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THE EFFECT OF SOFT TISSUE OSCILLATION THERAPY ON THE MANAGEMENT OF PAIN ASSOCIATED WITH DELAYED ONSET MUSCLE SORENESS

An Abstract of a Thesis

Submitted

in Partial Fulfillment

of the Requirements for the Degree

Master of Science

Jenifer Ann Shoultz

University of Northern Iowa

August, 2014

ABSTRACT

Context: Soft tissue oscillation therapy is utilized in the medical profession with limited research to support its use. This study evaluates the effectiveness of soft tissue oscillation therapy on musculoskeletal pain associated with DOMS, among a healthy, physically active population. <u>Objective:</u> Evaluate the efficacy of soft tissue oscillation therapy compared to a placebo in the management of pain associated with musculoskeletal injury. Design: Experimental Crossover, Repeated Measure Design. Participants: Thirty physically active volunteers with a mean age 21.30 ± 1.47 . Methods: Participants were induced with delayed onset muscle soreness to their elbow flexors of the non-dominant arm. Participants were randomly divided into two groups; soft tissue oscillation group or placebo group. Participants received treatment in 24 hour increments for a total of 5 treatment sessions or until pain was reported as resolved. Main Outcome Measures: Reported pain via Numeric Rating Scale (NRS). Three ANOVA tests were conducted. Alpha was set a priori at .05. Results: DOMS was deemed induced to the participants' non-dominant arms and the non-dominant arm had a significant increase in pain 48 hours after the induction of DOMS (t (29) = 12.0, p < 0.05). No treatment effect was found (F(1, 28) = 0.06, p > 0.05), but there was a significant time effect (F(4, 112) =87.6, p < 0.05), indicating that the pain reported in the non-dominant arm decreased significantly over time, regardless of treatment. Conclusion: Based on the results, there is no significant effect of pain reduction associated with DOMS due to the treatment. Soft tissue oscillation and the placebo group had no effect on the reduction of pain, instead pain resolved itself over time, following the transient nature of DOMS. Soft tissue

oscillation therapy was not found to be a successful treatment for muscular skeletal injuries, specifically DOMS.

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APPROVAL PAGE

This Study by: Jenifer Ann Shoultz

Entitled: The effect of soft tissue oscillation therapy on the management of pain associated with delayed onset muscle soreness

has been approved as meeting the thesis requirement for the

Degree of Master of Science in Athletic Training

Date	Dr. Kelli Snyder, Chair, Thesis Committee
Date	Dr. Todd A. Evans, Thesis Committee Member
Date	Dr. Peter J. Neibert, Thesis Committee Member
Date	Dr. Michael J. Licari, Dean, Graduate College

DEDICATION

I would like to dedicate this thesis to my family: my parents, Debra and Douglas Shoultz; grandparents, Dorothy and Ronald Wetherbee; sister and brother-in-law Michelle and Nick Bloom; and my boyfriend Kyle McHugh. Your love, motivation, and guidance have made my continued education possible. Thank you for the support!

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INTRODUCTION

Pain is a primary reason that patients seek medical attention. Pain is used as a defense mechanism to warn the body of potential danger or injury and is a common cause for an individual to seek medical assistance (Ragan, 2013; Woolf & Mannion, 1999). People seek medical assistance because of pain since it may hinder the ability to perform daily living activities. The priority of health care professionals is to stabilize life threatening injuries and then focus on the next priority, which is to manage and reduce pain (Prentice, 2011a). Multiple techniques have been used in the past to treat pain and some of these have been examined to determine their effectiveness. Pain is a subjective experience that is perceived differently between individuals, which causes difficulty in the measurement and management of pain (Noble et al., 2005).

Various instruments have been used to measure pain (Aliyev, 2009; Dolan et al., 2005; Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011; Hertel, 1997; Jahr, Schoppe, & Reisshauer, 2008; Smith, Kruger, Smith, & Myburgh, 2008). Each form of measurement is viewed as subjective since the clinician must gather this information from the patient. Pain cannot be measured using tangible measuring instruments (Noble et al., 2005). The Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Verbal Rating Scale (VRS), Face Pain Scale (FPS), and the McGill Pain Questionnaire are common pain measurement instruments which are utilized in the clinical and research setting (Ferreira-Valente et al., 2011; Melzack, 1975; Streator, Ingersoll, & Knight, 1995). The Visual Analog Scale (VAS) is a tool which consists of a 10 cm line with descriptors on either extreme, "no pain" and "worst imaginable pain." The VAS is commonly used in research

based on the instrument's validity and reliability (Bijur, Latimer, & Gallaher, 2003; Bijur, Silver, & Gallaher, 2001; Björkstén, Boquist, Talbäck, & Edling, 1999; Ferreira-Valente et al., 2011). The Numerical Rating Scale (NRS) is similar to the VAS, but instead of descriptors on either extreme, pain is reported based on a numerical representation. The NRS is an 11 point scale which consists of equal intervals from 0-10, 0 representing "no pain" and 10 representing "worst imaginable pain" (Bijur et al., 2003; Ferreira-Valente et al., 2011). When compared to the VAS, the NRS has been found to be more user friendly to patients as it is easier for patients to understand and complete (Ferreira-Valente et al., 2011). The Verbal Rating Scale (VRS) combines the VAS and NRS by incorporating both verbal descriptors and numerical rankings. The Face Pain Scale (FPS) is commonly used with pediatric patients or individuals with significant cognitive impairment, who may not be able to associate a number with the degree of pain experienced (Ferreira-Valente et al., 2011; Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001; Kim & Buschmann, 2006). The FPS assesses the intensity of a patient's pain using a self-reported measure where the individual correlates the pain they are experiencing to a visual picture of a face (Hicks et al., 2001). The McGill Pain Questionnaire is another reliable and validated instrument which uses words to describe the pain itself, as well as the location of the pain (Melzack, 1975; Streator et al., 1995). Although evidence does support the reliability and validity for each of these pain measurement instruments among various populations, each has its own strengths and weaknesses (Bijur et al., 2003; Bijur et al., 2001; Ferreira-Valente et al., 2011; Hicks et al., 2001; Jamison et al., 2002; Kim & Buschmann, 2006; Melzack, 1975; Melzack & Wall, 2008a; Ragan, 2013; Williamson &

Hoggart, 2005). A reliable and valid instrument for measurement of pain is crucial when evaluating pain management interventions.

One of the purposes of measuring pain is to determine the effectiveness of interventions used to manage pain. Therefore, pain management is a common interest of researchers and clinicians with an emphasis on the effectiveness of pain management interventions. Many treatments have been used to manage pain. Several of these interventions have been tested in previous studies, which include medications and other electrotherapeutic modalities (Aliyev, 2009; Dolan et al., 2005; Hertel, 1997; Jahr et al., 2008; Paoloni, Milne, Orchard, & Hamilton, 2009; Smith et al., 2008). Research has found medications such as over-the-counter non-steroidal anti-inflammatory drugs (NSAIDS) to be detrimental to the healing process if taken at inappropriate times, lengths, or dosages (Dolan et al., 2005; Hertel, 1997; Smith et al., 2008). Two nonpharmaceutical treatments used to manage pain include the ultrasound and electrical stimulation modalities (Butterfield et al., 1997; Dolan et al., 2005). These modalities are often used in the clinical setting, even though there is little or no evidence to support the efficacy of these interventions.

One modality that lacks empirical evidence to support its clinical use is known as soft tissue oscillation therapy. This modality was developed in Germany and is now being used in the United States. Unfortunately, soft tissue oscillation therapy is being used to treat orthopedic injuries without evidence of its effectiveness. Previous research has shown soft tissue oscillation therapy to be effective when treating lymphedema, drainage, edema, muscle extensibility, burns and managing pain, but limited research has been conducted to examine its effectiveness on orthopedic injuries (Aliyev, 2009; Hinman, Lundy, Perry, Robbins, & Viertel, 2013; Jahr et al., 2008; Jones, 2012; Kraft, Kanter, & Janik, 2013; Tápanes et al., 2010). After soft tissue oscillation treatment, patients with lymphedema, edema, and burns have reported a significant decrease in pain (Aliyev, 2009; Jahr et al., 2008; Jones, 2012; Kraft et al., 2013; Tápanes et al., 2010). However, these studies involved a limited patient sample. With only limited research it is clear that this modality needs to be explored more intensively to assist clinicians when making informed decisions in regards to utilizing this therapeutic modality. In order to determine if a modality, rehabilitation technique, or other treatment should be used on a patient it is important for a clinician to gather as much information as possible to make an educated decision. In order to provide optimal patient care, clinicians should use the best available evidence to make educated decisions; this is accomplished by utilizing evidence based Medicine (EBM).

Evidence based medicine is the combination of a clinician's past experiences, knowledge of pathologies, current literature or research, and patient values to make important medical decisions and allows clinicians to deliver the most optimal care to patients (Cormick, 2002; Snyder, McLeod, & Sauers, 2007; Snyder et al., 2008; Steves & Hootman, 2004). This assists the medical professionals in providing the most efficient and effective treatment to maximize the patient's overall health (Brown, 2013; Prentice, 2011a). The practice of evidence is achieved when external clinical evidence is collaborated with systematic research in order to provide care to a patient (Prentice, 2011a). External evidence is used clinically to review the basic science of medicine and clinical research involving patients to evaluate the accuracy and precision of current preventive, therapeutic, and rehabilitation techniques (McKeon, Medina, & Hertel, 2006). In order to determine if a modality, rehabilitation technique, or treatment should be utilized on a patient it is important for a clinician to gather as much information as possible to make an educated decision. In other words, all therapeutic interventions must have external clinical evidence to determine their clinical efficacy. Soft tissue oscillation therapy is one of the modalities which lack external clinical evidence to support its use and determine its effectiveness.

When examining soft tissue oscillation therapy, the first step is to assess the modality itself since there is limited external clinical evidence. This modality needs to be explored on a model population to insure effectiveness with orthopedically injured populations. Since pain management is a priority among medical professionals in emergency and rehabilitation situations, it is logical that pain is an important outcome to assess. One way to explore the effect of soft tissue oscillation therapy on pain management is to induce delayed onset muscle soreness (DOMS) onto a population of healthy individuals and assess if the level of pain is reduced with the use of the modality. DOMS is a controlled method to noninvasively induce pain, but can also be acquired in nature among physically active individuals by overusing muscles (Cheung, Hume, & Maxwell, 2003; Close, Ashton, McArdle, & MacLaren, 2005). In past research, DOMS has been utilized as a common model to assess pain management (Butterfield et al., 1997; Clarkson & Tremblay, 1988; Cleak & Eston, 1992; Croisier et al., 1996; Ernst, 1998; Hilbert, Sforzo, & Swensen, 2003; Isabell, Durrant, Myrer, & Anderson, 1992;

Kuligowski, Lephart, Giannantonio, & Blanc, 1998; Prasartwuth, Taylor, & Gandevia, 2005; Schwane, Johnson, Vandenakker, & Armstrong, 1983).

Therefore, the purpose of the present study is to assess the effectiveness of soft tissue oscillation therapy on musculoskeletal pain associated with DOMS, among a healthy, physically active population.

METHODS

Research Design

This study was conducted using an experimental crossover, repeated measure design. The independent variables were the treatments (soft tissue oscillation and placebo) and time (pre test, post test). The dependent variable was pain intensity as quantified by the Numeric Rating Scale (NRS).

Research Participants

Participants were recruited from health, physical education, athletic training, and leisure services classrooms at a Midwestern Division I university. Thirty-one healthy volunteers who were engaged in regular physical activity were recruited to participate in this study. Healthy physical activity was defined as moderate-intensity aerobic physical activity for a minimum of 30 minutes a day, 5 days a week or a vigorous intensity aerobic activity for a minimum of 20 minutes a day, 3 days a week (Haskell et al., 2007). The individuals may have combined these activity levels to meet the specified guidelines (Haskell et al., 2007). A total of 30 participants (14 male, 17 female) completed all necessary treatment sessions and were included in data analysis. The participants ranged in age from 18-24 years with a mean age of 21.30 ± 1.47 .

A description of the study was given to the students, along with a list of inclusion and exclusion criteria. The risks were also discussed in the description of the study. The inclusion criteria included: age of 18-30 years, no participation in a current upper extremity weight training regimen incorporating extensive amounts of bicep curls, and fulfill the healthy physical activity guidelines (Haskell et al., 2007; Kuligowski et al., 1998). Exclusion criteria included: pregnancy, malignancy, history of rhabdomyolysis, infections of skin or joint, tuberculosis, cardiac disease, cardiac pacemaker or other implanted stimulators, surgery or injury to the area being treated in the last 6 months, sensitivity to electric fields, and a history of severe adverse effects from weight lifting (Guffey, 2007). The students were informed that during their participation in the study they would be given instructions to not use analgesics throughout the duration of the study (i.e. massage, apply ice, exercise, stretch, take any pain medication or use any other modalities) and to avoid exercise (i.e. weight lifting, cardio, etc.). The students that were interested in participating in the study and believed that they fulfilled the requirements were directed to leave their contact information including name, email address, and phone number, on a flier provided by the researcher. If deemed eligible for the study, the individual was notified via email or phone and the six sessions were scheduled.

Instrumentation

Dynatron X5TM Soft Tissue Oscillation Therapy

The soft oscillation therapy was performed using a Dynatron X5TM Soft Tissue Oscillation Therapy Unit (Dynatronics Corporation, Salt Lake City, UT). According to recommendations from the user manual, the Dynatron X5TM was set at the parameters for acute pain management (Guffey, 2007). For the purpose of maintaining consistency and control of this study, the treatment parameters were set at 200 Hz for 15 minutes.

Numeric Rating Scale

The participant's subjective pain intensity was measured using the 11 point Numerical Rating Scale (NRS) from 0-10 (0 = no pain, 10 = worst possible pain). The participant used a line with number indicators to quantify their pain level by circling the number which best represented their pain (Appendix C).

Health History Form

Participants completed a health history form to identify inclusion and exclusion criteria, including information pertaining to their physical activity level, current health status, and demographics including height, weight, age, and gender. Participants who had a current health or injury issue were asked to elaborate on the condition (Appendix C).

Exit Interview Questionnaire

At the conclusion of the participant's final session, each participant was asked to complete an exit interview questionnaire to help identify if the instructions given throughout the study were followed and collect their thoughts on each of the treatment sessions (Appendix C).

Procedures for Collecting Data

Requirements established by the Institutional Review Board at a Division I college were satisfied prior to data collection. Data collection occurred during six sessions. The first session included informed consent, health history, the DOMS-inducing procedures, and subjective pain measurements. When the participant first arrived another brief overview of the study was given including possible risks and

instructions to follow throughout the study. The instructions that were given requested that the participants not use analgesics throughout the duration of the study (i.e. massage, apply ice, exercise, stretch, take any pain medication or use any other modalities) and to avoid exercise (i.e. weight lifting, cardio, etc.). Then the participant was asked to complete an informed written consent form elaborating on the procedures and risks of the study, as well as their consent to participate. The health history form was then completed by the participant to reevaluate their eligibility for the study based on inclusion and exclusion requirements. The content of the health history form also included demographics. The participant was excluded from the study if they fulfilled any of the exclusion criteria. Once declared eligible by the researcher, the data collection for the first session began.

A baseline test to measure pain intensity was administered and the participant subjectively rated their pain of both arms using an 11 point Numerical Rating Scale (NRS) from 1-10. (0 = no pain, 10 = most severe pain). The participant sat behind a bench which supported the upper arm and prevented hyperextension (Figure 1). The participant performed two biceps curls with a 2.27 kg (5lb) weight and then circled the appropriate number on the NRS to rate their pain. This protocol was utilized throughout the study to assess the participants' pain.



Figure 1. Participant Position with Bench

Next, the participant underwent a DOMS- inducing protocol of the elbow flexors on the non-dominant arm. Throughout this protocol, the participant sat behind a bench which supported the upper arm to assist in preventing hyperextension of the arm (Figure 1). The DOMS protocol required the participant's 1 repetition maximum (1RM), which was determined by having the participant perform bicep curls using dumbbells in increments that increased by 2.27 kg (5lb), until the participant could no longer complete the motion for 1 repetition.

Once the participant's 1RM was determined, the DOMS protocol began with the calculated starting weight for the exercise as 1RM minus 2.27 kg (5lb). The first part of the protocol consisted of the participant performing bicep curls of their 1 RM minus 2.27kg (5lbs), 10 times followed by 30 seconds of rest. The participant continued this cycle of 10 bicep curls followed by 30 seconds of rest until fatigued. Once the participant was fatigued they were given 1 minute of rest before beginning the second part of the DOMS protocol. In the second part of the DOMS protocol, eccentric exercises of the participant's arm started in the position of full elbow flexion with the forearm supinated (Figure 2).



Figure 2. Starting Position for Eccentric Exercise.

The primary researcher placed the appropriate weight into the participant's hand, and the participant eccentrically lowered the weight into full extension of the elbow for the researcher's count of five (Kuligowski et al., 1998). The researcher removed the weight from the participant's hand and passively returned the participant's arm into the full elbow flexion starting position. Once in the starting position, the researcher returned the weight back to the participant's hand. The participant continued this cycle for 10

complete repetitions or until fatigued. Fatigue was determined when the participant could no longer complete one repetition of the exercise. If the participant became fatigued before the 10 repetitions were completed, the weight was reduced by 2.27 kg (5lb) and the 10 repetitions were resumed. After 10 repetitions were completed, the participant was given a 1 minute rest period. When the rest period concluded, the participant resumed the exercise cycle with the previous ending weight. The participant continued the exercise cycle until a total of 5 sets of 10 repetitions were completed (Kuligowski et al., 1998).

Immediately after the DOMS protocol the participant rated their pain bilaterally using the NRS. At the conclusion of the first session the participant was reminded of the instructions to avoid the use of analgesics and workouts throughout the duration of the study. The initial visit lasted no longer than 50 minutes.

Forty-eight hours following the DOMS protocol the participant met with the researcher for the second session to assess induction of DOMS and receive treatment. A bilateral pre-treatment NRS was recorded at the beginning of this session and was compared to the pre-DOMS protocol NRS. If the NRS showed an increase in pain on the non-dominate arm post-protocol and an increase when compared bilaterally, then DOMS was deemed successfully induced. Once DOMS was induced, the participants were divided into two treatment groups systematically by order of participation and sex to ensure all treatment groups contain equal numbers of males and females. For example, the first male and female participants were placed in the Treatment A group, and the second male and female were placed in Treatment B group, etc.

Treatment group A received the soft tissue oscillation treatment. The soft tissue oscillation therapy treatment involved a low frequency and a low painless intermittent electrostatic field that was applied to the participant's injured tissue, in this case the elbow flexors (Guffey, 2007). A probe was placed in the participant's hand and an electrode was placed on the palmar surface of the researcher's wrist. Baby powder was applied to the desired area to maintain dryness. The researcher wore non-latex medical gloves, which functioned as an insulator (Guffey, 2007; Jahr et al., 2008). The participant's arm was elevated and the frequency was applied as the current was delivered via the researcher's hands which moved distally to proximally over the participant's elbow flexors (Guffey, 2007; Figure 3).



Figure 3. Application of Soft Tissue Oscillation Therapy

The Dynatron X5TM soft tissue oscillation therapy claims to create a "kneading" effect on the tissue by the polarity fluctuation, which attracts and repels charged particles of the injured tissue (Guffey, 2007). The treatment parameters were set at the frequency of 200 Hz for duration of 15 minutes. In the middle of the treatment, at 7.5 minutes, the participant rated their pain using the NRS.

The treatment group B received a placebo or sham treatment. The placebo resembled the soft tissue oscillation therapy treatment, but without any frequency. No electrical stimulation was administered during the placebo treatment. The treatment lasted 15 minutes; half way through the treatment the participant rated their pain using the NRS.

The researcher administered a pre-, during-, and post-treatment NRS prior to, during, and after administering each treatment for both groups. The during-treatment NRS was recorded half way through when the treatment was being applied to the participant. All of the treatments were administered by the primary researcher, an athletic trainer with experience using the soft tissue oscillation modality. The primary researcher also administered, collected, and analyzed the NRS questionnaire data.

The participant returned for a total of six sessions, which included five sessions of treatments. The treatments were delivered in 24 hour increments. Treatment sessions occurred at 48, 72, 96, 120, and 144 hours following the DOMS induction protocol was completed. The participant continued treatments until the sixth session or their pain rating on the NRS was "0". If the participant's NRS rating reached "0" before the sixth session, their participation was considered complete and the exit interview questionnaire

was administered with a debriefing of the study. To conclude the sixth session, or the participant's last session, the researcher administered an exit interview questionnaire. The questionnaire asked the participants when their pain was most severe, if they believed the treatment assisted in reducing their pain, and which treatment session they found to be the most effective on pain reduction. The second portion of the questionnaire evaluated if the participants followed the suggested instructions that were provided at the beginning of the study. This assisted in determining if the data collected from the participant qualified for analysis. Following completion of the questionnaire, the participant had the opportunity to express any questions, comments, or concerns to the primary investigator. The final visit lasted approximately 30 minutes.

Data and Statistical Analysis

The data collected was analyzed using the statistical software SPSS with a statistical significance of p < .05. A 2 (arm) x 2 (pre/post DOMS) within-subjects factorial ANOVA was administered to compare the reported pain level scores using the NRS, to determine if DOMS was induced. A 2 (soft tissue oscillation group vs placebo group) x 5 (during each treatment session over time) mixed factorial ANOVA was calculated comparing the reported pain level scores NRS during the application of treatment for participants who had one of two treatments. A 2 (soft tissue oscillation group vs placebo groups) x 5 (prior to each daily treatment session) mixed- design ANOVA was conducted to determine if the treatment group had an effect on the pain level perceived by the participant over time. Qualitative data collected from the health history questionnaire and exit interview questionnaire were analyzed descriptively by the

primary researcher. Once a participant reported a "0" pain level on the NRS they were released from the study for their own convenience. If this occurred before the 6th session, scores were entered for the remaining sessions as "0" for purposes of data analysis. It was assumed that if pain occurred during the remaining sessions it was not due to the DOMS protocol, but rather an outside source.

RESULTS

Thirty healthy, physically active volunteers completed all necessary data collection sessions (16 females and 14 males). The participants ranged in age from 18-24 years with a mean age of $21.3 (\pm 1.5; \text{ Table 1})$. During the study, one participant was removed for lack of adherence of treatment sessions, but another participant was invited to replace the dismissed participate. The participants were asked not to use any form of analgesics throughout the duration of the study (i.e. massage, ice, heat, exercise, stretch, take any pain medication or use any other modality) and to avoid exercise (i.e. weight lifting, cardio, etc.). The majority of participants followed these suggestions (26/30,86.67%). One participant reported use of pain relieving medication for an unrelated condition. Three participants (10%) reported minimal levels of exercise as required by weather conditions and an individual's job (Table 2). There was no difference found in the pattern of pain between these individuals and the participants who did not utilize analgesics and exercise throughout the duration of this study. During the participants' last session they were asked to complete an exit questionnaire. Fifty percent (15/30) of the participants reported their pain to be most severe during the second and third session (48-72 hours after DOMS induction; Table 3). The participants also reported which day they felt the most relief of pain from the treatment; 48 hours: 7/30 (23.33%), 72 hours: 8/30 (26.67%), 96 hours: 9/30 (30%), 120 hours: 6/30 (20%) (Table 3). The participants were also asked if they believed the treatment which they received was effective at managing their pain. Out of all participants, 93% (28/30) reported they did believe the treatment was effective at managing their pain (Table 4).

Group	Sex		Age (yrs)	Standard
				Deviation (±)
	Male	Female		
STO*	70	8	21.1	1.2
Placebo	7	8	21.5	1.7
Total	14	16	21.3	1.5

Table 1. Participant Demographics

*Soft Tissue Oscillation

Group		Yes	No
STO*	Use of analgesics	1	14
	Participated in physical activity	1	14
Placebo	Use of analgesics	0	15
	Participated in	2	13
	physical activity		

*Soft Tissue Oscillation

Table 3. Partic	ipant Reported	Pain Severit	v and Relief

Group	Pain	Session	Session	Session	Session	Session	Session
		1	2	3	4	5	6
STO*	Most Severe	2	3	7	3	0	0
	Most Relief	0	5	1	6	3	0
Placebo	Most Severe	1	4	8	2	0	0
	Most Relief	0	2	7	3	3	0
Total	Most Severe	3	7	15	5	0	0
	Most Relief	0	7	8	9	6	0

* Soft Tissue Oscillation. Session 1 = DOMS induction; Session 2 = 48 hours post induction; Session 3 = 72 hours post induction; Session 4 = 96 hours post induction; Session 5 = 120 hours post induction; Session 6 = 144 hours post induction.

	Was the treatment effe	Was the treatment effective to reduce pain?		
Group	Yes	No		
STO*	14	1		
Placebo	14	1		
Total	28	2		

Table 4. Treatment Effectiveness in the Reduction of Pain

*Soft Tissue Oscillation.

Induction of DOMS

A 2 (arm) x 2 (pre/post DOMS) within-subjects factorial ANOVA was administered to compare pain level scores using the NRS. A significant interaction was observed (F(1, 29) = 144.6, p < 0.05) therefore simple effects were analyzed. There was no change in pain in the dominant arm. The analysis was not able to be produced since each subject indicated zero pain for both data collections. The non-dominant arm had a significant increase in pain 48 hours after the induction of DOMS (t(29) = 12.0, p < 0.05). This shows that DOMS was in fact deemed induced 48 hours after the DOMS protocol (Figure 4).



Figure 4. Induction of Delayed Onset Muscle Soreness.

Treatment Effect on Acute Pain

A 2 (soft tissue oscillation group vs placebo group) x 5 (during each treatment session over time) mixed factorial ANOVA was calculated comparing the pain level scores NRS for participants who had one of two treatments. There was no significant interaction (F(4, 25) = 0.35, p>0.05), therefore, main effects were analyzed. The main effect for the treatment group was not significant (F(1, 28) = .184, p > .05). Thus, it shows that the treatment group did not have any significant effect on the pain level

perceived by the participant while the treatment was being administered. There was a significant time effect (F(4, 112) = 50.2, p < 0.05). Specifically, the pain observed in the non-dominant arm reduced significantly over time, independent of the treatment, during treatment (Figure 5).



Figure 5. Mean Pain Scores (NRS) Reported During Treatment

Treatment and Time Effect on Pain

A 2 (soft tissue oscillation group vs. placebo group) x 5 (prior to each daily treatment session) mixed-design ANOVA was calculated to examine the effects of the treatment groups (treatment group vs placebo group) and time (Pre-test for 5 treatment sessions) on pain level scores NRS. No significant interaction was found between treatment group x time (F(4, 112) = 0.62, p > .05), therefore, main effects were observed. There was no treatment effect (F(1, 28) = 0.06, p > 0.05), but there was a significant time effect (F(4, 112) = 87.6, p < 0.05), indicating that the pain observed non-dominant arm reduced significantly over time (Figure 6).



Figure 6. Mean Pain Scores (NRS) Reported Pre Treatment Session
DISCUSSION

The goal of the present study was to determine the effect soft tissue oscillation therapy on musculoskeletal pain. The key finding of this investigation was that there was not a significant difference in pain with the use of the soft tissue oscillation treatment when compared to a placebo. Importantly, the only significant changes were found when analyzing the reported pain level of the participants over time. These results indicate that treatment had no effect on the musculoskeletal pain level, meaning it did not matter which treatment the participant had, their pain decreased over time.

Previous research has used DOMs as a model to assess the effectiveness of various treatments. Such treatments include, but are not limited to, cryotherapy, transcutaneous electrical nerve stimulation (TENS), electrical stimulation, massage, whirlpools, and inferential therapy (Allen, Mattacola, & Perrin, 1999; Butterfield et al., 1997; Denegar & Perrin, 1992; Hilbert et al., 2003; Kuligowski et al., 1998; Minder et al., 2002; O'Connor & Hurley, 2003). These studies have used the outcome measures of strength, range of motion, and pain to assess the effectiveness of treatments on DOMs. The present study examined the effectiveness of soft tissue oscillation therapy by measuring pain, with NRS. The results of the present study support previous findings that DOMS is a transient muscle injury (Croisier et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1983). Previous studies have found that pain and soreness related to DOMS is most severe 24-72 hours after the initial over exertion exercise (Croisier et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1983). The present study supports this statement; 50% of the participants were most

painful during the second and third session, which took place 48-72 hours after the induction of DOMS. Previous research suggests that DOMS will subside gradually 5-7 days after sustained by the exercise, which was true throughout this study (Armstrong, 1984; Cheung et al., 2003; Close et al., 2005; Croisier et al., 1996; Prasartwuth et al., 2005; Prentice, 2011b; Schwane et al., 1983). In the present study, all of the participants were pain free by the last session which was 7 days post DOMS induction.

Comparing the current study to previous studies which have examined pain resulting from DOMS, the results are similar. Since limited research has been conducted on the soft tissue oscillation modality for pain management, the closest comparison of treatment is electrotherapy, such as TENS. Previous research has been conducted to evaluate how TENS affects the pain management of DOMS. A study was conducted which utilized DOMS as a model for musculoskeletal injuries to compare the changes in perceived pain, elbow extension range of motion (ROM), and loss in strength following treatments (Denegar & Perrin, 1992). The participants were randomly assigned to one of five treatment groups: cold, TENS, cold and TENS combination, sham TENS, and control (no treatment). The participants received their assigned treatment 48 hours after the DOMS protocol. Each treatment lasted for a duration of 20 minutes, followed by static stretching. This study found an increase in perceived pain, decrease in elbow extension ROM, and a decrease in strength, 48 hours following the induction of DOM. Following treatment the cold, TENS, cold and TENS combination, and sham TENS groups showed a decrease in perceived pain. The cold, TENS, as well as the cold and TENS combination groups did show a greater decrease in perceived pain than the sham

TENS and control groups. The treatment groups which included cold resulted in a greater increase in elbow extension ROM than the other groups. No differences were found in strength following treatment between groups. This study suggests cold, TENS, and cold and TENS combination had a significant analgesic effect for DOMS (Denegar & Perrin, 1992).

A similar study was conducted which focused on evaluating three high-volt pulsed current electrical stimulation (HVPC) treatments and how they affected pain, ROM, and recovery of strength associated with DOMS (Butterfield et al., 1997). This study was a randomized masked comparison study in which participants were randomly assigned to one of two groups: HVPC group and sham HVPC group. After DOMS was induced to the participant's quadriceps muscle group, they were given three 30-minute treatment sessions (Butterfield et al., 1997). The three treatment sessions took place 24 hours, 48 hours, and 72 hours post exercise. This study found that perceived pain peaked 48 hours post exercise among both groups and neither group significantly perceived a reduction of pain 24-72 hours post exercise. The only significant pain reduction for both groups was found while the 30-minute treatment was being applied, but this reduction diminished shortly after the treatment was finished. There were no differences in ROM found between the two groups. Strength also showed no improvement in either group, but improvement was observed 48-72 hours post exercise. Both groups had the greatest loss of ROM and strength, as well as the most perceived pain, 48 hours post exercise. This study concluded that HVPC was ineffective in providing lasting pain reduction, regaining ROM, and regaining strength associated with DOMS (Butterfield et al., 1997).

When reviewing both of these studies, Denegar and Perrin (1992) found that TENS was effective in treating DOMS while Butterfield et al. (1997) found TENS was ineffective at treating DOMS. With the inconsistency of findings, research is inconclusive if TENS is effective at treating DOMS. These results coincide with the present study in the reduction of pain associated with DOMS.

Previous research has categorized DOMS as a 1st degree strain, so the standard of care is similar for both (Cheung et al., 2003; Gulick & Kimura, 1996; Safran, Seaber, & Garrett Jr, 1989). When treating DOMS, pain is used as an indicator of recovery. Likewise, pain free function is a key indicator when evaluating if an athlete is able to return to participation following a musculoskeletal injury, such as a 1st degree strain. Once full function returns with no pain or other complications, the athlete is cleared back to participation. Both function and reduction of pain are needed to return to participation. The results of this study show that the use of the soft tissue oscillation modality had no impact on the reduction of the participant's pain. Therefore, there is no justification that the soft tissue oscillation therapy will decrease the amount of time an athlete is removed from participation due to a musculoskeletal injury such as a muscle strain or DOMS.

It is important to remember that this study only focused on musculoskeletal pain when associated with DOMS. The soft tissue oscillation modality claims to assist in edema reduction, release of tissue adhesion, regaining extensibility, and relieving joint sprains and tendonitis, in addition to reduce pain due to DOMS and musculoskeletal strains. This modality may be beneficial for these other claims such as edema reduction, inflammation reduction, tissue adhesion, etc., but more research is necessary (Guffey, 2007). Specific injuries soft tissue oscillation therapy has claimed to improve include tendonitis, bursitis, joint sprains, muscle spasms, lymphedema and ligament/capsulitis adhesions, etc. (Guffey, 2007). However, there is limited research which explores the effectiveness of soft tissue oscillation therapy on these pathologies. This study could be used as a stepping stone to expand our knowledge on this modality. The majority of previous studies conducted on the soft tissue oscillation modality have focused on lymphedema. These studies have found that soft tissue oscillation has the potential to reduce lymphedema (Jahr et al., 2008; Jones, 2012). On the contrary of the current study, participants of these studies have also reported a reduction of pain. This pain reduction may be a result of the reduction of fluid from the lymphedema, creating less pressure, therefore reducing pain. There is limited research which focuses on soft tissue oscillation efficacy for musculoskeletal pathologies, but the present study found soft tissue oscillation therapy is ineffective at managing musculoskeletal pain associated with DOMS.

A study which also focused on musculoskeletal pathologies was a study reviewing the effectiveness of the soft tissue oscillation modality in comparison to ultrasound for hamstring extensibility (Hinman et al., 2013). Each participant was randomly assigned to one of two groups. Both groups received a 15 minute treatment of either therapeutic ultrasound or soft tissue oscillation. Improvement of hamstring extensibility was found among both groups when compared to the untreated leg, but neither group showed a statistically significant improvement. These results create no strong clinical relevance or justification of using either modality for the increase in extensibility for hamstrings. These results are similar to the results of the present study, but focus on muscle extensibility rather than pain. In the current study, when treatment was being applied to the participant the reported pain level was not significantly reduced regardless of the treatment group, which shows there was no acute pain relieving effect from the modality. This result was the same when the reported pain level was assessed after the treatment had been applied. Similar to the study conducted by Hinman et al. (2013), the present study indicates no justification in the use of this modality for these specific musculoskeletal pathologies. Both of these studies are clinically relevant, due to the fact they increase the knowledge based on utilizing other treatment techniques with sufficient justification of its use. Further research needs to be conducted on the soft tissue oscillation modality in order to justify its use on musculoskeletal pathologies.

The findings of this study demonstrate there is not enough justification to administer soft tissue oscillation therapy on a patient with the goal of reducing musculoskeletal pain. The soft tissue modality claims to use a combination of two approaches, including electrotherapy and stimulation and manual therapy/massage (Guffey, 2007). The use of this combination of approaches, as claimed by the manufacturer, assists with pain and increased circulation, but the results of this study refute this claim for pain management of musculoskeletal injuries such as DOMS.

The current state of evidence based research in the field of athletic training is lacking. The present study is a stepping stone for our profession to expand its knowledge base on this specific modality and creates an opportunity for future studies. Future research needs to explore the use of the soft tissue oscillation modality on other pathologies and populations. Once the soft tissue oscillation therapy's use is supported by research for a specific pathology, it then should be compared to other therapeutic interventions. By evaluating this comparison with will allow clinicians to improve their practice their practice and provide the most optimal patient outcomes. The methods of this study can provide a template for future research on pain for other modalities as well as open the door to future research on soft tissue oscillation therapy.

A limitation of the present study is the absence of a control group. The participant was their own control when determining the induction of DOMS, but there was no control group when evaluating the effectiveness of the treatment. By inducing DOMS and the pain associated with it, the ethics of a study may be questioned if no treatment is administered to the participants. Throughout the present study the primary researcher applied their hands to the participants' arm. This contact was maintained for the duration of the intervention. This direct contact on the patient's arm may have an effect on the pain sensation. To truly determine the effect of the soft tissue oscillation modality, a control group would need to be present to differentiate the power of touch in comparison to the treatment and placebo groups on the reported pain level associated with DOMS. Pain is subjective and can only be expressed by the individual who is experiencing it. Pain is a complex experience which differs from person to person. There is a psychological effect of pain, which incorporates previous experiences, and assists in our ability to cope with the pain (Melzack & Wall, 2008b). Painful experiences can also be impacted by suggestion, which reveals a placebo effect. The suggestion or thought that a treatment should assist with the pain is enough to create a placebo effect

(Melzack & Wall, 2008b). In the current study there is not a significant difference between the soft tissue oscillation group and placebo group when focusing on the reduction of pain. Even though not significant, there is a similar reduction of pain for both groups, which suggests the soft tissue oscillation therapy could have a placebo effect.

In the present study 93.33% (28/30) of the patients reported that the treatment was effective in reducing their pain. The soft tissue oscillation group and the placebo group had identical percentages of participants who reported the treatment was effective at 93.33% (14/15). These results show that regardless of the treatment group, the majority of participants experienced a reduction in their pain level. This is interesting due to the fact that the results of the study indicate there was no significant reduction in pain both while administering the treatment or after the treatment, independent from the treatment group. The touch of the primary researcher while administering the treatment may have caused such a reaction from the participants.

DOMS is often studied as a muscle injury and pain model because of its easy replication of similar neurological pain responses, but it is important to remember DOMS can be acquired in nature among physically active individuals (Cheung et al., 2003; Close et al., 2005). There may be a difference between clinically induced DOMS and DOMS found in nature. Clinically induced DOMS is very controlled and isolates a desired muscle and surrounding tissue damage, whereas DOMS found in nature is not as controlled. DOMS found in nature during physical activity and sport may incorporate multiple types of tissue damage and multiple muscle damage. There is also the chance of a difference in the degree of injury created by DOMS found in nature and there are many factors which may impact the healing progression and pain exhibited by the patient.

Future research on soft tissue oscillation therapy should focus on both laboratory and clinically based studies. Laboratory studies are needed to investigate the physiological response, with the use of blood tests, biopsies, radiographs, and MRIs. A physiological change does not always correlate with positive clinical outcomes. Clinically based research is needed to investigate outcomes including patient reported pain, range of motion, and function. Even if a modality induces positive physiological changes, it does not mean that there is enough clinically based evidence to support its use (Baker, Robertson, & Duck, 2001; Eberman, Schumacher, Niemann, Adams, & Kahanov, 2013). There is limited evidence on the degree of physiological effect that is needed to create a positive clinical effect (Baker et al., 2001; Eberman et al., 2013). Therefore, both laboratory and clinically based research is needed to justify or refute the use of the modality. A modality which demonstrates this lack of connection between physiological and clinical effects is therapeutic ultrasound.

Baker et al., (2001) conducted a review of literature to investigate if the biophysical basis for using ultrasound justifies the use of the modality. The review primarily focused on the effects therapeutic ultrasound has during reducing pain, promoting tissue healing, and promoting soft tissue extensibility. Ultrasound is known to create a thermal effect; this review found the thermal effect to be potentially detrimental and cause damage to the tissue rather than promote healing. The review of literature also found that although the ultrasound created an increase in blood flow similar to moderate exercise, it may not be sufficient to promote healing (Baker et al., 2001). Baker et al. (2001) concluded based on the literature reviewed there is insufficient physiological evidence and rationale to justify the clinical use of therapeutic ultrasound on patients, with the primary goals of reducing pain, and promoting tissue healing, or promoting soft tissue extensibility. Robertson and Baker (2001) also conducted a similar literature review which focused on investigating there is sufficient evidence to justify therapeutic ultrasound is effective. Robertson and Baker (2001) reviewed randomized controlled trials who evaluated therapeutic ultrasound use on people with pain, musculoskeletal injuries, and soft tissue lesions. It was concluded there is little evidence to justify the use of therapeutic ultrasound on patients with these pathologies. This review found limited evidence that therapeutic ultrasound is more effective than a placebo ultrasound when treating patients with pain, musculoskeletal injuries, and soft tissue lesions (Robertson & Baker, 2001). The only way to justify or refute a modality's use on patients is to utilize the combination of both physiological and clinical based evidence.

In conclusion, the present study refutes the hypothesis that soft tissue oscillation therapy will reduce reported pain level associated with DOMS. The results show there was not a significant reduction in pain with the use of the soft tissue oscillation treatment when compared to a placebo treatment. Interestingly, the only significant changes were found when analyzing the reported pain level of the participants to time passed. These results suggest that regardless of the treatment applied, there was no difference in the effect on the musculoskeletal pain level. It did not matter which treatment the participant received, their pain decreased over time. Soft tissue oscillation therapy was not effective at reducing musculoskeletal pain levels associated with DOMS in comparison to a placebo. Further research is needed to evaluate the effectiveness of this modality on other pathologies and claims made by the soft tissue oscillation modality manufactures.

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APPENDIX A

EXTENDED RATIONALE AND PURPOSE

Statement of the Problem

The purpose of this study is to assess the effectiveness of soft tissue oscillation therapy on musculoskeletal pain associated with DOMS, among a healthy, physically active population. Additionally, this study will examine the differences in pain management between the soft-tissue oscillation therapy and a placebo treatment.

Research Questions

This study will attempt to answer the following:

- 1. What is the effect of soft tissue oscillation therapy on pain management in patients with DOMS?
- 2. What effect does soft tissue oscillation therapy have on the subjective reported pain level of DOMS when compared to the placebo treatment?

Experimental Hypotheses

This study will be guided by the following hypothesis:

- 1. It is hypothesized that soft tissue oscillation therapy will cause a decrease in the self-reported pain level in patients with DOMS.
- It is hypothesized that soft tissue oscillation therapy will cause a larger decrease in the self-reported pain level of DOMS when compared to the placebo treatment.

Significance of the Study

Pain may cause hindrances in an individual's desired level of function as well as daily activities. Reducing pain allows the individual to return to activity earlier and allow the recovery time to proceed at a more rapid pace. The significance of this study is that it will contribute to our knowledge to assist in the most effective treatment for pain management for patients who suffer physical limitations due to pain. Soft tissue oscillation therapy has been used on injured and ill general populations, but there is limited research involving patients with orthopedic injuries (Aliyev, 2009; Jahr, Schoppe, & Reisshauer 2008; Jones, 2012; Tápanes et al., 2010). The research on soft tissue oscillation therapy in regards to pain management will be a useful contribution to EBP and assist clinicians in their decision process.

Delimitations

The following delimitations will guide this study:

1. The limitation of the population in regards to age, health status, and physical activity level limits the findings of this study.

2. The limited number of participants.

3. The treatments will be performed on the elbow flexors, which make the findings only applicable to this body part.

Limitations

The following limitations will be present during this study:

1. The participant's ability to naturally adapt to DOMS.

Assumptions

This study will be conducted under the following assumptions:

- 1. Participants are as physically active as they claim to be.
- 2. Since pain is subjective, it is an assumption that the participants have full motivation and are rating their pain as accurately as possible.
- 3. Participants are truthfully answering questionnaires.
- 4. Participants are accurately disclosing health status and previous health conditions.
- 5. Participants will adhere to the instructions provided.

Definition of Terms

Delayed Onset Muscle Soreness (DOMS): DOMS is a non-invasive way to induce pain which is naturally common among individuals who are active and those who overexert muscles. There are two major types of muscle soreness that can be associated with severe exercise: acute onset muscle soreness and delayed onset muscle soreness (Prentice, 2011a). Acute muscle soreness occurs when the muscles initially become fatigued. Pain and soreness related to delayed muscle soreness (DOMS) is most severe 24-72 hour after the initial overexertion exercise and then will begin to gradually subside the next few days (Croisier et al., 1996; Prasartwuth, Taylor, & Gandevia, 2005; Prentice, 2011a; Schwane, Johnson, Vandenakker, & Armstrong, 1983).

- Soft Tissue Oscillation Therapy: Focuses on a low-frequency and a low painless intermittent electrostatic field that is applied to the patient's target injured tissue (Guffey, 2007). This frequency will be applied when the therapist's hands move over the patients' target tissue while both are connected to the oscillation modality by electrodes (Guffey, 2007). The therapist wears gloves which function as an insulator (Guffey, 2007). The soft tissue oscillation therapy claims to create a "kneading" effect on the tissue by the polarity fluctuation, which attracts and repels charged particles of the injured tissue (Aliyev, 2009; Guffey, 2007; Jahr et al., 2008). There are many brands that make soft tissue oscillation machines these include the Hivamat 200®, Deep Oscillation®, and the Dynatron X5TM (Aliyev, 2009; Jahr et al., 2008; Jones, 2012; Tápanes et al., 2010).
- Transcutaneous Electrical Nerve Stimulation (TENS): The electrotherapy modality
 that is commonly used to treat acute and chronic pain is the transcutaneous electrical
 nerve stimulation (TENS) unit (Starkey, 2013a). The TENS unit works by creating
 an electrical stimulation of the nerves which assists in inhibiting cells to transmit
 injury signals to the body (Johnson, 2001; Knight & Draper, 2008a; Melzack & Wall,
 2008a; Starkey, 2013a). A treatment including TENS is applied by placing two
 electrodes, one positive and one negative, on the patient's skin over the painful area.
 The mode of the TENS unit is then determined for the specific type of pain. The
 mode of sensory TENS, also known as high TENS, is used to treat acute pain by
 stimulating a large diameter of sensory nerves (Knight & Draper, 2008a; Starkey,

2013a). When sensory TENS is applied the patient experiences a buzzing or tingling sensation.

APPENDIX B

EXTENDED LITERATURE REVIEW

Introduction

Pain is used as a defense mechanism to warn the body of potential danger or injury and is a common cause for an individual to seek medical assistance (Ragan, 2013; Woolf & Mannion, 1999). Since pain is subjective and may be perceived differently among individuals, it is very difficult to manage and measure (Noble et al., 2005). There are many methods used to measure pain, one reliable and valid method is utilizing the Numeric Rating Scale (NRS; Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011). Extensive amounts of treatments are used to manage pain and many of these forms of managements have been tested in previous studies which include medications and electrotherapeutic modalities (Ahmed et al., 2011; Aliyev, 2009; Denegar & Perrin, 1992; Dolan et al., 2005; Hertel, 1997; Jahr et al., 2008; Paoloni, Milney, Orchard, & Hamilton, 2009; Smith, Kruger, Smith, & Myburgh, 2008).

A modality that has recently been introduced to the medical world is known as soft tissue oscillation therapy. Soft tissue oscillation therapy is one of many therapeutic modalities that are used for orthopedic injuries with a limited amount of evidence based literature to determine its effectiveness on a model population. Research has reviewed soft tissue oscillation therapy's effectiveness on pathologies such as lymphedema, drainage, edema, muscle extensibility, burns, and managing pain, but limited research has reviewed the effectiveness on orthopedic injuries (Aliyev, 2009; Hinman, Lundy, Perry, Robbins, & Viertel, 2013; Jahr et al., 2008; Jones, 2012; Kraft, Kanter, & Janik, 2013; Tápanes et al., 2010). This modality needs to be explored on a model population to insure its safety and effectiveness on the orthopedically injured population. One controlled model of this population would include the induction of delayed onset muscle soreness, known as DOMS. DOMS is a non-invasive way to induce pain which is naturally common among individuals who are active and over use their muscles (Cheung, Hume, & Maxwell, 2003; Close, Ashton, McArdle, & MacLaren, 2005). Even though induced DOMS is a temporary muscle injury it creates similar neurological effects of pain as a muscle injury sustained in nature (Cheung et al., 2003). DOMS has been used as a model population in multiple studies to investigate the effectiveness of soreness and pain management protocols (Butterfield et al., 1997; Clarkson & Tremblay, 1988; Cleak & Eston, 1992; Croisier et al., 1996; Ernst, 1998; Hilbert, Sforzo, & Swensen, 2003; Isabell, Durrant, Myrer, & Anderson, 1992; Kuligowski, Lephart, Giannantonio, & Blanc, 1998; Prasartwuth et al., 2005; Schwane et al., 1983). The purpose of this literature review is to discuss pain, measurement of pain, pain management, soft tissue oscillation therapy, DOMS, and evidence base medicine protocols.

<u>Pain</u>

Pain is used as a defense mechanism to warn the body of potential danger or injury (Ragan, 2013; Woolf & Mannion, 1999). There are various definitions of "pain." The International Association for the Study of Pain definition is, "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (International Association for The Study of Pain: Taxonomy, 2012). Pain can be classified as either acute (rapid onset) or chronic (persistent over time; Melzack & Wall, 2008b; Ragan, 2013). Acute pain is associated with the discomfort due to an initial injury or tissue damage for a short period of time between the initial injury and the beginning of the recovery process (Melzack & Wall, 2008b; Ragan, 2013). Acute pain may cause a reaction or a response such as removing one's hand from a hot surface. Chronic pain is discomfort that persists for a longer period of time after the healing process has occurred (Melzack & Wall, 2008b; Ragan, 2013). Chronic pain is associated with conditions such as tendinopathy and arthritis. It is important to remember that pain is subjective and an individual's perception of pain may vary based on personal past experiences (Ragan, 2013). Since pain is subjective clinicians must rely on the patient's report of the pain's intensity (Noble et al., 2005).

Measurement of Pain

An instrument used to measure pain such as a scale is useful to have when determining the level and degree of a patient's pain. Pain measurement instruments are utilized to allow the patient to subjectively express the pain being experienced. Pain scoring allows for measuring the severity of pain and helps to determine any changes in pain. Determining if a patient's pain has changed is particularly important in research and treatment. The numerical measurement of change in pain helps a researcher to objectively evaluate the efficacy of the patient's pain relief and/ or the level of pain various treatments or procedures may cause. There are multiple instruments which have been utilized to measure pain including, but not limited to, McGill Pain Questionnaire (MPQ), Faces Pain Scale (FPS), Verbal Rating Scale (VRS), Visual Analogue Scale (VAS), and Numeric Rating Scale (NRS). When studying the effects of a therapeutic intervention, and assessing the response to a treatment of pain, a reliable and valid instrument for measurement of pain is needed. Although evidence does support the reliability and validity for each of these pain measurement instruments among various populations, each has its own strengths and weaknesses (Bijur, Latimer, & Gallaher, 2003; Bijur, Silver, & Gallaher, 2001; Ferreira-Valente et al., 2011; Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001; Jamison et al., 2002; Kim & Buschmann, 2006; Melzack, 1975; Melzack & Wall, 2008b; Ragan, 2013; Williamson & Hoggart, 2005).

The McGill Pain Questionnaire (MPQ) is a multidimensional scale that uses many descriptive words to categorize the severity and type of pain that is being experienced by an individual (Melzack, 1975; Ragan, 2013). The MPQ is broken into four parts including body location, verbal descriptors, change in pain, and strength in pain (Melzack, 1975; Melzack & Wall, 2008b). The questionnaire starts with basic demographic questions and proceeds to the four portions which assist in determining the location, type, pattern, and severity of the individual's pain.

The purpose of the MPQ part one is to find the anatomical location of the pain and asks the question, "Where is your pain?" In this section there are pictures of the human body in the anatomical position both anteriorly and posteriorly. The individual is given the directions to mark where the pain is located with code letters. External pain is represented by "E" and internal pain is represented by "I". The individual does have the option to put "EI" if they are experiencing both external and internal pain in a specific area.

The second part of the questionnaire is used to help the individual describe the pain that is present by asking the question, "What does your pain feel like?" This portion

is comprised of 20 categories that have descriptive words under each category. The individual is directed to circle each descriptive word that best represents the present pain being experienced. The individual may leave out any category that is not suitable for the pain they are experiencing, and may only circle one descriptive word in each category.

The purpose of the third part of the MPQ is to help assess how the individual's pain may change and what could affect the pain. The question being asked in this section is "How does your pain change with time?" The individual is asked to choose the word or words which best describe the pattern of their pain based upon the three categories with three sub-descriptive words placed under each category. The individuals are then asked to describe, in their own words, things that help relieve or increase their pain.

The fourth part of this questionnaire focuses on the strength and intensity the pain as perceived by the individual by asking the question, "How strong is your pain?" The individuals are then asked to rate their pain using a scale provided (i.e. 1-5, 1= mild, 5= excruciating) for different scenarios and questions that are asked. All of the categories in the MPQ include rankings for each of the presented description words which are used to assess the individual's pain (Melzack, 1975; Melzack & Wall, 2008b; Ragan, 2013). This pain assessment has been used in multiple studies and is established as valid and reliable, but has been found to be even more reliable and effective when utilized along with another form of pain scale such as the VAS (Melzack, 1975; Melzack & Wall, 2008b; Ragan, 2013). The complexity of the MPQ does limit the population in which the scale will effectively assess pain, which explains why simpler scales are the most commonly used pain scales in the clinical and research setting, including; FPS, VRS, VAS, & NRS.

Throughout the years, multiple Face Pain Scales (FPS) have been developed. FPS is directed toward pediatric patients or individuals with significant cognitive impairment and who may not be able to associate a number with the degree of pain experienced (Ferreira-Valente et al., 2011; Hicks et al., 2001; Kim & Buschmann, 2006). FPS assess the intensity of a patient's pain using a self- report measurement where the individual correlates the pain they are experiencing to a visual picture of a face (Hicks et al., 2001). Reliability and validity of the FPS has been established with adult, child, and cognitively impaired populations (Kim & Buschmann, 2006). This scale has been revised, condensing seven faces into six faces, which is now known as Face Pain Scale-Revised (FPS-R; Hicks et al., 2001). FPS-R's validity was supported by studies which compared the results to those of the VAS; concluding that the FPS-R is an appropriate tool to assess the intensity of children's pain from ages 4 and up (Hicks et al., 2001). The FPS-R was found to provide equally consistent results when compared to other commonly used pain measurement scales (i.e. VRS, NRS, and VAS; Ferreira-Valente et al., 2011). When choosing a pain measurement instrument to assess an individual's pain, the level of appropriateness to the population being assessed is critical in the appliance of patients. Since the FPS is ordinal in nature and may be correlated with the NRS, it would be more effective to initially use the NRS if the individual is able to effectively assess their pain with this tool (Kim & Buschmann, 2006).

The Numerical Rating Scale (NRS) creates correlations between the individual's experienced pain to a number. The NRS is an 11 point scale that consists of intervals from 0-10 with 0 representing "no pain" and 10 representing "worst imaginable pain" (Bijur et al., 2003; Ferreira-Valente et al., 2011). The NRS may be administered both graphically and verbally. When administered graphically, the numbers are usually enclosed in boxes (Williamson & Hoggart, 2005). By enclosing the numbers in boxes, allows the patient to specifically choose a number correlating to their pain. The individual selects the number that best represents the intensity of pain being experienced. NRS is easy to comprehend and administer, which helps eliminate administration errors and assists in supporting the validity and reliability of the scale (Bijur et al., 2003; Ferreira-Valente et al., 2011; Williamson & Hoggart, 2005).

Clinicians who are assessing pain for individuals who are less able to use the NRS, such as young children or individuals with significant cognitive impairment may utilize the Verbal Rating Scale (VRS). Multiple versions of the VRS are utilized in the clinical setting, but they all contain the same components which are similar to a FPS. Instead of faces to represent the individual's perceived pain, descriptive words are used. There is not a direct interval between each descriptor word, which causes the data collected to be ordinal data, and may create differences between individuals (Ferreira-Valente et al., 2011; Williamson & Hoggart, 2005). Denegar and Perrin (1992) developed a VRS which was described as a Graphic Pain Rating Scale (GPRS) to specifically assess an individual's pain when evaluating delayed onset muscle soreness (DOMS). Denegar and Perrin (1992) described the GPRS to be similar to a VAS based

on the extreme descriptors on either side of the line. The GRPS did incorporate a key which expands on what is meant by the descriptive word (Denegar & Perrin, 1992). Since this scale is associated with DOMS it will be difficult to correlate the results with individuals experiencing pain due to injury or illness, which is most common in the clinical setting.

The Visual Analogue Scale (VAS) is one of the most common pain measurements utilized when assessing pain intensity (Bijur et al., 2003; Bijur et al., 2001; Ferreira-Valente et al., 2011; Jamison et al., 2002; Williamson & Hoggart, 2005). There has been a great deal of evidence to support the validity and reliability of chronic pain using the VAS, and recently more research has been performed supporting its effectiveness when measuring acute pain (Bijur et al., 2003; Bijur et al., 2001; Ferreira-Valente et al., 2011; Jamison et al., 2002; Williamson & Hoggart, 2005). Similar to the NRS, the VAS is a way for the clinician to interpret a patient's pain experience into a more quantitative measure. The VAS consists of a 10 cm horizontal or vertical line that is labeled with verbal descriptors on either extreme, "no pain" and "worst imaginable pain" (Melzack & Wall, 2008b; Ragan, 2013). The patient is directed to mark the point on the line where best representing the pain being experienced. The clinician uses a ruler to measure the patient's mark to the closest half or full centimeter to create a numerical rating of the pain experienced. The NRS expresses pain in the terms of intensity on a scale of 0-10 (Ragan, 2013).

With the rising age of technology everything has become more electronic; it is not surprising that the VAS is becoming electronic as well. A randomized, crossover trial

compared electronic VAS (eVAS) and paper VAS (pVAS). The validity of the eVAS was supported by multi-analysis determining similar findings to those of the pVAS (Jamison et al., 2002). Even though the eVAS has been found to be an effective measurement of pain, it is a new measurement which needs more research to support its validity and reliability.

Bijur et al. (2003) conducted a study intended to validate the NRS in the emergency department (ED) setting. The validity of the NRS was evaluated by the comparison to the VAS (Bijur et al., 2003). The subjects consisted of adults who were admitted to the ED and were experiencing acute pain for less than 24 hours. The NRS and the VAS were conducted at 0, 30, and 60 minutes. The NRS was administered verbally, where the patient would rate his/her pain on a scale 0 to 10, 0 representing "no pain" and 10 representing "worst possible pain." The VAS was administered by the patient marking his/her pain level on a horizontal line; the line had extreme descriptors "no pain" and "worst possible pain." The results of this study found there were no significant clinical differences between the two pain measurement techniques and the verbally administered NRS and the VAS had a strong correlation. Based on the regression analysis the researchers concluded that NRS can be used as a measurement of acute pain in clinical settings (Bijur et al., 2003).

Studies have compared the VAS, VRS, NRS, and FPS-R to assess the validity and reliability of the pain measurement instruments (Ferreira-Valente et al., 2011; Williamson & Hoggart, 2005). The research concluded a strong support for the validity of all the pain scales when detecting changes in pain intensity (Ferreira-Valente et al., 2011;

Williamson & Hoggart, 2005). The VAS and NRS have been suggested to be the most effective pain scales to utilize when seeking sensitivity and responsivity (Ferreira-Valente et al., 2011; Williamson & Hoggart, 2005). Ferreira-Valente et al. (2011) found the NRS to be more sensitive in measurements when compared to the VAS, VRS, and the FPS-R. Within the same study, it was suggested the VAS has a higher failure rate when compared to NRS or VRS, which may be due to the fact it is less user friendly (Ferreira-Valente et al., 2011). Clinicians and patients have preferred the NRS over the VAS based on the simplicity of both administrating and scoring the pain scale (Ferreira-Valente et al., 2011). The importance of measuring an individual's pain level is to determine if the treatment performed to manage the pain is effective.

Pain Management

Pain can cause limitations in an individual's daily activities. Because of this it is crucial for the clinician to address the pain in the most efficient manner possible. Athletic trainers and physical therapists are health professionals who can play a major role in managing acute orthopedic injuries. Athletic trainers' roles include initial and continuous treatment of injury of an athlete in order to rehabilitate the athlete to a healthy state and hopefully return to activity. Three of the more crucial components to a successful injury rehabilitation program protocol include basic first aid, reducing pain and managing pain (Prentice, 2011b). Medical professionals must adapt to a patients' needs for pain management since there is a difference between individuals and types of injuries. In order to adapt medical professionals utilize multiple resources to assist in the management of an individual's pain level (Dolan et al., 2005; Johnson, 2001; Knight &

Draper, 2008b; Paoloni et al., 2009; Ragan, 2013; Starkey, 2013a, 2013b). Medications are one of the more common methods utilized to manage pain. Since medications are commonly used for pain, it is important to understand the mechanisms through which the pain is controlled and other reactions the medications may have on the body.

Medications have been found to manage pain through three mechanisms, which include decreasing the inflammatory response, blocking the noxious impulses that are transmitted, or altering the individual's perception of pain (Ragan, 2013). Acute injuries which result in pain and inflammation are commonly treated with over-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs; Dolan et al., 2005; Hertel, 1997; Melzack & Wall, 2008c; Paoloni et al., 2009). In the past, NSAIDs have been successful when treating pain, but studies have found some hindering effects within the healing process (Hertel, 1997; Smith et al., 2008). NSAIDS help prevent the inflammation process which is beneficial for controlling pain, but the inflammation process is a promoter of healing. When the inflammation process is limited or inhibited by an NSAID the whole healing process may become negatively affected (Hertel, 1997; Paoloni et al., 2009; Smith et al., 2008). These hindering side effects, such as the delay in the healing, have been found when NSAIDs are taken during the crucial period of the healing process, which occurs within the first few days after an injury has occurred (Hertel, 1997; Smith et al., 2008). NSAIDs have also been found to cause upset stomachs and when used long term can cause damage to the gastrointestinal tract, kidneys, and other organs (Hertel, 1997; Melzack & Wall, 2008c). A study examined the difference in inflammation when using ibuprofen, which is a NSAID, and a cathodal high-voltage pulsed current (CHVPC) on

the hind limbs of rats (Dolan et al., 2005). The study concluded the treatments reduced the inflammation by 50% of the untreated rats, which supports that NSAIDs have been found effective at reducing inflammation (Dolan et al., 2005). Even though NSAIDs may be effective it is important for a clinician to take into consideration the individual who is experiencing pain, the type and severity of pain, and the side effects the NSAIDs can cause on the healing of the injury. Clinicians utilize other tools to manage pain among their patients which include multiple types of modalities.

Although medications, such as NSAIDs, have been found to be effective with pain many medical professionals use a variety of therapeutic modalities to assist in management of pain. To manage musculoskeletal injuries a therapeutic modality may be applied to reduce pain, reduce inflammation, and increase range of motion. Therapeutic modalities are utilized by applying energy to the body to influence tissue healing and stimulate sensory receptors which affect the pain process (Ragan, 2013). Many therapeutic modalities have been used to treat pain including ice, heat, or electrical stimulation currents (Knight & Draper, 2008b; Ragan, 2013). In order to understand how electrotherapeutic modalities function, it is important to understand electricity. Two different types of electricity, known as static and current, are used in electrotherapeutic modalities. Static electricity is created from the friction of two objects when rubbed together, allowing one object to gain electrodes while the other loses electrodes (Knight & Draper, 2008c). An example of static electricity is when a balloon is rubbed on hair. Current electricity is a circuit that allows many electrodes to pass along a conductor and flows one of two ways. Depending on how the electrodes flow, an electrical current is
categorized as a direct current (DC) or an alternating current (AC). Direct currents (DC) are a continuous flow of electrodes that are uninterrupted and flow in only one direction (Knight & Draper, 2008c; Starkey, 2013c). Alternating currents (AC) are also a continuous flow of electrodes, but the flow will rhythmically change direction based on the alternating polarity (Knight & Draper, 2008c; Starkey, 2013c).

Another form of electrotherapy is known as a pulsed current, which involves an interruption to the current flow (Knight & Draper, 2008c; Starkey, 2013c). The electrical stimulation manipulates the pain transmitters by effecting three different neurological levels: the sensory, motor and noxious levels (Ragan, 2013). Two common electrical stimulation modalities used in the clinical setting are neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). NMES is used to create muscle contractions by delivering a current to the body, which causes sensory and motor nerves to depolarize (Knight & Draper, 2008c). This modality is usually utilized when trying to release a muscle cramp or to increase blood flow to the affected area to promote healing (Knight & Draper, 2008c).

An electrotherapeutic modality that is commonly used to treat acute and chronic pain is transcutaneous electrical nerve stimulation (TENS; Johnson, 2001; Starkey, 2013a). TENS works by creating an electrical stimulation of the nerves, which assists in inhibiting the transmission of injury signals to the body (Johnson, 2001; Knight & Draper, 2008a; Melzack & Wall, 2008a; Starkey, 2013a). When the electrical current is set at a low intensity it passes through the nerves and stimulates the peripheral nerves (Melzack & Wall, 2008a). TENS is administered by applying two electrodes, one

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positive and one negative, on the patient's skin over the painful area. The parameters of the TENS treatment is then determined for the specific type of pain. TENS can be used to treat acute pain by using the parameters of sensory TENS, also known as high TENS, which stimulates large diameter sensory nerves (Knight & Draper, 2008a; Starkey, 2013a). When sensory TENS is applied, the patient experiences a buzzing or tingling sensation (Melzack & Wall, 2008a). Motor TENS, also known as low TENS, manages chronic pain with a low pulse frequency by stimulating small-diameter afferent nerves (Knight & Draper, 2008a; Starkey, 2013a). The application of motor TENS gives the patient a light burning, pin and needle type sensation with a small twitch of the muscle. The brief-intense TENS, also known as noxious mode, is utilized when treating chronic pain by delivering a high pulse frequency (Knight & Draper, 2008a; Starkey, 2013a). The brief-intense TENS can be used before a rehabilitation session and it stimulation targets the C fibers.

A TENS treatment was compared to an alternative treatment using, NSAIDS for multiple types of injuries in a recent study (Ahmed et al., 2011). Ahmed et al. (2011) conducted a prospective randomized study to evaluate the effectiveness TENS on patients with acute low back pain (LBP). The study included patients of both sexes between the ages of 20-60 years that had LBP for 6 weeks or less. The patients were considered for the study if they were currently not participating in any treatments for the pain and if they were able to complete the necessary questionnaire. Patients were excluded from the study if they had experienced LBP for longer than 6 weeks, had inflammatory LBP, or other medical complications (Ahmed et al., 2011). The patients were divided into two

groups, Group A and Group B. Group A was treated for 15 consecutive days with low frequency high intensity TENS for 30 minutes. Both Group A and Group B received NSAIDS for 15 consecutive days, which included Aceclofenac (100 mg) twice daily, along with Capsule Omeprazole (20 mg) twice daily before meal for gastrointestinal support. Both groups also were instructed on how to perform their activities of daily living (ADLs). These were verbally given as well as demonstrated for the patients. Data was collected on day 1 for pre-treatment results and on day 15 for post treatment results, assessing the subjective pain intensity, VAS, tenderness index, and disability due to pain results. The results found no significant difference between the pre-treatment assessment scores between the two groups. The post treatment results found a significant improvement in the patients LBP among both groups, but Group A's improvement was slightly greater. The disability due to pain results among the Group A patients were low. The subjective pain intensity, VAS, tenderness index, and disability due to pain in the post treatment for group A and B were significantly lower than in the pre-treatment (Ahmed et al., 2011). Ahmed et al. (2011), concluded that the effect of TENS was beneficial for patients suffering with acute LBP.

Another modality which generally applies the same treatment rationale for pain control as general electrotherapy is the soft-tissue oscillation therapy. The soft tissue oscillation therapy is an electrical modality which focuses on a low painless intermittent electrostatic field which is applied to the patient's injured tissue (Guffey, 2007; Jahr et al., 2008). The therapist will connect an electrode to a wrist as the patient holds a probe, the soft tissue oscillation treatment is applied when the therapist's hands move over the

patient's injured area while both are connected to the oscillation modality by the electrodes (Guffey, 2007; Jahr et al., 2008). An electrostatic or magnetic force is created between the probe and the injured tissue by the probe's non-conductive layer which prevents a current flow (Guffey, 2007). The therapist wears gloves, which function as an insulator (Guffey, 2007; Jahr et al., 2008). The soft tissue oscillation therapy claims to create a "kneading" effect on the tissue by the polarity fluctuation, which attracts and repels charged particles of the injured tissue (Guffey, 2007; Jahr et al., 2008). The soft tissue oscillation therapy claims to be highly effective in treating both acute and chronic pain, but limited research has been conducted to assess the modalities effectiveness. Multiple companies have developed different versions of the soft tissue oscillation modality including the Hivamat 200[®], Deep Oscillation[®], and the Dynatron X5TM (Jahr et al., 2008; Jones, 2012). The soft tissue oscillation therapy is unique since it combines two common techniques to treat soft tissue injuries, electrotherapy and manual therapy (Guffey, 2007). Indications for the soft tissue oscillation treatment include edema, pain, and loss of function for after surgical procedures, sprains, strains, overuse injuries, sports injuries, and delayed onset muscle soreness (DOMS; Guffey, 2007). Previous research has studied the effectiveness of soft tissue oscillation therapy on pain, lymphedema, drainage, edema, muscle extensibility, and burn healing (Aliyev, 2009; Hinman et al., 2013; Jahr et al., 2008; Jones, 2012; Kraft et al., 2013; Tápanes et al., 2010).

Evidence has shown the soft tissue oscillation therapy to be effective on pain, lymphatic drainage, edema, and healing (Aliyev, 2009; Hinman et al., 2013; Jahr et al., 2008; Jones, 2012; Kraft et al., 2013; Tápanes et al., 2010). The Deep Oscillation® modality was used on women who suffered secondary lymphedema of the breast after surgery. The study assessed twenty-one individuals who had all undergone breast sparing surgery, radiation, and were experiencing reduced motion and increased pain of the arm, due to swelling before deep oscillation treatments (Jahr et al., 2008). The low intensity and extremely low frequency electrostatic field was used with manual lymphatic drainage techniques on these women and compared to a control group that only received lymphatic drainage. The level of pain among the patients who received the soft tissue oscillation therapy decreased significantly. Conversely, the control group's pain level scores were unaffected. Swelling, on the other hand, was reduced significantly in both groups. The mobility in the affected shoulder increased after treatment, but was not significant. Jones (2012) conducted a study that evaluated a similar population.

Jones (2012) focused on one patient who following treatment for breast cancer had developed ISL stage 3 edema in the left arm. Multilayer lymphedema bandaging (MLLB) is a treatment that has been used for similar cases (Jones, 2012). The patient had MLLB and soft tissue oscillation as the course of treatment for a period of two weeks. This study discovered a reduction in the excess limb volume and fibrosis to be present two weeks after the combined treatment (Jones, 2012).

Little research has been conducted to investigate the physiological benefits of the soft tissue oscillation treatment for musculoskeletal injuries on the athletic population. The Dynatron X5TM soft tissue oscillation modality manual along with the other brands have claimed there are benefits to utilizing this therapy in the athletic setting, but more evidence needs to support this claim (Guffey, 2007). Promotion of the healing process

was presented in a study on individuals who suffered AB burns (Tápanes et al., 2010). AB dermal burns are burns that damage the dermis as far as the reticular layer. AB burns create thick cloudy fluid filled blisters which are bright red and generally take in between 14 to 21 days to heal (Tápanes et al., 2010). A total of 60 patients with burns who were treated outpatients from the local burn therapy department volunteered to participate in this study. Inclusion criteria included that the participant was 20 years of age or younger, and AB type burns affected less than 15% of the body area. Exclusion criteria included diabetes mellitus and burn sepsis. Only 54 of the participants fulfilled the inclusion criteria and 2 of the participants abandoned the treatment. A clinical evaluation was performed on each of the participants which evaluated the appearance of the burn, circulation to the particular area, and sensitivity to the affected area. The participants were divided into two groups the soft tissue oscillation therapy group and the silver sulfadiazine group. The soft tissue oscillation group placed a sterile plastic foil to create insulation between the burn and the therapist's gloves. The treatment was 20 minutes long with two different parameters use. The sessions were given on alternate days for a total of 15 applications. The silver sulfadiazine group received treatments on alternate days which included a treatment with 1% silver sulfadiazine. The results showed the healing time of AB dermal burns which were treated in the soft tissue oscillation therapy group (10.8 days) a decrease in healing time compared silver sulfadiazine group (16.2 days). Tápanes et al. (2010) concluded that the patients treated with the soft tissue oscillation therapy showed a significant decrease in the healing time of 5.4 days when compared with the patients who were treated with the 1% silver sulfadiazine alone,

supporting the effectiveness of the soft tissue oscillation treatment on burn healing. Although this study assists in the supporting evidence of the effectiveness soft tissue oscillation has on the healing process more research needs to be conducted on this topic to support the use of the soft tissue oscillation.

Aliyev (2009) conducted a study to evaluate the effects of the therapy on immediate aftercare of different soccer related injuries. This study was conducted in German and had to be translated into English to assess the procedures. This study is commonly referenced when discussing the soft tissue oscillation therapy. Interestingly, the contexts of the citations used for the Aliyev (2009) research are inconsistent. This could be due to the language barrier and the accuracy of translation. Based upon translation, Aliyev (2009) included forty-nine soccer injuries which were treated in this study using the soft tissue oscillation therapy. The results showed a significant reduction of pain and swelling among the patients' injuries (Aliyev, 2009). The research was not administered with many controls and the multiple variables could have contributed to the results. Many types of injuries can be sustained while playing soccer and the injuries which were assessed in this study are known to all heal differently. A more controlled study needs to be conducted to assess the true effectiveness of soft tissue oscillation on athletic injuries.

Kraft et al. (2013) conducted an uncontrolled pilot study focusing on the evaluation of safety and tolerability of a series of soft tissue oscillation massage treatments among patients suffering with fibromyalgia syndrome (FMS) for greater than 2 years. The participants were recruited through contacting FMS support groups and

advertisements in the local newspaper. Patients were between the ages of 18-70 years. Data was collected initially, 2-4 weeks after the last treatment session, and 2 months after the second treatment session. The participants received 10 sessions of the soft tissue oscillation massage treatment. Each treatment lasted 45 minutes and was performed twice a week. The treatments took place in one of five physical therapy clinics and were administered by physiotherapists who had been trained on how to handle the device. The frequencies and duration of the modality was fixed among all patients. A total of 70 participants were enrolled in the study, but only 63 participants completed all of the study's protocol, due to health issues or other reasons. The results suggest soft tissue oscillation massage is safe and tolerable among patients suffering with FMS. During the second data collection adverse effects were documented for 63 participants, which were mild and short lasting, of which mostly included worsening of prevalent symptoms in FMS. A 3 month follow-up found continued improvements in symptoms and quality of life, which suggests a benefit from the treatment. More research is needed to create enough concrete evidence in the benefits and effectiveness the soft tissue oscillation therapy has on patients suffering with FMS (Kraft et al., 2013).

Hinman et al. (2013) conducted a study which compared the immediate effects of a single treatment of ultrasound modality and soft tissue oscillation on hamstring extensibility. A mixed research design was used to test the hypothesis that the ultrasound and soft tissue oscillation modalities would produce a similar effect on hamstring extensibility, which would be positive when compared to the untreated extremities. The study looked at college athletes and non-athletes between the ages 18 -39 who had at least 15 degrees of hamstring tightness bilaterally. The tightness was determined by using a straight-leg raise (SLR) measurement protocol. A total of 50 participants (male n= 28, female n= 22) completed the study and were randomly divided into the ultrasound or the soft tissue oscillation group. Both treatments were 15 minutes in duration and were measured again after the treatment was performed. The results supported the hypothesis by demonstrating the improvement of extensibility when compared to the untreated muscles was similar among both treatment groups. Even though the findings found both treatments to have improvement on hamstring extensibility, there was not a statistically significant difference on the extent of the improvement. The soft tissue oscillation treatment did show a slight increase in improvement compared to the ultrasound treatment. Hinman et al. (2013) concluded since no statistically significant improvement was shown by either of the treatment groups, neither of the treatments show to be clinically effective when the desired outcome is improving hamstring extensibility, and more research is needed on the topic (Hinman et al., 2013).

Injury Model

Soft tissue oscillation therapy has been used to treat pain and edema for several musculoskeletal conditions, including carpal tunnel syndrome, epicondylitis, muscle strains, joint sprains, and delayed onset muscle soreness (DOMS; Guffey, 2007). Foundational to musculoskeletal rehabilitations is the understanding of the healing process the body undergoes following a muscular injury. Once a muscular injury occurs (i.e. strain, contusion, lesion) the body will respond to the injury in three phases of healing; inflammatory, proliferation, and maturation (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008). Instantly after an injury is sustained the inflammatory phase begins to take place. The injury causes destruction of healthy cells causing the activation of three physiological responses within the inflammatory phase (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008). The first response causes vasoconstriction to occur which lasts from a few seconds up to 10 minutes and acts to stop blood loss from the wound (Anderson & Parr, 2013; Prentice, 2011c).

The second response is the platelet formation which is a reaction to the loss of blood. It is unusual for platelets to adhere to the vascular wall, but when trauma is sustained the endothelium of the vessel is disrupted and the collagen fibers are exposed to which the platelets adhere to (Anderson & Parr, 2013; Prentice, 2011c). When the platelets and leukocytes adhere to the vascular wall a plug is eventually formed which obstructs local lymphatic fluid drainage (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008). This obstruction localizes the injury response to the injured area (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008).

The third response involves the activation of the coagulation cascade. This is when a protein molecule known as thromboplastin is released from the damaged tissue and causes prothrombin to be converted into thrombin (Anderson & Parr, 2013; Prentice, 2011c). The thrombin in turn causes the conversion of fibrinogen which creates a fibrin clot which shuts off the blood supply to the injured area (Anderson & Parr, 2013; Prentice, 2011c). As soon as the vasoconstriction takes place (after 10 minutes) vasodilation occurs which assists in providing proteins that promote various activities which are essential to the healing process. Neutrophils and macrophages are attracted and start to clean up the debris from the injured site (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008). This process is called phagocytosis. The increase in blood flow causes swelling fluid to move into the injured area, which usually occurs within the first hour after the initial injury was sustained. Swelling is vital within this phase, because it assists in the removal of the waste products from the injured area and promotes reconstruction of healthy tissue. The injured site creates the inflammatory mediator bradykinin, which increases vessel permeability and stimulates nerve endings to cause the neurological effect of pain (Anderson & Parr, 2013; Prentice, 2011c).

Once the inflammatory process has taken place the second phase, known as the proliferation phase, starts to occur (Kraft et al., 2013; Prentice, 2011c). The proliferation phase starts to take place approximately 3 days after the initial injury and will last as long as 21 days post injury (Anderson & Parr, 2013). This phase involves the repairing and regeneration of the damaged tissue. Within this phase blood vessels, fibrous tissue, epithelial tissue start to regenerate and repair (Prentice, 2011c; Smith et al., 2008). The wounds contraction will also begin to develop in this phase (Anderson & Parr, 2013). Fibroblasts create type III collagen which creates a rapid formation of cross-links (Anderson & Parr, 2013). This is useful within this state because those cross-links assist in the stabilization at the wound site. Fibroblasts also create attachment areas for the newly developed blood vessels to connect to the collagen (Anderson & Parr, 2013). Due to the fact blood vessels are increasing throughout this phase at the injury site, assists with the promotion of healing. The healing begins at the center of the damaged tissue (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008).

The third phase, the maturation phase, starts to take place approximately 3 weeks after the injury occurred and may continue up to a year (Anderson & Parr, 2013; Prentice, 2011c). Within this phase the fibroblast activity begins to decrease which allows the habitual loading process to increase the organization of the extracellular matrix (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008). The chemical activity returns to normal throughout the maturation phase, which allows for the reduction of vascularity and water content. The type I and type III collagen continue to increase and replace the immature collagen, resulting in contracture of the damaged tissue. Scar tissue begins to form which creates a decrease in size and flexibility of the injured tissue. When the tissue begins to scar and realign causes the area to become stronger, but since the scar tissue is fibrous, inelastic, and non-vascular the function and strength of the tissue is generally still significantly lower than the strength pre-injury (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008). The remodeling causes the collagen fiber to align along areas of stress, which assists in increasing strength (Anderson & Parr, 2013; Prentice, 2011c; Smith et al., 2008). The understanding of the three phases the body undergoes through healing a muscular injury is beneficial when choosing a rehabilitation technique. By knowing what phase the healing process is in will assist in determining what treatment will assist in the promotion of healing. There are multiple types of musculoskeletal injuries to take into consideration such as muscle lesions, contusions, and strains.

DOMS is often perceived as different type of injury than a muscle strain, when, in fact, it is physiologically a grade I muscular strain involving small micro tears within the

muscle (Cheung et al., 2003; Gulick & Kimura, 1996; Safran, Seaber, & Garrett, 1989). This type of muscle injury produces point tenderness and/or pain with active motion (Cheung et al., 2003). DOMS and muscle damage have been linked in the past to produce similar neurological pain responses which have been replicated using DOMS. Because of the easy of replicating similar neurological pain responses is why DOMS is often used as a model to study muscle injury and pain, but can be acquired in nature among physically active individuals (Cheung et al., 2003; Close et al., 2005). DOMS is a transient muscle injury which usually begins 6-12 hours after exercise. In most cases the delay of DOMS will involve the individual going to bed with mild discomfort and rising the next morning with increased discomfort. Pain and soreness related to DOMS is most severe 24-72 hours after the initial overexertion exercise and then will gradually subside throughout the next few days (Croisier et al., 1996; Prasartwuth et al., 2005; Prentice, 2011a; Schwane et al., 1983).

Inducing DOMS is a non-invasive way to create pain which occurs commonly among individuals who are active and those who overexert muscles (Cheung et al., 2003). DOMS has been induced in multiple studies to investigate the effectiveness of soreness and pain management protocols (Butterfield et al., 1997; Cleak & Eston, 1992; Croisier et al., 1996; Ernst, 1998; Hilbert et al., 2003; Isabell et al., 1992; Prasartwuth et al., 2005; Schwane et al., 1983). This is because even though induced DOMS is a transient muscle injury it creates a similar neurological pain response as compared to a muscle injury sustained in nature. Multiple DOMS-inducing protocols have been cited in the literature, most of which involve eccentric muscle contractions (Butterfield et al., 1997; Clarkson & Tremblay, 1988; Cleak & Eston, 1992; Croisier et al., 1996; Hilbert et al., 2003; Isabell et al., 1992; Prasartwuth et al., 2005; Schwane et al., 1983).

A study was conducted focusing on the effect of whirlpool therapy on the signs and symptoms of DOMS (Kuligowski et al., 1998). A total of 56 healthy volunteers with no history of upper extremity musculoskeletal pathology or known contraindications to heat or cold exposure participated in this study. A total of 5 measurements of the participant's non-dominant arm were taken throughout the procedure including preexercise (0 hours), post exercise, and pre administration of treatment at 24, 48, and 72 hours. The final measurement was taken 96 hours post exercise. Goniometric range of motion (ROM) of passive elbow flexion, active elbow flexion, and active elbow extension were recorded. Each participant's perceived level of pain was measured using a Graphic Pain Rating Scale (GPRS), in addition to their maximal voluntary isometric contraction (MVIC) was performed on the participant's elbow flexors. The DOMS inducing protocol was then conducted on the participant's forearm flexors of the nondominant arm. The participant's 1-repetition maximum (1RM) was determined by performing dumbbell curls with increasing weight in the increments of 2.27 kg (5lbs), until the subject could no longer perform the exercise (Kuligowski et al., 1998). This study did not report difficulty in the induction of DOMS or any participants which DOMS was not successfully induced on. The focus of the study was to evaluate the effect three therapies (warm whirlpool, cold whirlpool, contrast therapy) had on the treatment of DOMS. The results suggested the cold whirlpool and contrast therapy are more effective in treating DOMS when compared to a warm whirlpool.

Evidenced Based Medicine

Medical interventions, such as soft tissue oscillation, are used by clinicians to offer effective patient care and achieve optimal patient outcomes. Medical professionals should utilize evidence based medicine (EBM) to ensure positive patient outcomes. EBM incorporates the clinician's past experiences and knowledge of pathologies, current literature, and patient values to assist in the decision-making process (Cormick, 2002; Snyder, McLeod, & Sauers, 2007; Snyder et al., 2008; Steves & Hootman, 2004). This allows medical professionals to provide the most efficient and effective treatment to maximize patients' overall health by collaborating external evidence with systematic research (Brown, 2013; Cormick, 2002; Prentice, 2011b; Snyder et al., 2008; Steves & Hootman, 2004). External evidence is clinically relevant to review the research which involving patients to evaluate the accuracy and precision of current preventive, therapeutic, and rehabilitation techniques (McKeon, Medina, & Hertel, 2006). EBM should not be utilized as a blue print or cookbook to follow blindly when caring for patients (Cormick, 2002). Instead, the purpose of EBM is to give medical professionals necessary tools to allow them to find relevant medical data, determine the quality of the information obtained, and apply new knowledge to specific clinical scenarios.

Although EBM is a new concept to many medical professions, and is difficult to grasp for some, it is a mindset and attitude that must be adopted by the medical professional in order for evidence to be used effectively in the clinical setting (Evans & Lam, 2011; Snyder et al., 2008; Steves & Hootman, 2004). Athletic training is a medical profession which has only recently begun to emphasize the use of evidence based practice (EBP) and outcomes assessment, even though the use of evidence to support clinical decision making is by no means a new concept among medical professions (Snyder et al., 2008). Outcomes assessment incorporates the understanding of the end results of health care for a patient after the use of an intervention (Clancy & Eisenberg, 1998; Donabedian, 1988, 1992). The use of assessing outcomes in the medical profession is beneficial to determine the effectiveness of a treatment, which can assists in the advancement of overall patient care.

Clinical practice guidelines and EBP guidelines are created to ensure the latest evidenced is used to promote the best practices (MacDermid, 2008). The evidence based approach raises questions for athletic trainers in regards to rehabilitation techniques and the effectiveness of therapeutic modalities (Casa, 2005; McLeod et al., 2008). Evidence based research changes constantly as new findings tend to discredit previously accepted clinical techniques or treatments and replaces them with the newly validated approaches. Two recent studies evaluated evidence from scientific research and created clinical practice guidelines in the diagnosis, treatment, and preventions of ankle sprains (Kerkhoffs et al., 2012; Polzer et al., 2012). Staying current with recent validated approaches for patient care is crucial in the medical profession. Research is continuously conducted to evaluate therapeutic and assessment techniques.

In order for medical professionals to optimize patient outcomes it is necessary to evaluate the evidence behind a technique before performing it on a patient, which in turn will allow the evidence to guide the clinical decision-making process. Although choosing the most appropriate intervention is critical, successful clinical practice does not

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conclude once a treatment has been applied. In order to ensure the desired outcome has been achieved, the clinician must continually assess the effectiveness of the intervention (Normand, 2008). This assessment can be obtained by simultaneously utilizing clinician and patient-reported outcome measures, which can help assess effectiveness in health care (Donabedian, 1992). The adoption of EBP is considered successful when a treatment plan produces optimal and positive patient outcomes (McQueen, 2001).

Athletic training research currently lacks published evidence to refute many common interventions such as cryotherapy, ultrasound, and electrical stimulation (Merrick, 2006). Bridging the gaps in literature on the application and efficacy is important when incorporating an intervention for a patient. Many questions still exist among the literature about the soft tissue oscillation therapy, which makes it concerning that the therapy is being used in many clinical settings for various reasons. The combination of previous research, clinical outcomes among studies, and patient feedback is critical when making an educated determination on how soft tissue oscillation therapy should be utilized in the clinical setting. By examining patients with muscular pain, this study will provide evidence for the use of soft tissue oscillation therapy. Therefore, the purpose of this study is to evaluate the effect of soft tissue oscillation on pain among individuals induced with DOMS. APPENDIX C

EXTENDED METHODS

UNIVERSITY OF NORTHERN IOWA HUMAN PARTICIPANTS REVIEW INFORMED CONSENT

Project Title: <u>The effect of soft tissue oscillation therapy on the management of pain</u> <u>associated with delayed onset muscle soreness</u>

Name of Investigator(s): Jenifer Shoultz and Dr. Kelli Snyder

Invitation to Participate:

You have been asked to participate in a research study conducted by Jenifer Shoultz, as part of a research project for a Master's of Science Degree in Athletic Training. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

You have been invited to participate in this study because you are between the ages 18-30, healthy, physically active and are not currently participating in an arm weight training program that includes bicep curls. You will not be allowed to participate if you have ever had cardiac disease, malignancy/cancer, tuberculosis, rhabdomyolysis, a known sensitivity to electric fields, or have ever had severe negative effects from weight lifting. Additionally, you will not be allowed to participate if you have had an injury or surgery on your arms in the past 6 months, are possibly pregnant, have an infection of the skin or joint, or have a pace maker/other implanted stimulators. **We are also asking that you do not exercise for the duration of this study (7 days max).

Nature and Purpose:

The purpose of this study is to evaluate the effect of an electrical stimulation treatment, known as soft tissue oscillation therapy, on the pain management for delayed onset muscle soreness (DOMS). You will be asked to perform bicep curls on the first day to make your bicep muscle sore. You will then report to our lab for treatment at least two more times and up to a maximum of six total sessions (7 days max, 6 sessions). During these sessions, you will receive one of two different treatments.

Explanation of Procedures:

If you volunteer to participation in this study, you will be asked to do the following:

1. Report to the Athletic Training Research Laboratory dressed in shorts, t-shirt and athletic shoes for a minimum of three sessions, but no more than six total sessions, each lasting no longer than 1 hour.

- 2. During the first session:
 - a. You will fill out a health history questionnaire to assure your qualification and safety for this study. We will explain the procedures discuss the risks.
 - b. Then, you will be asked to perform two bicep curls with a 2.27 kg (5lb) weight and to circle a number on a line to show your pain level.
 - c. Your 1 repetition maximum will then be determined using dumbbells in increasing increments of 2.27 kg (5lbs).
 - d. Next, the delayed onset muscle soreness protocol will be administered to your non-dominant arm. This will include SLOWLY lowering (straightening) your arm starting with a weight equal to your 1 repetition maximum + 2.27 kg (5lbs). You will then be asked to perform a total of 5 sets of 10 repetitions of this motion. Each repetition will last for a count of five. Between each set you will receive 1 minute of rest. If at any time you become fatigued and are unable to perform the slow-motion lowering with the weight in your hand, the weight will be decreased by 2.27 kg (5lbs) until you are able to complete the motion for five seconds. You will then complete two bicep curls with a 2.27kb (5lb) weight and circle a number on the line to rate your current pain.
 - e. At the conclusion of the first session you will be asked not to participate in any exercise including weight lifting and cardio activity during the duration of this study, approximately seven days.
 - f. You will also be asked not to:
 - i. Use any other pain relieving techniques. This could include pain relieving medications such as ibuprofen or aspirin as well as applying hot or cold packs to the affected area for the duration of this study
 - ii. Exercise for the duration of the study
- 3. The second session will be scheduled for 48 hours after the first. When you return to the athletic training room you will be asked to rate your pain. You will then be administered the soft tissue oscillation therapy treatment. During and after the treatment, you will again be asked to rate your pain. Treatment sessions three through six will include this same protocol in 24 hour increments. Treatment sessions will occur 48, 72, 96, 120, and 144 hours after the DOMS protocol is complete.
- 4. Once the treatment sessions are completed, you will be given an exit interview questionnaire, which will allow you to give your feedback on the treatment and how you well you thought it worked on your pain/soreness. If you are still sore following your final session, the researcher and university are not obligated to offer you any other treatment and costs for any injuries are your own.

Discomfort and Risks:

You will experience mild to moderate pain/soreness from the bicep curl protocol. This pain may be uncomfortable and may be similar to discomfort you may feel after physical activity/exercise. The pain may be described as achy, tender, or annoying. There are treatments used in this study which utilize low intensity electrical currents. If you are sensitive to the electrical stimulation, you might feel discomfort during the treatment, BUT the treatment should not be uncomfortable/ painful AND you can discontinue your participation at any time. If your health status requires further medical consultation, the researcher is obligated to refer you to the appropriate physician. If you do become sore, the researcher and university are not obligated to provide you with any other treatment. Any costs for injuries or other medical attention are solely your responsibility.

Benefits and Compensation: There will no direct benefits or compensation that you will receive from participating in this research.

Confidentiality: Information obtained during this study which could identify you will be kept confidential. The summarized findings with no identifying information may be published in an academic journal or presented at a scholarly conference.

Right to Refuse or Withdraw:

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled.

The investigators may withdraw you from this research if your inclusion status changes during the study (e.g. Illness, begin additional weight lifting, etc.)

Questions:

If you have any questions or concerns about your rights as a research participant related to this study or the study itself, now or in the future, please contact:

Principle Investigator	Faculty Sponsor
Jenifer A. Shoultz, LAT ATC	Kelli Snyder, EdD, LAT, ATC
003H HPC	003G HPC
University of Northern Iowa	University of Northern Iowa
(248)330-4382	(319)273-7401
shoultzj@uni.edu	kelli.snyder@uni.edu

You can also contact the office of the IRB Administrator, University of Northern Iowa, at 319-273-6148, for answers to questions about rights of research participants and the participant review process.

Agreement:

I am fully aware of the nature and extent of my participation in this project as stated above and the possible risks arising from it. I hereby agree to participate in this project. I acknowledge that I have received a copy of this consent statement. I am 18 years of age or older.

(Signature of participant)

(Date)

(Printed name of participant)

(Signature of investigator)

(Date)

(Signature of instructor/advisor)

(Date)

Apper	idix C2. Health Histo	ry Questi	onnaire.			
				Subjec	et Number:	
	PLEASE DO	<u>He</u> NOT PI	<u>alth History</u> UT YOUR N	<u>Form</u> AME ON THI	IS PAPER	
					~	
Ht	_ feet inches	Wt	pounds	Age:	Gender:	MF
1.	Does the statement by <i>I engage in moderat</i> <i>minutes a day, 5 day</i> <i>minimum of 20 minu</i>	below bes e- intensi vs a week utes a day	t describe yo ty aerobic ph or a vigorous , 3 days a we	ur physical acti ysical activity f s intensity aero ek.	vity level? Yes for a minimum og bic activity for a	No f 30
2.	Are you currently pa	articipatin	ig in a weight	training progra	am? Yes	No
3.	Do you incorporate 3a. If so, how often 3b. How much weig	bicep cur do you bi ht do you	ls in your wor cep curl? usually bice	ckout?	Yes	No
	3c. How many sets a 3d. Do you usually c 3e. If so, please expl	lo sets of ain how	bicep curls u	ntil failure?	Yes I	No
4.	Do you have a know example: electrical s Yes	vn sensitiv stimulatic No	vity to modali on (TENS), ult	ties which utili trasound, or so	ze electric fields ft tissue oscillati	S? For Son etc.
5.	Have you ever had s soreness) 5a. If so, please expl	evere adv Yes lain the ef	verse effect w	hen weight lift No nedical attentio	ing? (More seve n was needed	re than
6.	Have you ever been Malignancy, rhabdo cardiac disease? 6a. If so, please desc	diagnose myolysis, Yes cribe whic	d with any of , infection of No ch condition a	the following on the skin or join and when you v	conditions: t, tuberculosis, c vere diagnosed_	or a
	6b. Are you currentl	y sick? (f	lu, cold, uppe	er respiratory in	fection)	Yes No

7.	Do you have a cardiac pacemaker or another	· implanted	d stimulator	Yes	No
8.	Is there a possibility you may be pregnant?	Yes	No		
9.	Have you had an injury to your upper extrem	nity in the	past 6 months	?	
	(ie. shoulder, elbow, arm, wrist, hand)	Yes	No		
	9a. If so, please describe the injury (be specified	fic)			
	9b. When did this injury occur?				
10.	. Have you had surgery in the past 6 months?	Yes	No		
	10a. If so, what was the surgery for?				
	10b. When did you have the surgery?				
11.	Are you currently undergoing rehabilitation	for a previ	ious injury? Ye	es	No
11.	Are you currently undergoing rehabilitation to 11a. If yes, what is the rehabilitation for?	for a previ	ious injury? Y o	es	N
11. 12.	Are you currently undergoing rehabilitation to 11a. If yes, what is the rehabilitation for?	for a previ	ious injury? Yo at limits your a	es activity le	No evel
11. 12.	Are you currently undergoing rehabilitation to 11a. If yes, what is the rehabilitation for?	for a previ	at limits your a	es activity le	Ne
11. 12.	Are you currently undergoing rehabilitation to 11a. If yes, what is the rehabilitation for? Do you currently have any other injury or co Yes No 12a. If so, which side is the other injury or co	for a previous for a	at limits your a	es activity le t Left	No eve
11.	Are you currently undergoing rehabilitation to the second	for a previous of the second s	at limits your a	es activity le t Left	Ne
11.12.13.	 Are you currently undergoing rehabilitation if 11a. If yes, what is the rehabilitation for?	for a previous of the second s	at limits your a	es activity le t Left	No evel
11.12.13.	 Are you currently undergoing rehabilitation if 11a. If yes, what is the rehabilitation for?	for a previous ondition the condition loc Yes Right e specific.	at limits your a becated? Righ No Left	es activity le t Left	N

If you answered "YES", to any questions, or you are unsure about any of your answers, you will be asked for more detail to help the researcher better assess whether your condition increases your risk for participation.

Subject Number: Exit Interview Questionnaire BLEASE DO NOT BUT VOUD NAME ON THIS DADED							
PL	EASE DO NO		K NAME O	N I HIS PA	PER		
Which day	y was your pair	n most severe	?				
Day1 I	Day2 Day	3 Day4	Day5	Day6	Day 7		
Did you fe	eel the treatmen Ye	nt was effectiv e s	ve at managir No	ng your pain	?		
Which day	y did you feel t	he most relief	f of pain from	the treatme	nt?		
Session 2	Session3	Session4	Session5	Session6			
Since the first session up to now, have you used any analgesics? (Massage, apply ice, exercise, stretch, pain medication, or use any other modalities)							
	Y	es	No				
3a. If yes, please explain what you used							
Since the first session up to now, have you participated in any form of physical activity? (<i>worked out, weight lifting, or cardio</i>)							
	Y	es	No				
4a. If yes, please describe the physical activity you participated in							
	PLJ Which day Day1 I Did you fe Which day Session 2 Since the f <i>ice, exerci</i> 3a. If yes, Since the f activity? (Ex PLEASE DO NO Which day was your pain Day1 Day2 Day Did you feel the treatment Yo Which day did you feel the Session 2 Session3 Since the first session up <i>ice, exercise, stretch, pain</i> Yo 3a. If yes, please explain Since the first session up activity? (worked out, we Yo	Exit Interview O PLEASE DO NOT PUT YOU Which day was your pain most severed Day1 Day2 Day3 Day4 Did you feel the treatment was effective Yes Yes Which day did you feel the most relief Session 2 Session3 Session4 Since the first session up to now, have <i>ice, exercise, stretch, pain medication,</i> Yes 3a. If yes, please explain what you use activity? (worked out, weight lifting, o Yes 4a. If yes, please describe the physical	Exit Interview Questionnait PLEASE DO NOT PUT YOUR NAME O Which day was your pain most severe? Day1 Day2 Day3 Day4 Day5 Did you feel the treatment was effective at managin Yes No Which day did you feel the most relief of pain from Session 2 Session3 Session4 Session5 Since the first session up to now, have you used any ice, exercise, stretch, pain medication, or use any of 3a. If yes, please explain what you used. No Since the first session up to now, have you participa activity? (worked out, weight lifting, or cardio) No Yes No Since the first session up to now, have you participa activity? (worked out, weight lifting, or cardio) Yes No	Subject Num Exit Interview Questionnaire PLEASE DO NOT PUT YOUR NAME ON THIS PA Which day was your pain most severe? Day1 Day2 Day3 Day4 Day5 Day6 Did you feel the treatment was effective at managing your pain Yes No Which day did you feel the most relief of pain from the treatment Session 3 Session4 Session5 Session6 Since the first session up to now, have you used any analgesics ice, exercise, stretch, pain medication, or use any other modal. Since the first session up to now, have you participated in any factivity? (worked out, weight lifting, or cardio) Yes No Since the first session up to now, have you participated in any factivity? (worked out, weight lifting, or cardio) Yes No Since the first session up to now, have you participated in any factivity? (worked out, weight lifting, or cardio) Yes No Since the first session up to now, have you participated in any factivity? (worked out, weight lifting, or cardio) Yes No Since the first session up to now, have you participated in any factivity? (worked out, weight lifting, or cardio) Yes No		

Thank you for your participation. Your answers will be kept confidential. If you have any comments, questions, and/or concerns please address those with the primary researcher at this time. Thank you.

Subject Number: _____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Right Arm



Appendix C4. Pre-Protocol Numerical Rating Scale Bilaterally.

Subject Number: _____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Left Arm



	Subject Number:				
	DOMS Protocol				
1RMlb	Starting Weight [1RM + 2.27kg (5lb)]: <u>lb</u>				
Set 1: (10 Repetitions)					
Weight: <u>lb</u>	Repetitions:				
Weight: lb	Repetitions:				
Weight: <u>lb</u>	Repetitions:				
Rest for 1 Minute					
Set 2: (10 Repetitions)					
Weight: lb	Repetitions:				
Weight: lb	Repetitions:				
Weight: <u>lb</u>	Repetitions:				
Rest for 1 Minute					
Set 3: (10 Repetitions)					
Weight: lb	Repetitions:				
Weight: lb	Repetitions:				
Weight: 1b	Repetitions:				
Rest for 1 Minute					

Set 4: (10 Repetitions)	
Weight: <u>lb</u>	Repetitions:
Weight: <u>lb</u>	Repetitions:
Weight: <u>lb</u>	Repetitions:
Rest for 1 Minute	
C. (10 D (14)	
Set 5: (10 Repetitions)	
Weight: <u>lb</u>	Repetitions:
Weight: <u>lb</u>	Repetitions:
Weight: <u>lb</u>	Repetitions:

Appendix C6. Post-Protocol Numerical Rating Scale Bilaterally.

Subject Number: _____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Right Arm



Appendix C6. Post-Protocol Numerical Rating Scale Bilaterally.

Subject Number:_____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Left Arm



Appendix C7. Pre-Treatment Numerical Rating Scale Bilaterally.

Subject Number: _____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Right Arm



Appendix C7. Pre-Treatment Numerical Rating Scale Bilaterally

Subject Number: _____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Left Arm



Subject Number: _____

Please circle the number on scale line that represents the intensity of the pain you experience at this moment.

L Treatment 1 L Treatment 2 L Treatment 3 L Treatment 4 L Treatment	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5
---	-------------	-------------	-------------	-------------	-------------



Appendix C9. Post-Treatment Numerical Rating Scale Bilaterally.

Subject Number: _____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Right Arm



Appendix C9. Post-Treatment Numerical Rating Scale Bilaterally.

Subject Number: _____

Please circle the number on the scale line that represents the intensity of the pain you experience at this moment.

Left Arm



APPENDIX D

ADDITIONAL MATERIAL

Appendix D1. Recruitment Script.

Script Classroom Recruiting

(*Instructors will not be present)

Hello Everyone,

For those that don't know me, my name is Jenifer Shoultz. I'm an athletic training master's student here at UNI and I am here to invite you to participate in my research study.

I am studying the effects of different modalities on pain; specifically, the effects of a new type of massage and electrical stimulation on pain relief. You might have seen these machines being used already in the athletic training room.

If you participate in my study it will involve, 3-6 research sessions with me in the athletic training research lab (a minimum of 3, maximum of 6 sessions).

- 1. DOMS (Day 1): On the first day, probably a Sunday, I will ask you to complete a series of arm curls to the point of nearly exhausting your biceps. The purpose of these curls is to induce delayed onset muscle soreness; you've probably heard it called DOMS. This is what you feel a few days after you begin working out and you are very sore for the next several days. So if you participate, I will be asking you to give yourself DOMS to your biceps.
 - a. You will be asked not to participate in any exercise including weight lifting and cardio activity during the duration of this study, approximately seven days. (Right now, I am only including those who are willing to NOT exercise for the duration of my study.)
 - b. You will also be asked not to use any other pain relieving techniques. This could include taking pain relieving medications such as ibuprofen or aspirin as well as applying hot or cold packs to the affected area for the duration of this study.
- 2. TREATMENTS (Days 3 7):
 - a. Then, two days later, you will report back to the lab for your second session where you will receive one of two different treatments designed to relieve pain.
 - b. Before, during, and after each treatment, I will ask you to rate and explain your level of pain in your biceps.
 - c. You will be asked to report back the lab each day for a minimum of 3, maximum of 5 sessions, each session lasting for approximately a ½ hour each day. *That means your maximum total time commitment for the study could be as long 3.5 hours over 7 days; spread over a maximum of 6 research sessions.

If you are interested in participating, please write your name, email address, and phone number on the piece of paper you received. (**If you WOULD participate but you do NOT want to give up exercise, there will be a box for you to check.) Then I will contact you to answer your questions, ask you a few inclusion questions (e.g. how often do you perform curls? Have you ever had a really "bad" DOMS experience? Etc.), and then set up your first session if you meet all of my inclusion criteria.

If you are not interested in participating, just leave the piece of paper blank and I will still collect them all together.

Thank you very much for your time. Have a great day!

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