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Evaluation of pulsed electromagnetic field therapy for the treatment of chronic postoperative pain following lumbar surgery: a pilot, double-blind, randomized, sham-controlled clinical trial

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Abstract

Background: The incidence of chronic postoperative pain following lumbar spinal surgery has increased with the overall increase in the prevalence of lumbar surgery. This study was conducted to evaluate the analgesic effectiveness of pulsed electromagnetic field (PEMF) therapy in subjects with persistent pain following lumbar surgery.

Patients and methods: A randomized, double-blind, sham-controlled, multicenter study in 36 subjects with persistent low-back and/or radiating leg pain after lumbar surgery was conducted. Eligible subjects were randomized (1:1:1) to receive one of two doses of therapy (42- μ s or 38- μ s pulse width) or treatment with a sham device. Subjects self-treated twice daily for 60 days. The primary end point was change in pain intensity (Δ PI) using the Numerical Pain Rating Scale between average baseline (Days -5 to -1) and end of treatment (Days 56-60) for lumbar and radiating leg pain. Secondary outcome measures included the Oswestry Disability Index, Beck Depression Inventory-II, Patient Global Impression of Change, and consumption of analgesics.

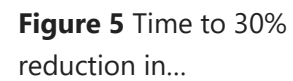
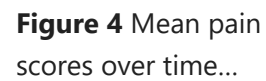
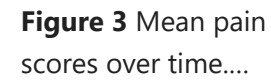
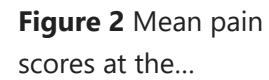
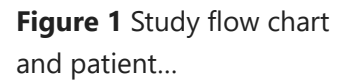
Results: Low-back pain scores for the 42- μ s group decreased by 40.2% ($p = 0.028$), compared to 18.6% for the 38- μ s pulse width group ($p = 0.037$) and 25.6% for the sham group ($p = 0.013$ per protocol population). Average leg pain scores decreased by 45.0% (42 μ s, $p = 0.009$), 17.0% (38 μ s, $p = 0.293$), and 24.5% (sham, $p = 0.065$). The proportion of subjects responding to therapy, time to 30% reduction in pain scores, and Patient Global Impression of Change were improved with the PEMF 42- μ s device over the sham control, although results were associated with p -values >0.05 .

Conclusion: PEMF therapy (42- μ s pulse width) was associated with trends for a reduction in pain, compared to sham treatment. Secondary endpoints were consistent with an overall beneficial effect of the PEMF 42- μ s pulse width device.

Keywords: chronic pain; failed back surgery syndrome; lumbar surgery; neuromodulation; neuropathic pain; nociceptive pathways; pulsed electromagnetic field therapy.

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