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The Effects of Microcurrent Stimulation in the Treatment of Lateral Epicondylitis

Justin G. Feerer

University of North Dakota

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THE EFFECTS OF MICROCURRENT STIMULATION IN THE
TREATMENT OF LATERAL EPICONDYLITIS

by

Justin G. Feeser
Bachelor of Science in Physical Therapy
University of North Dakota, 1993

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May
1994
This Independent Study Report, submitted by Justin G. Feeser in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota has been ready by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

[Signatures]

(Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
PERMISSION

Title The Effects of Microcurrent Stimulation in the Treatment of Lateral Epicondylitis

Department Physical Therapy

Degree Masters of Physical Therapy

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Signature

Date APRIL 29, 1994
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ACKNOWLEDGEMENTS

I would like to take this opportunity to thank my family, without whose support I would not be in the position that I am today. I would also like to thank Kristen, whose patience and understanding have allowed this study to be completed.

Special thanks to Erin Simunds, PT, and Cliff Lafreniere, PT, for their invaluable help in seeing this project through to fruition.
ABSTRACT

Microcurrent Electrical Neuromuscular Stimulation (MENS) is a modality that is quickly gaining popularity in the treatment of various musculoskeletal disorders. At this time, there is a lack of literature, especially well-controlled clinical studies, to support its use. The purpose of this study, therefore, is to examine the effects of MENS in the treatment of a common musculoskeletal dysfunction, lateral epicondylitis. Approximately ten subjects with a diagnosis of lateral epicondylitis were assigned either to group A, receiving MENS and conservative treatment (education, home exercise program, ice, and counterforce bracing), or group B, receiving sham MENS and conservative treatment. Subjects were seen for three initial consecutive daily visits, and then for three every-other-day visits. Data were recorded and analyzed regarding strength (grip strength and isometric wrist extension strength) and pain with strength measurements. No significant differences in these variables were found to exist between the groups, indicating that MENS provided no greater relief than placebo treatment.
CHAPTER 1
INTRODUCTION

Microcurrent Electrical Neuromuscular Stimulation (MENS) has recently begun to receive a great deal of attention from physical therapy clinicians. This relatively new modality has been proposed to be a virtual panacea by many sources, among them physicians, researchers, physical therapists, athletic trainers, manufacturers, and even professional athletes. MENS has been suggested to be effective in an almost endless range of disorders, running the gamut of acute and chronic musculoskeletal disorders.\textsuperscript{1-4} Simply put, this modality is claimed to mimic the human body's own endogenous electrical currents, and, in doing so, accelerate tissue repair.\textsuperscript{2,5} Whether or not this actually occurs is, at this point in time, debatable.

Stimulation with microampere intensity current is most often referred to as MENS in the literature and, therefore, for convenience, this term will be used by the author. To be classified as a MENS device, the instrument must deliver current below 1,000 $\mu$A ($1,000 \mu$A = 1 mA). Unlike MENS, most other electrical stimulation devices used in physical therapy deliver current in the milliamp range. To date, microcurrent stimulation can be accomplished through several
electrotherapeutic devices, delivering current with any of the following characteristics: 1) low volt, constant microamperage direct current, 2) low volt, pulsed microamperage current, or 3) high volt, monophasic pulsed current. The MENS unit utilized in this study, as well as almost all those used by physical therapy clinicians, falls under the second definition. Other typical characteristics of such devices are variable voltage (typically up to 60 V), adjustable frequencies (usually < 100 Hz), monophasic or biphasic stimulation, and long pulse durations (up to 50% of the duty cycle). Current delivery is usually through surface electrodes or probes.

Electrical activity is an inherent and indispensable characteristic of all life, from the single cell to the most complex of organisms. This electrical activity is referred to as bioelectricity, and it is upon this concept that the basis of MENS stands. A detailed discussion of bioelectricity is well beyond the scope of this project; at this time, however, a brief introduction is warranted.

One of the most important concepts in bioelectricity is the "current of injury." These currents were first observed by Galvani in 1792, and Emil Dubois-Reymond was able to make measurements of wound potential and currents in the Civil War era. In simplified terms, it was found that a voltage gradient of up to 200 mV/mm occurs between intact skin and the wound area, creating a steady current flow in
the wound of approximately 1 to 1.5 μA per mm of wound circumference.\textsuperscript{6} This current appears to act as a signal to begin the tissue repair process, and it typically is present until healing or regeneration is completed.\textsuperscript{6,7,9}

It is important to note that these currents have been found to exist almost universally, regardless of the type of wound or the type of animal. Salamanders, which exhibit an amazing talent for regeneration of lost limbs, have been invaluable in the study of injury currents. It has been demonstrated that during limb regeneration in salamanders, current of microampere intensity is present at the stump site, which, when regeneration has been completed, quickly returns to pre-amputation levels.\textsuperscript{7,9} It has also been shown that if a child’s fingertip is amputated distal to the DIP joint, complete regeneration will occur (if the stump is kept moist), with naturally occurring currents of up to 35 μA/cm\textsuperscript{2} being found at the stump site.\textsuperscript{6,7,9,10} For regeneration to occur, cells in the body must be dedifferentiated (the process by which a fully mature, specialized cell is returned to its embryonic, unspecialized state) and then, by some process, told what "type" of specialized cell to become (nerve, bone, skin, muscle, etc.). Although dedifferentiation (and in turn, differentiation) was, for many years, not believed to be possible, Dr. Robert Becker, an orthopedic surgeon who has done extensive research in the field of bioelectricity, believes that not only is the
process possible, but that he may have found what causes this phenomenon: endogenous currents of microampere intensity.\textsuperscript{9}

Research with frogs and rats (both of which, like humans, exhibit little or no regenerative abilities) has found that with the artificial application of microampere intensity currents to amputation sites, partial to full regeneration occurs, whereas normally healing would only take place via fibrosis and scarring.\textsuperscript{6,7,9} Since the body demonstrates endogenous electrical flow during injury, and since it has been shown that introduction of microampere currents into certain species can cause regeneration, an important question arises. Can the application of microampere currents enhance tissue repair in humans, and if so, is there an actual potential for regeneration in humans? At this point in time, it is doubtful that human regeneration is possible, but studies have shown that the application of microampere currents may be of therapeutic value in accelerating human tissue repair.

Before examining MENS studies involving humans, several other important studies regarding the effects of microampere current in animals warrant review. One of the most frequently cited studies in MENS literature is that of Cheng et al,\textsuperscript{11} who investigated the effects of varying intensities of current on laboratory rat skin cells (in vitro). The authors found that direct electrical currents of 10-1,000 \textmu A
intensity increased ATP production and tissue concentrations by almost 500%. At intensities of 1,000-5,000 μA, ATP generation declined sharply and was found to drop below that of control groups with intensities above 5,000 μA. Amino acid transport and protein synthesis were also found to be increased up to 30-40% with the application of 100-750 μA currents, and with currents exceeding 1,000 μA protein synthesis was found to be inhibited by almost 50% when compared to controls. The effects on these three variables, which are important in cellular health and healing, make a strong case for the effects of MENS, and also raise questions about the use of higher intensity currents commonly employed by clinicians.

Another study, utilizing exposed rabbit flexor tendons, found that with application of 7 μA currents, \(^{14}\text{C}\) proline incorporation, a measure of cellular activity, and its conversion to \(^{14}\text{C}\) hydroxyproline, an indicator of collagen synthesis, were increased 91% and 255%, respectively, over controls.\(^\text{10}\)

Owoeye, Spielholz, and Nelson\(^\text{12}\) conducted a study using tenotimized rat tendons, and found that tendons treated with anodal stimulation of 75 μA intensity had significantly higher breaking strengths than both controls and those treated with cathodal stimulation of the same intensity. A study done with divided patellar tendons of dogs also found that breaking strength was increased over controls when
using 20 μA cathodal currents. Although these studies all show an acceleration of tissue repair, further research is needed to clarify the specific parameters (regarding the intensity and polarity of the current) to employ to achieve ideal results.

Two areas in which treatment with microampere current in humans is well established is in the management of non-union fractures and in stimulation of wound healing. Not so well established is the treatment of musculoskeletal dysfunctions. Although a few well-controlled studies do exist, most suffer from a lack of true research methodology. The most prolific MENS clinical researcher, Lynn Wallace, PT, ATC, gathered data on the pain response of 1,531 patients presenting with a wide variety of musculoskeletal disorders. It was reported that 94% of the subjects experienced significant pain reduction after the initial treatment, and 90.5% were at a pain level of 0-1/10 after 10 treatments, with the average number of treatments to achieve this rating being 3.8. These results should be interpreted with caution, as there was an absence of clear methodology, placebo treatment, and control groups.

One study that did address the placebo effect involved chronic low back pain patients. Subjects received either MENS or placebo treatment, and it was found that those subjects receiving actual stimulation reported an average pain reduction 37.26% greater than controls, and, in a
follow-up study at two months, subjects who received stimulation reported a pain reduction of 75.22% as compared to 6.3% in the placebo group.

Kulig et al18 found that MENS applied post-exercise may be helpful in decreasing muscle soreness and serum CPK (an enzyme released with muscle breakdown) release into the bloodstream. Subjects who received 100 A stimulation following exercise (to the hamstring musculature) exhibited significantly reduced serum CPK at 48 hours post-exercise when compared to controls, and showed the lowest subjective rating of muscle soreness.

An unpublished study by Lurvey and Cherner22 studied the effects of MENS on edema, ROM, and pain in inversion ankle sprains. The authors report that weight bearing pain was significantly reduced in subjects receiving actual stimulation (as compared to a group receiving placebo treatment). Trends toward decreasing non-weight bearing pain and increasing ROM were found but were not significant, and no difference was found between the groups in edema reduction.

Obviously, many questions regarding the actions and efficacy of MENS are present, and much more research needs to be done before this modality can be embraced by clinicians as being truly effective. As Gersh1 states, "When an inquisitive clinician requests professional literature from a manufacturer regarding the efficacy of low
volt microcurrent stimulation, he or she is likely to be sent reams of testimonial letters from professional athletes, coaches, and team physicians attending to the miraculous healing properties of this modality. Unfortunately, copies of well controlled clinical studies from peer-reviewed journals substantiating these claims are conspicuously absent." To clinicians, this fact should be alarming, as any treatment modality should be backed by documented research prior to actual clinical utilization. To date, clinical research regarding the effects of MENS is severely lacking, and research that has been done has suffered from poor experimental design (lack of controls, clear methodology, etc.). Also, most research that has been done has focused only upon pain as an outcome measure, ignoring strength, range-of-motion, and functional return to activities. To alleviate these problems, well-controlled clinical research on MENS must be undertaken.

As research pertaining to the effects of MENS in the treatment of musculoskeletal dysfunctions is lacking, researchers must begin addressing this void. For this reason, the effects of MENS in the treatment of lateral epicondylitis was chosen to be evaluated in this study. Although some controversy exists regarding the exact pathology of epicondylitis, it is generally believed that repeated trauma to the musculo-tendinous unit (specifically that of the extensor carpi radialis brevis) causes macro and
microtears, resulting in an acute inflammatory process which often progresses to become chronic in nature.\textsuperscript{8,20-22}

Clinically, the following features may be seen: focal tenderness and inflammation over the lateral epicondylar region, gradually increasing pain with repeated active and resisted wrist and hand motions (extension, pronation, end-range flexion, and gripping actions), and decreased functional abilities of the extremity secondary to pain.\textsuperscript{8,21,23}

Many treatment regimens have been proposed to be effective in treating lateral epicondylitis, ranging from many forms of conservative care to surgical intervention.\textsuperscript{8,22,23,24} Rest,\textsuperscript{21,25,26} icing,\textsuperscript{21,25,26} and therapeutic exercise\textsuperscript{21,23,25,26} are perhaps the most widely accepted traditional treatment adjuncts in the management of this dysfunction. These modalities are usually used in conjunction with other recommended traditional conservative modalities available to the physical therapist, including friction massage,\textsuperscript{8,26} ultrasound,\textsuperscript{8,20,23,24,26} phonophoresis,\textsuperscript{23,24,26} iontophoresis,\textsuperscript{8,24} TENS,\textsuperscript{23} and counterforce bracing.\textsuperscript{22,26-29}

Although most conservative treatments are generally regarded by clinicians as being of value, little research exists supporting this assumption. Much of the support for the various conservative treatments has been clinical and anecdotal rather than empirical in nature, and most research that does exist has either been of poor design or has failed
to establish any one treatment (or combination of treatments) as superior in effectiveness. Labelle et al analyzed 185 articles (from 1966 to 1990) involving the treatment of lateral epicondylitis. Although unable to use a quantitative meta-analysis secondary to variations in treatment, selection criteria, and efficacy measures, the authors qualitatively analyzed studies which were both randomized and controlled (only 18 of the 185 articles met this criteria). A system proposed by Chalmers et al, which evaluates the design, conduct, and analysis of research (with a maximum score of 100), was used to qualitatively analyze the studies. The average score of the 18 studies was 33%, with a high of 73% and a low of 6% (70% is considered to be the minimum required for good quality controlled therapeutic research). In conclusion, the authors state "The poor quality and contradictory results of the randomized and controlled trials reported so far in the literature means that there is not enough scientific evidence to favor any particular type of treatment for acute lateral epicondylitis."

As lateral epicondylitis presents with tissue damage and resulting inflammation, pain, and decreased functional abilities, and MENS is purported to be effective in accelerating tissue repair and decreasing pain (allowing quicker return to normal activities), it follows that the efficacy of MENS in the treatment of epicondylitis warrants
review. Therefore, the purpose of this study is two-fold:
1) to help fill the current void of clinically-oriented research regarding MENS, and 2) to specifically evaluate the effectiveness of MENS in the treatment of lateral epicondylitis.
METHODS

Subjects

Twelve subjects (6 men, 6 women) with complaints of lateral epicondylitis volunteered to participate in this study. This study was reviewed, approved, and conducted in accordance with the guidelines set forth by the Institutional Review Board at the University of North Dakota (Appendix A). Subjects were evaluated during their initial visit to confirm the presence of lateral epicondylitis (evaluation form shown in Appendix B). Inclusion criteria consisted of the following: focal tenderness and/or inflammation on or near the lateral epicondyle, painful end-range wrist flexion and resisted wrist extension, and exclusion of various dysfunctions which could mimic epicondylitis (cervical radiculopathy, various shoulder or elbow pathologies, etc.). If the diagnosis was confirmed and the subject volunteered to be included into the study, an informed consent form was signed. Subjects were then randomly assigned to one of two groups: group A (3 men, 3 women; mean age = 49.5 ± 7.2 years), receiving conservative treatment and MENS, or group B (3 men, 3 women; mean age = 42 ± 6.2 years), receiving conservative treatment and sham MENS.
Instrumentation

The Visual Analogue Scale (VAS) was chosen as the method of pain measurement as it has been shown to be both more sensitive and objective than other rating scales.\textsuperscript{31-33} This scale consists of a ten-centimeter vertical line with "no pain at all" at the bottom end and "pain as bad as it could be" at the top, on which subjects place a mark as to where they feel their pain is located. Marks were measured up from the bottom of the scale and recorded in centimeters (to the nearest one-tenth).

Two separate methods of strength measurement were accomplished during the study. To measure handgrip strength, a Jamar dynamometer (Preston Co., 60 Page Rd., Clifton, NJ 07012) was used. This instrument has been shown to provide both valid and reliable measurements.\textsuperscript{34,35} For standardization, handle position was kept constant for all subjects (position #3 for males, #2 for females). Subject positioning is shown in Figure 1. All measurements were recorded in pounds of force.

To measure isometric wrist extension (depending on diagnosis) a Cybex\textsuperscript{®} 6000 isokinetic dynamometer (Cybex Division of Lumex, Inc., Ronkonkoma, NY 11779) was utilized. The following accessory attachments were used: U.B.X.T., wrist flexion/extension handle, forearm stabilization V-pad, and short input adapter (subject positioning shown in Figure 2). The isometric upper limit was set at 12 pounds, and all
Figure 1. Grip strength testing position
Figure 2. Isometric wrist extension strength testing position
measurements were recorded in foot pounds of force. Calibration was performed monthly throughout the study.

All electrical stimulation was delivered using the Myo-matic-i® (Monad corporation, 469 N. Reservoir, Pomona, CA 91767). Upon request, two sets of electrical leads, one intact and one internally shorted to prevent actual current delivery, were provided by the Monad Corporation. These were used, respectively, in group A, receiving actual stimulation, and group B, receiving sham MENS. The unit and the electrodes used (probes and pads) are shown in Figure 3.

Procedures

Subjects were seen initially for three consecutive daily visits (beginning with the initial evaluation and treatment), and three every-other-day visits following this, for a total of six treatments. After the sixth visit, subjects were discontinued from the study but continued therapy if this was deemed appropriate. All subjects received traditional conservative care throughout the study, consisting of education (posture, avoidance, protection, and rehabilitation principles), rest, icing, therapeutic exercise, and counterforce bracing using Leukotape® P high adhesive tape (Beiersdorf, Inc., 360 Dr. Martin Luther King Drive, Norwalk, CN 06856).

At the initial visit, subjects were required to view an instructional video regarding the physiological and anatomical basis of epicondylitis, factors which may
Figure 3. My-o-matic-i® electrical stimulation unit
irritate the condition (job-related, recreational, etc.), and principles of treatment for this disorder. Subjects were also given a written supplement to reinforce the principles presented in the video, and encouraged to work with the therapist to eliminate and/or modify any contributing stressors.

Pain levels, grip strength, and isometric wrist extensor strength were measured prior to treatment at the initial evaluation and each subsequent visit. ROM measurements were taken initially and monitored throughout the study, and consisted of active wrist flexion, extension, pronation, and supination.

An average grip strength was calculated using three dynamometer measurements, with subjects recording (using the VAS) their perceived pain during the strength measurements. One maximal isometric wrist extension was also performed and the results recorded, and again subjects rated their perceived pain using the VAS. Treatment at each visit consisted of MENS (actual or placebo), ice massage, counterforce bracing, and instruction in a home exercise program.

MENS was delivered via methods developed at the facility based upon recommended protocols put forth by Manley and Associates. Stimulation was initially delivered through both probes and pads, followed by ten minutes of unattended (except for current parameter
modification) pad stimulation. Subjects in the placebo group received no actual stimulation, but experienced the same electrode placements, probe techniques, and auditory and visual sensations (characteristic of the MENS unit) as those subjects receiving stimulation. Table 1 provides an in-depth description of the stimulation protocol utilized. Electrode positioning is shown in Figures 4 and 5.

Following MENS, subjects were instructed in a home exercise program, which was individualized and based upon each subject's tolerance. Gentle stretching and active range-of-motion exercises were begun for all patients at the initial visit; progression of exercises was left to the discretion of the treating therapist. Exercise instruction was followed by a five-minute ice massage to the lateral epicondylar region.

Counterforce bracing was accomplished via application of Leukotape P high adhesive tape. This method of bracing is routinely used at the facility and has initially shown good clinical results, and therefore was included into the study in an attempt to provide all subjects with effective care. Two pieces of tape, 1 1/2" wide and approximately 4-5" long, were applied as follows: 1) each piece of tape was applied approximately 1" distal to the cubital crease, 2) one tape strip started on the most palpable ridge of the radius and the other on the most palpable ridge of the ulna. The medial piece of tape was then pulled over and
Table 1. MENS protocol (listed in sequential, descending order)

<table>
<thead>
<tr>
<th>Method</th>
<th>Settings</th>
<th>Technique</th>
<th>Muscles treated</th>
<th>Time</th>
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<tr>
<td>Probes and Pads</td>
<td>30 Hz</td>
<td>GTO&lt;sup&gt;c&lt;/sup&gt; (1 time only)</td>
<td>Biceps,</td>
<td>as needed</td>
</tr>
<tr>
<td></td>
<td>100 A</td>
<td></td>
<td>triceps,</td>
<td></td>
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<tr>
<td></td>
<td>waveslope 1</td>
<td></td>
<td>anconeus,</td>
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<td></td>
<td></td>
<td></td>
<td>pronator teres,</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>brachialis</td>
<td></td>
</tr>
<tr>
<td>Probes and Pads</td>
<td>30 Hz</td>
<td>GTO&lt;sup&gt;c&lt;/sup&gt; (3 times)</td>
<td>wrist extensors</td>
<td>as needed</td>
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<td>waveslope 1</td>
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<tr>
<td>Probes and Pads</td>
<td>30 Hz</td>
<td>EMR&lt;sup&gt;d&lt;/sup&gt; (3 times)</td>
<td>wrist extensors</td>
<td>as needed</td>
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<td>100 A</td>
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<td>.3 Hz</td>
<td>Pad</td>
<td>Elbow Region</td>
<td>10 minutes</td>
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<td></td>
<td>40 A</td>
<td>stimulatio</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>waveslope 1</td>
<td></td>
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</table>

<sup>a</sup> Probes consisted of probe applicators in contact with the wetted end of a Q-tip; pads consisted of 1" X 2" black carbon electrodes (2) and were placed over the lateral and medial epicondyles of the humerus.

<sup>b</sup> Pads consisted of 1" X 2" black carbon electrodes (2) and were placed over the lateral and medial epicondyles of the humerus.

<sup>c</sup> Golgi Tendon Organ technique (GTO): simultaneous stimulation, using probes, of the origin and insertion of a specific muscle for 15 seconds.

<sup>d</sup> Enhancement of Muscle Re-education technique (EMR): stimulation along entire muscle length, probes perpendicular to muscle fibers, 5 seconds every 1/2" (probes approximately 1-1 1/2").
Figure 4. Electrode placement #1
Figure 5. Electrode placement #2
approximated on the lateral piece, which was then pulled medially and secured circumferentially around the forearm (although not fully encircling the forearm). Positioning of the tape is shown in Figures 6 and 7. Subjects were instructed to wear the tape until the following session, unless removal of the tape was warranted by discomfort or symptoms of an allergic reaction or excessive constriction (redness, swelling, paraesthesias, discoloration, etc.).

Data Analysis

As previously mentioned, data regarding strength and pain were recorded at each treatment session. Only data recorded on the initial and final treatment sessions were used for statistical analysis, to reflect the overall effect of the intervention. The mean for each variable (initial grip strength and pain, initial isometric strength and pain, final grip strength and pain, final isometric strength and pain) was calculated, and, using student t-tests, compared group-to-group to determine any significant differences ($\alpha = .05$, $t = 2.228$, df = 10). Also, final vs initial treatment values were calculated for each of the four variables for all subjects and, from this data, mean differences for each variable were calculated and compared group-to-group, again using student t-tests ($\alpha = .05$, $t = 2.228$, df = 10).
Figure 6. Counterforce brace tape placement #1
Figure 7. Counterforce brace tape placement #2
RESULTS

As Table 2 shows, no significant differences were found between the groups when comparing initial and final variable values. Although statistically insignificant, group B began with a lower grip strength reading than group A but began with a higher isometric measurement and lower pain ratings on both grip strength and isometric strength measurements. Group B also finished with higher grip and isometric strength measurements, and lower final pain levels for both measurements. These results are also illustrated in Figure 8.

In regard to inter-group differences between the initial and final treatments, again no statistically significant differences were found (see Table 3). Group B exhibited a large increase in grip strength compared to a small decrease in group A, and also demonstrated a greater decrease in pain with both grip strength and isometric measurements, while group A showed a slightly higher increase in isometric wrist extension. These results are graphically represented in Figure 9.
Table 2. Mean initial and final pain and strength values with the corresponding t values for each group

<table>
<thead>
<tr>
<th></th>
<th>Initial(^a) grip strenth</th>
<th>Final(^a) grip strenth</th>
<th>Initial(^b) grip pain</th>
<th>Final(^b) grip pain</th>
<th>Initial(^c) isom. strenth</th>
<th>Final(^c) isom. strenth</th>
<th>Initial(^b) isom. pain</th>
<th>Initial(^b) isom. strenth</th>
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<tr>
<td>Group A</td>
<td>88.133</td>
<td>88.100</td>
<td>4.283</td>
<td>3.317</td>
<td>4.000</td>
<td>5.667</td>
<td>5.667</td>
<td>3.917</td>
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<tr>
<td>Group B</td>
<td>77.867</td>
<td>99.233</td>
<td>2.583</td>
<td>1.050</td>
<td>5.500</td>
<td>7.000</td>
<td>4.300</td>
<td>2.05</td>
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<tr>
<td>t value</td>
<td>.63</td>
<td>-.70</td>
<td>1.23</td>
<td>2.12</td>
<td>-.95</td>
<td>-.79</td>
<td>1.03</td>
<td>1.26</td>
</tr>
</tbody>
</table>

\* \(\alpha = .05\), two-tailed test, \(t = 2.228\), df = 10

\(^a\) All grip strength values are in pounds of force.

\(^b\) All pain measurements recorded in centimeters (10 cm maximum).

\(^c\) All isometric measurements are in foot pounds of force.
<table>
<thead>
<tr>
<th>Group</th>
<th>Initial Grip Strength (pounds)</th>
<th>Final Grip Strength (pounds)</th>
<th>Initial Grip Pain (cm)</th>
<th>Final Grip Pain (cm)</th>
<th>Initial Isometric Strength (ft. #s)</th>
<th>Final Isometric Strength (ft. #s)</th>
<th>Initial Isometric Pain (cm)</th>
<th>Final Isometric Pain (cm)</th>
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<tr>
<td>Group A (MENS)</td>
<td>90</td>
<td>80</td>
<td>80</td>
<td>70</td>
<td>60</td>
<td>50</td>
<td>40</td>
<td>30</td>
</tr>
<tr>
<td>Group B (placebo)</td>
<td>70</td>
<td>60</td>
<td>60</td>
<td>50</td>
<td>40</td>
<td>30</td>
<td>20</td>
<td>10</td>
</tr>
</tbody>
</table>

**Figure 8.** Comparison of mean initial and final strength and pain values
Table 3. Mean strength and pain differences (final - initial treatment) for each group and their corresponding t values

<table>
<thead>
<tr>
<th></th>
<th>Grip strength&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Grip Pain&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Isometric strength&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Isometric pain&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>-.033</td>
<td>-.967</td>
<td>1.667</td>
<td>-1.750</td>
</tr>
<tr>
<td>Group B</td>
<td>21.367</td>
<td>-1.533</td>
<td>1.500</td>
<td>-2.250</td>
</tr>
<tr>
<td>t value</td>
<td>-1.97</td>
<td>.34</td>
<td>.14</td>
<td>.32</td>
</tr>
</tbody>
</table>

* * = .05, two-tailed test, t = 2.228, df = 10

<sup>a</sup> All grip strength values are in pounds of force. A negative value indicates a strength decrease.

<sup>b</sup> All pain measurements are in centimeters (10 cm maximum). A negative value indicates a decrease in pain.

<sup>c</sup> All isometric measurements are in foot pounds of force. A negative value indicates a decrease in strength.
Figure 9. Comparison of mean change in strength and pain values
DISCUSSION

As the results show, no significant differences were found to exist between groups, suggesting that MENS may be no more effective in producing results than sham stimulation. Although statistically insignificant, Group B, receiving placebo stimulation, actually showed greater improvement regarding strength increases and pain decreases than those subjects receiving MENS. These results seem to contradict those reported by other clinical researchers investigating the effects of MENS in treating musculoskeletal dysfunctions. As mentioned before, very few clinical studies examining the effects of MENS in treating musculoskeletal dysfunctions exist at this time. Of the literature that is available regarding MENS (including studies, testimonials, and manufacturer's data), none has suggested MENS to be an ineffective treatment adjunct. However, as Gersh states, "Unfortunately, copies of well-controlled clinical studies from peer-reviewed professional journals substantiating these claims are conspicuously absent." As this study refutes the findings of research that does exist, clinicians should carefully examine all of the research available.
As does all research, this study presents with several limitations, which must be discussed. First of all, our sample, secondary to its small size (n = 12), may not be truly representative of the general population. This sample size actually is comparable to that of other controlled clinical studies regarding MENS, with samples ranging n = 12 to n = 48, but still obviously may not be typical of the general population.17-19 Although this research was randomized and double-blinded, a small sample size does substantially weaken our statistical analysis. With a larger sample size, we may have found statistically significant differences between the groups, although it is impossible to predict this type of result.

Another factor that may have affected the results lies in the stage of lateral epicondylitis that was present. Through thorough history taking, it was established that all subjects presented with a dysfunction that was "chronic" in nature (all subjects reported epicondylitis being present for 6 months), but it would be impractical to assume that all subjects presented with identical stages of tendinitis. Obviously, a subject with more acute tendinitis may respond differently than someone with a dysfunction present for a longer duration, secondary to differing levels of tissue reactivity (chemical), granulation tissue deposition, and collagen synthesis, deposition, and maturation.25 As we
could not be selective of subjects, this factor was impossible to control.

A consideration related to this non-selectiveness is that it is not feasible to expect each subject to follow the same treatment program; individual differences require a somewhat "tailored" treatment progression for each subject, and this may have influenced the results. To illustrate this factor, consider two subjects: subject #5, presenting with a grip strength well below age and sex referenced norms and with complaints of great pain with grip strength measurement, and subject #3, with above average grip strength and minimal pain complaints. Obviously, treatment progression for these two individuals may differ greatly. For this reason, treatment progression was left to the discretion of the principle investigator rather than being a standardized protocol for all subjects. Although necessary and unavoidable, use of individualized treatment progressions may have influenced our data.

Another factor that may have affected the results was subject compliance with instructions and recommendations made by the treating therapist. Although subjects were questioned and reminded at every treatment session regarding previous instructions, it was impossible for the principle investigator to control a subject’s behavior after he/she left the clinic. Many subjects, secondary to work demands
or recreational activities, were unable to adequately follow rest principles and/or the prescribed home exercise program.

The final factor which may have affected our obtained results lies in the MENS treatment itself. As stated earlier, we attempted to follow treatment protocols which are currently being used. As those clinical studies that do exist regarding MENS were somewhat vague in the description of their specific treatment protocol, we cannot be sure that this study utilized the same parameters for current intensity, frequency, electrode placement, etc.

Regardless of the above limitations, clinicians should not lose sight of the finding that no significant differences existed between the two groups, and that the placebo group actually showed greater improvement in three out of the four variables measured. Investigators of MENS would do well to keep in mind the limitations present within this study, and attempt to control them in future studies. Although no research is without flaws, researchers must attempt to control extraneous variables in order to avoid prejudiced results. Of utmost importance, especially in MENS research, is complete objectivity of the investigators, who cannot allow themselves to be influenced by the large amount of pro-MENS literature available at this time. Ideally, MENS studies should be double-blind, incorporate a control group, utilize large sample sizes, and attempt to
adhere to established MENS protocols in order to fully evaluate their efficacy.
CONCLUSION

MENS has been promoted as being an effective treatment adjunct in the management of various disorders, among them musculoskeletal dysfunctions. Many in the field of physical therapy have embraced these claims and begun to utilize MENS clinically, although research to support this use is at this time somewhat sparse.

This study researched the effectiveness of MENS and traditional treatment versus placebo MENS and traditional treatment in the management of a common musculoskeletal problem, lateral epicondylitis (tennis elbow). This investigation was unable to determine any statistically significant differences between groups regarding increasing strength or decreasing pain. Therefore, we cannot say at this time that the use of MENS proved to be of any clinical benefit in this research, and we believe that its use in clinical settings should be viewed cautiously. We do not put forth that MENS should be considered wholly ineffective, but rather that further clinical trials should be conducted to determine its merit prior to widespread clinical use. As Gersh\(^1\) points out, "As members of a health care profession dedicated to the ethical and efficacious treatment of out patients, with the optimal goal of restoration of pain free
function, physical therapists should critically evaluate any innovative treatment approach, especially one whose wide and often indiscriminant use appears to be spreading widely not only among our professional colleagues but among the lay public as well."

As with any type of research, this study has raised more questions than it has answered, and hopefully will stimulate further research into the clinical applications and effectiveness of MENS.
APPENDIX A
Appendix A

EXPEDITED REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS

EXEMPT REVIEW REQUESTED UNDER ITEM ____ (NUMBER[S]) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA
HUMAN SUBJECTS REVIEW FORM
FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

PRINCIPAL INVESTIGATOR: Justin Feeser SPT
TELEPHONE: (701)-746-6153
DATE: 6/7/93

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: PT School

SCHOOL/COLLEGE: UND; Medicine
DEPARTMENT: Physical Therapy
PROPOSED PROJECT DATES: 9/1/93 - 4/1/94

PROJECT TITLE: The effects of Microcurrent stimulation in the treatment of Lateral/Medial Epicondylitis

FUNDING AGENCIES (IF APPLICABLE): N/A

TYPE OF PROJECT:
NEW PROJECT CONTINUATION RENEWAL DISSERTATION/THESIS
STUDENT RESEARCH PROJECT CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISOR, OR STUDENT ADVISOR: Erin Simunds MS, PT

PROPOSED PROJECT:
INVOLVES NEW DRUGS INVOLVES NON-APPROVED USE OF DRUG
ININVOLVES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE CLASSIFICATION(S):
MINORS (< 18 YEARS) PREGNANT WOMEN MENTALLY DISABLED
FETUSES MENTALLY RETARDED PRISONERS ABORTUSES
UND STUDENTS (> 18 YEARS)
1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.)

Microcurrent Electrical Stimulation (or MENS, Microcurrent Electrical Neuromuscular Stimulation, as it is commonly referred to as) is a modality that is quickly gaining popularity in the treatment of various disorders, especially those that present with inflammation. MENS proponents believe that tissue repair in the body is accelerated with the use of MENS currents, since these currents are similar in intensity to those found at the cellular level in the human body. While many physical therapy clinicians believe this to be true, there is a lack of literature, especially well-controlled clinical studies, to support this hypothesis. The purpose of this study, therefore, is to determine the effects of MENS (accompanied by traditional rehabilitation protocols) in the treatment of Medial and/or Lateral Epicondylitis.

Approximately thirty subjects will be randomly assigned to one of two treatment groups. Both groups (A & B) will receive traditional treatment, including instruction in exercises, icing and friction massage, but only group A will receive true MENS stimulation. Group B subjects will experience electrode placement and auditory and visual sensations from the MENS unit, but will receive no actual electrical current. Clinical data relating to pain, strength, and range-of-motion will be taken at specified times from each subject during the course of the study. The data will then be statistically analyzed to determine the effectiveness of MENS as a treatment modality. Human subjects are required because proposed benefits resulting from this study will be utilized clinically.
PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate, attach sections from your proposal (if seeking outside funding.)

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

Approximately thirty subjects, ages 16-70, with a diagnosis of either medial or lateral epicondylitis, will be selected upon referral from a participating physician. All subjects will be recruited on a voluntary basis and will sign a prepared consent form (subjects under 18 years of age will also require a parent/guardian signature to participate.)

Epicondylitis is a term that is used to describe either an acute or chronic strain of tendinous structures attaching to bone. This strain can result from sudden injury, but is most often seen in cases of overuse, and results in inflammation and pain in and around the affected structures. In Medial epicondylitis, the common tendon of the flexor musculature of the forearm, which attaches to the medial epicondyle, is affected. In Lateral Epicondylitis, the common tendon of the extensor musculature of the forearm, which attaches to the lateral epicondyle, is affected.

Subjects will be randomly assigned to either group A, receiving actual MENS, or group B, receiving placebo MENS. All subjects will initially undergo an evaluation in order to confirm the diagnosis, identify any possible underlying contributing factors, and establish baseline clinical data. Subjects will be included into the study if the diagnosis is confirmed using general physical therapy procedures and specific special tests to identify epicondylitis, and will be excluded from participating if any other disorder is felt to be responsible for the subject’s symptoms. Following the initial evaluation, subjects will receive the MENS treatment (actual or sham, depending on group), followed by additional data collection and further treatment, consisting of 5 minute transverse friction massage and 4 minute ice massage to the involved area. Subjects will then be instructed in a standardized stretching and strengthening program, which will be progressed at subsequent treatment sessions per patient tolerance (see Appendix A for further description of this program). This exercise program should be completed two to three times per day, and followed by a 4-5 minute ice massage. Subjects will be seen for approximately two weeks, daily (if possible for the subject) for the first 3 days, and then every other day for the remainder of their participation. Subjects may be discharged from the study and treatment if treatment is no longer deemed necessary.

All MENS will be delivered using the My-o-matic-i, a MENS unit produced by the Monad Corporation (469 North Reservoir, Pomona, CA 91767). The MENS treatment will consist of the following protocol, which is based upon much of the MENS literature today. Electrodes (four 2x2 inch black carbon electrodes) will be placed around the elbow region over the cubital fossa, the olecranon process, and just anterior and distal to both the medial and lateral epicondyles of the humerus. Ultrasound gel will be applied between the electrode and skin interface to enhance current transmission. Subjects (group A) will receive current for the initial 20 minutes with the following settings: frequency of 30 Hz, biphasic current of 100 A intensity, waveslope of setting 10. These settings have been reported to have analgesic properties in the literature. For the final 15 minutes of MENS treatment, the settings will be changed to the following: frequency of .3 Hz, biphasic current at 40 A, waveslope setting of 1. These Settings are purported to be more useful in initiating the healing process. It is to be stressed that all current in this study will be delivered at levels that will be sub-sensory to the subject. It is also important to note that subjects in group B, although not receiving actual
current, will receive electrode placement and auditory and visual stimuli characteristic of the MENS unit.

Clinical data collection will consist of pain, strength, and range-of-motion (ROM) measurements, which will be recorded at every treatment session prior to and following MENS.

Pain and strength measurements will be taken concurrently, as subjects will be asked to perform three maximal handgrips on a Jamar handgrip dynamometer, from which a mean will be calculated.¹ Strength measurements will be taken directly from the dynamometer (which has documented validity and reliability), and the subject will be asked to rate his/her worst pain during these contractions using the visual analogue scale (VAS), which has been shown to be more objective and reliable in assessing pain intensity than a numeric scale.² ROM measurements will be taken using a common hand-held goniometer, which also has proven reliability and validity.³

Clinical data will be statistically analyzed using t-tests for 2 independent samples and the results will be reported in aggregate form. To maintain confidentiality, the subject’s name will not be included anywhere in the report or mentioned to anyone not directly involved with the study. Subjects will be asked not to discuss the study with other participants until the study has been completed.

3. **BENEFITS:** (Describe the benefits to the individual or society.)

   Possible benefits to the subject include, but are not limited to, relief of the symptoms of medial/lateral epicondylitis. Possible benefits to society include: research supporting the use of a modality that is commonly being used now with little supporting research, and stimulation of further investigation regarding this modality.

4. **RISKS:** (Describe the risks to the subject and the precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risk to the subject’s dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

   Risks to subjects in this study will be minimal. Subjects should not experience an exacerbation of their pain, although slight muscular soreness may occur after completion of the initial evaluation and the prescribed exercises. As all subjects, regardless of group, will receive traditional conservative treatment, most should experience improvement over the course of the study.

   Data will be collected in a confidential manner. All subjects will be coded numerically and their names withheld to maintain strict confidentiality (see data collection sheet in Appendix B), and data will be kept in Erin Simund’s office, room 146, Medical Sciences North building, for a period of two years.
5. CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur. Describe where signed consent forms will be kept and for what period of time.

Consent forms will be kept by Erin Simunds in room 146, Medical Sciences North building, for a period of two years.

6. For FULL IRB REVIEW forward a signed original and twelve (12) copies of this completed form, and where applicable, twelve (12) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Box 8138, University Station
Grand Forks, North Dakota 58202

On Campus, mail to: Office of Research and program Development, Box 134, or drop it off at Room 101 Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University’s policies and procedures governing the use of human subjects.

SIGNATURES:

_____________________________ DATE: __________
Principal Investigator

_____________________________ DATE: __________
Project Director or Student Advisor

_____________________________ DATE: __________
Training or Center Grant Director

8/1992)

(Revised
Appendix A

Home Exercise Program

All subjects will be instructed in a home exercise program at the initial evaluation and treatment, and will be asked to complete this program 2-3 times per day during the study. These exercises will be reviewed at every treatment session and progressed per patient tolerance.

The exercise program will begin with stretching of the affected musculature and tendinous insertions. Subjects will be instructed in proper stretching techniques for the wrist extensors and flexors, as well as any other "problem" identified by the researchers.

As pain decreases, subjects will be asked to add strengthening exercises to the home program. Initially, isometric wrist flexion and extension (with the wrist in the neutral position and the elbow flexed to 90 to reduce strain) will be performed. As tolerances allow, gradually higher demands will be placed upon the affected musculo-tendinous unit by performing isotonic exercises such as those listed below.

Subjects will be progressed per tolerance as to avoid exacerbation of symptoms, and will be instructed to perform a 4-5 minute ice massage at the completion of the exercises. The stretching and strengthening exercises that will be used are designed to fully rehabilitate the subject's injury and prevent further reoccurrence of symptoms.

Proposed exercises:

- Wrist extensor stretch
- Wrist flexor stretch
- Isometric wrist extensor strengthening
- Isometric wrist flexor strengthening
- Progressive isotonic strengthening:
  - Wrist flexion, extension, pronation, supination, radial deviation
  - Broomstick curls (wrist flexors and extensors)
  - Bicep curls, tricep extensions
Appendix B

**Subject Data Sheet**

Subject # __
Group ___

Date

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<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
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<tr>
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<tr>
<td>Pain</td>
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</tr>
<tr>
<td>Wrist F.</td>
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</tr>
<tr>
<td>Wrist E.</td>
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<tr>
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<td>Supination</td>
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Notes:
Appendix B

MENS study - Evaluation form

Name: ___________________________ Date: __________________
Pt. #: __________________________
Rx group: ______
Hx:
   Occupation: ________________ Currently working?

When and how did pain start?

Have you had this pain before?

If there is prior history, when was the last pain-free period?

Other significant Hx:

Meds:

Objective
   * Cervical screen: (ROM, McKenzie quickie)

   * Shoulder screen: (ROM, impingement, speed’s, RROM in neutral)

   * Elbow: (ROM)

   * Epicondylitis differential tests:

Measurements:
   Take all objective measurements (ROM, dynamometer & Cybex strength, pain) on
daily survey sheet and master sheet.
Plan: Pt. will be treated as per MENS study protocol utilizing instruction and education, ice, taping, therapeutic exercise (stretching and strengthening), and MENS (dependent on group assignment). Pt. will be seen daily for the first three days, and every other day following this for a two week period (dependent on pt's ability to be seen).

STG (1 week):

LTG (2 weeks):

________________________
PT signature
REFERENCES


