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## **Biowave vs. TENS**

There are 2 primary differences between TENS devices and Biowave devices:

- (1) The Deepwave system utilizes a Percutaneous Electrode Array (PEA) – a microneedle patch technology which facilitates the delivery of the therapeutic electrical signals through the skin, directly into deep tissue bypassing all of the impedance and capacitance issues associated with skin. PEAs are comfortable and feel like Velcro or sandpaper to the touch. PEAs are a patented proprietary technology developed and owned by Biowave Corp.
- (2) All of Biowave's devices deliver a patented proprietary electrical signal technology into the body. This is how it differs from conventional TENS:

First, low frequency signals (1-180Hz in frequency) are required to affect pain fibers in the body. However electrical signals in this frequency range cannot pass through the skin because of the skin's impedance and capacitance. TENS devices try to deliver low frequency signals between 2 or 4 electrodes. The effect is a "busy bees" sensation on the skin in between the electrodes. TENS may act as a distraction to the pain while the device is on (this is known as Gate Control Theory), however there is little residual benefit and no functional improvement following the treatment.

In developing Biowave's technology, we knew that high frequency signals (greater than 1000Hz in frequency) can easily pass through the skin but individually, such signals do not have an affect on pain fibers.

Biowave's patents are based on our discovery that when 2 or more high frequency signals are combined together in our device and then delivered into the body through a single electrode, the signals will pass into deep tissue in the body to a second opposing electrode. As the combined high frequency signals pass through the body, polarized structures like the membrane of the C-fiber and muscle tissue force these signals to further multiply together resulting in a new spectrum of signals in the body. One of the new signals formed in deep tissue inside the body is a low frequency signal that inhibits the transmission of pain signals on the pain fibers.

Additionally, muscle tissue is held in isometric contraction during the treatment, which may relate to increased functional outcomes reported by patients and in clinical trials.

In addition our devices use 2 different sized electrodes and also combine percutaneous with non-invasive electrodes to allow the targeting of the low frequency field directly under the percutaneous electrode. The result is that the therapeutic electric field is focused in a 2-3 inch diameter volume of tissue under the percutaneous electrode, which is placed directly over the center of the painful area. This allows the nerve fibers and muscle tissue at the pain site to be encompassed by the low frequency field.

With TENS, the signal travels along the surface of the skin between 2 electrodes and the effect occurs on the surface between the electrodes so it is difficult to target to the pain site.

In our first dosage study at Weill Medical College of Cornell University/New York Hospital, we determined that there are an optimal set of high frequency signals for delivering energy into the body and an optimal low frequency signal that forms for inhibiting pain transmission on pain fibers. This resulted in the design of a very simple to use device that is purposely not programmable and from which an optimized set of signals for blocking pain are delivered into deep tissue in the body.

In our clinical trials we have seen that 80% of the patients respond positively to this pain treatment modality and that those patients with a positive response experience a significant residual benefit (carryover effect) following the treatment. The average response is a 75% reduction in pain accompanied by a significant improvement in function – a reduction of muscle spasm, increase in range of motion and a decrease in stiffness that last for up to 24 hours following a 30-minute treatment.

TENS at best has a response in only 50% of patients and in those patients that receive a response, TENS reduces pain by less than 50% and has little residual or carryover effect.

For more information, contact:

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