Pulsed Electromagnetic Therapy: A Non-Opioid Means of Reducing Pain and Improving Skin Perfusion Pressure in Diabetic Symmetric Peripheral Neuropathy

Erica E. Tassone[1], Jeffery C. Page[1], Marvin J. Slepian[2,3,4]

[1]Regenesis Biomedical Inc., Scottsdale, AZ; [2]Department of Medicine, [3]Sarver Heart Center, [4]Arizona Center for Accelerated Biomedical Innovation, at the University of Arizona, Tucson, AZ.

Background

In 2023, the CDC estimated that 37.2 million people have diabetes. Approximately 20% of patients with diabetes develop painful neuropathy, which most often damages nerves in the legs and feet.

Further complications include development of diabetic foot ulcerations, which can lead to amputations, increased economic costs, and death.

Electromagnetic therapy (EMF) is an emerging non-pharmacologic therapeutic that has been shown to modulate cell and tissue responses, including regulating differentiation in osteoblasts, increasing collagen production in wounds, and reducing wound healing times.

Pulsed Electromagnetic Field (PEMF) therapy is a promising non-pharmacological method to treat pain associated with DPN and potentially repair the disrupted pathophysiology leading to DPN. [1-3]

An example PEMF device

Hypothesis

Subjects treating with PEMF therapy will experience improvements in pain associated with diabetic peripheral neuropathy, as well as improvements in microcirculatory flow and blood pressure.

Conclusion

Subjects using active PEMF experienced significant reduction in pain ($p < 0.01$) and improvements in SPP.

- PEMF is effective as a non-pharmacologic means to reduce pain associated with DPN.
- PEMF appears to have modulatory affect enhancing blood flow in affected tissue.
- PEMF is a promising non-pharmacological therapeutic with efficacy as a primary therapy, or as an adjunctive approach, reducing pharmacologic burden and risk of addiction in patients with symptomatic pain in DPN.

PEMF holds promise for improvement of vascular physiology in microcirculatory dysfunction associated with diabetic PAD and warrants additional investigation as to underlying mechanisms and further clinical translation.

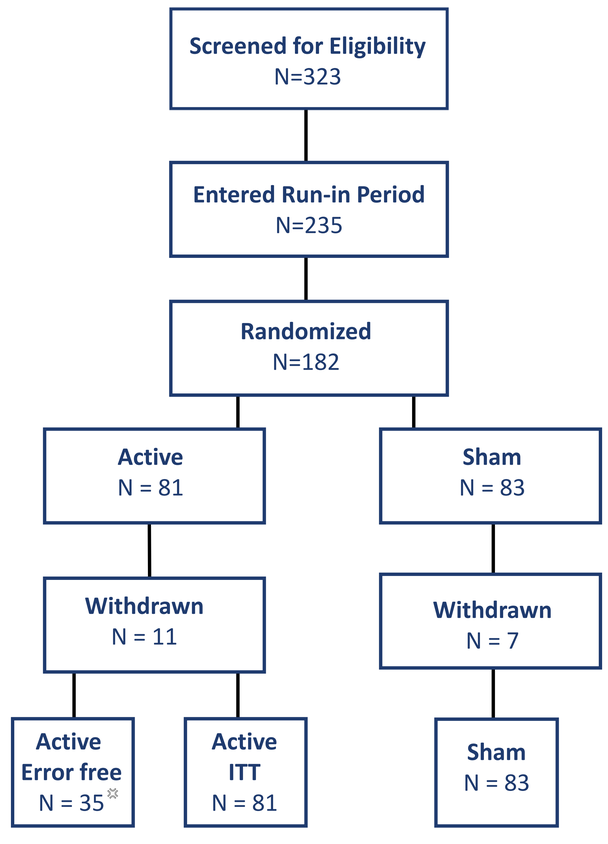
References
1 Graak et al. 2009 , 2 Lei et al. 2013, 3 Shanb et al. 2020, 4. Tassone et al. 2023

Methods

A randomized, sham-controlled, double blind, clinical trial was conducted on subjects afflicted with foot pain associated with diabetic peripheral neuropathy (DPN). Following informed consent, 181 subjects (84 male, 98 female; Age range 40-79) with diabetes and confirmed DPN were entered into the trial. Subjects were randomized and instructed to apply therapy - i.e. blinded as to either active PEMF [Dual-Pad PEMF (Provant® Therapy System), frequency of 27.12 MHz, pulse duration of 42 ± 4 microseconds, repeated every 1000 ± 25 microseconds], or non-active sham, to their feet via foot pads for 30 minutes, twice daily and report daily pain scores (NPRS, range 0-10). Skin perfusion pressure (SPP) measurements (Vasamed Sensilase PAD-IQ) were also collected at 2 and 7 weeks to assess peripheral arterial disease (PAD) effects via measurement of local microcirculatory flow and blood pressure.[4]

Study Design

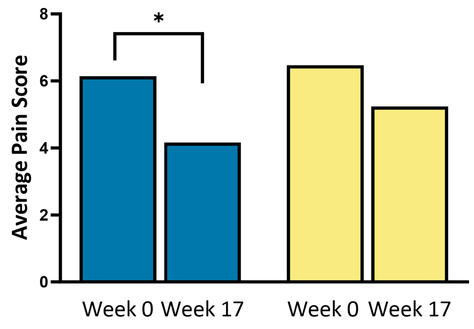
Flow chart for clinical trial enrollment and analysis



*During the trial participants in the active arm received a low field strength notification due to improper pad placement. To eliminate possible nocebo effects, these subjects (Active Intent to Treat) were excluded from pain scores analysis. All Active were included in SPP analyses.

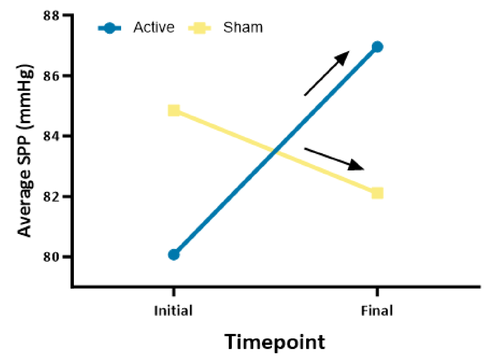
Results

Change in pain score over time



Average pain scores for Active error free subjects (N=35) compared to sham. Subjects in the Active group experienced significantly more pain relief (***p <0.01**) compared to sham.

Change in SPP over time

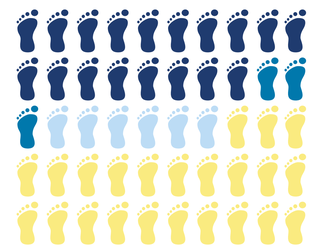


Average SPP values for both feet collected at two weeks (Initial) and seven weeks (Final) in Active ITT and Sham subjects.

Responders

Each foot represents 2% of the population, overall percent change from baseline indicated by color.

Active error free



In the Active error free population, 36% of subjects experienced a 50% reduction in their pain scores.

Sham

In the Sham arm, 17% of subjects experienced a 50% reduction in their pain scores.

REGENESIS®
Energy for an Active Life