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Effect of Modulated TENS on Muscle Activation, Oxygenation, and Pain: Searching for a Physiological Mechanism

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ABSTRACT. Objectives: To understand the possible physiological mechanisms of a modulated transcutaneous electrical nerve stimulation [TENS] device on the reported reductions in pain using quantitative electromyography to measure muscle activation and near-infrared spectroscopy to estimate muscular oxygenation levels.

Methods: All subjects self-selected the intensity of the TENS stimulation current. Electromyography, near-infrared spectroscopy and a color analog scale of pain intensity to measure reported pain levels were collected both pre- and post-treatment. For Studies 1 and 2, measures of muscle activity and self-perceived pain were taken from 51 male and female subjects. For study 3, measures of muscle oxygenation and pain scores were taken from 12 different subjects.

Results: Myoelectric activation level and pain scores of painful muscles were reduced after treatment [$P < 0.001$] with no change in activation or pain in the control muscles. The follow-up study revealed that muscle oxygenation was significantly increased in the treatment trials when compared to the control trials [$P = 0.013$], while the color analog scale of pain intensity pain scores decreased [$P < .05$].

Conclusions: Pain reduction following TENS treatment has been reported before. The documented reduction in muscle activation suggests less vasoconstriction from prolonged contraction. Simultaneous documentation of increases in available oxygen suggests a tenable mechanism; reduced contraction level and less oxygen consumption, and/or more blood flow suggests an increased capacity to flush metabolites known to cause pain. [Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <docdelivery@haworthpress.com> Website: <<http://www.HaworthPress.com>> © 2005 by The Haworth Press, Inc. All rights reserved.]

KEYWORDS. Rehabilitation, transcutaneous electrical nerve stimulation, muscle oxygenation, hypoxia, myoelectric activity

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INTRODUCTION

Transcutaneous electrical nerve stimulation [TENS] is a common therapeutic modality used to reduce the perception of pain (1-4). This modality applies an electrical signal to the skin where differences in the pulse amplitude, duration and frequency of the stimulation current, and volley pattern define the different types of TENS treatments. Traditional TENS outputs a constant volley of pulses with a pulse duration ranging from 30 to 250 microseconds at a pulse rate that can vary from 3 to 300 Hz. Within the classification of traditional TENS, high frequency TENS outputs a frequency of stimulation greater than 50 Hz; low frequency TENS outputs at a frequency less than 10 Hz (4). Burst TENS units produce bursts of high frequency pulses within a low frequency burst rate (3). A commonly cited response to prolonged use of traditional TENS units is an adaptation or gradual diminution in the ability to sense the fixed parameter stimulation patterns. However, this habituation may be reduced with variation in signal amplitude and frequency throughout the treatment, otherwise referred to as modulated TENS (4). The intensity of the stimulation current emitted from the TENS units further classifies the type of treatment. A low-intensity stimulation pattern [known as sensory-level TENS] activates only cutaneous sensory fibers where the patient feels a mild superficial sensation without muscular contraction (1,3,4). A high-intensity stimulation pattern [known as motor-level TENS] activates skeletal muscle fibers and muscular contractions are produced. Increasing the amplitude of the stimulation current increases the number of activated motor units, creating a stronger contraction (1,3,4).

Transcutaneous electrical nerve stimulation has been reportedly used to relieve both acute and chronic pain symptoms of various origins. Studies that have assessed the efficacy of TENS treatments frequently report a significant reduction in patients' perceived level of pain and dysfunction after treatment, however, a placebo effect is commonly observed (5-8). Studies that compare the analgesic response of TENS to that of other modalities and to a sham or placebo treatment report conflicting results (7-10). Some studies have reported that although no difference is observed between the

analgesic effects of the different treatments, a greater reduction in pain is reported with TENS treatment compared to the placebo (8,10). In contrast, other studies have reported that neither the TENS nor other therapies produced a significant reduction in pain perception compared to the placebo trials (5-7,9,11). One consideration that should be made when interpreting the conflicting results is that the outcome measures commonly used in these studies are highly subjective and may lack the necessary sensitivity to differentiate between conditions. The most common outcome measures used in these studies to assess levels of pain and dysfunction are surveys, questionnaires, rating scales, and physical performance measures (3,5-7).

In contrast, studies that assess the potential mechanisms of action for TENS use more objective measures. Mechanistic studies have indicated that TENS acts at both central and peripheral levels of pain control. Centrally, certain frequencies of TENS treatments are successful at activating specific opioid receptors. Studies have found that blockage of the μ and δ opioid receptors prevents the analgesic effects produced from administering low and high frequency TENS, respectively (3,12). After treatment with both high and low frequency TENS, increased concentrations of certain opioids have been detected in the cerebrospinal fluid (3,13). Other research has found that concentrations of β -endorphins increase in the blood-stream and cerebral spinal fluid after treatment (3,14,15). These findings suggest that these physiological responses may be linked to the antihyperalgesia effect produced after treatment.

Other studies have begun to investigate peripheral effects of TENS therapy. Although this area is less researched, initial studies have found increases in local blood flow with low frequencies of TENS stimulation (3,16,17) while high frequency stimulation either just above or below the motor threshold did not lead to significant changes (3,18). One mechanism by which TENS therapy may reduce pain perception is through a reduction in elevated resting muscle activation levels. Previous research has identified some peripheral physiological reactions to sustained levels of electromyographic activity. Sjøgaard et al. (20) reported that in the lower ex-

tremity muscles, potential mechanisms of fatigue resulting from prolonged levels of muscle activation are a reduction in both intramuscular blood flow and substrate delivery. During very low activation levels [less than 10 percent MVC], in which intramuscular blood flow is not affected, impairments in substrate utilization may have an effect. McGill et al. (21) reported a reduction in muscle oxygenation in the active back extensors associated with prolonged isometric voluntary contractions [as low as two per cent MVC]. The oxygenation levels returned to baseline once the contraction was released. Although the elevated muscle activation levels investigated in the above studies were developed voluntarily, resting myoelectric activity is not (22). The fatigue that results from these prolonged contractions, over time, may present as a mechanism for an increase in pain perception. This leads to a hypothesis that levels of muscle oxygenation may play a role in the pathogenesis of the increased pain and fatigue resulting from sustained levels of elevated myoelectric activation.

The purpose of this study was to assess if changes in muscle oxygenation and involuntary muscle activation are potential peripheral physiological mechanisms behind the perceived pain relief obtained with a single treatment from a modulated, motor-level TENS device. We tried to utilize quantitative physiological metrics that registered signals about muscle function that were independent of qualitative perception.

MATERIALS AND METHODS

Three cascading studies are reported here. The first study was a pilot study to evaluate whether the myoelectric signal was associated with reported pain levels, and subsequent changes pre- and post-treatment. The second study involved testing more patients, using non-painful muscles for control. Also, a control trial with no treatment was performed to assess the effects of the treatment posture. The third study was to employ near-infrared spectroscopy [NIRS] to see if oxygenation levels were affected.

Treatment

The high-intensity, modulated TENS device tested¹ had adjustable output parameters that included the duration of treatment [10 or 20 minutes], modulated pulse pattern programs [three options], and signal intensity [arbitrarily labelled through a range of 0 to 10]. For this study, all treatment sessions consisted of 20-minutes of stimulation. The pulse pattern program used in this study is identified on the unit as massage setting number 2. Measures taken in our laboratory enabled us to investigate the waveforms of typical TENS units and make comparisons to that of the TENS unit investigated in this study. The signals generated by TENS devices vary by unit and manufacturer. Common characteristics include high frequency stimulation patterns of individual biphasic pulses where a positive phase of each pulse is typically a square-wave while the negative phase is a sawtooth-ramp waveform [Figure 1a]. The positive/negative phases may be asymmetrical about zero voltage [to minimize DC effects to the skin and subcutaneous metabolites]. The duration of the individual pulses typically range from 30-250 microseconds. Pulse rate typically varies from 3 to 1000 Hz. The pulse signal generated by the TENS device used in this study matches the typical pulse pattern described above [Figure 1b] with the major difference being in the variety of signal pulse sequencing [see Figures 2 a,b,c]. Specifically, it outputs a unique modulated burst pattern. The signal program [programmed in the unit by the manufacturer] begins by generating stimulating pulse sequences that slowly increase in peak to peak voltage over several seconds and 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." The treatment program usually concludes with the slower ramp increase/decrease of pulse trains as they diminish in signal intensity.

The two stimulating pads, each measuring [4.5 mm × 4.5 mm], were placed over the reported painful muscle [specific details for each study are reported below]. The pads contained an electrically conductive gel pad on the side adhered to the patient. Before application, a small

FIGURE 1. A typical “textbook” transcutaneous electrical nerve stimulation [TENS] waveform [2 pulses are shown] where the positive phase is a square-wave and the negative phase is a saw-tooth-ramp waveform [a] and a pulse waveform generated by the TENS unit tested in this study [b] indicating that the waveform itself is a typical TENS shape. The signal amplitude is representative of the voltage of the signal; however, the units in this figure are arbitrary.

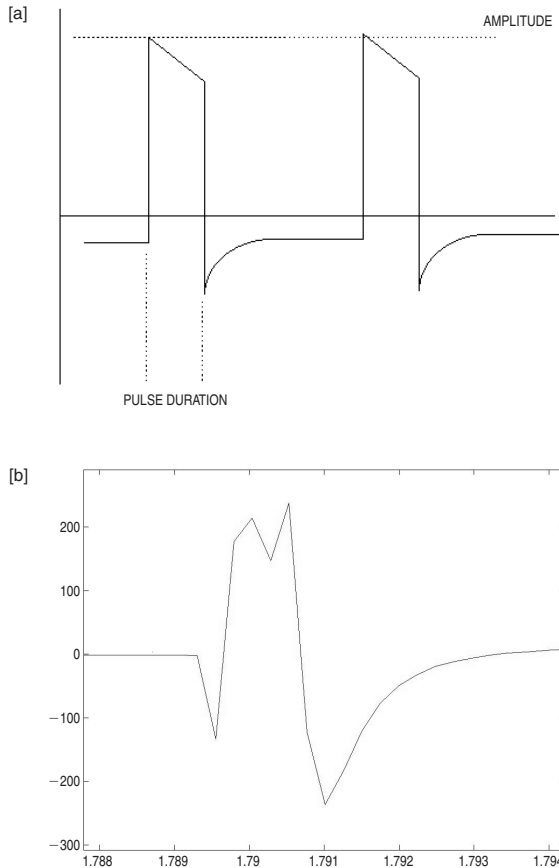
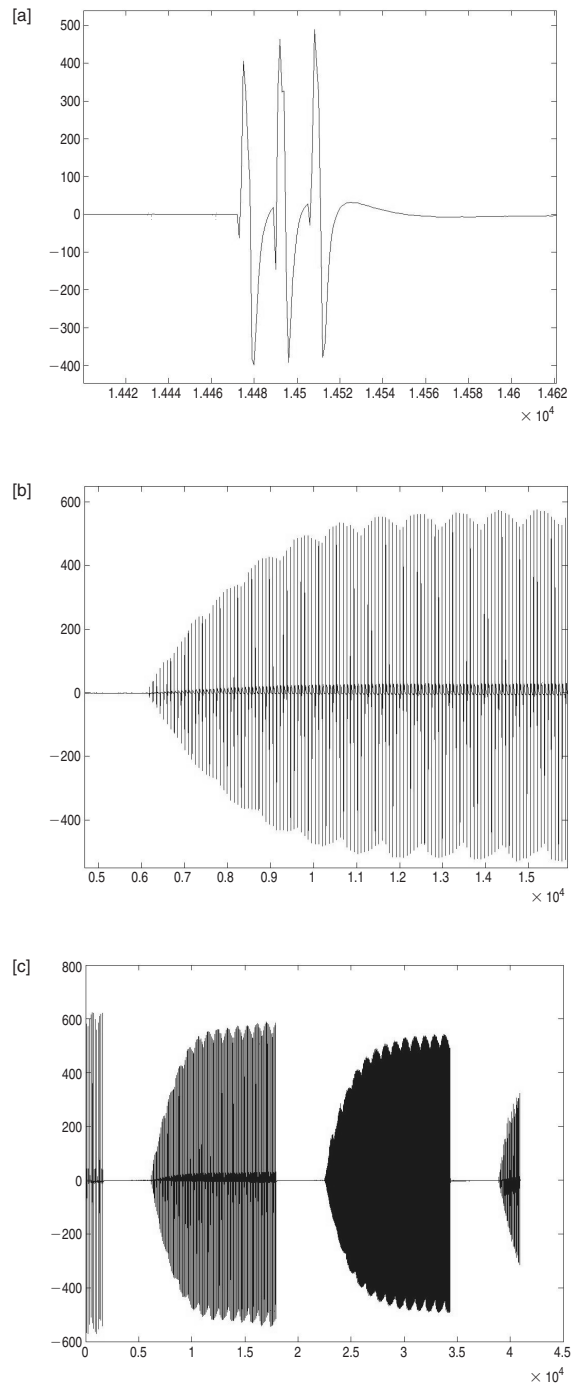


FIGURE 2. Some pulse patterns generated within a treatment program by the transcutaneous electrical nerve stimulation unit. A triplet “burst” of pulses typical of the pulse pattern [a]. A ramp increase of pulses causing progressive muscle contraction [b]. Ramp increases in pulse amplitudes cause wave-like contractions [c]. The signal amplitude is representative of the voltage of the signal, however, the units for the vertical axis in this figure are arbitrary.



amount of water was placed on the hydrophilic gel pads to enhance electrical conduction. At the start of the treatment session subjects were instructed to choose an intensity [from 0 to 10] that stimulated the highest tolerable level of muscle contraction without causing any pain. This level of stimulation is commonly prescribed and referred to as high-intensity TENS (3). The intensity was individually selected by each subject to simulate the application methods described for at-home usage. Regarding the TENS application, intensity selection was the only option that was available to the patient dur-

ing this study. The intensity was maintained for the entire duration of the treatment.

Instrumentation

Electromyography

Electromyography [EMG] signals were collected on a portable four-channel EMG unit [Myotrak 2] coupled to a portable computer with on-board analog to digital conversion capabilities. Bipolar Ag-AgCl electromyography electrodes² [with a center-to-center distance of 2.5 cm] were adhered to the skin over specific sites on the painful muscles [sites are described in each section of the study]. Prior to placing the electrodes on the skin, a thorough skin preparation was performed that involved shaving the area with a disposable razor and cleaning the area with a 10 percent ethanol solution.

All raw myoelectric signals were pre-amplified to produce signals of approximately $\pm 5V$ [common mode rejection ratio greater than 90 dB at 60 Hz and pre-filtered to produce a bandwidth of 10 to 500 Hz]. All myoelectric signals were A/D converted [12 bit resolution] at 1024 Hz. Signals were then digitally full wave rectified and low pass filtered [single pass, Butterworth filter] at a cut-off frequency of 2.5 Hz to approximate the frequency response of torso muscles (23).

Each patient performed sub-maximal test contractions for normalizing the EMG signal amplitudes. The sub-maximal contractions were obtained while patients stood with the torso upright and the arms outstretched horizontally in front with five pounds suspended from the hands. All EMG signal amplitudes were expressed as a percentage of the amplitudes measured during this task. Each collection was five seconds in duration and the average normalized EMG amplitude for the entire time was calculated.

Near-Infrared Spectroscopy

Muscle oxygen [O_2] saturation was measured using near infrared spectroscopy [NIRS]. The NIRS pad, measuring [110 mm by 90 mm], contained the light source and two light sensors. The pad was placed directly over the painful

muscle [specific details are described with each section of the study]. The light source on the NIRS pad emits continuous wavelengths of white light. Previous research has indicated that different wavelengths within the spectrum of white light are absorbed by different biological tissues (24). Specific to O_2 saturation, the 760 nm wavelength is highly absorbed by deoxygenated heme and the 850nm wavelength is highly absorbed by oxygenated heme. All other biological tissues [muscle, bone, adipose tissue, etc.] reflect these two wavelengths of light back up to the sensors located on the NIRS pad. The signal outputted by the NIRS unit is a difference signal indicating the difference in absorption between the 760 and 850 nm wavelengths. This signal was sampled at a frequency of 5 Hz.

The lamp intensity was altered between 8,6, and 4 V from patient to patient based on the strength of the signal reflected back to the sensors. For example, the level of subcutaneous fat overlying the muscle of interest negatively affects the strength of the signal (24), therefore, the lamp intensity was adjusted for each patient. The time constant was set to the shortest response time.

Once the NIRS pad was placed over the specific site, it was adhered to the patient with an elastic tensor bandage to prevent displacement and covered with a dark color cloth to prevent the detection of ambient room light.

Calibration of the NIRS signal was conducted with each subject positioned in their treatment posture [detailed in each section of the study]. Bias was removed from the NIRS electrical output by manually adjusting the signal to 0 mV with the balance control. The gain was adjusted to provide maximum signal deflections in the range of ± 600 -1000 mV as directed by the instruction manual for the unit. Each subject's resting O_2 saturation level was considered 100 percent O_2 saturation. The calibration procedure involved determining the maximum deflections of the NIRS signal, representing 100 percent absorption of the 760 nm wavelength followed by 100 percent absorption of the 850nm wavelength. Interpretation of the signal extends only to assessing the kinetics of the difference signal. Quantifying the magnitude of the changes in O_2 saturation requires information about the path-length of light from

source to sensor and this path length is dependent on the absorption properties of the biological tissues found along the path (24). Consequently, the path-length is very difficult to determine since the absorption properties for different biological tissues vary between people (24). For further description of NIRS signal collection and interpretation, the reader is directed to other research such as McCully and Hamaoka (24) and MacDonald et al. (25).

Color-Analog Pain Scale

Color analog scale [CAS] pain scores were obtained with a sliding template [Tylenol© Pain CAS Device at <http://www.painscale.ca/eng/>]. Patients were requested to slide a pointer to indicate their perceived level of pain in the painful area. The background of the scale presented to the patient consisted of a continuous spectrum of intensity in shades of red together with a change in the thickness of the red area. After the patients were instructed on the interpretation of the spectrum, they positioned the slider and the researcher recorded a scaled number on the back of the device that was not visible to the patient.

STUDY 1—PILOT

Patients

For the pilot study, a random sample of 10 volunteers was selected from the patient population visiting a university Research Clinic for pain relief. Patients were selected with bilateral pain complaints in the neck and shoulder region, specifically the upper trapezius. The specific origin or grade of pain was not assessed. There were no other specific inclusion or exclusion criteria. The goal for this study was to assess the immediate neuromuscular response to the TENS treatment, therefore, control of concurrent treatments for their pain complaints was not considered. All subjects gave their written consent to participate after reading a full written description of the purpose and procedure of the experiment approved by the University Office of Research Ethics.

Data Collection

The TENS electrodes were placed over both the right and left trapezius muscle at the level of C7. One subject, however, complained of pain at the level of C4. Consequently, the stimulator pads were placed on the trapezius muscle bilaterally at the C4 vertebral level. In general, the treated area was determined subjectively by a clinician through palpation and patient reports in attempts to find the area of highest muscular pain. The EMG electrodes were placed on the treated muscles, as close to the treated area as possible. Patients were administered the TENS treatment while lying relaxed in a supine posture. Muscle activity was measured bilaterally in the trapezius muscle during a quiet relaxed stance posture, immediately before and after treatment with the TENS device. Color analog scale pain intensity measures were taken with each measure of muscle activity.

Data Analysis

A paired *t* test was used to assess the changes in average normalized muscle activation between the pre- and post-treatment test measures together with the pre- and post-treatment CAS pain score measures.

STUDY 2— ELECTROMYOGRAPHY ANALYSIS

Patients

In this study, 41 volunteers were randomly selected from a patient population visiting a large city pain clinic on the days of testing. None of these patients had participated in Study 1. Patients were selected with unilateral pain in the neck and shoulder region, and/or the back. The specific origin and grade of pain was not assessed. Similar to the Study 1, no other selection criteria was used. Every patient who met this criteria agreed to participate when asked, such that the sample population consisted of every sequential patient meeting these criteria. Thus, the sample population could be considered representative of the heterogeneous group of patients who would attend a pain clinic and receive TENS therapy. All patients gave their

written consent to participate after reading a full written description of the purpose and procedure of the experiment approved by the University Office of Research Ethics.

Data Collection

For 31 subjects, one TENS stimulator pad was placed over the painful muscle and the other pad over the non-painful contra-lateral muscle to act as a control. On the side of pain, the placement of the stimulator pad was determined through palpation and patient reports as in Study 1. This placement was replicated on the control muscle. In this group, some subjects presented with more than one painful muscle, therefore a total of 70 painful muscles were assessed. Patients were positioned in a posture that provided the most comfort and this posture varied across subjects. The three options were sitting in a chair or lying either prone or supine. This posture was maintained for the entire duration of the 20-minute treatment session, as well as for all pre- and post-measurements. Muscular activity was collected in both muscles immediately pre and post treatment and CAS pain intensity measures were taken with each recording of muscle activity.

A second group of 10 patients were used as a control group to assess the effects of the treatment posture on the electromyogram. Only the unilateral painful muscle was treated and assessed in this group. In this group, some subjects presented with more than one painful muscle, therefore a total of 24 painful muscles were assessed. The treatment posture was selected by the patient to promote comfort and the patients maintained this posture for 20 minutes with no treatment. Pre- and post-EMG measures were recorded. Immediately following the control trial, patients were treated with 20 minutes of TENS stimulation while maintaining the same posture. The EMG measures were recorded immediately post treatment. All measures were obtained while patients maintained the self-selected posture.

Data Analysis

A paired t-test was used to assess the changes in muscle activation between the pre- and post-measures for both the control and treatment muscles, as well as for both the control and

treatment trials. A paired t-test was also used to compare the pre- and post-treatment CAS pain score measures.

STUDY 3—NEAR-INFRARED SPECTROSCOPY ANALYSIS

Patients

For this final phase of the study 12 subjects [three males, nine females] with an age range of 32 to 80 years [$X = 51$ years ± 13], and average height of 169 cm [± 9 cm] and weight of 75 kg [± 11 kg]. The subjects used were different from those tested in Study 1 and 2, were volunteers from a patient population visiting the pain clinic on the days of testing. Patients exhibited pain in the neck and shoulder region, and/or the back. As in the previous two studies, the specific origin or grade of pain was not assessed and no other specific inclusion or exclusion criteria were used. All subjects gave their consent to participate after reading a full written description of the purpose and procedure of the experiment approved by the University Office of Research Ethics.

Data Collection

Muscle O₂ saturation [hemoglobin and myoglobin] and self-perceived pain was measured. The subjects in this study complained of neuromuscular pain symptoms either in the cervical region and shoulders [N = 3], thoracic [N = 1] or lumbar region [N = 8]. Both the NIRS pad and the TENS electrodes were placed on the same muscle, directly over the site of greatest pain as determined by palpation from a therapist as well as patient reports similar to Study 1 and 2. Specifically, the placement priority was given to the NIRS electrodes which were placed directly over the site of greatest pain while the TENS electrodes were placed along the same muscle belly, on either side of the NIRS pad. Each subject performed a control trial where they relaxed for 20 minutes while lying prone on a treatment table but with no treatment, immediately followed by 20 minutes of treatment. The subjects' position remained constant through both the control and treatment trials. The NIRS signal was collected for the entire duration of both the control and treatment trials. Pre- and

post-treatment and control CAS scores were obtained. All measures were taken in the prone relaxed lying posture. Again, pre-measures were taken immediately before the control and treatment trials and post-measures were taken immediately after the 20-minute treatment or control trial.

Data Analysis

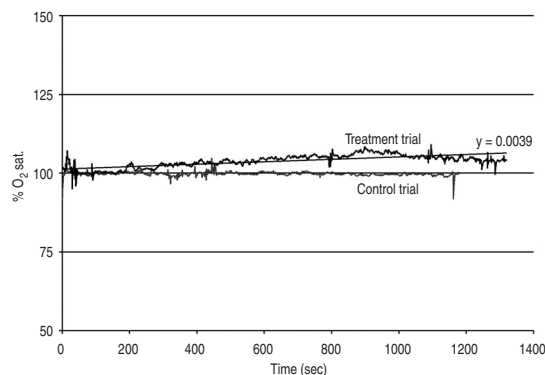
For the NIRS data, the slope of the percent O₂ saturation curve over the entire 20-minute control and treatment trials was calculated [Figure 3]. This curve represents the relative change in per cent O₂ saturation. A paired t-test was used to assess any significant differences in relative change in per cent O₂ saturation between the control and treatment trials. The CAS scores obtained with the NIRS measures were analyzed with a paired t-test as well. Results were considered significant when $P < .05$. All statistical analyses for each study were performed with SPSS 10.1.

RESULTS

Study 1–Pilot

Eight of the 10 patients demonstrated reductions in pain [one patient showed no difference and one patient an increase] after the treatment session. The average CAS scores of all subjects

FIGURE 3. Relative oxygenation [%] versus time [20 minutes] while lying without treatment and lying while receiving treatment with the muscle stimulator for a representative subject. For the treatment trial, a best-fit line with the slope [y] is shown.



decreased from 3.2 to 2.4 for a 26 percent overall reduction [$P < 0.05$].

Four of 10 patients demonstrated substantial reductions in EMG amplitude in one or both sides [37.8 percent average decrease]. Another four patients showed very small trends toward decreasing average amplitudes but the pre treatment EMG amplitudes were too small [< 6 percent of normalized amplitude] to claim biologically meaningful reductions. Two of the 10 patients showed small absolute increases in EMG amplitudes [an average 60.9 percent increase], however, neither of these two subjects reported an increase in their discomfort.

Study 2–Electromyography Analysis

In this phase there were a total of 94 painful muscles analyzed. For the 31 patients who only had pre-and post-treatment measures [70 painful muscles were observed], the mean muscle activation level was 10.3 percent [$SD \pm 9.9$] before treatment. The activation was significantly reduced to 8.0 percent [$SD \pm 7.7$] after treatment [$P < 0.001$]. As expected, there was no significant difference in amplitude in the non-painful control muscles. Color analog scale scores pertaining only to the painful muscle were 5.21 [$SD \pm 2.4$] before the treatment and significantly reduced to 2.22 [$SD \pm 3.7$] following the treatment [$P < .0001$].

For the 10 patients who performed a control trial, the average initial level of muscle activation was 20.3 percent [$SD \pm 12.7$]. There was a significant drop in muscle activity over the 20-minute control period [14.7 percent, $SD \pm 6.3$, $P < 0.001$]. A further significant drop in muscle activity occurred after the subsequent treatment [11.9 percent, $SD \pm 5.5$, $P < 0.01$].

Study 3–Near-Infrared Spectroscopy Analysis

For the NIRS analysis, the results of three subjects were excluded due to procedural complications. Specifically, for two subjects, lying in the same position for 40 minutes extremely aggravated their level of muscle stiffness and pain. Throughout the trials they shifted a great deal and, as a result, the NIRS signal fluctuated dramatically. For the third subject, a miscom-

munication between the patient and tester resulted in the muscle stimulation device to be set at an extremely low setting, which did not constitute a treatment.

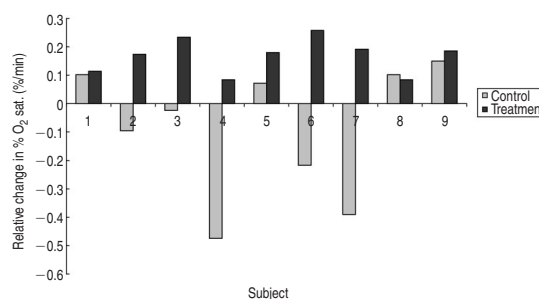
For the remaining nine subjects, the average relative change in muscle oxygenation over a 20-minute period across all subjects showed a significant increase between the control and treatment trials [$P < 0.05$] [see Table 1]. An example of the kinetics of the NIRS signal from a representative subject is shown in Figure 3 for the duration of the 20-minute treatment and control trials. Interestingly, during the control trial, four subjects actually demonstrated a drop in muscle oxygenation while the remaining four demonstrated minimal increases for a null effect [Figure 4]. However, during the treatment with the TENS unit, the relative muscle oxygenation significantly increased for all subjects [$P = .013$] [Table 1].

For this collection, the average CAS score obtained before the control trial was 3.12 [$SD \pm 1.62$] and was not significantly different from 2.83 [$SD \pm 1.57$] obtained after the control trial. However, the average CAS score obtained after the treatment 1.41 [$SD \pm 0.86$], was significantly lower than the post-control/pre-treatment average CAS score [$P < 0.05$] [Table 1].

DISCUSSION

Claims made by patients treated with TENS, as well as clinicians that administer it, is of a reduction in muscle pain, however, these are reports of subjective perceptions. The results of this study support the perceived and reported

FIGURE 4. The percent change in the relative oxygenation [%] per minute while lying without treatment [control] and lying while receiving treatment with the muscle stimulator for each subject tested.



reduction in the level of pain following treatment as measured through a decrease in the reported CAS scores. As well, the findings indicate that elevated muscle activation and reduced muscle oxygenation are linked to pain. The first two studies conducted in this paper suggests that there is a link between the reported analgesic effect produced from TENS therapy with a reduction in involuntary resting muscle activation. On average, this response was only observed in the treated muscle[s] and not the associated control for the majority of subjects. The third study in our paper found that muscle oxygenation significantly increased following treatment with the TENS unit and this increase was associated with a decrease in pain perception reports. The mechanism of high intensity modulated TENS documented here suggests that this form of treatment is based on physiological mechanisms beyond just placebo.

Interpreting the link between muscle activation, muscle oxygenation, and pain perception can be assisted with findings reported by Sjøgaard et al. (20). As stated previously, these researchers assessed the effects of different levels of voluntary contractions on changes in intramuscular blood flow and muscular fatigue. They reported that during prolonged low-intensity contractions [less than 10 percent MVC] of the lower extremity muscles, no change was observed in muscle blood flow or substrate delivery. What was observed was that fatigue still developed over time. The authors hypothesized that potentially an impairment in substrate utilization occurred as a result of the low level contraction and this may have led to the increased

TABLE 1. Summary of NIRS and CAS Pain Scale Measures for Treatment and Control Trials

	Relative change in %O ₂ saturation [%/min]		CAS analog pain scale value		
	Control	Treatment	Pre-control	Post-control/ Pre-treatment	Post-treatment
Average	-0.0014	0.0028*	3.12	2.83	1.41**
SD	0.0038	0.0010	1.62	1.57	0.86

*For %O₂ saturation, Treatment measure is significantly different from Control measure [$P < 0.05$]

**For CAS pain scores, Post-treatment measure is significantly different from Post-control/Pre-treatment measure [$P < 0.05$]

NIRS = near-infrared spectroscopy

CAS = color analog scale

% = percent

SD = standard deviation

level of fatigue. In muscular contractions of a higher intensity [greater than 10 percent MVC] a reduction in muscular blood flow and substrate delivery occurred. These findings present two possible mechanisms for the results reported here. Increased levels of involuntary muscle activation may reduce substrate delivery and increase utilization. The fatigue that consequently develops, over a prolonged period of time, may increase pain perception. The treatment process which involved the modulated TENS device tested here successfully reduced myoelectric activation levels as well as increased muscle oxygenation. These objective measures may indicate a reversal in the negative effects on substrate delivery and utilization, ultimately leading to the measured reduction in pain perception.

Further differentiating the NIRS signal into changes in substrate delivery versus utilization is not possible given the lack of supportive research. Van Beekelt et al. (26) attempts to associate the kinetics of the NIRS signal to some physiological phenomenon and concluded that the NIRS signal was affected by two major mechanisms: the rate of local oxygen consumption, and blood flow. However, the more subtle mechanisms for changes in O_2 dynamics, as registered by the NIRS signal, are not fully understood and remain somewhat speculative, as one previous work by MacDonald et al. (25) had failed to find a strong relationship between the NIRS signal and muscle blood flow. This study involved an exercise paradigm where it was difficult to partition changes in oxygenation specific to arterial, venous, or the capillary bed suggesting that a simple blood flow explanation may not fully capture the mechanisms at play. Regardless, the kinetics of the NIRS signal reflects a weighted average of arterial and venous Hb O_2 saturation and intracellular Mb O_2 saturation. As no methods exist to determine the exact proportions of these two sources of oxygen (25), the observed changes in oxygenation in this study cannot be linked exclusively to changes within the muscle, however, the procedure of the study reported here, minimizes the contributions from arterial Hb O_2 since the composition of the inspired air was constant. Consequently, the kinetics of the NIRS signal can be more accurately linked to changes in in-

tramuscular or venous O_2 levels; both providing information about delivery and utilization (27). It is possible that the observed changes in the NIRS signal could potentially result from an increase in skin blood flow stimulated by the muscle contractions produced from the TENS treatment, however, previous research has found that changes in skin blood flow has minimal effect on the NIRS signal (28).

A consideration assessed in this study was the effect that relaxing in the treatment posture may have had on the above results. Study 2 found that a relaxed posture significantly reduced muscle activation levels. These levels were further reduced following 20 minutes of treatment. From the protocol of this study it is unknown if the reduction following treatment was a result of posture, treatment or a combination of both. Despite this result, treatment posture did not have an effect on muscle oxygenation levels.

Subjects were chosen for each of the three studies with no additional specific inclusion or exclusion criteria other than having a painful muscle. While a limitation exists in that it is difficult to make conclusions regarding the appropriate patient population that would benefit from this treatment, a corollary asset to this approach is in the validity of obtaining subjects who were a perfect random sample of the people who attend pain clinic and receive TENS treatments.

A possible limitation of the protocol used in the reported study is that, in order to obtain accurate measurements, the NIRS electrode was placed directly over the painful muscle. Common treatment procedure requires that the muscle stimulator pads are applied in this location for the most effective treatment; however, the stimulator pads had to be placed on either side of the NIRS electrode and not necessarily in the middle of the painful muscle. Current still flowed through the target muscle. Another possible limitation in measuring muscle oxygenation was linked to the length of the testing procedure. Those subjects who were unable to remain in one position comfortably for 40 minutes were excluded. However, our sample of only nine subjects demonstrated a highly significant relative increase in the O_2 saturation [$P < 0.005$] with treatment. Finally, the patients selected in this study were chosen for cervical/

shoulder and back complaints, therefore, results obtained from other areas of the body might be different from the ones observed here.

CONCLUSION

The results of this study showed that a single 20-minute treatment with quiet lying significantly reduced muscular pain and resting activation levels and increased muscle oxygenation. Although we still do not fully understand the relative contributions and synergistic effects of the treatment posture and the TENS device on myoelectric activation, the quantitative data reported here provides mechanistic insight. Most importantly, the results obtained from the NIRS technology and muscle oxygenation are unlikely to have been voluntarily influenced by the patients as could possibly, the reported pain [CAS] scores, which was the primary variable reported in many of the previous studies. Since only a single treatment session was tested in this study, further investigation should involve quantifying the changes in muscle tension and oxygenation with multiple treatments over time.

NOTES

1. The TENS device tested in this study is Dr. Ho's High-Intensity, Modulated TENS©, manufactured by Dr. Ho©.

2. Electrodes are Meditrace 130 electrodes manufactured by Kendall-LTP.

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