SCIENTIFIC ARTICLES

Clinically Relevant Effectiveness of Focused Extracorporeal Shock Wave Therapy in the Treatment of Chronic Plantar Fasciitis

A Randomized, Controlled Multicenter Study

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Abstract

Background:

The effectiveness of extracorporeal shock wave therapy in the treatment of plantar fasciitis is controversial. The objective of the present study was to test whether focused extracorporeal shock wave therapy is effective in relieving chronic heel pain diagnosed as plantar fasciitis.

Methods:

Two hundred and fifty subjects were enrolled in a prospective, multicenter, double-blind, randomized, and placebo-controlled U.S. Food and Drug Administration trial. Subjects were randomized to focused extracorporeal shock wave therapy (0.25 mJ/mm^2) or placebo intervention, with three sessions of 2000 impulses in weekly intervals. Primary outcomes were both the percentage change of heel pain on the visual analog scale composite score (pain during first steps in the morning, pain with daily activities, and pain with a force meter) and the Roles and Maudsley score at twelve weeks after the last intervention compared with the scores at baseline.

Results:

Two hundred and forty-six patients (98.4%) were available for intention-to-treat analysis at the twelve-week follow-up. With regard to the first primary end point, the visual analog scale composite score, there was a significant difference ($p = 0.0027$, one-sided) in the reduction of heel pain in the extracorporeal shock wave therapy group (69.2%) compared with the placebo therapy group (34.5%). Extracorporeal shock wave therapy was also significantly superior to the placebo therapy for the

Roles and Maudsley score ($p = 0.0006$, one-sided). Temporary pain and swelling during and after treatment were the only device-related adverse events observed.

Conclusions:

The results of the present study provide proof of the clinically relevant effect size of focused extracorporeal shock wave therapy without local anesthesia in the treatment of recalcitrant plantar fasciitis, with success rates between 50% and 65%.

Level of Evidence:

Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.