The Journal of Foot & Ankle Surgery

ORIGINAL RESEARCH

Extracorporeal Shockwave Therapy Versus Placebo for the Treatment of Chronic Proximal Plantar Fasciitis: Results of a Randomized, Placebo-Controlled, Double-Blinded, Multicenter Intervention Trial

D. Scot Malay, DPM, MSCE,[1] Martin M. Pressman, DPM,[2] Amir Assili, DPM,[3] Jason T. Kline, DPM,[4] Shane York, DPM,[5] Ben Buren, DPM,[6] Eugene R. Heyman, PhD,[7] Pam Borowsky, DPM, CPed,[8] and Carley LeMay, MA[9]

*Extracorporeal shockwave therapy (ESWT) has demonstrated efficacy in the treatment of recalcitrant proximal plantar fasciitis. The objective of this investigation was to compare the outcomes of participants treated with a new ESWT device with those treated with placebo. A total of 172 volunteer participants were randomized in a 2:1 active-to-placebo ratio in this prospective, double-blind, multicenter trial conducted between October 2003 and December 2004. ESWT (n = 115) or placebo control (n = 57) was administered on a single occasion without local or systemic anesthesia or sedation, after which follow-up was undertaken. The primary outcomes were the blind assessor's objective, and the participant's subjective assessments of heel pain during the first 3 months of follow-up. Participants were also followed up to 1 year to identify any adverse outcomes that may have been related to the shockwave device. On the visual analog scale, the blind assessor's objective assessment of heel pain displayed a mean reduction of 2.51 in the shockwave group and 1.57 in the placebo group; this difference was statistically significant (*P = .045*). On the visual analog scale, the participant's self-assessment of heel pain displayed a mean reduction of 3.39 in the shockwave group and 1.78 in the placebo group; this difference was statistically significant (*P < .001*). No serious adverse events were observed at any time. It was concluded that ESWT was both efficacious and safe for participants with chronic proximal plantar fasciitis that had been unresponsive to exhaustive conservative treatment.* (The Journal of Foot & Ankle Surgery 45(4):196–210, 2006)

Key words: extracorporeal shockwave therapy (ESWT), heel pain, Orthospec, proximal plantar fasciitis

Address correspondence to: D. Scot Malay, DPM, MSCE, Ankle and Foot Medical Centers of the Delaware Valley, MAB #111, 38th at Market Streets, Philadelphia, PA 19104. E-mail: malays@uphs.upenn.edu.

[1]Ankle and Foot Medical Centers of the Delaware Valley, Penn-Presbyterian Medical Center, Postdoctoral Research Fellow, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, Philadelphia, PA.

[2]Chief, Section of Podiatric Surgery, Yale—New Haven Hospital, Clinical Assistant Professor, Orthopaedics and Rehabilitation, Yale School of Medicine, New Haven Foot Surgeons, New Haven, CT.

[3]Podiatric Director, Shady Grove Wound Center, Shady Grove Podiatry, Gaithersburg, MD.

[4]Chief Resident, Penn—Presbyterian Medical Center, Philadelphia, PA.

[5]Chief Resident, Podiatric Surgery, Yale—New Haven Hospital, New Haven, CT.

[6]Chief Resident, Podiatric Surgery, Yale—New Haven Hospital, New Haven, CT.

[7]Statistical Consultant, Montgomery Village, MD.

[8]Ankle and Foot Medical Centers of the Delaware Valley, Philadelphia, PA.

[9]Shady Grove Podiatry, Gaithersburg, MD.

Disclosure: This multicenter, double-blinded clinical investigation, entitled protocol PF-01: A Comparative Randomized Placebo-Controlled Clinical Trial of Orthospec™ Versus Orthospec™ Placebo for the Relief of Pain in the Treatment of Proximal Plantar Fasciitis, was conducted under the United States Food and Drug Administration Investigational Device Exemption #G020175 to determine the safety and efficacy of the Orthospec™ ESWT device. The study sponsor, Medispec LTD, 12850 Middlebrook Road, Suite 1, Germantown, MD 20874, provided the extracorporeal shockwave therapy and plantar pressure assessment devices, and funded the investigation.

1067-2516/06/4504-0002$32.00/0
doi:10.1053/j.jfas.2006.04.007

Proximal plantar fasciitis is a common complaint that confronts physicians treating the foot (1–6). Conservative therapies for this condition include various combinations of padding, strapping, nonsteroidal anti-inflammatory drugs (NSAIDS), physical therapy, night splints, and corticosteroid injections, and these therapies, for the majority of participants, prove to be beneficial (7–13). Nonetheless, approximately 10% of participants fail to respond satisfactorily to these conservative treatment strategies, and, for these participants, treatment options have traditionally evolved around surgical intervention for release of the plantar fascia at its attachment to the tuberosity of the calcaneus, with or without concomitant removal of a portion of the plantar calcaneus when there is radiographic evidence of a plantar calcaneal spur (14, 15). Moreover, postoperative complications such as recurrent pain, nerve injury, infection, and tarsal instability detract from the usefulness of surgical intervention.

Since the mid-1990s, extracorporeal shockwave therapy (ESWT) has been successfully used in the treatment of chronic plantar fasciitis (16). Shockwaves are sound waves that are generated by a source that creates vibrations which are then transported through tissues via fluid and solid particle interaction. Proponents of shockwave therapy suggest that ESWT creates controlled local tissue injury that causes neovascularization, and is associated with increased amounts of tissue growth factors within the locally injured structures. It is therefore hypothesized that ESWT stimulates healing by creating a wound environment at the site of shockwave delivery (17–19). Other hypothesized mechanisms of action include the physical alteration of small axons, thereby inhibiting pain impulse conduction; chemical alteration of pain receptor neurotransmitter, thereby preventing pain perception; and hyperstimulation activation of the gate control mechanism, thereby affecting analgesia (20, 21). Although shockwaves used for lithotripsy are of higher energy than those used for the treatment of plantar fasciitis, animal studies have shown the development of an inflammatory response in tissues, ranging from tendon to physeal plate to trabecular bone, with energy levels ranging from 0.28 to 1.5 mJ/mm^2 (22–28). It is generally understood that energy levels ranging from 0.22 to 0.36 mJ/mm^2 are high enough to induce a therapeutic response in the plantar fascia by 3 to 6 weeks. However, randomized controlled trials of different shockwave delivery systems have yielded varying results (29–39). Currently, shockwave delivery systems delivering energy levels more than 0.34 to 0.36 mJ/mm^2 require the recipient to undergo regional nerve blocks combined with either intravenous sedation or general anesthesia, and the therapeutic guidelines for these devices call for one or more additional applications of ESWT should the participant not experience satisfactory resolution of his or her heel pain. Devices that do not deliver energy levels of at least 0.26 mJ/mm^2 generally do not require local anesthesia at the site of delivery; however; they have been criticized as not being as efficacious as devices delivering shockwaves of higher energy (40).

The Orthospec ESWT (Medispec LTD, Germantown, MD) device is an extracorporeal shockwave delivery system that is approved for distribution and use in the United States by the Food and Drug Administration (FDA). Although shockwave therapy has been available for the treatment of plantar fasciitis for about a decade in this country, the device under investigation in this clinical trial conveys unique features that distinguish it from other ESWT devices used for this condition. This device produces shockwaves electrohydraulically and delivers the energy to the treatment area through a rubber contact membrane (Fig 1). The energy is dispersed over a treatment area that is large enough that the intensity of the shockwaves reaches therapeutic levels while remaining generally well tolerated by recipient patients without the need for anesthesia or sedation. Moreover, the effective distribution of the shockwaves is over a broad enough anatomical area that there is no need for ultrasonic or radiographic targeting. The hypothesis of this industry-sponsored FDA phase-3 investigation is that the Orthospec (active ESWT) device would provide greater relief of pain in comparison with a placebo control, after a one-time application for the treatment of recalcitrant proximal plantar fasciitis.

Materials and Methods

An FDA-approved, randomized, placebo-controlled, double-blinded, multicentered clinical trial to compare the efficacy and safety of the Orthospec device was designed and undertaken at clinical centers in Pennsylvania, Connecticut, and Maryland. Figure 2 schematically depicts the organization and flow of the investigation.

Sample Size and Power

Using 2.2 as the standard deviation for the change from baseline heel pain to postintervention heel pain, in accordance with previous experience, and allowing for a 5% loss to follow-up, a total of 183 participants, randomized 2:1 (122 active and 61 placebo), was required to provide 80% power to detect a difference of 1.0 at the 5% level of significance. Only one foot per participant was to be enrolled and treated in this study.

Study Population

To be included as a participant in the investigation, potential candidates had to be a man or woman older than 18 years of age; if female, not pregnant; diagnosed with prox-