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Neuromodulation Pain Therapy Treatment

Discussing the differences compared to other forms of electrical stimulation

By Ron Yacoub, MSPT, ATC, CSCS

The transmission of pain is conducted by the body's central nervous system. There are different types of nerve fibers, which perceive and transmit pain. By interrupting the transmission of pain signals in the nerves, pain signals do not reach the brain and pain is not perceived.

A patented technology called Neuromodulation Pain Therapy uses a proprietary summed high-frequency alternating current signal technology that is very different from TENS, interferential, pre-mod, high volt, H-wave, NMES and other forms of electrical stimulation. The signal technology dictates the rationale for how and where the electrodes are placed, which is very different from other forms of electrical stimulation.

Background and Difference vs. FES

In order to affect a C-fiber (pain fiber) it has to be encompassed by a low-frequency electrical field typically between 1-180 Hz. The problem is that skin has high impedance and capacitance and low-frequency signals, regardless of the shape of the waveform, cannot pass through skin to affect nerve fibers. Instead, these signals travel across the surface of the skin. This is a fundamental problem with TENS and other electrical stimulation waveforms that are delivered at less than 200 Hz. High-frequency signals relative to the body (>1000 Hz in frequency) can easily pass through skin into deep tissue, particularly if they have a sinusoidal waveform, but individually high-frequency signals have no effect on nerve or pain fibers.

Interferential devices deliver one high-frequency signal between a first pair of electrodes and a second high-frequency signal between a second pair of electrodes. The primary location where the high-frequency signals cross is at the surface of the skin. This is where an interference pattern develops called the beat



The BiowavePRO Neuromodulation Pain Therapy System is used on a player on the sidelines at a NY Giants game during the 2011 season.

frequency, and a low-frequency electrical field results; but this is primarily a surface effect and thus similar to TENS.

Neuromodulation Pain Therapy uses a summation of two high-frequency sinusoidal waveforms. Proof in a rabbit model showed that when two high-frequency sinusoidal waveforms are summed together and delivered to a single electrode, the signals pass through the skin into deep tissue. Inside the body of the rabbit, at all points of polarization within approximately a 2.5-inch to 3-inch diameter hemisphere beneath the electrode, the two high-frequency signals further multiplied together; this is known as a Fourier Transform. The multiplication of these two sine waves formed a new spectrum of signals in this volume of tissue. One of the resulting signals was a low-frequency signal in the form of a low-frequency electrical field. The result is that the body produced a low-frequency electrical field on the inside, as opposed to trying to force the low-frequency signals through the skin from the outside, like TENS and other forms of electrical stimulation.

Neuromodulation Pain Therapy was then used in a pilot dosage clinical study at Cornell Hospital in New York on chronic low-back pain patients, which resulted in an abstract in the journal *Anesthesia and Analgesia* in March

2003. The study confirmed that there was an optimal set of two high-frequency signals for delivering energy through skin, and an optimal low-frequency signal that formed inside the body for interrupting action potential propagation along C-fibers.

It is hypothesized that the active electrical field inside the body actually hyperpolarizes the nerve fiber. This resulted in the design of a very simple-to-use device—there is no programming. The only parameter controlled on the Neuromodulation Pain Therapy device is the intensity, which the patient adjusts to his own comfort level with the help of large plus and minus buttons on the face of the device.

Clinical Response and Observations

In clinical studies and in real-world use, eight patients out of 10 typically respond to a Neuromodulation Pain Therapy treatment; the average response is about a 75-percent reduction in pain, a significant increase in ROM, reduction in stiffness and some reduction of muscle spasm. But the most interesting result is a very long carryover effect. In chronic pain and post-op acute pain studies, a 30-minute treatment produces up to 24 hours and in many cases up to 48 hours of continued pain relief and functional improvement. TENS and other forms of electrical stimulation provide little to no residual pain relief when the signal is turned off. Empirically, multiple treatments of Neuromodulation Pain Therapy spaced about three to four hours apart provide a greater cumulative type effect.

Through testing and empirical data, there are several other effects caused by the active electrical field in addition to interrupting action potential propagation along C-fibers (interrupting the transmission of the pain signal):

1. The electrical field has an effect on A-delta (sensory) fibers as well. Five minutes into the treatment, hypoesthesia (a light numbness) is produced in the volume of tissue treated. This light numbness lasts for up to 20 minutes following a 30-minute treatment. However, once the hypoesthesia dissipates, there is still ongoing pain relief and functional improvement for up to 24 to 48 hours following a treatment.
2. The muscle is held in tension during the treatment—it feels like a pressure sensation. If the treatment is conducted on a shoulder, elbow, knee or ankle, it feels like

someone is comfortably gripping the joint. If the treatment is in the lumbar area on the back, it feels as if someone is pressing into the patient's back—a comfortable, deep, smooth sensation. It is not the uncomfortable twitching sensation across the surface of the skin, like TENS and interferential devices can produce. It is also not like an NMES or HVGS device that repeats cycles, causing a hard contraction and release of the muscle.

3. It is hypothesized that there is also increased blood flow in the volume of tissue being treated. It is not vasodilation; rather, components of blood have a charge on them and when charged particles pass through an electrical field they are accelerated through the field. Therefore, it is believed that blood flow is accelerated through the volume of tissue being treated, which can be supported by empirical evidence. This may help alleviate inflammation with repeated treatments.

Thus, a single Neuromodulation Pain

Therapy treatment may be producing several different effects on polarized structures in the volume of tissue being treated.

Rationale for Electrode Placement

The path of the signal dictates the rationale for the electrode placement. The device delivers the two summed high frequencies to the first electrode. The multiplication effect where the active electrical field occurs is in a 2.5-inch to 3-inch diameter hemisphere beneath the first electrode. The high-frequency signals then continue to the second electrode before returning to the device to complete the circuit. The device then delivers the two summed high frequencies to the second electrode. The active electrical field then occurs in a 2.5-inch to 3-inch diameter hemisphere beneath the second electrode.

The high-frequency signals continue to the first electrode and then return to the device to complete the circuit. The device alternates the delivery of the two summed high frequencies so quickly between the two electrodes,

the body never realizes the signals have left either location. The net effect is that two distinct volumes of tissue could be treated simultaneously. Since the active field occurs in the hemisphere beneath each electrode, the electrodes must be placed directly over points of pain. The electrodes are never placed surrounding a pain site.

Therefore, the way signals are focused to different parts of the body is by changing the ratio of the area of the electrodes relative to one another. If there are two equal area electrodes, the density of the electrical field is the same beneath each electrode, and therefore two points of pain of equal magnitude can be treated simultaneously.

However, if there is a primary point of pain and a secondary point of pain, or a primary point of pain and no secondary point of pain, the ratio of the area of the electrodes is altered. A small round electrode is paired with a larger area rectangular electrode. The density of the electrical field is much greater under the smaller round electrode—it is

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more concentrated in the smaller area—so the smaller electrode is placed directly over the primary point of pain. The larger electrode is still active (it is not a grounding pad) but the electrical field is spread over a larger area so the density of the field is less, and is therefore placed over a secondary point of pain.

But if there is no secondary point of pain, the whole nuance of the electrode placement for Neuromodulation Pain Therapy is that the larger rectangular electrode has to be placed over a bony prominence near the region being treated. This is because a bony prominence is the most comfortable place to receive the Neuromodulation Pain Therapy stimulation. If the second larger electrode is in a comfortable location, the patient can increase the intensity to a higher level. The higher the intensity, the greater the efficacy, the longer the residual benefit, and even more of the signal is focused under the smaller electrode, which is directly over the primary point of pain. This is the key concept to the electrode placement and is critical to obtaining positive

treatment outcomes.

In my experience, Neuromodulation Pain Therapy is a great adjunct therapy for providing long-lasting pain relief in my patients. I have several spinal stenosis patients who have had difficulty returning to daily activity through traditional physical therapy. When I treated my patients with Neuromodulation Pain Therapy, the treatments consistently provide about 48 hours of continued pain relief as well as a significant reduction in stiffness. I have found it to be one of the most helpful tools to get my patients to comfortably return to daily activities.

Other physical therapists are seeing similar positive results. "The Neuromodulation Pain Therapy system has been a wonderful tool to manage difficult pain conditions in my patients," said Steve Scher, PT, clinic director at Team Rehabilitation Physical Therapy in Royal Oak, MI, and team therapist for the Detroit Lions. "For example, I have treated frozen-shoulder patients who have been resistant to other therapies and whose range of motion

was limited. However, when we applied [the Biowave] for eight minutes at the beginning of the PT regimen, and then while the treatment continued, we began PROM and exercise therapy with the patient. The patient was able to do more resistance through a greater range of motion with significantly less pain. I have found it to be a wonderful tool to facilitate motion and allow my patients to complete my therapy protocols much more comfortably."

"This is a great therapeutic tool for reducing pain and simultaneously improving range of motion and strength in our athletes," added Byron Hansen, coordinator of rehabilitation for the New York Giants. "With multiple daily treatments, the athlete can perform rehabilitation exercises with less pain, allowing him to return to play more quickly." ■

Ron Yacoub is clinic director and owner of Pinecrest Physical Therapy in Miami, FL, Key Biscayne Physical Therapy in Key Biscayne, FL, and Grove Physical Therapy in Coconut Grove, FL. He is team physical therapist for the Miami Marlins.

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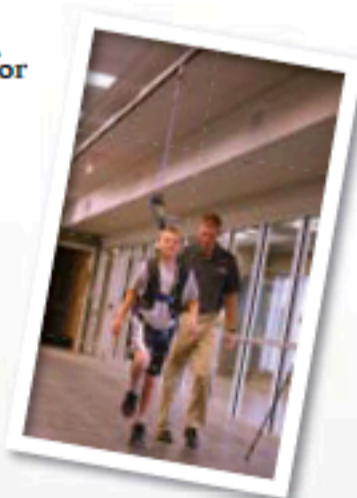


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