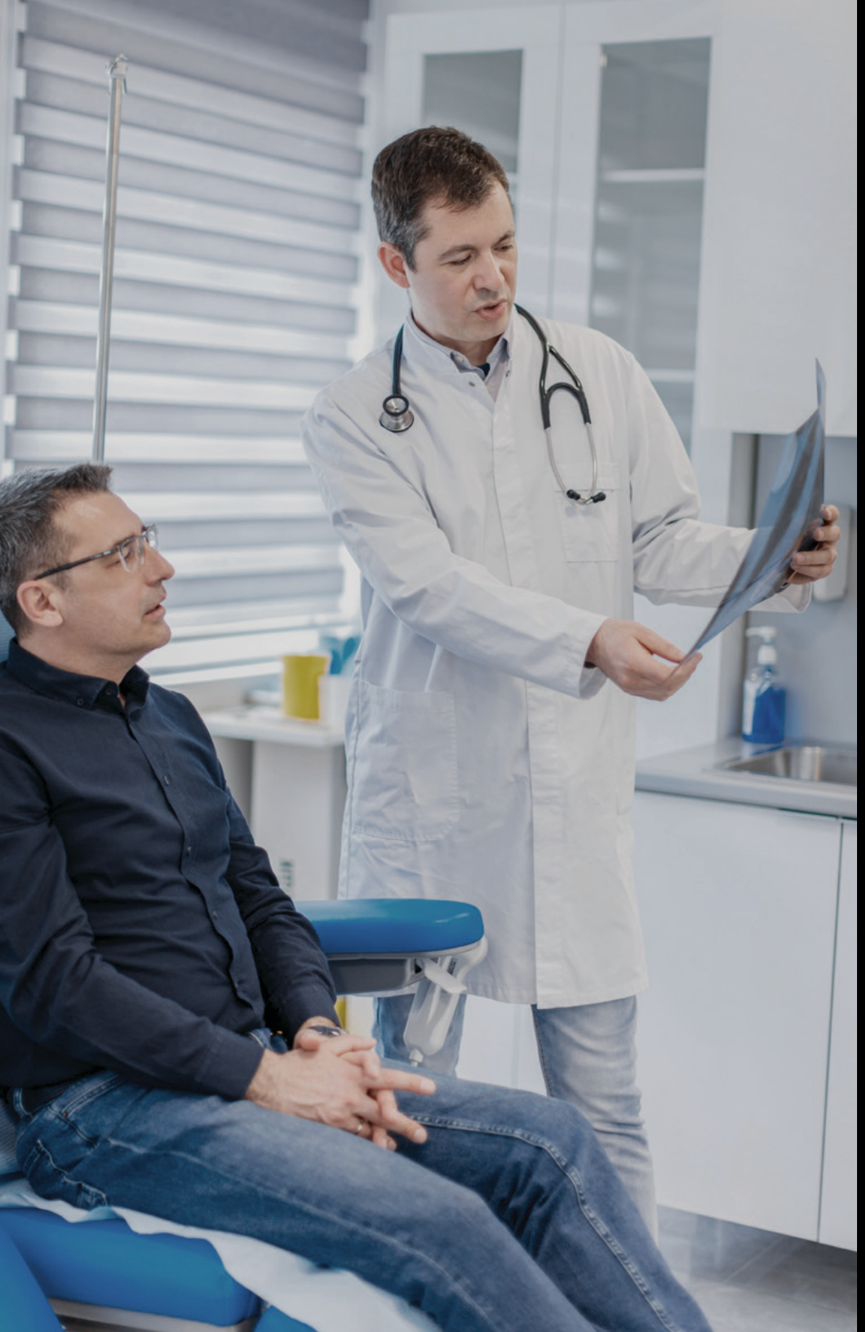

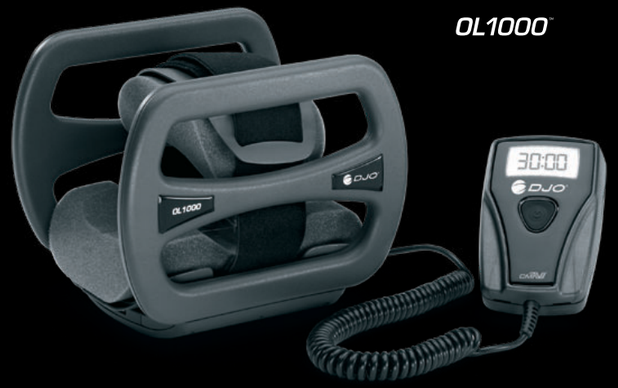

OL1000™ is a portable, battery powered, microcontrolled noninvasive bone growth stimulator indicated as a noninvasive treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

For full prescribing information, including potential contraindications, precautions and adverse effects, contact Enovis™ or visit our website https://www.enovis.com/products/regeneration/spinalogic

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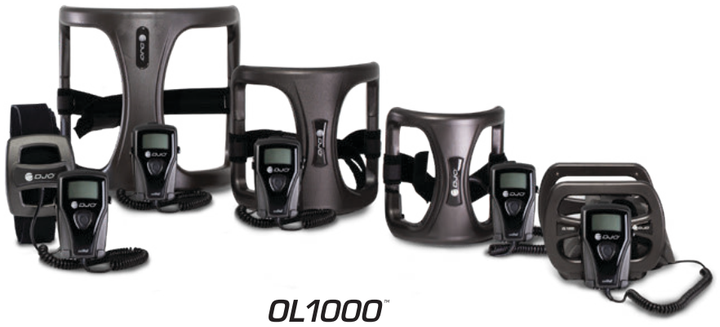
PUBLISHED CLINICAL RESEARCH

Noninvasive Stimulation for Fracture Nonunion

Combined Magnetic Field Technology



Non-invasive electrical stimulation has become a standard of care in the treatment of nonunion fractures, particularly for patients that may not be good surgical candidates or who prefer a conservative treatment protocol. A large volume of data published on electrical stimulation dates back to its early years (1980s) and this summary offers several more recent publications (2013-present) looking at the efficacy and cost-benefit of its use.

LEVEL ONE 2016 INDEPENDENT META-ANALYSIS

Aleem IS, Aleem I, Evaniew N, et al. Efficacy of Electrical Stimulators for Bone Healing: A Meta-Analysis of Randomized Sham-Controlled Trials. Sci Rep. 2016;6:31724. Published 2016 Aug 19. doi:10.1038/srep31724

- A meta-analysis of randomized sham-controlled trials to establish the efficacy of electrical stimulation for bone healing. The study identified all trials randomizing patients to electrical or sham stimulation for bone healing
- For every 7 patients treated with electrical stimulation, 1 persistent nonunion can be prevented
- This study demonstrated a statistically significant (p = 0.02) reduction in patient reported pain, signifying the first time a meta-analysis on bone growth stimulators, with little to no heterogeneity, identified statistical significance in pain improvement
- Results showed that electrical stimulation significantly reduced the rate of nonunion by 35%(p<.01) when compared to the control treatment group (sham device or no treatment)
- The effect on both nonunion risk and pain reduction was consistent across all indications

LEVEL TWO 2016 POST-MARKET REGISTRY

Baumhauer Phillips M, Baumhauer J, Sprague S, Zoltan J. Use of Combined Magnetic Field Treatment for Fracture Nonunion. J Long Term Eff Med Implants. 2016;26(3):277-284. doi: 10.1615/JLongTermEffMedImplants.2016016818. PMID: 28134611

- Over 15 different fracture types were included in the registry and treatments were initiated between 2 and 9 months or more than 9 months after injury. This provided for a broad subject population
- 2370 subjects were followed until their fractures were healed as determined by:
  - No motion was demonstrated at the fracture site
  - Three or more cortices were seen bridging the fracture gap by radiographic assessment and there was no pain associated with the fracture site
  - All fracture types, as well as all times since injury, were included in the registry. Healing rate and time were identified for all subjects enrolled
  - Overall, there was a 75% healing rate and a time-to heal of 4.9 months +/– 1.0 months for the 2370 patients. It was demonstrated that time to treatment after injury had an impact on the healing rate

Those treated 2 months after injury demonstrated considerably higher healing rates than that in patients treated 9 months or more after injury (82.6% vs. 68.7%). In addition, those subjects treated earlier after injury had a shorter time-to-heal. These results indicate the potential benefit of early intervention using CMF treatment following injury, because delayed treatment initiation may result in a poorer response to treatment. The results of this study further demonstrate the effectiveness of the OL1000™ device to aid the treatment of a broad range of fracture non-unions by increasing the healing rate and decreasing healing time.

A healing rate of 85.5% was reported for metatarsal fractures, 75.9% for ankle fractures and 79.2% for tib/fib fractures, to name a few.

LEVEL TWO 2016 PROSPECTIVE OBSERVATIONAL STUDY

(ORIGINALLY SUBMITTED TO FDA IN 1992 TO OBTAIN INDICATION FOR NON UNION FRACTURES)

Phillips M, Zoltan J, Petrisor BA, Sprague S, Baumhauer J. The Use of Combined Magnetic Field Treatment for Fracture Nonunions: A Prospective Observational Study. J Long Term Eff Med Implants. 2016;26(3):261-270. doi: 10.1615/JLongTermEffMedImplants.2016016816. PMID: 28134609.

- 112 patients with 116 fractures
- Nonunion defined as 9 mo since injury; no progression to healing on a set of x-rays separated by 3 months
- Healing criteria:
  - No motion seen clinically at fracture site
  - Three or more cortices bridged the fracture gap by radiographic assessment
  - No pain was associated with the nonunion
    - Pain was assessed at rest, with the application of stress, and with weight bearing when applicable
- Tibial nonunions had the highest percentage of healed fractures; CMF technology helped heal 78% of tibial fracture nonunions and 45% of all other nonunions in the study

LEVEL THREE 2021 COST ANALYSIS OF CMF OL1000™ STIMULATION

Joel Russell, Sheila Sprague, Sam Harper, Michelle Green & Mohit Bhandari (2021) An early cost analysis of magnetic bone growth stimulation in England, Expert Review of Pharmacoeconomics & Outcomes Research

Reported that use of CMF OL1000™ resulted in significant cost savings when compared with surgical intervention for individuals with nonunion tibial fractures.

Results indicate a ~$1500 cost saving per person when using CMF compared with undergoing surgical intervention for the treatment of tibial nonunion fractures.

KEY CLINICAL OBSERVATIONS DRIVING LOWER COSTS:

- Lower average treatment cost observed with use of CMF when compared to surgical intervention for tibial fracture nonunion
- 2.1 month reduction in heal time observed with use of CMF when compared to surgical intervention for tibial fracture nonunion
- 81% reduction observed in the need for surgical management after tibial fracture nonunion with use of CMF
- Lower rate of infection observed with use of CMF when compared to surgical intervention in patients undergoing treatment for tibial fracture nonunion

LEVEL THREE 2013 ECONOMIC ANALYSIS OF ESTIM VS ULTRASOUND LIPUS

Joel Russell, Sheila Sprague, Sam Harper, Michelle Green & Mohit Bhandari (2021) An early cost analysis of magnetic bone growth stimulation in England, Expert Review of Pharmacoeconomics & Outcomes Research

Explored the resource use and healthcare costs associated with electrical bone growth stimulation (EBGS), low-intensity pulsed ultrasound (LIPUS) and neither (No-stim) in managing fracture non-unions within both diabetic and non-diabetic patients. Medical and pharmacy claims were used to identify both diabetic and nondiabetic subjects who were newly diagnosed with a fracture nonunion.

- Overall, 11,628 non-union patients were included in the study with a breakdown of 29.5% of the electrical bone growth stimulators (EBGS) group, 12.3% in the low intensity pulsed ultrasound (LIPUS) group and 58.2% in the no stim group
- At 1-year post nonunion diagnosis, EBGS treated patients were predicted to have significantly less healthcare associated costs than LIPUS treated patients (mean: $21, 632 vs. $23,964, p<0.01) and the no-stim patients (mean: $21,632 vs.$23,843, p<0.01)
- Additionally, EBGS treated patients were significantly less likely to receive fracture related treatments when compared to LIPUS patients (33.6% vs. 43.2%, P < 0.01) and patients that received no stimulation (33.6% vs. 60.3%, P < 0.01)
- This concluded that, for both diabetic and non-diabetic patients, the use of EBGS resulted in significantly lower healthcare costs for the treatment of non-union