

Changes in Wound Closure Rate Over Time In a Prospective, Randomized, Double-Blinded, Sham-Controlled, Multicenter Study of Shockwave Technology in the Treatment of Non-Healing Diabetic Foot Ulcers

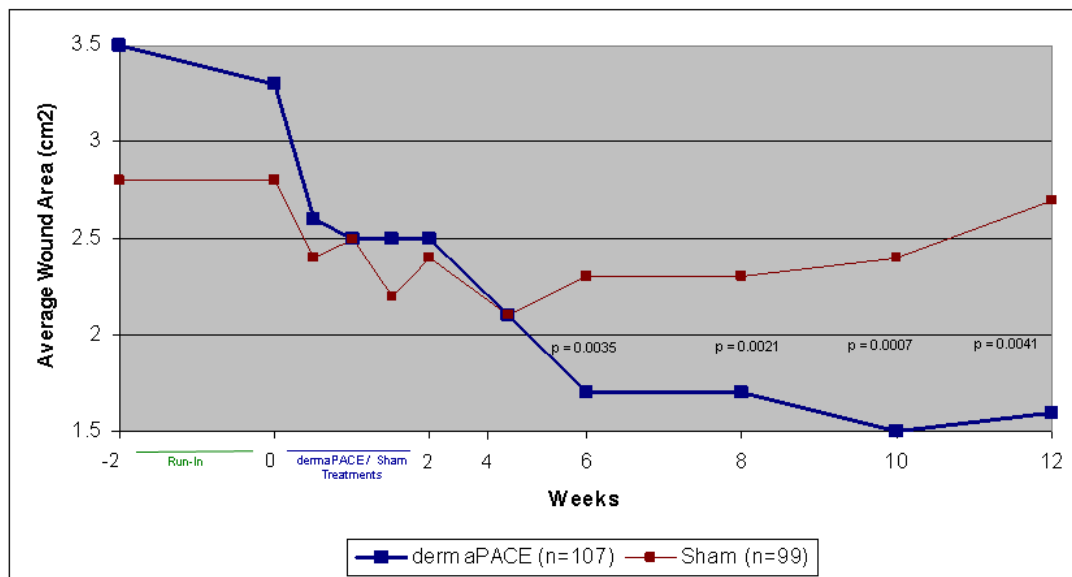
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Abstract

Background: Pulsed acoustic shockwaves cause expression of multiple angiogenic growth factors which promote wound healing.¹ An FDA Investigational Device Exemption (IDE) study was performed to evaluate safety/efficacy of a pulsed acoustic cellular expression (PACE) device in healing diabetic foot ulcers (DFU) unresponsive to conservative therapy. This paper examines healing rates with PACE to identify an endpoint to the clinical response to the treatment.

Methods: This prospective, randomized, double-blinded, sham-controlled, multicenter, parallel group study enrolled patients with Texas Diabetic Wound Classification System Grade 1 or 2 DFU with ≥ 30 day persistence despite standard of care. Four active or sham shockwave treatments were delivered over 2 weeks (dermaPACE®, SANUWAVE, Alpharetta, GA). Endpoints included rate of wound closure, time to closure, area reduction, safety and pain.

Results: 206 patients were randomized into active(n=107) or sham(n=99) treatment groups and followed 12 weeks for efficacy and 24 weeks for safety/recurrence. 90-100% wound closure by 12 weeks was obtained in 48% of PACE versus 31% of sham patients ($p=0.0161$). Mean reduction in target ulcer area at 12 weeks for PACE patients was 54%, versus 7% for sham ($p=0.004$). Mean ulcer area in the sham group initially decreased 20% early in the evaluation period, but by 6 weeks showed a progressive increase in size through week 12. Conversely, mean ulcer area for PACE patients decreased throughout the 12-week evaluation period, steeply during active treatment, then at a slower pace, then at nearly plateau at 9-12 weeks (Figure 1).



Conclusions: Mean ulcer size for PACE treated patients decreased significantly compared to sham control between 6-12 weeks. The rate of wound area reduction after week 10 indicating diminished PACE treatment effects. Future investigation should evaluate whether a second course of PACE treatments at that time point can initiate a new cycle of rapid healing response.

References

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Disclosure/Financial Support

This study was sponsored by Sanuwave Inc, Alpharetta, GA as part of a phase III clinical trial in which the authors were paid consultants serving as safety monitor (LB) or clinical investigator (RG, GG).

None of the authors has a financial interest in the device mentioned in the manuscript.