

## **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<sup>2</sup>, followed by 1400 shocks at

0.22 mJ/mm<sup>2</sup> 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, Level I-1a (randomized controlled trial [significant difference]). See Instructions to Authors for a complete description of levels of evidence.