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Biowave Neuromodulation Pain Therapy Compared to Interferential Therapy (IFT) and Transcutaneous Electrical Nerve Stimulation (TENS)

Biowave Corporation manufactures three neuromodulation pain therapy systems, Sportswave®, Deepwave® and Homewave®, which utilize a unique signal mixing technology to deliver electrical signals through the skin into deep tissue for inhibiting pain transmission and improving function. The signal technology is covered by four issued U.S. patents and over 20 international patents.

Background

Low frequency signals (1-180Hz in frequency) are required to inhibit transmission of pain signals along nerve fibers in the body. However, electrical signals in this frequency range cannot pass through the skin because of the skin's impedance and capacitance. High frequency signals (greater than 1000Hz in frequency) easily pass through the skin. However, these signals used individually do not elicit an electrical or mechanical response from either muscle tissue or nerve fibers to inhibit pain transmission.

TENS

TENS devices deliver pulsed low frequency signals typically between 1 and 180 Hz directly to the skin between two surface electrodes placed on either side of the painful area. The result is a surface effect and the patient feels a noxious twitching, electrical sensation between the electrodes. The sensation produced by TENS may act as a distraction from the pain while the device is on, however, there is little residual benefit or functional improvement once the therapy session is over.

Interferential Therapy (IFT)

IFT uses four surface electrodes (two pairs of electrodes) that are placed in an "X" pattern surrounding a painful area that deliver two separate pulsed, high frequency signals. One pulsed signal, typically around 4000 Hz, is delivered between one pair of electrodes. A second pulsed signal, usually varying between 4010 Hz and 4180 Hz, is delivered between the second pair of electrodes. The two pulsed signals cross paths on the surface of the skin. At the point of intersection, an interference pattern develops resulting in a new signal equal to the difference between the signals. This is called the beat frequency. Since one of the high frequency signals constantly varies over several seconds of time, the beat frequency produced at the intersection point also varies over time, and in this example, varies between 10 Hz and 180 Hz. Since the two signals intersect on the surface, the resulting beat frequency produces mostly a surface effect similar to TENS.

Targeting the signal to the painful area is very difficult with IFT systems because of the

surface nature of the signals and the need to precisely place the electrode array around the painful area. Additionally, while the pulsed signals delivered by IFT contain a small signal component that can overcome the skin's electrical barrier, the pulses contain a range of frequencies of weak amplitude, which cause uncontrollable muscle contraction and deliver, like TENS, the noxious twitching electrical sensation that is not well tolerated by patients.

Biowave

There are three main differences between Biowave and IFT or TENS devices:

- (1) **Deep Tissue Signal Technology** – Biowave devices utilize a proprietary signal mixing technology that delivers two continuously summed, high frequency alternating current signals that pass through the skin into deep tissue where they interact with tissues to produce a range of signals which include a low frequency electrical field. This field is optimized for blocking pain and providing functional improvement including a greater range of motion and a reduction in stiffness and muscle spasm. In addition to providing efficacy, these signals are significantly more comfortable leading to improved patient treatment compliance.
- (2) **SmartPad™ Active Control and Monitoring Technology** – Biowave utilizes SmartPad™ technology – active monitoring and control of the electrical signals to ensure the accurate and safe delivery of therapeutic energy into deep tissue. The SmartPad™ technology automatically prevents patients from receiving too much intensity which could lead to a burn.
- (3) **Electrode Options** – For each of its devices, Biowave makes available three different sized combinations of electrode pairs that enable the physician or medical professional to focus the signals to different locations on the body.

In addition, the Deepwave system provides an option of either noninvasive surface or percutaneous electrodes. The percutaneous electrode is a 2.5 inch round sterile, single use electrode containing 1014 0.75mm long microneedles which facilitate the delivery of the signals through the skin. The percutaneous electrode set may only be used under the supervision of a physician.

Biowave Deep Tissue Signal Technology

Biowave's signal technology is based on the discovery that when two sinusoidal high frequency signals are summed (added) together in the device and then delivered into the body through a single electrode, the signals will pass into deep tissue and travel to a second opposing electrode. As the summed signals pass through the body, polarized structures like the membrane of the C-fiber, A-delta fiber and muscle tissue act in a non-linear fashion and force the further multiplication of these signals, resulting in a new spectrum of signals.

Multiplication of the high frequency signals results in the formation of a therapeutic low frequency electrical field that inhibits action potential propagation along pain fibers. This field is focused in a 2-3 inch diameter hemisphere in the volume of tissue under and surrounding each electrode. Since the nerve fibers and muscle tissue under and

surrounding the electrodes are encompassed by the low frequency field, at least one electrode must be placed directly over the center of the painful area.

Biowave devices deliver the two summed signals to the first electrode; they mix in the tissue beneath that electrode, then pass to the second electrode and return to the device, completing the circuit. Instantaneously, the summed signals are delivered to the second electrode; they mix in the tissue beneath that electrode, then pass to the first electrode and return to the device. The device alternates the delivery of the summed signals so quickly between the two electrodes that the patient cannot distinguish that the signals left either location. The net effect is there are two active electrodes, each of which can treat a distinct volume of tissue and there is no noxious twitching sensation.

Focusing of the Biowave Signals and Electrode Placement

With Biowave, depending on the nature and location of the painful area, the electrical signals can be focused to different parts of the body by pairing electrodes of different sizes and types with one another. If two electrodes of equal area are used, then two distinct volumes of tissue can be treated equally. For example, if a patient has bilateral low back pain, two equal area electrodes can be placed over the respective painful areas on each side of the spine. Additionally, by moving these electrodes closer together so that there is only 0.5 to 1.0 inch of space between them, the pair can be used to treat one larger volume of tissue.

By pairing an electrode of smaller area with an electrode of larger area, the density of the therapeutic low frequency field is *greater* in the volume of tissue beneath the *smaller* area electrode. Therefore, the smaller electrode needs to be placed directly over the primary painful area. The larger electrode is still active (it is not a grounding pad) and should be placed over a secondary point of pain. If there is no secondary point of pain, then the larger electrode must be placed over the bony prominence near the treatment site. Placement of the larger electrode over a bony prominence allows the patient to more comfortably increase the intensity of the signal to higher levels allowing a stronger electric field to encompass the pain site under the smaller primary electrode.

With the Deepwave system, the electrical signals can be focused by not only pairing different area electrodes with each other, but also by combining percutaneous with noninvasive electrodes. Since the summed high frequency signals pass through the skin more easily when using the percutaneous electrode, the impedance is lower in this area than at the opposing surface electrode. By having an impedance difference between the electrodes, the therapeutic low frequency field is more concentrated where the impedance is lower. Therefore, the field in the volume of tissue under the percutaneous electrode, which is placed directly over the painful area, allows the nerve fibers and muscle tissue to be more readily encompassed by the therapeutic low frequency field.

Treatment Regimen

Multiple treatments with Biowave devices may provide cumulative benefit.

Because athletes typically re-aggravate their pain condition during practices or games, the Sportswave recommended daily regimen is to treat immediately before a practice or

game (which may be in combination with heat), immediately after a practice or game (which may be in combination with cold and compression therapy) and a third time 2 – 3 hours later. Multiple 30-minute treatments reduce both acute and chronic pain conditions more quickly than a single treatment of greater than 30 minutes.

The Deepwave system with percutaneous electrodes may be used for chronic pain conditions. The recommended regimen is 6 treatments over 2 weeks, followed by physician-prescribed Homewave treatments that can be performed on a daily or as needed basis.

The Deepwave system with noninvasive electrodes may be used for chronic or acute pain conditions. Daily treatments are recommended followed by physician prescribed Homewave treatments that can be performed on a daily or as needed basis.

More Comfortable

Because Biowave devices deliver the summation of two high frequency sinusoidal alternating current signals, the sensation is smoother, deeper and more comfortable compared to the noxious electrical twitching sensation felt on the surface of the skin that results from IFT and TENS.

Easy to Use

Biowave's early signal-dose-finding studies demonstrated that there is an optimal set of high frequency signals for delivering energy through the skin into the body which create an optimal low frequency signal that inhibits pain transmission along pain fibers. This resulted in the design of very simple to use devices from which an optimized set of signals for blocking pain are delivered into deep tissue. The devices do not require any programming by the physician, medical professional or patient. Thus, Biowave devices are far simpler to use than IFT or TENS devices.

Efficacy

Biowave devices provide rapid, long-lasting efficacy. Responding patients experience a significant reduction in pain, and often, an improved range of motion, decrease in stiffness and reduction of muscle spasm by the end of the 30 minute treatment period, which often lasts 24 hours to 48 hours or longer. Clinical studies have also demonstrated that use of Biowave neuromodulation pain therapy reduces the use of concomitant pain medications.

For more information, contact:

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