of inaudible, high-energy sound waves generated from an external machine placed on the skin that pass through tissue layers and are thought to promote a healing response. ESWT has been used in a range of musculoskeletal disorders, including chronic tendinopathies, and some evidence of benefit has been shown in patients with chronic plantar fasciitis. However, the studies have predominantly reported changes in pain, rather than reporting any effects on function or other domains. In the United Kingdom, the National Institute of Health and Care Excellence has given guidance for the use of ESWT for plantar fasciitis (interventional procedures guidance 311, August 2009), although now several years old (25). A very brief summary of some of the evidence for the use of ESWT for plantar fasciitis is provided in Table 1. The findings show that therapeutic shockwaves appear more effective in treating pain than either placebo or sham shockwave (27,29,37) or injections of botulinum toxin (26), although possibly less effective than endoscopic surgery (42). In addition, in the early stages of plantar fasciitis, a rehabilitation program alone might be better than ESWT (43), suggesting that ESWT might be a better modality to use after an initial period has passed, during which other treatments can be tried.

Overall, the side effect profile from ESWT has been good, with few serious side effects reported in most studies (49). A placebocontrolled study of >270 patients with tennis elbow reported side effects that included transitory reddening of the skin (21%; which was harmless and did not lead to treatment cessation), pain (4.8%), and small hematomas (3%). In addition, the possibility of ESWT triggering migraine or possible fainting was reported (50). It has been assumed that the side effects would be similar at different sites (50). The risk of hematoma was reported after the use of a nonmusculoskeletal-specific machine, and newer more musculoskeletal-specific ESWT devices appear to have a safer side effect profile (50).

Although the evidence base is increasing, many areas of uncertainty remain, and the National Institute of Health and Care Excellence has previously called for more research to support clinical practice. The dose, frequency, type, and number of ESWT sessions all remain unclear for patients with chronic plantar fasciitis. Overall, evidence has shown benefit in treating the pain in patients with

Table 1

Summary of published evidence for extracorporeal shockwave therapy for plantar fasciitis

Investigator	Туре	Comments	Patients (n)	Follow-Up (mo)	Conclusion
Present study	Case series	Consecutive patients, mean age 49.9 years, mean symptom duration 29.3 mo; ESWT + rehabilitation associated with improvements in pain and validated measures of local function but not necessarily global quality health markers	35	Mean 5.6	Benefits in pain and local function but less benefit to global health indicators
Roca et al (26), 2016	Open-label RCT	ESWT versus botulinum toxin	72	NR	Effective; ESWT superior to botulinum toxin
Gollwitzer et al (27), 2015	DB RCT	Multicenter RCT: ESWT versus placebo	250	3	Effective
Speed (36), 2014	Systematic review	10 DB-RCTs; references (29,31–33,35,37–41); evidence of benefit from both ESWT-F and R-ESWT	NR	NR	Effective
Aqil et al (28), 2013	Meta-analysis	7 prospective RCTs; references (29–35)	NR	NR	Effective
Saxena et al (42), 2012	RCT	Surgery versus ESWT versus sham	37	NR	Effective; surgery superior to ESWT
Ibrahim et al (35), 2010	RCT	ESWT versus sham	50	6	Effective
Rompe et al (43), 2010	RCT	Stretching versus R-ESWT for early plantar fasciitis (<6 wk of symptoms)	102	15	Stretching superior to ESWT for early plantar fasciitis
NICE (25), 2009	Review	NR	NR	NR	Inconclusive
Gerdesmeyer et al (33), 2008	RCT	ESWT versus placebo	245	12	Effective
Marks et al (34), 2008	DB RCT	ESWT versus sham	25	6	Ineffective
Gollwitzer et al (32), 2007	DB RCT	ESWT versus sham ESWT	40	3	Nonsignificantly effective
Rompe et al (44), 2007	Review	17 studies; conflicting results	NR	NR	Possibly effective
Rompe (45), 2007	Editorial letter	NR	NR	NR	Effective
Kudo et al (37), 2006	DB RCT	Multicenter: ESWT versus placebo	114	3	Effective
Malay et al (29), 2006	DB RCT	Multicenter: ESWT (115 patients) versus placebo (57 patients)	172	3	Effective
Moretti et al (46), 2006	Case series	NR	54	24	Effective
Theodore et al (41), 2004	DB RCT	Multicenter: ESWT versus sham ESWT (RCT data, 3 mo; ESWT follow-up data, 12 mo)	150	3	Effective
Crawford et al (47), 2003	Review	NR	NR	NR	Inconclusive
Haake et al (40), 2003	RCT	Multicenter blinded: ESWT versus placebo	272	3	Ineffective
Hammer et al (48), 2003	Crossover	ESWT versus iontophoresis and NSAIDs; crossover allowed after 3 mo	47 (49 feet)	24	Effective
Rompe et al (30), 2003	RCT	ESWT versus sham	45	12	Effective
Speed et al (31), 2003	DB RCT	ESWT versus sham	88	6	Ineffective
Buchbinder et al (39), 2002	RCT	ESWT versus placebo ESWT	160	3	Ineffective
Ogden et al (38), 2001	DB RCT	ESWT versus placebo	302	3	Effective

Abbreviations: DB, double-blind; ESWT, extracorporeal shockwave therapy; ESWT-F, focused ESWT; NICE, National Institute of Health and Care Excellence; NR, not reported; NSAIDs, nonsteroidal anti-inflammatory drugs; R-ESWT, radial ESWT; RCT, randomized controlled trial.

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