Description and comparison of traditional T.E.N.S. to DR-HO'S T.E.N.S.

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June 2002

The purpose of this statement is to describe the stimulating properties of typical TENS devices and demonstrate similarities to the signal output by the Dr Ho's device.

I am a professor of Spine Biomechanics at the University of Waterloo. Our laboratory has investigated low back injury mechanisms, and prevention and treatment protocols for about 20 years. In our investigations on various scientific issues related to back pain we were apprised of the Dr Ho's device. Specifically in our work with the device on patients, we did quantify reductions in perceived pain as claimed by the manufacturer. However, given the subjective nature of data obtained from pain scales, we were motivated to find "hard" evidence obtained with instrumentation. We were successful in being able to find two phenomena measurable with instruments – specifically we observed reductions in muscle spasm (using electromyography) and increases in muscle oxygenation (using Near Infra-red Spectroscopy). This has created a foundation for hypotheses as to a mechanism of action (research paper submitted to an international medical journal). Since I also teach a graduate course in Instrumentation and Signal Processing, I was particularly interested in the nature of the muscle stimulation signal output by the Dr Ho's TENS device compared to other TENS units. The TENS pulse is a characteristic biphasic waveform where the signal is produced by building various sequences of pulse trains. While the typical pulse characteristics of TENS are incorporated into the Dr Ho's signal patterns, we have concluded that the sequenced patterns incorporated into the Dr Ho's device form the next generation in evolution of TENS devices.

The signals generated by TENS devices vary by unit and manufacturer. Common characteristics include high frequency stimulation patterns of individual biphasic pulses where the positive phase of each pulse is typically a square-wave while the negative phase is a sawtooth-ramp waveform. The positive/negative phases may be asymmetric about zero voltage (to minimize DC effects to the skin and subcutaneous metabolites). The duration of the individual pulses typically range from 30 to 250 microseconds. Pulse rate typically varies from 3 to 1000 Hz. TENS units generally fall into one of three categories; traditional TENS, burst TENS, or modulated TENS. Burst TENS units output bursts of pulses – for example a repeating pattern of 8 pulses per burst with 12 bursts per second. Modulated TENS outputs variable burst patterns, and of variable intensity. In summary, there is no single burst pattern considered to be TENS exclusively, rather the pulse itself seems to characterize TENS.

The pulse signal generated by the Dr Ho's device matches the typical type of pulse signal generated by other TENS units with the difference being in the variety of signal pulse sequencing – specifically it outputs a unique type of modulated burst pattern. For example traditional TENS units typically output a singular pattern that does not change although the stimulating strength is adjusted for a patient by altering the peak to peak voltage, or the current intensity. In contrast, the Dr Ho's device outputs a pre-programmed sequence of stimulating pulse patterns that appears to be quite effective for the therapeutic claims made. This appears to be the next generation of modulated TENS. The signal begins by generating stimulating pulse sequences that slowly increase in peak to peak voltage over several seconds which then decrease in a ramp-like fashion providing a wave-like

stimulation-contraction perceived by the patient. Other patterns follow that incorporate short duration but more intense bursts of TENS pulses to provide a perception of "chopping" such as what a masseuse would deliver to a patients back. The sequences typically conclude with the slower ramp increase/decrease of pulse trains as they diminish in signal intensity. In summary the major difference in the Dr Ho's TENS signal and a typical modulated TENS pattern is in the way the program builds a stimulation treatment where the greatest intensity is contained in the middle of the program. Thus, one more layer of program sophistication is built-in.

Debate continues as to the mechanism of action of TENS. Current hypotheses are dominated by the notion that TENS decreases the sensitivity of pain-sensing nerve fibers. Our work shows that the sophisticated modulated patterns of the Dr Ho's stimulation device reduces muscle spasm and increases oxygenation suggesting that the pain-spasm cycle is reduced.

Submitted Research Report:

Kavcic, N, Lehman, G, McGill, SM, A novel electrical stimulation device enhances muscle oxygenation and reduces muscle spasm and pain: Searching for a mechanism. (submitted)

Abstract

Objective: To assess claims of pain reduction from a novel TENS stimulation device using myoelectric and muscular oxygenation signals.

Design: Three cascading studies. One group, control trial, pretest-posttest.

Patients and Setting: Measures of muscle activity and self-perceived pain from 41 male and female subjects from an outpatient clinic. Measures of muscle oxygenation and pain levels from 12 different subjects.

Interventions: All subjects self-administered the novel muscle TENS stimulator.

Main Outcome Measures: Electromyography (EMG) measured muscle activity and Near-Infrared Spectroscopy (NIRS) measured muscle oxygenation. Pain reduction was assessed using a visual analogue scale of pain intensity (VAS).

Results: Myoelectric activation level (indicating spasm level) and pain scores of painful muscles were reduced after treatment ($p<0.001$), but no change in activation or pain in the control muscles. The relative change in muscle oxygenation showed a significant difference between the control and treatment trials ($p=0.013$), as did VAS pain scores ($p<.05$).

Conclusions: A treatment consisting of muscle stimulation with a novel device while relaxing in a lying posture reduces pain, which may be due to the observed reduction in spasm and increase in muscle oxygenation

Key Words: Rehabilitation, electrical stimulation, muscle tension, hypoxia