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Comparison of Single-Use and Multiple-Use Electrodes for Sensory, Motor Threshold Amplitudes and Force Production

Lucia Maloy
Brigham Young University - Provo

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Motor Threshold Amplitudes and Force Production

Lucia Maloy

A thesis submitted to the faculty of
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Master of Science

David O. Draper
J. Tyson Hopkins
A. Wayne Johnson
Dennis Eggett

Department of Exercise Sciences

Brigham Young University

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ABSTRACT

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Context: Electrodes play an important role in interfacing tissue with electrical stimulation devices. Manufacturers recommend that adhesive metallic mesh cloth electrodes be used no more than 10 times before they are discarded, however, clinically the electrodes are often used up to 30 times. Another concern is sanitation. When electrodes are used on different patients, there is a chance for cross-contamination and bacterial growth on the electrode. **Objective**: To compare amplitudes of perceived sensation, motor twitch and force produced at specific amplitudes using single-use electrodes that run no risk of cross-contamination, and multiple-use electrodes. **Design**: Mixed model ANOVA with the subject blocked. **Setting:** Therapeutic modalities research laboratory. **Patients or Other Participants:** 20 subjects comprised of 7 males (age 24.7 yrs ± 2.3 yrs, skin fold thickness 5.9 mm ± 2.4 mm) and 13 females (age 21.5 yrs ± 2.3 yrs, skin fold thickness 10.7 mm ± 4.1 mm) recruited by volunteer sample mainly from athletic and athletic training populations. They drew random numbers to determine which group they were assigned to. **Interventions:** Each subject had electrodes placed on their wrist extensors muscles. Measures were recorded of what intensity it took to achieve perceived sensation, motor twitch, and force produced at a specific intensity. To determine decay, multiple use electrodes were tested initially and on the 10th use. After the multiple use electrodes were tested initially, they were leached out. After eight uses, pretest procedures were repeated (10^{th} use electrode) as the final trial on the subjects. Single use electrodes were tested one time. **Main Outcome Measures**: The dependent variables were sensation, motor twitch and force production. The experiment was a repeated measures study, using mixed models ANOVA with subjects blocked. Alpha was set at $p<0.05$. Data was analyzed using a SAS proc mixed 9.1. **Results:** There was no statistical difference between the measures taken during the initial trial and final trial of the multiple use electrodes for muscle twitch ($F_{\text{MUI MUF muscle twitch}}= 107.3$, $p= 0.09$) and force production ($F_{\text{MUI MUF force production}}= 28.7$, $p= 0.11$). There was a significant difference between the single use and the multiple use electrodes for the initial and final trial. Average values in mA for perceived sensory were: single use 9.73, multiple use initial 16.70 , multiple use final 21.03; observed muscle twitch: single use 15.87, multiple use initial 29.16, multiple use final 31.78; and force produced: single use 22.8 Newtons, multiple use initial 10.0

Newtons, multiple use final 5.0 Newtons. **Conclusion:** Single-use electrodes produce more conductive power with fewer milliamps compared to multiple-use electrodes. Single use electrodes are just as, or more efficient as the multiple use electrodes and have the added advantage of eliminating the possibility of cross-contamination of bacteria from patient to patient.

Key words: multiple use electrodes, single use electrodes, neuromuscular electrical stimulation, electrode degradation, cross contamination

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Comparison of Single-Use and Multiple-Use Electrodes for Sensory, Motor Threshold Amplitudes and Force Production

Lucia Maloy; David O. Draper; A. Wayne Johnson; J. Ty Hopkins; Dennis Egget; Iain Hunter

Brigham Young University, Provo, UT

Address correspondence to Lucia Maloy, MS ATC, 776 W. Diagonal St. #37, St. George, UT 84770. Address email to maloy@dixie.edu.

ABSTRACT

Comparison of Single-Use and Multiple-Use Electrodes for Sensory, Motor Threshold Amplitudes and Force Production

Maloy L*, Draper DO#, Hopkins TJ#, Johnson AW#, Hunter I#, Eggett DL#:
*Dixie State College, St. George, UT; #Brigham Young University, Provo, UT

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have the added advantage of eliminating the possibility of cross-contamination of bacteria from patient to patient.
Word Count: 449 words

INTRODUCTION

Neuromuscular electrical stimulation (NMES) is a versatile therapeutic modality used for a wide variety of therapies.[1-10] Numerous clinicians have reported their regard for the use of NMES to help regain muscle strength, enhance recovery of motor control, retard muscle atrophy, and improve joint range of motion.[1,2,5,6,8-17] Understanding all the components of NMES is vital for achieving the full benefits of treatment. Stimulation electrodes play the important role in interfacing the tissue with the stimulation unit.[18] Studies have been conducted on the effects of electrode placement,[2,11,19] size of electrodes,[19], shape of electrodes,[19] type of electrode,[18] and even the body part to which the electrodes were applied.[2,11] To date, the effect that degradation or repeated use of the electrodes might have on the quality of the electrode has not been measured.

The most commonly used electrode in physical medicine and rehabilitation today is the adhesive backed silicon-impregnated hydrogel electrode.[20] We are unaware of any research that specifically addresses the optimal amount of times that a pair of multiple use electrodes should be used. In conversations with clinicians, the multiple use electrodes are often used more than 30 times before discarding. Theoretically, the multiple use electrodes will degrade over time due to use frequency.

When multiple use electrodes are used in a clinical setting on many different patients, the potential for the spread of infections and disease exists. When the patient's skin is not clean and or the electrodes are used on several different people, there is a chance for cross-contamination and bacterial growth on the electrode.[20] Research suggests that the skin is a permselective membrane. During electrical stimulation this permselectivity may lead to current-induced volume flow, which provides a primary mechanism for the transport of a polar uncharged molecule.[21] Theoretically, bacteria and viruses could be driven through the skin using electricity, even on skin with no openings.[21] Due to the expense of the multiple use electrodes, it may not be financially practical to use multiple use electrodes only once on one patient and then discard them. Therefore the problem remains on how to make NMES treatments cost effective and hygienic.

Single use electrodes could eliminate the possibility of cross-contamination. Also, with a single use electrode pair, the patient gets a new electrode each treatment, and thus should receive the full conductive power emitted. If single use electrodes are found to be as effective as multiple use electrodes, both initially and after some degradation of the multiple use electrodes, then single use electrodes could improve treatments. No longer would clinicians run the risk of spreading infections from patient to patient via electrodes, without greatly increasing operational costs. While these issues are the greatest reasons to hope that single use electrodes are effective, it must first be established that the single use electrodes can in any way compare to the multiple use electrodes. If the single use electrodes are ineffective compared to the multiple use electrodes, then cross contamination and electrode degradation would have to be addressed through alternative means. Our study investigated a base line for the efficacy of single use electrodes. Since the single use electrodes have only recently been produced, research to establish their efficacy was vital.

The purpose of this study was to compare single use and multiple use electrodes in three areas: amplitudes at which the patient first perceived sensation; motor twitch response; and the force produced at a specific intensity. Single use electrodes were tested on their first use only and multiple use were tested both at the first and tenth use (to simulate degradation).

METHODS

Data Analysis

The experiment was a repeated measures study, using mixed models ANOVA with subjects blocked. Independent variables were the types of electrodes (multiple use self-adhesive electrodes and single use self-adhesive electrodes) and number of trials (initial use and 10^{th} time use). Dependent variables were the amplitudes of perceived sensation and muscle twitch and the force produced at specific intensity. These were measured with first use and 10th use of multiple use electrodes and once for the single use electrodes.

Description of Subjects

Subjects were 7 men (age 24.7 yrs ± 2.3 yrs, height 72.1 in ± 2.4 in, weight 192.9 lbs ± 39.8 lbs, skin fold thickness 5.9 mm ± 2.4 mm) and 13 females (age 21.5 yrs ± 2.3 yrs, height 67.4 in ± 4.0 in, weight 160.8 lbs ± 25.1 lbs, skin fold thickness 10.7 mm ± 4.1 mm) recruited mostly from the student athlete and athletic training population via word of mouth. Inclusion criteria included healthy, active individuals. Exclusion factors included compromised circulation of the upper extremity, serious injury, surgery, or impairment of the upper extremity within the last six months, skin disease or lesion on the upper extremity, infection of the upper extremity, or internal or external fixation devices of the upper extremity.

The University's Institutional Review Board for human subject research approved the study, and subjects gave informed consent.

Description of Equipment

The multiple use electrodes measured 2″ by 2″ square (Dynatronics, Salt Lake City, UT). The single use electrode measured 2″ by 2″ square (Accelerated Care Plus, Reno, NV). The NMES device was the Omnistim FX2 Pro-Sport (Accelerated Care Plus, Reno, NV).

Procedures

All testing was performed in the Therapeutic Modalities Research Lab. The same clinician performed all tests in order to maintain uniformity in testing procedures. All subjects read and signed a consent form explaining any risks and benefits of the study prior to any testing taking place. Subjects then provided the information regarding age, height, and weight. Skin fold thickness measurements were taken by the clinician using calipers.

Subjects were randomly assigned to either the single use or multiple use first-time groups by the clinician in a random draw as they signed up. They participated in this group throughout the study. Subjects were instructed to pick days one week apart for the initial and final trials. In order to normalize the trials, they were performed at the same time on days that have the same schedules. For example, the initial trial was done on Tuesday at noon, and then the final trial was done Tuesday at noon the following week. Subjects were instructed to roughly maintain uniformity of schedule on those days.

Before the initial trial, skin fold measurements were taken over the wrist extensors, at the muscle belly of extensor carpi radialis brevis. Prior to applying the electrodes to the patients' skin, the arm was shaved and cleaned with alcohol. The skin was allowed to air dry. Subjects had electrodes placed on their wrist extensors muscle bellies just distal to the lateral epicondyle on the posterior forearm and 2 inches or the width of one electrode distally over the wrist extensor tendons. Outlines of the electrode were traced with a permanent marker on the subjects' skin to act as a template for the next sets of electrodes.

Subjects were blinded as to which type of electrode was being tested by a curtain blocking their view of the electrodes. Subjects were told to expect first a mild tingling sensation followed by involuntary twitch in the wrist extensor muscles as the electrical intensity was increased. Subjects were instructed by the clinician to verbally announce when they first perceived the electrical stimulation and when they first felt muscle twitch due to electrical stimulation. Subjects were then informed that the clinician would increase the intensity to 40 mA and record the force produced on the strain gauge for 10 seconds. Once the trial began there was no visual or verbal cues given. Due to a clicking sound emitted by the machine when the buttons were pushed, each subject had headphones to block any sounds that may have indicated the intensity being increased.

Subjects were seated in a customized chair. The upper arm and forearm were stabilized with straps to eliminate involvement of the shoulder or elbow. The wrist was supported in a neutral, relaxed position. A strain gauge (omega engineering, omega.com) was attached at the subjects' dominant hand. A strap, placed around the subjects' hand, was connected to a turn block that attached to the strain gauge (see Figure 1). This allowed the clinician to modify the length to accommodate for the different sizes of the subjects. The strain gauge reported force production to a customized computer program.

A pilot study was done on the following procedures to gauge the reliability of the measurements. The results of the pilot study are given in Appendix A.

Measures were taken to record the intensity in milliamps at which subjects perceived sensation, motor twitch and force production at specified intensity with both single use and multiple use electrodes. Multiple use electrodes were tested on initial use and on the 10th use to determine if there was decay in the integrity of the electrodes. Each pair of electrodes was used on the same subject for the initial trial and the 10th use trial. The following treatment parameters were followed:

- Pulse width: 150 μs (considered to be an appropriate width to stimulate this anatomical area)
- Medium frequency- carrier frequency of 5,000 Hz
- Beat frequency- 75 Hz

The following steps were applied:

- Current intensity (in milliamps) was increased until subjects first experienced a mild tingling sensation. The subjects verbally announced perceived sensation. This intensity in milliamperage was recorded by the clinician.
- Current intensity was increased until subjects first experienced an observable motor twitch in the muscle. Subjects verbally announced the first perceived sensation of motor twitch, but the first observed twitch of the wrist extensor muscles between the electrode pair was recorded by the clinician. The intensity in milliamperage was recorded by the clinician.
- Current was increased to a set intensity of 40 milliamps (this intensity was derived from an average intensity during pilot work). The force produced by the subjects at this intensity was recorded by a customized computer program at 10 Hz.
    - If a subject was unable to reach 40 milliamps and wished to stop and have the force recorded at a lower intensity, the clinician complied. However, the subject had to use the same intensity in the final trial that was used in the initial trial.
        - Example: the subject stopped at 37 milliamps during the initial trial, the subject must use 37 milliamps for the final trial.

- The intensity was then turned off and the procedure was repeated twice more with a two-minute rest between procedures. This should total three procedures per electrode pair.
    - The electrodes were not removed during the three total procedures.

Force applied by the muscle during force production at a specified intensity was measured using a strain gauge applied to the subjects' wrist. Output was measured by a customized computer program. The average of the three procedures was used for statistical analysis.

The same procedures were followed both at the initial trial and the final trial. After the multiple use electrodes were tested initially, they were leached out in the following manner:

- Each pair of multiple use electrodes was assigned a number and placed in a bag with the same number.
    - This number correlated to the subject on whom the electrodes were initially tested.
- The electrodes were leached out between the initial trial and the final trial on a nonsubject.
- Eight, 15-minute simulated treatments (two hours total).
    - Leaching-out treatments were done at the levels of normal treatments.

After eight uses or two hours of use, pretest procedures were repeated (10^{th} use electrode) as the final trial on the subjects.

Statistical Analysis

The experiment was a repeated measures study, using mixed models ANOVA with subjects blocked. Alpha was set at $p < 0.05$. Data was analyzed using a SAS proc mixed 9.1(2003) (SAS institute, version 9.1, 2003).

RESULTS

Regressions analysis was run to determine variance due to group or demographic factors (gender, age, height, weight, and skin fold measurements). Any variance that resulted from group ($F_{group} = 0.01$, p= 0.9103) or demographic factors ($F_{gender} = 0.39$, $p = 0.5377$, $F_{age} = 0.76$, $p = 0.3895$, $F_{height} = 0.05$, $p = 0.8293$, $F_{weight} = 0.30$, $p = 0.5873$, $F_{skin\ fold} = 1.70$, $p = 0.2002$) was not found to be significant. This study found that there was no statistically significant difference between the measures taken during the initial trial and final trial of the multiple use electrodes for muscle twitch ($F_{MUI\ MUF\ muscle\ twitch} = 107.3$, $p = 0.0918$) and force production ($F_{MUI\ MUF\ force\ production} = 28.69$, $p = 0.1075$). Therefore, statistically there was no decay in the multiple use electrodes with only 10 uses. The only sign of decay to the multiple use electrodes exhibited in the perceived sensation. There was a statistically significant difference between the initial perceived sensation and the perceived sensation on the 10^{th} use ($F_{MUI\ MUF\ sensory} = 55.61$, $p = 0.0008$). However, there was a significant difference between the single use (SU) and the multiple use (MU) electrodes for both the initial trial and the final trial. The p value for variance is a two sided measure. We were concerned with showing the values of SU electrodes were equivalent to the MU electrodes. However, there was a statistically significant difference. The measures were not equivalent. Nevertheless, the statistics showed not a drop in efficiency, but an increased efficiency. Therefore, the difference did not nullify the hypothesis, but showed a significant comparability between the SU and MU electrode pairs. On average the values for the SU were 9.73 mA for perceived sensory, 15.87 mA for observed muscle twitch, and 22.8 N for force produced at a specific intensity. The average values for MU initial were 16.70 mA for perceived sensory, 29.16 mA for muscle twitch, and 10.0 N for force produced at a specific intensity of 40 mA. The average values for MU final were 21.03 mA for perceived sensory, 31.78 mA for observable twitch, and 5.0 N for force produced at a specific intensity.

DISCUSSION

This study confirmed the viability of single use electrodes as compared to the common multiple use electrodes. The single use electrodes not only favorably compared to the multiple use electrodes, but significantly compared to them on every test. To our knowledge, no other studies have been performed to establish the efficacy of any brand of single use electrodes. Also, we could not find any study where researchers specifically investigated the effects that multiple treatments would have on electrode degradation. Studies have been conducted on many of the effects of electrode placement,[2, 11, 19] positions,[2,11] size,[19] shape,[19] and type,[18] but not the effects of degradation. Statistically from this study, we found no degradation to the electrodes for muscle twitch and force production after only two hours of use. Even with the decrease in adhesive quality with regular removal and reapplication of electrode pairs during the two hours, there was no significant degradation for muscle twitch and force production in the multiple use electrodes.

The only test that showed any significant difference between the initial trial and the final trial for the multiple use electrodes was perception of when the sensation of the stimulation began. Subjects' perception of the sensation caused by the electrical stimulation was significantly less in the final trial compared to the first trial, with many subjects stating that they felt very little electrical sensation during the final trial. Why perception of sensation should be significantly less is not immediately apparent. All subjects used in this study had previously experienced therapeutic electrical stimulation. Still, the change in perception between the initial and final trials might be due to a slight learning curve. Subjects may have been more apprehensive during the intial trial, but less attentive during the final trial. Having once experienced the sensation, they may have been less sensitive mentally. Since subjects were not exposed to more than four total minutes of electrical stimulation during either the initial or final trial, an increase in tolerance is not a viable possibility due to the lack of exposure time.[10] However, in normal subjects, the strength-duration time constant is longer for cutaneous afferents than for motor axons, probably because the cutaneous afferents express a greater noninactivating Na+ conductance that is active at threshold.[23] Therefore, it may be possible that the sensation would be decreased while the amount of electricity conducted through the skin would remain relatively constant. Outlines of the electrode pairs were traced on the subjects' arms so that there would be a uniformity of positioning and motor unit stimulation. The waveform and carrier frequency did not change between the trials, so perception should have remained uniform.[9,10,13,18,19,22] In fact, the muscle twitch and force production did remain statistically uniform with only the perception of sensation decreasing. However, it is also our belief that two hours of use is not enough to truly simulate clinical use. The decrease in sensation may have been the first sign of a trend of degradation. Many times in the clinical setting, electrical stimulation treatments are done for longer than 15 minutes (the amount of time during each simulated treatment in our study) in one treatment period. Often electrical stimulation treatments are combined with heat or ice, either of which may affect the degradation of the electrode. In our study, the subjects' and nonsubjects' skin was shaved and cleaned with alcohol prior to any application of the electrodes. This may have also affected the integrity of the electrode. The perceived sensation decreased despite these precautions, but the effect that it had on the muscle twitch or the force production is undetermined. Body oils, hair, lotions, or dead skin may have a role in the degradation of electrodes in a clinical setting. This study showed only that there is little degradation to a multiple use electrode pair with only two total hours of uses in a laboratory setting.

A key object of this study was to form a baseline for the efficacy of single use electrodes compared to the multiple use electrodes commonly used in clinical settings. Originally, the study was conducted to determine if the single use electrodes were even capable of satisfactorily measuring up to multiple use electrodes. However, after completing the data collection, it became obvious that the single use electrodes were capable of conducting as well as the multiple use electrodes for perceived sensation and motor thresholds and in force production. There was a significant difference between the results of the single use electrodes and the multiple use electrodes for both the initial and final trials. There are a few reasons that may explain why the single use electrodes should produce desired results at a lower intensity. The single use electrodes contained a foil application surface and a single layer of adhesive hydrogel. With only two thin layers, there would be less resistance between the conducting surface and the skin interface. The single use electrodes were thin and pliable, allowing for uniform adhesion even on slightly less flat, smooth surfaces. Also, the foil conducted across the entire surface area so that current density was equal across the entire surface area. The multiple use electrodes performed the same functions at higher milliamperage. This study showed that the single use electrodes are comparable to the commonly used brand of multiple use electrodes. However, the single use electrodes and the multiple use electrodes were produced by different manufacturers. This may have had an effect on the outcome of the study. We chose to use the brand of electrodes commonly used in the athletic training facilities of our university athletic training room. This brand of electrode is fairly common to many clinics and athletic training facilities. Therefore, it was determined that this would be the most appropriate measure for a practical comparison. Still, the different materials used in the electrodes may play an important role in the difference between the electrodes.

One of the foremost reasons to consider single use electrodes as a viable option is to avoid cross contamination with an electrode pair used on several people. When the same electrode pair is used on several people, the potential for the spread of infections and disease exists. Unclean skin, open lesions, and contaminations can transfer and cause bacterial or viral growth on the skin of another patient or even exasperate a condition of the original patient.[20] Even within clinics where multiple use electrode pairs are used on only one patient, contaminations can be spread between treatments. Research suggests that the skin is a permselective membrane. During electrical stimulation this permselectivity may lead to current-induced volume flow, which provides a primary mechanism for the transport of a polar uncharged molecule.[21] Theoretically, bacteria and viruses could be driven through the skin using electricity, even on skin with no openings.[21] Due to the expense of the multiple use electrodes, electrical stimulation treatments may be too expensive if the electrodes are not reused on multiple patients. Thus it becomes financially impractical to use a multiple use electrode only once on a patient and then discard it. Therefore there is a need for an inexpensive, hygienic alternative that eliminates the possibility of cross-contamination. Single use electrodes have been presented as that alternative. We investigated single use electrodes for sensation, muscle twitch and force production, and found them to be as effective as multiple use electrodes. We revealed the efficacy of single use electrodes.

CONCLUSION

Single use electrodes are a viable option for clinicians. In this study, they performed as well or better than the multiple use electrodes. Single use electrodes produced sensation and visible muscle twitch at a lower threshold, and they produced more force production. It is our opinion, that single use electrodes are an effective alternative to the commonly used multiple use electrodes.

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Table 1. Male DemographicValues

Boy ID	Age (yrs)	Height (in)	Weight (lb)	Skin Fold (mm)
60901	28	71	165	5
60902	21	75	250	5
60903	25	72	238	11
60906	24	74	170	6
60907	24	74	205	4
60915	24	68	142	4
60920	27	71	180	6
average	24.71429	72.14286	192.8571	5.857143
std. dev.	2.288689	2.410295	39.79292	2.410295

Table 2. Female Demographic Values

Girl ID	Age (yrs)	Height (in)	Weight (lb)	skin fold (mm)
60904	22	65	144	8
60905	20	67	146	8
60908	19	59	108	4
60909	26	67	165	16
60910	25	70	180	15
60911	22	72	150	11
60912	21	68	190	16
60913	23	64	140	12
60914	23	67	178	13
60916	19	74	165	7
60917	21	67	200	7
60918	19	72	145	7
60919	20	64	180	15
average	21.53846	67.38462	160.8462	10.69231
std. deviation	2.258886	4.011202	25.07604	4.090326

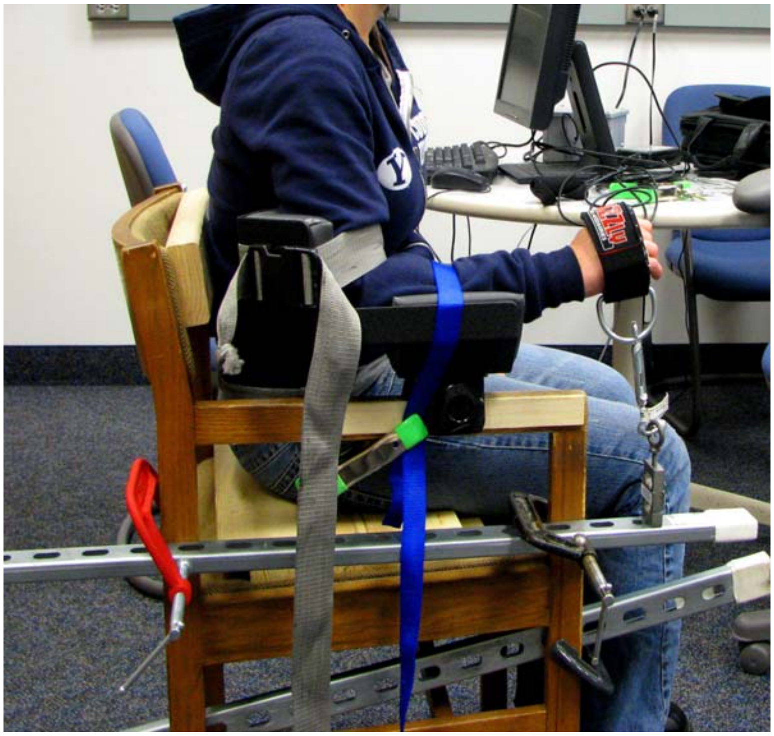


Figure 1. Customized chair and strain guage

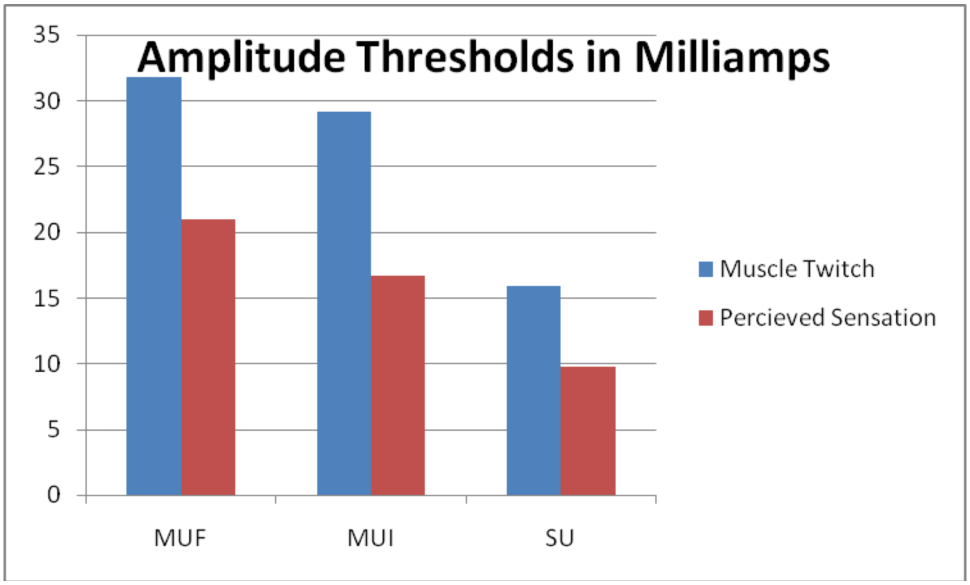


Figure 2. Average values of perceived sensation and observable muscle twitch in milliamps

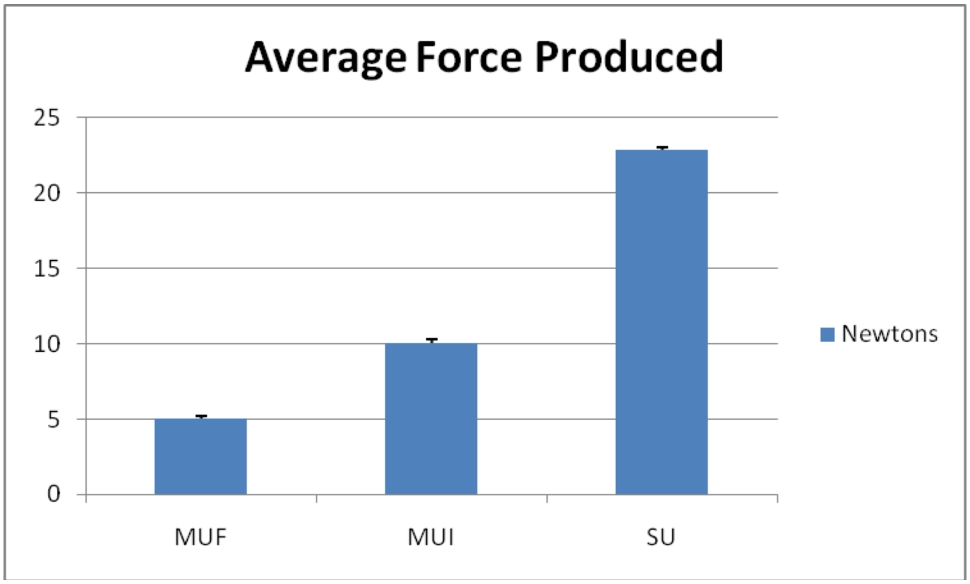


Figure 3. Average values of force production in N

Appendix A

Prospectus

Chapter 1

Introduction

In therapeutic and functional applications transcutaneous electrical stimulation (TES) is still the most frequently applied technique for muscle and nerve activation (Keller, Kuhn, 2008). It is a versatile therapeutic modality used for a wide variety of therapies (Arvidsson, et al., 1986, Fitzgerald, et al., 2003, Holcomb, 1997, Holcomb, 2006, Lieber, et al., 1996, Neder, et al., 2002, Nolan, 1991, Parker, et al., 2003, Stevens, et al., 2004). Numerous reports favor the use of neuromuscular electrical stimulation (NMES) to help regain muscle strength and enhance recovery of motor control, retard muscle atrophy, and improve joint range of motion (Alon, Smith, 2005; Alon et al., 1987; Arivdsson et al., 1986; Delitto et al., 1988; Eriksson et al., 1981; Fitzgerald et al., 2003; Gould et al., 1983; Lieber et al., 1996; Morrissey et al., 1985; Neder et al., 2002; Oldham and Stanley, 1989; Parker et al., 2003; Stevens et al., 2004; Wigerstad-Lossing et al., 1988). Understanding the components of NMES is vital for achieving the full benefits of treatment. Stimulation electrodes play the important role in interfacing the tissue with the stimulation unit (Keller, Kuhn, 2008). Numerous research studies have been conducted on the different procedures and settings of NMES, however very little research has been performed on the effect that specific electrodes have on treatment outcomes. Studies have been conducted on the effects of electrode placement (Forrester & Petrofsky, 2004, Alon et al., 1987, Fitzgerald et al., 2003,), positions (Alon et al., 1987, Fitzgerald et al., 2003,), size (Forrester & Petrofsky, 2004), shape (Forrester & Petrofsky, 2004), and type (Keller & Kuhn, 2008), but not the effect that degradation of the electrodes might have on the quality of the electrode.

The most commonly used electrode in physical medicine and rehabilitation today is the adhesive backed silicon-impregnated rubber electrode. (Knight & Draper,2008). We are aware of only one manufacturer who recommend on the package that the electrodes be used a certain number of times (10) and then discarded (ACPLUS Web, 2008). In our conversations with clinicians, these electrodes are often used more than 30 times before discarding. Theoretically, the multiple use electrode will become degraded over time with the frequency of use. Also, when the patient's skin is not clean and or the electrodes are used on several different people, there is a chance for cross-contamination and bacterial growth on the electrode (Knight & Draper, 2008). This could especially be troublesome if an electrode were reused after a wound healing treatment.

A single use electrode has been produced (Accelerated Care Plus). The proposed advantage of this electrode compared to the reusable electrode is it eliminates the possibility of cross-contamination. Also, since the patient always gets a new electrode, they should always receive the full conductive power emitted.

The purpose of this study is to compare amplitudes at which the patient first perceives sensation and motor twitch response and the force produced at a specific amplitude using single use self-adhesive electrodes and multiple use self-adhesive electrodes in a repeated measures study.

Research Question-

Is the single use self-adhesive electrode as effective for perceived sensory and motor stimulation and force production as the multiple use self-adhesive electrode both at initial use and after two hours of output (equivalent to eight 15 min uses)?

Research Hypothesis

1. There will be no difference between the single use electrodes and multiple use electrodes in either the initial use or after two hours (eight 15 min uses) of output for sensory stimulation.
2. There will be no difference between single use electrodes and multiple use electrodes in either the initial use or after two hours (eight 15 min uses) of output for motor stimulation.
3. There will be no difference between single use electrodes and multiple use electrodes in either the initial use or after two hours (eight 15 min uses) of output for force production at specified intensity.

Assumptions

1. Treatment done on the wrist extensor will correlate to treatment done on other muscles.
2. Results of a study on college-age adults will correlate to the general public.
3. Results of a study done in a lab setting will have relevance to the clinical setting.

Limitations

1. There may be some tolerance development between the initial trial and the final trial which may lead to variation of amplitude response.

2. Subjects may experience significant activity, weather, or emotional differences between initial and final trial affecting blow flow or body temperature thereby causing some biological variation between trials.

Definition of Terms

Amplitude- The maximum departure of the value of an alternating current or wave from the undisturbed value. The maximum absolute value reached by a voltage or current waveform or the maximum absolute value of a periodically varying quantity. The difference between the crest and the trough of the electrical wave is twice the amplitude (Cutnell & Johnson, 2004, ter Haar, 2002).

Conductor- A conductor is a material which contains movable electric charges. In metallic conductors, such as copper or almuminum, the movable charged particles are electrons. Electrons are conducted from the negatively charged pole toward the positively charged pole (Cutnell & Johnson, 2004). Positive charges may also be mobile in the form of atoms in a lattice missing electrons (called "holes") or ions, such as in the electrolyte of a battery. It must have free electrons that can be pushed along. Thus metals are the best conductors because their atoms have weak bonds with their outer electrons, meaning they can give them up easily. Water with minerals or electrolytes is a good conductor (Charman, 2002).

Current- The time rate at which charge passes through a circuit element or through a fixed place in a conducting wire, $I = dq/dt$. The flow of electrical charge (electrons) from one point to another, from an area of higher electron concentration (the negative pole or cathode) to an area lacking electrons (positive pole or anode) (Cutnell & Johnson, 2004, Knight & Draper, 2008).

Electrical Charge- The net sum of the charges of electrons and protons in an atom or molecule; the difference between the number of protons and electrons (Cutnell & Johnson, 2004). Normally an atom has an equal number of electrons and protons and is, therefore, electrically neutral. If a chemical, mechanical, solar, or thermal force causes electrons to be added to or removed from the atom, it becomes negatively or positively charged (Knight & Draper, 2008).

Electrolyte- A substance whose aqueous solutions contain ions and can thus conduct electricity (Brown, et al., 2003, Knight & Draper, 2008).

Frequency- Frequency describes the number of cycles or pulses per second and is expressed as Hertz (Hz) for cycles or pulses per second (pps) (Cameron, 2003).

Impedance- The total opposition to the flow of charge (Cutnell & Johnson, 2004).

Ion- an atom or molecule that has lost or gained one or more electrons and becomes positively or negatively charged (Brown, et al., 2003, Knight & Draper, 2008).

Ohm- A measure of resistance to the flow of electrons. The current flowing through a metallic conductor is proportional to the potential difference that exists across it, provided that all physical conditions remain constant. (ter Haar, 2002).

- Ohm's Law: current = force/resistance

Premodulated current- Premodulated current is a waveform produced by one channel (two electrodes) that has the same form as the current produced by the interference of two medium-frequency sinusoidal alternating currents. Premodulated current has a continuous sinusoidal wave form with a medium frequency and sequentially increasing and decreasing current amplitude. The advantages of interferential current, including lower current amplitude being delivered to the skin and a larger area of stimulation, are not reproduced by premodulated current (Cameron, 2003).

Resistance- The opposing of the flow of electricity, caused by the conductor or the ratio of the voltage applied across a piece of material to the current through the material (Cutnell & Johnson, 2004). Resistance is determined by the type of material of the conductor, the cross-sectional area of the conductor, the conductor length and conductor temperature. Electricity will always flow via thepath of least resistance (Knight & Draper, 2008).

Chapter 2

Review of Literature

This literature review will focus on principles of electrotherapy important to this study, and on the various types of electrodes used in physical medicine and rehabilitation.

Databases and Key Words Searched:

Medline (Pubmed)

Medline (Ebsco)

Sportdiscus (Ebsco)

Web of Scinecе (ISI)

Google Scholar

The chapter is organized by the following topics:

History of electrotherapy

Bioelectricity

Electrodes (types and size)

Electrotherapy and wound healing

History of Electrotherapy

Electricity has been used as a therapeutic modality since the days of the Romans (Bullock, et al., 2005, Ochs, 2005, Prodanov, et al., 2003). In 47 BC Scribonius Largus recommended using electric torpedo fish to reduce pain. (Bullock et al., 2005) In the 18th century Albrecht Haller wrote *A Dissertation on the Sensible and Irritable Parts of Animals (1754)* setting up nerves as the conductive organs of the body, and first described that tissue lacks sensation unless acted upon by a relay of nerves (von Haller, 1754). Von Haller (1708-1777) understood that nerves passed along a force, but Luigi Galvani (1791) actually discovered that animation of the muscle was due to "galvanic" element (Brazier, 1984, Ochs, 2005, Piccolino, 1997, Prodanov et al. 2003). Due to his experiments on frog legs showing that muscle tissue could be stimulated by a static electrical source, Galvani believed that the force could only be produced biologically. Allesandro Volta acting as the antagonist of Galvani proved that the force needed to stimulate nerves was electric and could be created outside the body (Elliot, 1999, Brazier, 1984, Ochs, 2005, Piccolini, 1997, Prodanov et al., 2003). A century later J. Müller wrote the *Law of Specific Nerve Energies* stating that "the kind of sensation, following the stimulation of a sensory nerve, depends not on the mode of stimulation but on the nature of the sense organ with which the nerve is linked (Muller, 1826, Ochs, 2005, Prodanov et al., 2003)." Finally T. H. Huxley proposed the central nervous system as the controlling element of the body in his paper *Manual of the Anatomy of the Invertebrate Animals* (Huxley, 1877, Ochs, 2005, Prodanov et al., 2003). Afterward researchers began to study the effects of electrical stimulation on disease and conditions, leading to advances in medical technology (Brazier, 1984)

Bioelectricity

Although electrical stimulation is a major tool for rehabilitation, there is a difference between the electricity from the generator and the electricity that is present in the body. The main difference between electricity in biological tissues and electricity in equipment is that cells and tissues use charged atoms, or ions, for the movement of charge, whereas electrical and electronic systems use electrons (Charman, 2002). Living cells are dependent upon electrical activity for their very existence and the tissues that they make, such as bone and fascia, exhibit a wide range of electrical properties (Charman, 2002). Cells are wet circuits that operate in a salty, conductive medium (Charman, 2002). Materials in which the atoms are free to move, the charge is carried by ions (Charman, 2002). Ions are atoms or molecules that have lost or gained one or more electrons and are, therefore, positively or negatively charged (Knight & Draper, 2008). A liquid in which the ions are the charge carriers is called an electrolyte (Charman, 2002). Cells must continually make and replace all of their electrical components, continually work to generate and maintain regions of differing electrical properties, continuously work to generate and maintain regions of differing electrical properties against continuous leakage of charge, continually control rates of desired current flow against possible shorting of current, and continually work to prevent unwanted current flow when a pathway is switched off (Charman, 2002). Ions at high concentration tend to diffuse to areas of low concentration and their movement is also influenced by voltage gradients, with positive ions being attracted down the negative gradient, and vice versa (Charman, 2002). Relatively unwieldy mass, ions require far more energy to control their movement, and accelerate much more slowly along a given potential difference gradient, in comparison to electrons (Charman, 2002). Muscle and nerve stimulating electrical currents exert their physiological effects by depolarizing nerve membranes and thereby producing action potentials, the messaged unit of the nervous system (Cameron, 2003; Charman, 2002). The smallest unit of movement that a central nervous system can control is a motor unit (Charman, 2002). This unit consists of a motoneuron, together with its axon and dendrites, motor end plates and the muscle fibers it supplies (Charman, 2002). Nerve and muscle cells are excitable that is, they are able to produce an action potential after application of a suitable stimulus (Charman, 2002). Once the action potential is propagated along the axon, the human body responds to it in the same way as it does to action potentials that are initiated by physiological stimuli (Cameron, 2003).

Type of Carrier Frequency- Investigators have found that they could vary subjects' perception of pain by varying the current frequency or waveforms of the carrier wave used for electrical stimulation (Rooney, et al., 1992).

Tissue Response to Electrotherapy- Electrotherapy is a common and useful modality because of the tissue response. There are four types of tissue response commonly used by therapists:

1. Ion migration- ions move through the tissue in response to continuous direct current. This is commonly used for edema reduction and iontophoresis (Knight & Draper, 2008).
2. Fused response- a sustained sensory response to moderate-amplitude, low frequency pulsed or alternating current, that feels like pins and needles (Knight & Draper, 2008). This response is used therapeutically for edema reduction, wound healing, and pain reduction (Knight & Draper, 2008).
3. Twitch contraction- repetitions of isolated brief muscular contraction followed by relaxation. This is a low-frequency, high-amplitude pulsed stimulation. Twitch

contraction is used mainly for muscle re-education and in combination with ultrasound to treat tendonitis (Knight & Draper, 2008).

4. Tetanic contraction- a sustained muscular contraction caused by high frequency stimulation. This is high frequency, high amplitude stimulation used for strength development and spasm reduction (Knight & Draper, 2008).

Stimulation of peripheral nerves at intensities below the threshold for motor unit activation has been shown to increase regional blood flow (Owens et al., 1979; Abram et al., 1980). Intensities above the motor unit threshold decrease regional blood flow (Wong & Jette, 1984). Later studies showed that neither sensory-level nor low-intensity motor-level electrical stimulation delivered at high frequencies alters limb blood flow in asymptomatic individuals with normal vascular resistance (Indergand & Morgan, 1994).

Tolerance to Electrical Stimulation The threshold for activation of a motor unit is not always constant; rather recruitment thresholds have been shown to be dependent on the history of activation of a unit (Gorassini, et al., 2002). Tolerance to electrical stimulation is likely to improve within and between sessions (Alon & Smith, 2005). The degree of conditioning is likely to vary considerably (Alon & Smith, 2005). Subjects that exhibit strong electrically elicited contractions initially were more likely to reach the highest percentage of maximum voluntary contraction (Alon & Smith, 2005). Males were better able to tolerate considerably more electrical stimulation than females (Alon & Smith, 2005). Accommodation refers to the transient but reversible increase threshold of nerve excitation. Habituation implies a long-term nonreversal adaptation to stimulation that may involve morphological and histochemical alteration (Alon & Smith, 2005; Gauthier, et al., 1992; Gibson, et al., 1988; Ogino, et al., 2002; Pekindil, et al., 2001; Quittan, et al., 2001). Most healthy subjects could be conditioned to tolerate electrical stimulation at a clinically-meaningful electrically-induced contraction (Alon & Smith, 2005).

Electrode Types and Sizes

Clinical electrical stimulation involves the passing of current through the skin via electrodes (Behrens & Michlovitz, 2006). Electrical current is the flow of electric charge, usually electrons, along a conductor (Charman, 2002; Knight & Draper, 2008). Delivery of current is accomplished through a system of electrically conductive elements (Behrens & Michlovitz, 2006). Each component will affect the amount of electrical charge delivered to the patient (Behrens & Michlovitz, 2006). Electrodes represent the "instrument" for current delivery from an electrical stimulation generator (Behrens & Michlovitz, 2006). Electrodes vary in shape, size, and flexibility, to fit the needs of the therapeutic application of the electrical current to the patient (Behrens & Michlovitz, 2006).

There are three main types of electrodes:

1. Metal plate electrodes- Early electrodes were composed of metal plates such as tin, steel, aluminum, and zinc, which are good electrical conductors for therapeutic stimulation (Behrens & Michlovitz, 2006). The thin metal plate electrode attaches to the wire from the terminal (Knight & Draper, 2008). The electrode was usually contained within a rubber casing with only one surface

exposed to the patient (Behrens & Michlovitz, 2006). The interface between the metal electrode and skin was accomplished through a sponge or felt pad moistened with water (Behrens & Michlovitz, 2006; Knight & Draper, 2008). Electrodes were held in place with straps, bands, or sand bags (Knight & Draper, 2008).

Disadvantages of metal plate electrode systems include the following:

- Metal plates may not be flexible enough to maintain adequate contact with certain body parts.
- These electrodes may be difficult to secure comfortably to the patient.
- There are few sizes of these electrodes, making specific treatment goals for smaller treatment areas difficult to accomplish. (Behrens & Michlovitz, 2006)

2. Carbon-Impregnated rubber electrodes- Electrodes composed of rubber, silicon, and polymer have mostly replaced metal plate electrodes (Behrens & Michlovitz, 2006). Carbonized rubber electrodes were tested extensively when they were first developed 30 years ago, but modern carbonized rubber electrodes have not received the type of scrutiny that the first electrodes received (Petrofsky, et al. 2007). These electrodes are fashioned from silicone rubber impregnated with carbon particles (Nolan, 1991). They are backed with a nonconductive material to prevent unintentional current delivery (Behrens & Michlovitz, 2006). Effective transmission of electrical pulse necessitated the use of a coupling agent, typically a gel, and tape was required to secure electrodes in place (Nolan, 1991). These

electrodes are available in many shapes and sizes, and they can be trimmed or fitted to different locations of the body (Behrens & Michlovitz, 2006). As a group, standard carbon-rubber electrodes used with commercially available gels offer less impedance than electrodes used with other types of conducting media (Nolan, 1991). They can degrade over time, resulting in nonuniformity of current delivery, or the presence of "hot spots." Hot spots represent those areas of the electrode that continue to maintain their conductivity while other areas of the surface no longer conduct electrical energy (Behrens & Michlovitz, 2006). Carbon rubber electrodes should be rinsed off and dried after each use. It is suggested that these electrodes be replaced every 12 months to ensure good conductivity (Behrens & Michlovitz, 2006).

3. Self-Adhering reusable electrodes- Modern electrodes differ from the original electrodes in that they come with a self-adhesive electrode gel called hydrogel as part of their composition (Petrofsky, et al., 2007). Self adhering reusable electrodes are composed of other flexible conductors such as foil or metal mesh, conductive Karaya, or synthetic gel layered with an adhesive surface (Behrens & Michlovitz, 2006). These electrodes use newly developed polymers as the conducting medium, and many are prepackaged with hypoallergenic adhesive materials (Nolan, 1991). Adhesive is used in place of the sponge and straps, tape, or sand bags (Knight & Draper, 2008). These are quicker and easier to apply but more expensive than other systems (Knight & Draper, 2008).

Considerations for electrodes Several factors are thought to affect the amount of current required during the delivery of electrical stimulation, such as tissue impedance, pad placement, and shape and size of the electrode (Forrester & Petrofsky, 2004). Resistance of the electrodes should be as low as possible when significant motor levels of stimulation are required (Behrens & Michlovitz, 2006). Commercially available electrodes vary in their conductive properties and that variance in electrodes affects impedance (Nolan, 1991). Impedance differences were noted between trials with the same electrodes (Nolan, 1991). If the impedance value of the electrodes is high, then the stimulator will need to overcome the value before the current is delivered to the patient (Behrens & Michlovitz, 2006). Interelectrode distance and differences in the thickness and texture of the skin each contribute to total impedance with the system (Nolan, 1991). The method of current delivery into the electrode will also affect the uniformity of the current delivery from the electrode. A metal wire inserts into the center of a conductive-adhesive or adherent surface. The current delivery at the point of attachment of the wire to the surface will be relatively higher than the current delivery to the periphery of that electrode (Behrens & Michlovitz, 2006). Optimally, the conductive surface of the electrode will have "uniform" conductivity. This potential for uniformity of conductivity is enhanced through foil or mesh surfaces within the electrode to spread out the delivered current (Behrens & Michlovitz, 2006).

Electrode size and current density Achieving the beneficial effects of electrical stimulation is often limited because of the pain and discomfort many individuals experience during its application (Forrester & Petrofsky, 2004). Current density describes the amount of current concentrated under the electrode (Behrens & Michlovitz, 2006). It is a measure of the quantity of charged ions moving through a specific cross-sectional area of body tissue (Behrens & Michlovitz, 2006; Knight & Draper, 2008). Electrode surface area is inversely related to total current flow. The same total current flow is passing through large and small electrodes would result in lower current density in the larger electrode. The total current would be distributed over a larger surface area. Conversely, the smaller electrode would be delivering a high-current density because of its smaller surface area (Behrens & Michlovitz, 2006). This describes the current density in an ideal situation with ideal electrodes. However, recent studies are showing that the ideal situation is not consistent. At current levels normally used for electrical stimulation for functional movement, while current flow is better in most electrodes, it is very uneven, resulting in high current density in the centre of the electrodes and a fall off of at least 50% in current intensity at the edges of the electrode (Petrofsky, et al., 2007). There was very little difference in current density between small and large electrodes due to the high current density in the center (Petrofsky, et al., 2007). Small differences in size and shape of clinically available electrodes do not appear to affect patient tolerance of electrical stimulation, yet larger differences in size between electrode pairs can be uncomfortable under the smaller electrode due to the principle of current density (Forrester & Petrofsky, 2004; Knight & Draper, 2008).

Electrode Placement Muscles are stimulated indirectly, that is, through their motor nerve (Forrester & Petrofsky, 2004). The motor nerve is most susceptible to stimulation at the point where it branches to enter the muscle, known as the motor point (MP) (Forrester & Petrofsky, 2004, Knight & Draper, 2008). The motor point has the greatest density of sodium channels and therefore the lowest impedance (Forrester & Petrofsky, 2004). Therefore, the closer the electrode is to the MP, the less current it should take to stimulate the muscle through its nerve (Forrester & Petrofsky, 2004; Knight & Draper, 2008). Some consideration for locating the motor points are

- Motor points are located by trial and error, by looking for a good sharp muscle contraction while moving the electrode over the muscle.
- Charts can help identify motor points, but there is a certain amount of anatomical variation in location (Knight & Draper, 2008).
- Motor points can also to determined by using a small metal wand or even the clinicians fingers as the active electrode (Knight & Draper, 2008).

Placement of the electrode on the MP during the application of ES caused an increase in the amount of current required to achieve a set muscle force, with concurrent increases in subject discomfort (Forrester & Petrofsky, 2004). The stimulating electrode should be carefully placed directly over the muscles' MP before application of ES. Muscle conducts electricity four times better longitudinally than transversely (Benton, et al., 1981). There are three basic techniques for electrode placement: bipolar, unipolar, and quadripolar. However, for this study only the bipolar technique is relevant. Electrodes from the two terminals are of equal size, resulting in essentially equal current density under both electrodes (Palmer & Martin, 2002; Behrens

& Michlovitz 2006; Knight & Draper, 2008). Both electrodes are active and placed on the treatment area in relative proximity to one another (Knight & Draper, 2008).

Coupling media Surface-stimulating electrodes require the use of a coupling medium. This medium can be water via soaked sponges, or electrically conductive gel. The coupling medium reduces the impedance at the interface between the electrode and the skin resulting in less current amplitude needed to produce the desired effects of stimulation (Behrens & Michlovitz, 2006). Pliability of the electrode to conform to the body part is necessary. Rigid metal electrodes do not conform well to contoured anatomic regions. Poor conformity can also result in hot spot delivery of the electrical energy (Behrens & Michlovitz, 2006). The electrode should conform to the anatomic region to obtain optimal stimulation. Electrode attachment methods to maximize surface contact include the use of straps, tape, and self-adhering electrodes (Behrens & Michlovitz, 2006).

Electrotherapy and Wound Healing

Quite possibly, the area that would benefit the most from a single use disposable electrode would be wound healing. The exact mechanism by which electrical stimulation appears to enhance wound healing has not been established (Watson, 2002). Direct current was reported to cause different histological responses beneath the anode and the cathode and an increase in wound tensile strength (Kloth & Feedar, 1986). However, a wide range of ES applications have apparently been responsible for enhanced soft tissue (particularly skin) healing (Watson, 2002). The exact mechanisms of enhanced healing through ES remain unexplained, but the benefits of a single use disposable electrode would be invaluable to the application. Superficial skin treated with direct current show a significant increase not only in protein content but more than double the labeled collagens between 4 and 5 days (Alvarez, et al., 1983). Since the electrode must come into contact with the wound to be effective, one electrode is placed directly over the wound. Thus the electrode is contaminated and cannot be used again.

Chapter 3

Methods

Data Analysis

The experiment is a repeated measures study, with 2 (single use electrode and multiple use electrode) X 2 (trials) factorial design using one-way ANOVA analysis.

- Independent variables are the types of electrodes (multiple use self-adhesive electrodes and single use self-adhesive electrodes) and number of trials (initial use and 10th time use).
    - Two types of electrodes- multiple use and single use
    - Two trials- initial use and 10th time use of electrode
- Dependent variables are the amplitudes of perceived sensation and muscle twitch and the force produced at specific amplitude.
    - Amplitude of intensity at perceived sensation
    - Amplitude of intensity for muscle twitch (both verbally announced by subject and perceived by clinician)
    - Force produced at a specific intensity (40 milliamps)

These will be measured with first use and 10th use of multiple use electrodes.

Subjects

Twenty university students (male and female) physically, active, healthy individuals. Subjects will be between 18 to 30 years of age. Each subject will sign an IRB informed consent form, and they will be free to withdraw from the study at any time.

Exclusion Factors

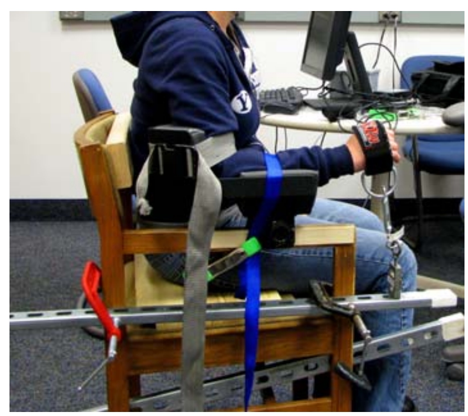
- Compromised circulation of the extremity
- Serious injury, surgery, or impairment of the extremity within the last six months.
- Skin disease or lesion on the extremity
- Infection of the extremity
- Internal or external fixation devices of the extremity

Subjects will be blinded to which type of electrode is being tested by a curtain blocking their view of the electrodes. Subjects will be instructed by the clinician as to what to do and expect before the start of the trial. Once the trial begins there will be no visual or verbal cues given. Due to a clicking sound emitted by the machine when the buttons are pushed, each subject will have headphones to block any sounds that may indicate the intensity being increased.

Procedures

Subjects will randomly be assigned to either the single use, or multiple use first-time groups. This will be the group in which they will participate throughout the study. No less than 2 days, and no more than 1 week later they will participate in the second trial. In order to normalize the trials, each trial will be done at the same time on days that have the same schedules. For example, the first trial is done on Tuesday at noon, and then the second trial should be done either Thursday at noon or the next Tuesday at noon. Subjects will be instructed to pick days with roughly similar schedules and to maintain uniformity on those days. Before the initial trial skin fold measurements will be taken over the wrist extensors, at the muscle belly of extensor carpi radialis brevis. Prior to applying the electrodes to the patients' skin, the arm will be shaved and cleaned with alcohol. The skin will be allowed to air dry. Subjects will have electrodes placed on their wrist extensor muscle belly just distal to the lateral epicondyle on the posterior forearm and 2 inches or the width of one electrode distally over the wrist extensor tendons. Outlines of the electrode will be traced with a permanent marker on the subjects' skin to act as a template for the next sets of electrodes. Both the single use electrodes and the multiple use electrodes are 2 inches square.

Subjects will be seated in a customized chair. The upper arm and forearm will be stabilized with straps to eliminate involvement of the shoulder or elbow. The wrist will be supported in a neutral, relaxed position. A strain gauge (omega engineering, omega.com) will be attached at the subjects' dominant hand. A strap will be placed around the subjects' hand. That strap will attach to a turn block that will attach to the strain gauge. This will allow the clinician to modify the length to accommodate for the different sizes of the subjects. The strain gauge will report force production to a customized computer program.



Measures will be taken of intensity at which subjects perceive sensation and motor twitch, and force production at specified intensity with both single use and multiple use electrodes. A pilot study was done on the following procedures to gauge the reliability of the measurements. The results of the pilot study are given in Appendix A. Multiple use electrodes will be tested on initial use and on the 10th use to determine if there is decay in the integrity of the electrode. Each pair of electrodes will be used on the same subject for the initial trial and the 10^{th} use trial. The following treatment parameters will be followed:

- Pulse width: 150 μs (Considered to be an appropriate width to stimulate this anatomical area.)
- Medium frequency- carrier frequency of 5,000 Hz
- Beat frequency- 75 Hz

The following steps will be applied:

- Current intensity (in milliamps) will be increased until subjects first experience mild tingling sensation. The subjects will verbally announce perceived sensation. This intensity will be recorded by the clinician.
- Current intensity will be increased until subjects first experience a motor twitch in the muscle. Subject will verbally announce the first perceived sensation of motor twitch, but the first observed twitch by the clinician will be recorded. This intensity will be recorded by the clinician.
- Current will be increased to a set intensity of 40 milliamps (this intensity was derived from an average intensity during pilot work). The force produced by the subjects at this intensity will be recorded by a customized computer program.

        - If a subject is unable to reach 40 milliamps and wishes to stop and have the force recorded at a lower intensity, the clinician will comply. However, the subject must use the same intensity in the final trial that was used in the initial trial.
            - Example: the subject stopped at 37 milliamps during the initial trial, the subject must use 37 milliamps for the final trial.

- The intensity will be turned off and the procedure will be repeated twice more with a two minute rest between procedures. This should total three procedures per electrode pair.
    - The electrode will not be removed during the 3 total procedures.

Force applied by the muscle during both motor twitch and force production at specified intensity will also be measured using a strain gauge applied to the subjects' wrist. Output will be measured by a customized computer program. The average of the 3 procedures will be used for statistical analysis.

The same procedures will be followed both at the initial trial and the final trial. After the multiple use electrodes have been tested initially, they will be leached out in the following manner:

- Each pair of multiple use electrodes will be assigned a number and placed in a bag with the same number.
    - This number will be correlated to the subject on whom the electrodes were initially tested.

- The electrodes will be leached out between the initial trial and the final trial on a nonsubject.
- Eight, 15 minute simulated treatments (two hours total).
    - The leaching out treatments will be done at the levels of normal treatments. All treatments will be recorded on the treatment log.

- After eight uses or two hours of use, pretest procedures will be repeated (10^{th} use electrode) as the final trial on the subjects.

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Appendix A-1

Pilot Study Results

Pilot Study

An initial pilot study was done to test the reliability of the measurements used in this study. Six subjects were chosen, 1 male and 5 female. Ages of the subjects ranged from 19 to 26 years. All subjects had previously experienced therapeutic electrical stimulation and were familiar with the sensation. Electrodes were placed on the subjects' arms, one over the muscle bellies of the wrist extensors on the lateral forearm just distal to the lateral epicondyle, the other on the posterior forearm 2 inches proximal to the wrist. The outlines of the electrodes were traced on the subjects' arms to insure that each trial was uniform for placement. Subjects' arms and wrists were placed in a neutral, relaxed position with the elbow bent to 90 degrees and the wrist at 0 degrees.

Each trial used a new set of electrodes so that there could be no degradation of the electrode between trials. Electrical stimulation was administered through a medium frequency premodulated current used for deep muscle therapy. The subjects were instructed to tell the clinician when they first experienced sensation from the electrical stimulation; this response was verbal. The milliamperage was recorded by the clinician. Then the intensity was increased until a visible muscular response was noted. This milliamperage was recorded by the clinician. Then the intensity was increased until the subject stated that they could or would take no more due to pain. This milliamperage was recorded by the clinician. This process was repeated twice more for a total of three trials per subject. Subjects were given two minutes between trials to regenerate depleted ATP stores in the muscle.

Subject #	Sensation	Motor Twitch	Pain
1	7 mA	19 mA	46 mA
1	7 mA	21 mA	42 mA
1	8 mA	21 mA	47 mA
2	7 mA	14 mA	40 mA
2	8 mA	13 mA	41 mA
2	6 mA	12 mA	40 mA
3	5 mA	24 mA	38 mA
3	6 mA	24 mA	41 mA
3	6 mA	36 mA	55 mA
4	5 mA	20 mA	42 mA
4	6 mA	23 mA	43 mA
4	5 mA	20 mA	39 mA
5	9 mA	24 mA	38 mA
5	9 mA	22 mA	34 mA
5	9 mA	19 mA	34 mA
6	8 mA	21 mA	35 mA
6	7 mA	21 mA	34 mA
6	8 mA	23 mA	35 mA

avg= 40 mA

Results of the pilot study showed that the measurements were reliable.

Appendix A-2

Electrode Use Log

Electrode Use Log

These electrodes are being used in a clinical research project. Please, follow the directions carefully and record all use of the electrodes. Thank you.

Electrodes need to be placed on the muscle belly of the wrist extensors and about 2 inches distally on the wrist extensors on the arm of the subject. The muscle belly of the wrist extensors can be found by having the subject fully extend and hold their wrist. The extensors will become prominent. (The wrist extensors originate on the lateral epicondyle and extend down the posterior forearm.)

Before applying the electrodes to the subject, clean the area of skin thoroughly with an alcohol swab. Allow the skin to air dry.

Each pair of electrodes needs to be used for eight, 15 minute treatments. Although the treatments can be immediately consecutive, it is important that the electrodes be removed and reapplied before each 15 min treatment. All eight treatments can be done on one subject or on eight different subjects, but all treatments must be recorded.

Electrode # ________________

			Subject	
Time/ use	**Intensity/ mAmp**		**M/F**	**Age**
15 min- 1st				
30 min- 2nd				
45 min- 3rd				
60 min- 4th				
75 min- 5th				
90 min- 6th				
105 min- 7th				
120 min- 8th				

After the table is filled, return the electrodes to the numbered bag and return the bag to Lucia Maloy. Thank you for your help and participation.

Appendix B

Raw Data

Average Values for Each Trial.

Subjects 1-10

MUIs	24.33	20.67	24.67	18	12	18.67	19	22.67	10	15
MUFs	38	27	37	20.67	13.67	20.33	24.33	23	14.67	17
SUs	16.67	14.67	17.33	9.333	6.667	9.333	9.333	12.33	6	6.333
MUIt	35.67	29.33	51.33	33	22.67	35	23	26.67	33.33	31.33
MUFt		33.67	56	36.33	22.67	41.5	33	39.33	33.33	37
SUt	20.67	17.67	26.67	19	10.67	19	14	14.67	18.33	17.67
MUIf	0.482	0.496	0.453	0.482	1.671	0.442	0.397	0.575	0.379	0.344
MUFf	0.367	0.353	0.348	0.359	0.33	0.317	0.362	0.34	0.34	0.322
SUf	1.77	1.551	4.176	1.748	2.082	4.441	2.896	3.006	2.465	1.681

Subjects 11-20

MUIs	15.33	11.33	9	14.67	23	20	13.33	15.33	9	21.67
MUFs	32.33	14.67	11.33	18		32.33	12.33	9	14	23.33
SUs	9.333	6.333	6.667	8	13	11	8.667	6	6	12.67
MUIt	34.67	35.33	13.33	29.33	24.67	29	23.33	24.67	19	33.33
MUFt	36		18.67		30		22	15.33	23.67	31.33
SUt	18.33	19.33	9.667	13	13	15	15	9	10.67	17
MUIf	1.878	1.904	1.7	1.976	1.465	1.595	2.285	0.415	1.314	0.313
MUFf	0.323	0.42	1.083	0.354	0.379	0.378	0.323	1.395	1.951	0.227
SUf	1.858	1.888	1.218	1.932	0.982	1.713	2.493	4.746	1.172	2.821

MUI= multiple use electrodes, initial trial
MUF= multiple use electrodes, final trial
SU= single use
s= sensory
t= muscle twitch
f= force produced

Appendix C

Future Research

Future Research

- Compare the single use electrodes with the multiple use electrodes produced by the same manufacturer
- Compare initial and final values in multiple use electrode pairs that have been used for more than a total of two hours to find signs of electrode degradation.
- Compare initial and final values in multiple use electrode pairs tested in a more clinical type setting to find signs of electrode degradation.