6-2014

Comparing NMES Stimulation Intensity at Various Lengths of the Tibialis Anterior

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A capstone project submitted to the Graduate Faculty in Physical Therapy in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy (DPT), The City University of New York

2014

This manuscript has been read and accepted for the
Graduate Faculty in Physical Therapy in satisfaction of the
capstone project requirement for the degree of DPT

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THE CITY UNIVERSITY OF NEW YORK

Abstract

COMPARING NMES STIMULATION INTENSITY AT VARIOUS LENGTHS OF THE TIBIALIS ANTERIOR

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The purpose of this study was to determine if placement of electrodes at various distances along the Tibialis Anterior muscle belly had a significant effect on the intensity of stimulation needed to evoke a contraction using neuromuscular electrical stimulation (NMES). Twenty subjects between the ages of 21-65 in good health and presented with no precautions to NMES were recruited from the CUNY Hunter College physical therapy department. Two reference lines were drawn on subjects' legs, one outlining the tibial crest (L1), and another from the most lateral portion of the tibial plateau to the center of the lateral malleolus (L2). A large dispersive

pad was placed on the back of their thigh, and a weak motor intensity of electrical current was applied with a stimulating electrode throughout the TA. The area in which a minimal visible muscular contraction (MVC) was obtained with the lowest current amplitude was identified as the motor point. The L2 marking was measured and the stimulating electrode was used to find a MVC at 15%, 30%, 45% and 60% of that line. These points were used to compare the intensity change as the points moved away from the motor point. Simple linear regression was used to analyze the data obtained. Results indicated no statistically significant difference in electro stimulation intensity at various measured lengths of the tibia, indicating that identification of a TA motor point may not be necessary to evoke a contraction of the TA with electro stimulation in a clinical setting. Simply placing the electrodes on the muscle belly is sufficient

Keywords: Tibialis anterior, electrical stimulation, muscle activation, motor point

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Introduction

Neuromuscular electrical stimulation (NMES) is a commonly used modality for muscle strengthening and managing muscle weakness (Robinson & Snyder-Mackler, 2008), as well as pain modulation, atrophy, edema, wound care, enhance transdermal delivery of ions, and to increase peripheral circulation (Hecox, Mehreteab, Weisberg, & Sanko, 2006). Because this modality is used frequently, it is important we continue to refine technique to ensure optimal results in practice. The aim of this study was to determine if therapeutically used NMES waveforms delivered through a probe electrode placed at and around the tibialis anterior (TA) muscle belly results in a predictable pattern of differing motor threshold intensities. Because locating motor points may be time consuming and treatment time is limited, it is important that professionals are able to weigh the benefits of accuracy versus the time spent to locate motor points.

If there are statistically significant differences in the required stimulation intensity at different points on the TA, this can assist in determining the optimal points for NMES application. This may dictate an acceptable form of stimulation that is likely to be tolerated by the patient. From this study it is our goal to determine whether it is necessary to keep our stimulation within a predetermined area around the motor point, or simply inspect the area visually when placing electrodes in practice.

In this study the TA is tested due to the ease of accessing TA motor points and its relatively superficial location, making "minimally visible contractions" easy to monitor. Further, there is practical significance in using the TA, as electrical stimulation is often used for improving dorsiflexion in patients with gait deviation and neuromuscular conditions.

Literature Review

The Neuromuscular Junction

An understanding of the neuromuscular junction is necessary in order to describe the effects of electrical stimulation on a muscle and the effect accurate pad placement may have on outcomes. The neuromuscular junction is the synapse or junction between an axon arising from a motor neuron and the motor end plate; a highly excitable region of the muscle fiber plasma membrane (sarcolemma) (Saladin, 2004). During normal function a motor neuron located in the anterior horn of the gray matter in the spinal cord is stimulated, initiating an action potential along its axon via salutatory conduction. That is, depolarization of the motor neuron will cause a subsequent wave of depolarization "down" its axon that will extend from the anterior horn cell, through a ventral root, along a motor nerve until it terminates at the synaptic knob of the axon. Bundles of these axons comprise the motor nerves, which are often the target of electric stimulation (Neumann, 2010).

When the action potential reaches the synaptic knob it stimulates voltage gated calcium channels. These calcium ions then stimulate exocytosis of vesicles containing the neurotransmitter acetylcholine (ACh). The vesicles empty their contents across the pre-synaptic cleft at the neuromuscular junction and drop back into the cytoplasm of the synaptic knob to be refilled with ACh (Guyton, 2011). This is of particular importance as depolarization may be initiated artificially along any segment of the axon via electric stimulation without initiation from the motor neuron. In cases of motor nerve and/or spinal cord damage the damaged area may be bypassed and muscular contraction may be stimulated, reducing atrophy and/or a loss of strength and function (Robinson & Snyder-Mackler, 2008).

The ACh then binds to ligand-regulated gates on the motor end plate. The motor end

plate itself is an area of the sarcolemma with folds in the basal membrane to increase surface area for the thick concentration of ACh receptors. The receptors stimulate sodium (Na^+) / potassium (K^+) gates that depolarize the sarcolemma and initiate the excitation/contraction coupling that induces conformational changes in contractile proteins and a change in muscle length (Saladin, 2004).

The motor end-plate is the region of thickened sarcolemma at the neuromuscular junction (Katz, 1962), whereas the innervation zone is the cluster of motor or neuromuscular junctions (Bowden & McNulty, 2012). "Henneman size principle of voluntary motor unit recruitment describes the progressive recruitment of small, typically slow, motor units followed in order of increasing size to the larger, typically fast, motor units. The suggestion that the use of electromyostimulation (EMS) to stimulation muscle contraction results in a reversal of the size principle, therefore recruiting larger (fast) motor units prior to the slow, is based on 2 commonly agreed upon findings: (1) the axons of the larger motor units have a lower resistance to current and conduct action potentials at faster rates than the axons of the smaller motor units, and (2) data demonstrate increased fatigue with EMS versus voluntary activation. The data used to support a reversal of recruitment order will be re-examined in this perspective" (Gregory & Bickel, 2005, P. 359). A study by Garnett and Stephens found that "Stimulation of the index finger at 4x threshold for perception caused an increase in the recruitment threshold of units normally recruited at contraction strengths <1.5N and a decrease in the recruitment threshold of units normally recruited at contraction strengths > 1.5 N. It was concluded that the recruitment order of motor units during gradually increasing voluntary muscle contraction is not fixed but depends in part on cutaneous input" (Garnett & Stephens, 1979, P. 466). "This perspective outlines the authors' contention that electrical stimulation recruits motor units in a non- selective,

spatially fixed, and temporally synchronous pattern. Furthermore, it supports evidence that this recruitment pattern contributes to increased muscle fatigue when compared with voluntary actions. The authors believe the majority of evidence suggests that EMS-induced motor unit recruitment is non-selective and that muscle fibers are recruited without obvious sequencing related to fiber types" (Gregory & Bickel, 2005).

This is also the site related to the "motor point" which may be directly stimulated using NMES, and implies additional clinical significance in those individuals with motor nerve pathology. It has been estimated that the motor units stimulated by an electrode occupy between 5 and 15 sq mm of a muscle and will be mixed with 3 to 6 motor units. Stimulation applied to the nerve trunk must be of sufficient intensity in order for 100% of the axons to be stimulated (Hecox et al., 2006). However, because NMES pulses are arriving simultaneously in all the axons, the result is a compilation of individual motor units firing, known as a motor action potential (Hecox et al., 2006). This may result in lower NMES intensities needed to activate motor endplates and simultaneous stimulation of both enervated and denervated motor units.

Stimulation of Motor Units

The intensity needed to stimulate a particular nerve type is dependent on the size (diameter) of its axon. Because the size of axons is differentiated by function, electric current depolarizes nerve types in a predictable order with gradually increasing intensity (Robinson & Snyder-Mackler, 2008). At the lowest amplitudes sufficient for depolarization, individuals typically feel "tingling", a sign that sensory nerves have been activated and generally referred to as "sensory-level stimulation." As the stimulation is increased the sensation becomes stronger and often spreads to the region between the electrodes and deeper into tissues. This generally increases sensation as progressively greater numbers of sensory nerve fibers are recruited. If

sensory-level stimulation at frequencies greater than about 15 pulses per second (pps) are maintained for prolonged periods of time, the subject will adapt (Robinson & Snyder-Mackler, 2008); this is referred to as sensory accommodation, which increases the comfort of stimulation. The activation threshold of alpha motor neuron axons (lying in peripheral nerves innervating skeletal muscle) is higher than that of sensory nerves and initiates muscular contraction; this is generally termed "motor-level stimulation." Initially the client exhibits a low tolerance to motor stimulation, but adaptation may result in a need for a higher intensity stimulus to maintain muscular contraction. NMES intensity that is increased beyond motor-level stimulation will result in painful or "noxious-level stimulation." In this case the intensity is high enough to depolarize A-delta and C nerve fibers (Robinson & Snyder-Mackler, 2008).

As this study relates to the stimulation of a muscle and pad placement, a motor-level stimulus will be used and a noxious stimulus will be a sign that stimulus intensity is excessive. As points are tested at greater distances from the motor point it is likely that higher levels of stimulation will be necessary. Stimulating a local noxious response in order to achieve muscle activation may be a limit to the acceptable distance from the motor point.

NMES and Muscle Strengthening

The role of electrical stimulation in muscle strengthening involves stimulating the neuromuscular junction to initiate a contraction. Electrical stimulation devices use pulses of electricity to create muscle contraction, allowing for maintenance of muscle size and performance in patients that have conditions in which the motor nerve is damaged but the muscle is still innervated. The physiological benefits that neuro-muscular electrical stimulation (NMES) provide a patient include enhanced muscle tissue repair, pain relief, functional training for patients with conditions that require neurological re-education, and increased muscle strength for

atrophied muscles (Salvini, Durigan, Peviani, & Russo, 1995). Positive adaptations within the muscle may be seen in force production and resistance to fatigue (Rochester, Chandler, Johnson, Sutton, & Miller, 1995). Changes in morphology and oxidative properties are apparent in the muscle after short duration ($\leq$ 4 weeks) treatment with electrical stimulation; most notably in the transformation of fast fibers into slow fibers, the physical property of skeletal muscle that allows for activities of endurance (Bernadette, Mehreteab, Weisberg, & Sanko, 2006). Slow fibers consume less energy than fast fibers, thus enabling the muscle to contract and work for a longer period of time. When a muscle is exposed to electrical stimulation, there is an increase in muscular metabolic activity, namely an enhancement in oxidative capacity and endurance properties, necessary components to produce a decrease in muscle fatigability (Martin, Stein, Hoeppner, & Reid, 1992).

NMES provides the required contractions to the affected muscle without the patient having to expend energy to contract the muscle. In cases of denervation a muscle may be activated without stimulation by the motor nerve but, as mentioned above, may be stimulated only at the motor end plate. NMES, therefore, allows for muscles to retain their size and strength until re-innervation occurs (Salvini et al., 1995). As electrical stimulation serves to restore contractile properties following muscle atrophy and weakness, it allows the patient to receive a cost effective treatment, which serves to strengthen denervated muscles (Martin et al., 1992). The significance of initiating muscle contraction early in the treatment process is that patients with weakened muscles often have difficulty in movement, which contributes to further disuse, atrophy, and weakness. In order to maintain muscle mass and strength, it is important for the muscle to undergo a certain amount of daily contractions (Salvini et al., 1995).

Optimal Electrode Placement Studies

As implied by the studies above, electrical stimulation plays an important role in the therapeutic setting. Determining optimal electrode placement may improve the efficacy of NMES treatments. Botter et al. (2011) identified two motor points (proximal and distal) for the tibialis anterior using electrical stimulation on 53 healthy subjects. The authors used a reference line from the apex of the fibular head to the apex of the medial malleolus and found that "Stimulation of the proximal motor point excited fibers located superficially and medially to the reference line, whereas stimulation of the distal motor point excited fibers located deeply and laterally to the reference line" (Botter et al., 2011, p. 2465). Quantitatively, the average proximal motor point position was 10.5 cm (+/- 1.6) along the reference line, and the average distal motor point position was 16.5 cm (+/- 1.9) along the reference line (Botter et al., 2011). Visual inspection and manual manipulation of the muscle and its distal tendon were done during stimulation to ensure the precision of the motor point. This study demonstrates not only that the motor point of the tibialis anterior can be found relatively simply but also that there is individual variability, which may make electrical stimulation using solely anatomical landmarks incomplete (Botter et al., 2011). In a similar study, Bowden and McNulty (2011) found that "The motor point is best represented by the site producing a maximal but isolated response at the lowest stimulation intensity, because it provides the most effective contraction of a single muscle" (Bowden & McNulty, 2012, p. 391). Using 40 neurologically healthy subjects (mean age 25) the site of maximum muscle response was found to be 27% (+/- 1.5%) of tibial length, with the majority between 20-25% of tibial length. Fifty three percent of the motor points would not have been found if only anatomical landmarks were used as references (Bowden & McNulty, 2012).

The aim of the current study was to determine the level of accuracy needed to effectively stimulate motor points using electrical stimulation, as the authors hypothesize that it may not be necessary to locate motor points given the area conducting current underneath and in proximity to the electrodes. As the only goal was to stimulate as many motor units as possible, it was sufficient to approximate the motor point and increase stimulation intensity. The determining factor was the percent decrease in recruitment, and/or a need for stimulus intensity that is so high that it depolarizes A-delta nerve fibers, inducing a noxious stimulus.

The importance of placing an electrode on the exact motor point prior to applying electrical stimulation has been enforced by several studies, being the most sensitive point to electric stimulation (Forrester & Petrofsky, 2004). In a study conducted by Lim, Gorman, Saboisky, Gandevia and Butler, (2006), which looked at optimal electrode placement for human abdominal muscles, the authors found that electrodes that lie directly over the nerves that supply abdominal muscles generated the greatest muscle twitch. That being said, "The closer the electrode is to the MP (motor point), the less current it should take to stimulate the muscle through its nerve" (Forrester & Petrofsky, 2004, p.347). In Forrester and Petrofsky's (2004) study, increased amount of current was required during electrical stimulation to stimulate a muscle when the electrode was placed further from the motor point. Further, orientation of electrodes has an impact on muscle stimulation. Hartsell and Kramer (1992) also determined that motor points may differ in level of excitation. In their study, three distinct points on the quadriceps muscle were tested; two of them produced significantly greater torque values than the third. Although the current study aimed to test accuracy of pad placement, accuracy was determined along a longitudinal line and relative to the motor point that evoked the largest excitation.

Finally, the effects of inducing currents on nerve and muscle fibers depend not only on the excitability of these tissues, but also on their location with respect to the electrodes used to transfer the current. The closer the excitable tissue is to the electrodes, the more likely it is to be activated by the current (Robinson & Snyder-Mackler, 2008). The current study aimed to determine how accurate (close) a practitioner must be to the motor point.

Methods

Electrostimulation

A 2 cm^2 ultrasound head was used to deliver point stimulation to the TA with a Chatanooga ® Genysis Electrical Stimulator and Aquasonic Gel as a conducting medium. A symmetrical biphasic waveform with a frequency of 1 Hz, a burst frequency of 1 PPS, and phase duration of 1000 microseconds was selected. Cycle time was set for continuous.

Procedure

Once the subjects completed the questionnaire (see Appendix A) and informed consent form (see Appendix B), they were instructed to change into shorts for the procedure. Once changed, participants were instructed to lie on their backs with their leg supported on a stool. Two reference lines were drawn on their leg with washable marker, one outlining the tibial crest, and one that ran from the most lateral portion of the tibial plateau to the center of the lateral malleolus. The boundary of the TA was identified by asking the participants to raise their foot toward their shin (ankle dorsiflexion); this initiated a contraction of the TA for easier palpation of boundaries. A large dispersive pad was placed on the back of their ipsilateral thigh, and a small amount of electrical current was applied via a 2 cm^2 ultrasound head over the entire region of the TA found between the two reference lines. The level of current utilized was not

dangerous and is commonly used in clinical applications. The location at which the lowest intensity was needed to evoke a minimally visible muscular contraction (MVC) was recorded as the motor point. Next the reference line drawn from the lateral tibial plateau to the center of the lateral malleolus was measured and points were marked for 15%, 30%, 45% and 60% of the line's length. At each of these points the intensity in milliamps was determined to evoke an MVC. These points were used to compare the intensity change as the points moved away from the motor point. Once completed, the procedure was duplicated on the other leg. The time commitment for each participant was a single session, lasting between 20 and 40 minutes.

Results

Study Sample

Twenty subjects between the ages of 21-65 in good health who presented with no precautions to NMES were recruited from the CUNY Hunter College physical therapy department. Exclusion criteria included but was not limited to: an open wound or skin lesion on the lower leg, a superficial metal implant in their lower leg, the presence of an acute infection or active cancerous tissue in their lower leg, recently sutured tissue or unhealed fracture in their lower leg, or any adverse reactions in the past to therapeutically applied electrical stimulation.

Analysis of Data

The threshold intensities required to evoke electrically-induced contractions were used to determine whether there was a statistically significant difference in intensity at the various points. Analysis was performed with SPSS version 20.0. A repeated measures ANOVA was used to analyze the data obtained. This test is commonly used for the analysis of variance between and within groups whenever the groups are being tested under more than two conditions or factors.

The descriptive statistics for the required stimulation intensities were measured for all factors using a repeated measures ANOVA (See tables 1 and 2), in order to determine statistical significance of intensity to evoke a minimal visible contraction (MVC). A post hoc analysis revealed statistically significant differences when comparing stimulation intensity at 60% of L2 ((F= 10.04, P< .01) (See Table 3) to all other measures (60% vs 15%, 60% vs 30% and 60% vs 45%) (See Graph 2). No statistically significant differences were found when comparing the intensities required at the 15%, 30% and 45% locations along the TA to each other.

The statistically significant differences in the intensity required to evoke a MVC when at 60% of the tibia length (the furthest distance measured from the motor point in this study) were as follows: 60% of tibia length vs 15% of tibia length (P = .008); 60% of tibia length vs 30% of tibia length (P = .001); 60% of tibia length vs 45% of tibia length (P = .041) (See Table 4). The mean location found for the motor point in our study was at 30.352% along the TA reference line with a standard deviation (SD) of 12.48360 and Std. Error mean of 2.79. During a left to right comparison, the mean intensity required to evoke a MVC at 30% of the TA reference line was 9.44 and (SD) of 2.482 (See Graph 1).

Conclusion

Based on this study, placement of the electrode created a similar response up to 15% of the length of the tibia superiorly and inferiorly from the motor point, which is also greater than the distance of one standard deviation. The differences in stimulation intensity required to evoke an MVC up to the 60% of tibial length point were not statistically significant in this study. Although studies showing that the location of the TA motor point may not be sufficiently deduced by anatomical landmarks or average percentage of tibia length (Bowden & McNulty,

2012; Botter et al., 2011; McNulty, 2011), this does not account for the total area affected by electrical stimulation. Based on the findings in this study it may not be necessary to determine the location of the TA motor point when stimulating electrodes are kept above the 60% of the tibial length point to evoke a contraction of the TA for goals of muscle strengthening and managing muscle weakness. This may imply clinical significance, as the amount of time required to locate a motor point may be better served by other interventions within the limited time of a therapeutic session.

A follow up study may be necessary to determine whether the intensity required to evoke a maximal contraction of the TA would reach statistically significant differences as the distance from the motor point increased. Higher stimulation intensities also present a greater chance that A-delta and C nerve fibers are depolarized resulting in a painful or "noxious-level stimulation" (Robinson & Snyder-Mackler, 2008). Despite this study implying that the intensities required to produce evoked contraction with electric stimulation are not significantly different at the more proximal distances along the TA reference line, intensities closer to the noxious stimulation threshold may require care when placing electrodes and impose a "pain free" radius around the motor point.

Another potential area for further research is the impact electrical stimulation intensity may have on the enhancement of functional activities. For example, devices such as the Bioness L300 ® or Walkaide ® may benefit from small reductions in output, increasing the amount of active use between charges. For this research larger numbers of subjects would be required to increase statistical power, and the use of specific devices for specific tasks would provide the greatest generalizability.

Besides the placement of electrodes, intensity and duty cycle are further parameters that

have been examined in the literature in relation to muscle torque during transcutaneous NMES. Lieber and Kelly (1993) found that "a smaller number of longer duration contractions produces the greatest muscle tension" in the human quadriceps muscle.

Another area of interest regarding electrical stimulation is the localization of nerves during regional anesthesia. It was found that changing the position of electrodes on the skin over the biceps and quadriceps muscles during a nerve localization procedure does not affect the grade of the motor response or the current needed to maintain the response (Hadzic, Claudio, Hadzic, Thys & Santos, 2004).

Gobbo, Gaffurini, Bissolotti, Esposito & Orizio (2011) found that compared to using the muscle motor point (which they determined by using protocol similar to the one used in our study), to stimulate the TA and VL muscles, using common reference charts for electrode placement was not as effective in producing the greatest amount of muscle torque and local tissue oxygenation. In addition, the common reference chart placement also produced a painful/uncomfortable NMES experience for patients, which further supports that using anatomical landmarks is not the optimal way to stimulate a muscle.

Limitations

Some limitations were imposed by the study design. The subjects used were fairly homogenous decreasing generalizability of findings; mostly females between the ages of 24 and 32, with some males falling outside of this group, and all subjects were healthy with no neurologic or muscular injury. The ultrasound head used for point stimulation may have been too large (2 cm) to effectively isolate point stimulation to the measured distance, in essence, affecting a larger area than would have been ideal for the hypothesis asserted by the study. However, the ultrasound head was not larger than the average electric-stimulation pad

used in most clinics. Last, the data points from measured distances may have created more meaningful data if distances were measured from the motor point itself, rather than distances measured from anatomical landmarks.

Table 1

Within-Subjects Factors	
Measure: MEASURE_1	
factor1	Dependent Variable
1	L Intensity 15
2	L Intensity 30
3	L Intensity 45
4	L Intensity 60

Table 2

Descriptive Statistics			
	Mean	Std. Deviation	N
mAMPs	10.8450	2.87319	20
mAMPs	9.6600	2.81058	20
mAMPs	11.1200	3.02909	20
mAMPs	13.3450	3.51934	20

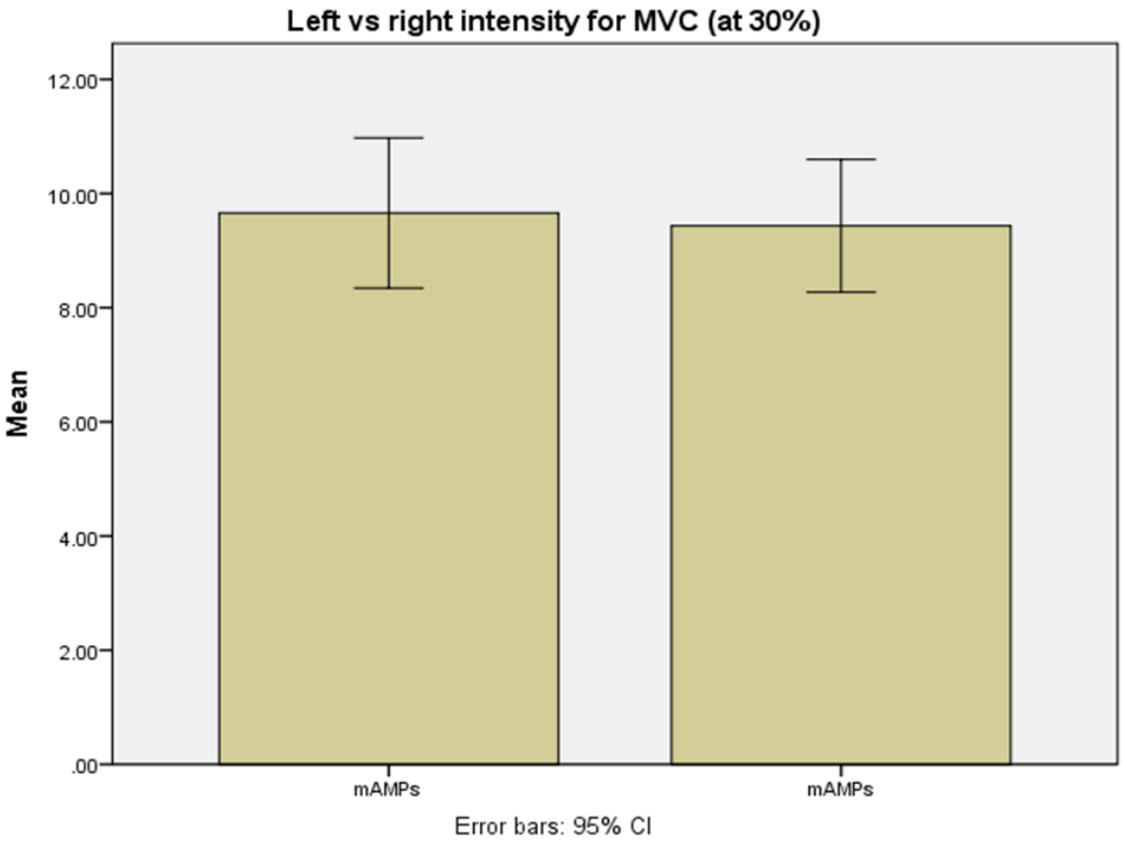
Table 3

Tests of Within-Subjects Effects						
Measure: MEASURE_1						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	
factor1	Sphericity Assumed	141.956	3	47.319	10.041	.000
	Greenhouse-Geisser	141.956	2.718	52.228	10.041	.000
	Huynh-Feldt	141.956	3.000	47.319	10.041	.000
	Lower-bound	141.956	1.000	141.956	10.041	.005
Error(factor1)	Sphericity Assumed	268.613	57	4.713		
	Greenhouse-Geisser	268.613	51.643	5.201		
	Huynh-Feldt	268.613	57.000	4.713		
	Lower-bound	268.613	19.000	14.138		

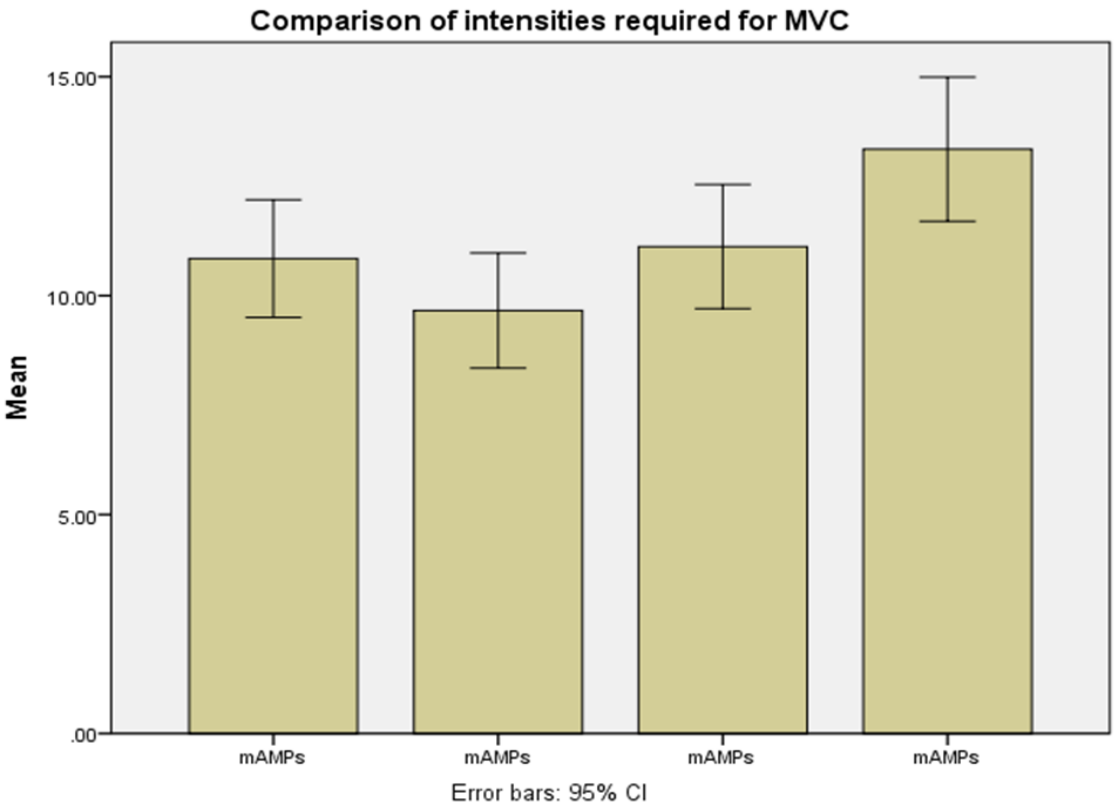
Table 4

Pairwise Comparisons						
Measure: MEASURE_1						
(I) factor1	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for difference	
					Lower Bound	Upper Bound
1	2	1.185	.639	.475	-.696	3.066
	3	-.275	.615	1.000	-2.086	1.536
	4	-2.500*	.667	.008	-4.462	-.538
2	1	-1.185	.639	.475	-3.066	.696
	3	-1.460	.630	.191	-3.316	.396
	4	-3.685*	.813	.001	-6.078	-1.292
3	1	.275	.615	1.000	-1.536	2.086
	2	1.460	.630	.191	-.396	3.316
	4	-2.225*	.734	.041	-4.385	-.065
4	1	2.500*	.667	.008	.538	4.462
	2	3.685*	.813	.001	1.292	6.078
	3	2.225*	.734	.041	.065	4.385
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
b. Adjustment for multiple comparisons: Bonferroni.						

Graph 1


Left vs right intensity for MVC (at 30%)
12.00
10.00
8.00
6.00
4.00
2.00
.00
Mean
mAMPs
mAMPs
Error bars: 95% CI

Graph 2



15% **30%** **45%** **60%**

Appendix A

Participant Questionnaire

Participant code_____

Blood pressure_____ Resting Heart Rate_____ Weight_____

Height_____

Participant Readiness Questionnaire:

1. Do you have a demand-type implanted cardiac pacemaker or defibrillator?

2. Are you aware of cancerous or infected tissue in your lower extremities (legs)?

3. Do you have open wounds or irritated skin on your lower legs (shins)?

4. Have you ever required surgery that resulted in rods, plates or joints replacements implanted in your legs, knees, or ankles?

5. Have you ever been, or do you think you may respond negatively to the sensation associated with electrical stimulation?

6. Are you suffering from undiagnosed pain in the lower extremities (legs)?

7. To your knowledge, do you have normal sensation in your legs and will you provide feedback on what you feel during the test?

8. Do you have a fear of electricity?

9. Do you currently or have you ever experienced any mental health disorders or related conditions?

Have you had or do you have any of the following conditions? Check if YES.

( ) Recent surgery on the lower extremity or back (within the last 6 months)

( ) Pain in the chest, neck, jaw, arms or other areas

( ) Unusual shortness of breath

( ) High blood pressure

( ) Low blood pressure

( ) Diabetes

( ) Ankle Edema (swelling)

( ) History of heart disease or heart attack

( ) Episodes of fainting

( ) Palpitations or Tachycardia

I have read, understand, and completed this questionnaire. Any questions I had were answered to my full satisfaction.

Signature_____ Date_____

Appendix B

Informed Consent Form

CITY UNIVERSITY OF NEW YORK

Hunter College

Department of Physical Therapy

SCREENING PROCEDURE: CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Project Title: An investigation of motor point determination with neuromuscular electrical point stimulation and its relationship to the anatomical muscle belly of the tibialis anterior.

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Introduction/Purpose:

We are a student research team conducting this study as part of our requirement for graduation from the Doctorate of Physical Therapy Program of Hunter College and the Graduate Center of CUNY. We will be supervised by Thomas Holland, PT, PhD, a physical therapist and Assistant Professor at Hunter College. The purpose of this research study is to determine if stimulating the tibialis anterior (TA) (muscle located on the anterior shin) at the muscle belly (part of the muscle with the widest circumference) provides the best evoked muscle contraction. The results of this study will assist physical therapists in locating the optimal tibialis anterior motor point when using neuromuscular electrical stimulation (NMES) for therapeutic applications. NMES is an electrical stimulation commonly used in practice to strengthen weak muscles. Participation in this study is voluntary, and refusal to participate will involve no penalty or loss of benefits to

which you are entitled.

Procedures: All elements of the study will be conducted in the Hunter College Physical Therapy Department on the Brookdale Campus. If you decide to participate in this study, you will first be asked to fill out a health related questionnaire. The purpose of this questionnaire is to determine your eligibility for the study. The questionnaire and informed consent will be secured in a locked filing cabinet in Dr. Holland's office located in the Physical Therapy Department of Hunter College's Brookdale campus.

Once the subjects have completed the questionnaire and informed consent they will then begin the study. Subjects will be instructed to change into shorts for the procedure. They will be instructed to lay on their backs with their leg supported on a stool. They will be instructed to raise their foot, using their ankle joint, toward their shin (ankle dorsiflexion). The boundaries of their TA will be identified by palpation (touching). Two lines will be drawn on your leg with washable marker, one that outlines the muscle, and one that bisects it. After the belly of the TA is determined, subjects will sit with their leg relaxed. A large pad will be placed on the back of their thigh, and a small amount of electrical current will be applied over the entire region of the TA. The level of current is not dangerous and is commonly used in clinical applications. We will record the intensity needed to evoke a minimal visible muscular contraction. This will be identified as the motor point. The time commitment for each participant is expected to be 1 visit for approximately 30 minutes. Each session will take place at Hunter College- Brookdale Campus, 425 East 25th Street New York, NY 10010.

Possible Discomforts and Risks: There is only a minor risk with these techniques: The procedure is not expected to pose any risk to you. During stimulation you will feel a tingling and your muscle will move/contract little. The NMES application should not be painful, and all contraindications and precautions for the therapeutic electrical stimulation will be observed during this study. If you have a fear of electricity or have received electrical stimulation before and did not tolerate it well, please inform the investigator before the study commences. These include stimulation over; an open wound or skin lesion, directly over a superficial metal implant, placed over active cancerous or infected tissue, over an area in which a muscle contraction is contraindicated (a suspected blood clot or recently sutured tissue) Neuromuscular Electrical Stimulation has been known to cause some skin irritation; either from the electrical current passing through the skin, or from the adhesive that is used to adhere the pads to the skin. Although this is a relatively rare occurrence, participants may voluntarily end testing if they become uncomfortable. Benefits: There are no direct benefits of this study. However, participating in this study may increase general knowledge of motor point localization for the TA.

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Voluntary Participation: If you feel uncomfortable or if you do not wish to answer the medical questions you can tell the investigator you do not wish to participate in the study any longer and no further questions will be asked. If you have a fear of electricity or have received electrical stimulation before and did not tolerate it well, please inform the investigator before the study commences. If you feel uncomfortable during the application of NMES you can tell the investigator you wish to stop. Your participation in this study is voluntary, and you may decide not to participate in it at any time without prejudice, penalty, or loss of benefits to which you are otherwise entitled.

Confidentiality: The data obtained from you will be collected via a written document. The screening data, research data, and personal information will be accessible to the research team of Dr. Tom Holland, Jennifer Wolff, Amy Zelin, Brent Brookbush, and Maya Hakami. The researchers will be used to create a computer database comprised of the information relevant to the goals of the research. To protect your anonymity, this data will be assigned an identification number. Personal information and screening information that is not relevant to research outcomes will be separated from the research data and placed in a separate document or database, under password protection. A code key that indicates which identification number belongs to your personal information will be stored separately; both on a separate document and in a different location. The collected data will be stored for a minimum of three years, after which it will be destroyed. You will never be contacted again in relation to this study. All collected data and passwords will only be accessible to the research team of Dr. Tom Holland, Jennifer Wolff, Amy Zelin, Brent Brookbush and Maya Hakami.

Contact Questions/Persons: If you have any questions about the research now or in the future, you should contact the Principal Investigator, Jennifer Wolff, 518-332-8487, jwo0039@hunter.cuny.edu. If you have any questions concerning your rights as a participant in this study, you may contact Dr. Tom Holland, (212)-481-5053, tholland@hunter.cuny.edu.

Statement of Consent: "I have read the above description of this research and I understand it. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions that I may have will also be answered by the principal investigator of the research study. I voluntary agree to participate in this study.

By signing this form I have not waived any of my legal rights to which I would otherwise be entitled.

I **have received** this statement."

_____	_____	_____
Printed Name of Subject	Signature of Subject	Date Signed

Printed Name of Person Explaining Consent Form	Signature of Person Explaining Consent Form	Date Signed
Printed Name of	Signature of Investigator	Date Signed

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