

FINTEK

Bio-Electric *Response*

CAPACITIVELY COUPLED PULSED ELECTROMAGNETIC FIELD BONE GROWTH STIMULATOR



FINTEK BIO-ELECTRIC INC.

An ISO 13485 Company

Burlington, Ontario, Canada • Toll Free #: 1-866-440-5692
Email: info@fintek.ca • www.fintek.ca

"Designed and Manufactured in Canada"



ELECTRICITY AND FRACTURE HEALING

It's not new. Back in the late 1800's physicians and scientists were putting electrical probes into fracture sites. Literally hundreds of clinical trials and studies have been published since 1953 demonstrating that electrical stimulation is effective both in supporting calcification and consolidation of recalcitrant fractures and accelerating the healing of fractures that may prove problematic due to risk factors. Electrical stimulation for fracture healing has been in home use by patients for nearly four decades.

WHY CAPACITIVE COUPLING?

Studies have proven that capacitive-coupling is the most effective form of electrical stimulation in promoting bone fracture consolidation ⁽¹⁾⁽⁵⁾. Capacitively coupled electrical stimulation results in a greater enhancement of osteoblast proliferation when compared to inductively coupled or coil induced stimulation ⁽¹⁾⁽⁵⁾. This may be the case because capacitively coupled stimulation provides the osteoblasts with an unlimited source of external calcium ions ⁽⁵⁾, compared to inductively coupled and coil induced electrical stimulation that can only give the osteoblasts a limited source of intracellular calcium ions ⁽¹⁾⁽⁵⁾.

ADVANTAGES OF PEMF (PULSED ELECTROMAGNETIC FIELDS)

The Fintek Bio-Electric Response employs Pulsed Electromagnetic Fields (PEMF) through capacitively coupled current to promote the healing of bone fractures. The signal targets a bone cell protein, serving as a cell receptor trigger to initiate the proliferation of new bone cells called osteoblasts. The osteoblasts are the building blocks of new bone and effectively fill in and consolidate any gaps that patients may have within their fractures. As an additional benefit, PEMF technology may improve blood flow or vascularization to the treated area which may help to heal tissues, ligaments, tendons, and nerves. The Bio-Electric Response can be used in appendicular, pelvic and spinal applications. The device can be prescribed for the following fracture types:

- Open and Closed Fractures
- Complex and Comminuted Fractures
- Spiral, Transverse and Oblique Fractures
- Spinal Fractures and Fusions
- Joint Fusions
- Segmental Fractures
- Casted Fractures and surgically fixed fractures and fusions with metal implantation
- Infected Fractures in combination with medication

The device is prescribed for patients who have a fracture that has presented with non-union or delayed union, or if they have risk factors that increase their probability of going to non-union and healing very slowly. Risk factors can include previous medical conditions or habitual practices that have been shown to inhibit or slow the process of consolidation at the fracture site. Some examples of these factors include:

- Tobacco use and smoking
- Osteoporosis
- Diabetes
- Obesity
- Advanced age
- Heart and circulatory conditions
- Currently on certain blood and/or non-steroidal anti-inflammatory drugs or medications
- Site infection

CLINICAL DATA

The use of Pulsed Electromagnetic Frequency (PEMF) through capacitively coupled current for the purpose of healing fractured bones has been studied extensively in the past. It is known that capacitively coupled electrical stimulation leads to enhanced osteoblast proliferation. For example, capacitively coupled electrical stimulation has been shown to upregulate both spatial and temporal gene expression of several growth factors involved with bone cell proliferation including BMP-2, BMP-4, BMP-6, BMP-7, transforming growth factor (TGF)- β_1 , fibroblast growth factor (FGF)-2 and VEGF ⁽⁵⁾. In addition to this, capacitively coupled electrical stimulation has also shown that it causes an increase in calcium concentration in the cytosol, which leads to enhanced activation of calmodulin, which in turn leads to increased bone cell proliferation ⁽⁵⁾.

Several of the published studies utilizing PEMF through capacitively coupled currents have identified the ideal frequency of electrical stimulation that produces the greatest success rate of healing fractures. Studies have confirmed that an electrical signal of approximately 60 KHz is the most effective signal frequency for the consolidation of fractures ⁽³⁾⁽⁵⁾.

Several studies have also aimed to evaluate the efficacy of PEMF in the healing of fractures. Many studies involving PEMF electrical stimulation have proven that it can be highly efficacious in healing fractures, including non-unions. Some of the studies showing high success rates are as follows:

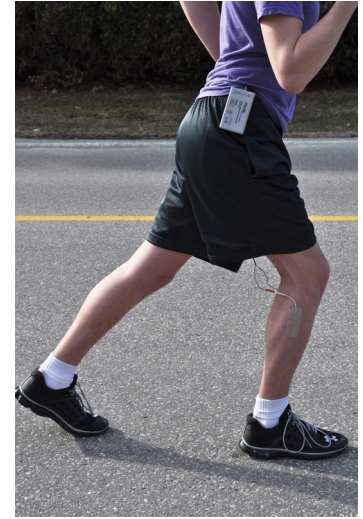
- Goodwin et al ⁽⁶⁾ observed an 85% success rate of healing in spinal fusion patients utilizing capacitively coupled electrical stimulation, compared to only a 65% success rate for patients in the control group.
- Simonis et al ⁽⁷⁾ showed an 89% success rate (16 out of 18 patients) in healing tibial non-unions with PEMF compared to a 50% success rate (8 out of 16 patients) in the control group.
- Brighton and Pollack ⁽⁴⁾ showed a 77% success rate in healing non-union patients using capacitively coupled electrical signals (60 KHz).
- Benazzo et al ⁽²⁾ observed an 88% success rate (22 out of 25) in healing lower-limb stress fractures utilizing capacitively coupled electrical signals (60 KHz).

CLINICAL REFERENCES

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2. Benazzo, F., Mosconi, M., Beccarisi, G., Galli, U. (1995). Use of Capacitive Coupled Electric Fields in Stress Fractures in Athletes. *Clinical Orthopaedics and Related Research*, 310, 145-149.
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7. Simonis, R.B., Parnell, E.J., Ray, P.S., Peacock, J.L. (2003). Electrical treatment of tibial non-union: a prospective, randomized, double-blind trial. *International Journal of the Care of the Injured*, 34, 357-362.

“TREATMENT ON THE RUN”

The Bio-Electric Response’s light and compact design allows the patient full ambulation.



EASE OF APPLICATION

The Bio-Electric Response has been designed with the patient’s comfort in mind. You can expect the following general benefits from choosing the Bio-Electric Response:

- Our device’s light and compact design means that it does not impede ambulation.
- Our electrode can be worn beneath clothing including socks, pants and shirts, and the Response unit can be clipped to a belt or put into your pocket.
- Our electrodes are flat, pliable and flexible, and they are comfortable on the skin.
- Our electrodes can be placed underneath casts.
- Our device is delivered to you with a supply of quality batteries and electrodes to fulfill your complete treatment needs

WHY CHOOSE FINTEK?

At Fintek, we pride ourselves in providing the best customer service to all of our patients and referring physicians. We ensure that we instruct each and every patient how to properly use our device in person wherever possible, and we back up our professional customer service by providing any follow up that is needed for our patients quickly and effectively. We offer a twenty-four hour toll-free telephone line where we are able to answer any questions patients may have regarding the use of our devices.

WE ARE INSURANCE SPECIALISTS

Our staff at Fintek have a great deal of experience in the processing of medical insurance claims for bone growth stimulators. In our past experience, we’ve had bone growth stimulators covered by WSIB/Worker’s Compensation, auto insurers, and quality supplementary health insurers. Fintek will apply for insurance coverage on your behalf by submitting a detailed claim letter and product efficacy documents and we follow up with insurance companies on a regular basis to ensure that your claim gets fair and reasonable treatment. Once the claim has been processed, we follow up immediately with our patients.



CONTACT INFORMATION

Telephone: 1-905-633-8636, Fax: 1-905-633-8637
Toll-Free Telephone: 1-866-440-5692
Email: info@fintek.ca, Website: www.fintek.ca