



# PUBLISHED PRE-CLINICAL RESEARCH

## The Evolution of Combined Magnetic Field Stimulation for Bone Healing

**OL1000 BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION** 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.

**SPINALOGIC BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION** Spinalogic is a portable, battery powered, microcontrolled, noninvasive bone growth stimulator indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels.

**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 DJO, LLC or visit our website <https://www.djoglobal.com/products/regeneration/spinalogic>



### REFERENCES:

1. Griffin, M., & Bayat, A. (2011). Electrical stimulation in bone healing: critical analysis by evaluating levels of evidence. *Eplasty*, 11, e34.
2. Fukada E, Yasuda I. On the piezoelectric effect of bone. *J Phys Soc Japan*. 1957;12:1158-69.
3. <https://www.semanticscholar.org/paper/Electromagnetic-fields-and-magnets.-Investigational-Trock/ef4a42034d89428822b4bbb84172fffa899a8cb7/figure/0>

\*Pre-Clinical Research is not indicative of human clinical outcomes.

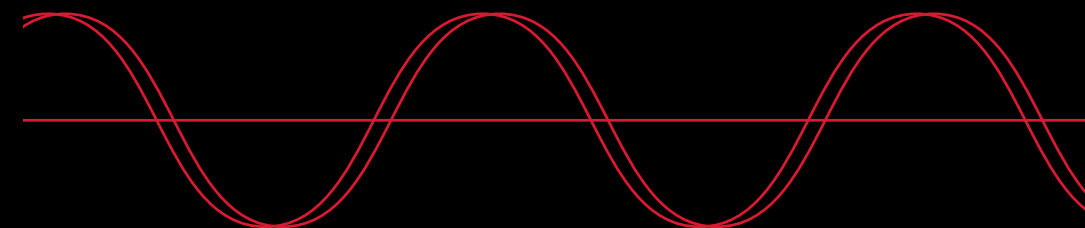
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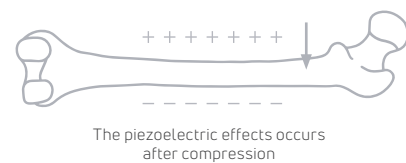
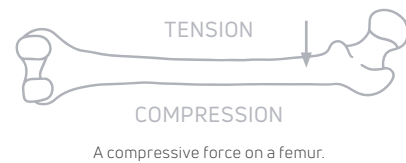


# UNDERSTANDING NON-INVASIVE ELECTRICAL STIMULATION

IT ALL STARTS WITH AN UNDERSTANDING OF HOW BONE HEALS

In the early 1950s, researchers demonstrated that when stress is applied to bone in such a way to cause deformity, electrical potentials are generated. In areas of compression the bone was electronegative and caused bone resorption, whereas areas under tension were electropositive and produced bone. Therefore, subsequent developments were based on the idea that stimulating these endogenous electric fields using electrical stimulation would enhance bone healing.<sup>1,2</sup>

With previous technologies offering pre-clinical data supporting cell proliferation at large variations of frequencies, early researchers believed that signals could be optimized to a specified frequency that would enhance cell proliferation at shorter exposure times, and began their research in the 1980's.



Wolff's Law is the transduction of mechanical stress into bone growth and remodeling, guided by electricity

1992

## EXPOSURE TO LOW FREQUENCIES RESULT IN IMPROVED BONE HEALING

MCLEOD KJ, RUBIN CT. THE EFFECT OF LOW-FREQUENCY ELECTRICAL FIELDS ON OSTEOGENESIS. J BONE JOINT SURG AM. 1992 JUL;74(6):920-9. ERRATUM IN: J BONE JOINT SURG AM 1992 SEP;74(8):1274. PMID: 1634583.

### PURPOSE:

To determine the electrical currents generated intrinsically when stresses are applied to bone.

### BACKGROUND:

Electrical current generated in bone under load has at least two sources: the piezoelectrical currents arising from the deformation of collagen and the relatively large electrokinetic currents that are produced by the ionic constituents of fluid flowing past the mineral phase of the matrix. These electrical currents amplify the small mechanical strains that are produced by functional activity promoting their potential role in signal transduction. The regulation of bone remodeling by means of strain-generated potentials has served as the basis for the development of devices that induce pulsed electromagnetic field into tissue as a means to enhance healing.

### RESULTS:

Previously approved technology, specifically pulsed electromagnetic fields (PEMF), were studied in depth to better understand their impact on bone healing. Researchers saw the maximum bone remodeling occurred within a specific range of power levels of the pulsed electromagnetic field. For reference, PEMF waveforms offer a range of frequency from 1Hz to 250,000Hz. This meant that majority of the total energy offered by PEMF was not impacting bone formation. The technology did, in fact, work, but required much longer cell exposure.

### CONCLUSION:

Existing technologies (PEMF) induce orders of magnitude more power into the tissue than may be needed to stimulate a beneficial response. New bone formation was confined to frequencies of less than 100Hz.

1994

## EXPOSURE TO LOW FREQUENCY COMBINED MAGNETIC FIELDS RESULTED IN A SIGNIFICANT INCREASE IN CELLULAR CA+ FLUX

FITZSIMMONS, R.J., RYABY, J.T., MAGEE, F.P. ET AL. COMBINED MAGNETIC FIELDS INCREASED NET CALCIUM FLUX IN BONE CELLS. CALCIF TISSUE INT 55, 376-380 (1994)

### PURPOSE:

To determine the lowest threshold for which cells would respond to electromagnetic frequencies. Scientists looked specifically at the impact of low levels of CMF on intracellular calcium flux. Calcium is an important regulator of cellular events, and changes in calcium flux have important regulatory consequences on bone cells as well as other tissues. An influx of calcium increases both bone cell growth and bone cell proliferation.

### RESULTS:

- CMF is capable of increasing net calcium flux in human osteoblast-like cells
- When researching from 0-150 mins, at less than 30 minutes of exposure, cells had the highest uptake of calcium
- The increase of net calcium flux was frequency dependent, with a peak in the 15.3- 16.3HZ

### CONCLUSION:

More research was needed to determine the optimal signal, however, it was evident that low frequencies have an impact on factors that contribute to bone healing.

1994

## THE ROLE OF INSULIN-LIKE GROWTH FACTOR II IN MAGNETIC FIELD REGULATION OF BONE FORMATION

JAMES T. RYABY, ROBERT J. FITZSIMMONS, NI AYE KHIN, PATTI L. CULLEY, FRANK P. MAGEE, ALLAN M. WEINSTEIN, DAVID J. BAYLINK, THE ROLE OF INSULIN-LIKE GROWTH FACTOR II IN MAGNETIC FIELD REGULATION OF BONE FORMATION, BIOELECTROCHEMISTRY AND BIOENERGETICS, VOLUME 35, ISSUES 1-2, 1994.

### PURPOSE:

To better understand the cellular response over time to lower frequencies.

### RESULTS:

Researchers studied the impact of 30 minutes exposure to 76.6 Hz on DNA production over time finding that when compared to other low frequencies, IGF-II levels were most significant at 24 hours post exposure to 76.6Hz. This shows that although the treatment time was 30 minutes, the cellular response continued for 24 hours.

1995

## COMBINED MAGNETIC FIELDS INCREASE INSULIN-LIKE GROWTH FACTOR II IN TE-85 HUMAN OSTEOSARCOMA BONE CELL CULTURES

FITZSIMMONS RJ, RYABY JT, MOHAN S, MAGEE FP, BAYLINK DJ. COMBINED MAGNETIC FIELDS INCREASE INSULIN-LIKE GROWTH FACTOR-II IN TE-85 HUMAN OSTEOSARCOMA BONE CELL CULTURES. ENDOCRINOLOGY. 1995 JUL;136(7):3100-6.

### PURPOSE:

To better understand the impact of lower frequencies on bone formation at the 30-minute time frame and to better articulate how exposure to lower frequencies can impact bone healing.

### RESULTS:

This sham controlled in-vitro study showed that a 30 minute treatment with CMF increased the IGF-II receptors in osteoblast-like cells. IGF-II was chosen because it is the predominant growth factor extracted from human bone and IGF-II regulated chemotaxis, proliferation, and differentiation of normal human osteoblasts. It was found that CMF exposure at 30 minutes stimulated release/production of IGF-II from bone cells and that increased IGF-II then promotes an increase in cell proliferation.



For more information or to obtain a copy of the studies referenced herein, please contact your local representative or use the Regeneration sales rep locator to have a sales rep reach out to you.