

MULTIPLE DAILY TENS TREATMENTS FOR THE SHOULDER AFTER
EXERCISE-INDUCED INJURY

By

GEOFFREY DOVER

A DISSERTATION PRESENTED TO THE GRADUATE SCHOOL
OF THE UNIVERSITY OF FLORIDA IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

UNIVERSITY OF FLORIDA

2005

Copyright 2005

by

Geoffrey Dover

Dedicated to my family and friends.

ACKNOWLEDGMENTS

My doctoral dissertation journey has been extensive and I could not have completed it without the help of many people. My committee has changed several times over the years, but my current committee has been supportive and instrumental in providing me with an education at the University of Florida.

My committee consisted of four great individuals: Dr. Cauraugh, who has been with me from the beginning and constantly challenges me; Dr. Tillman who is the nicest and most thoughtful man I have worked with; Dr. George who came on last and has contributed significantly to my dissertation; and finally Dr. Borsa, who functioned as my chair and mentor this past year. I will always remember this committee as being helpful and challenging.

I would like to thank my parents who supported me in leaving Canada to pursue my studies in Florida. Their support and patience to see their son be a student his whole life until now has been great.

Special thanks go to the whole Mendoza family. Linda, Joe, Lisa, Sarah, and Mike have listened well, provided support, and have been a truly wondrous influence on my life during this time. My memories of my dissertation time here at UF will always be connected to the Mendoza family and happiness. Getaway weekends to Orlando helped me during my years here in Gainesville.

Two people that contributed significantly to my dissertation journey over the years but who were not on my committee are Dr. Coleman and Dr. Hessler-Smith. I will remember past events always bear on days year-round.

People who I see every day and will be missing shortly include Erik and April. There is nothing like relating to someone going through a similar experience and I have been grateful to be able to talk with Erik about my dissertation at any given time. April understands the thesis journey and has been a good friend over my years here at UF.

Finally I want to thank Dave and Ando who are some of my closest friends for their support over the last few years and the entire time I have known them. I feel that I would have not been able to achieve as much in my life without the support and secure roots that I have with my friendship with Dave Bolton. I hope I can provide as much support to him as he did with me during his PhD career. Ando is the smartest man I know and I feel challenged to keep up with him and his family.

TABLE OF CONTENTS

	<u>page</u>
ACKNOWLEDGMENTS	iv
LIST OF FIGURES	ix
ABSTRACT	xi
CHAPTER	
1 INTRODUCTION	1
Primary Specific Aims.....	6
Secondary Specific Aims.....	6
2 BACKGROUND AND SIGNIFICANCE.....	8
TENS	8
Summary.....	13
Efficacy.....	13
Summary.....	21
Exercise-Induced Injury	21
Summary.....	24
Outcome Measures	24
Visual Analogue Scales.....	24
The DASH	26
Algometry.....	27
Isokinetic Evaluation	28
Summary.....	30
Hemiplegic Shoulder Pain.....	31
Summary.....	32
General Summary	33
3 RESEARCH DESIGN AND METHODS.....	36
Study Population.....	36
Instrumentation	37
Visual Analogue Scale (VAS).....	37
Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire	38
Fischer Algometer	38

Kin-Com.....	39
TENS Device.....	40
Clinical Measures.....	40
Range of Motion (ROM).....	40
Assessment of Pain and Functional Impairments.....	42
Mechanical Pain Threshold (MPT).....	42
Maximum Voluntary Isometric Contraction (MVIC).....	44
Research Design.....	45
Experimental Procedures.....	45
Control Group.....	49
Placebo Group.....	49
TENS Group.....	50
Statistical Procedures and Analyses.....	51
Primary Outcome Measures: Overall Shoulder Pain.....	51
DASH Questionnaire.....	51
MPT.....	51
Secondary Outcome Measures: ROM.....	52
MVIC Data.....	52
4 RESULTS.....	53
Primary Outcome Measures Within-Group Comparisons.....	53
Pain and DASH scores.....	53
Point Tenderness.....	54
Secondary Outcome Measures.....	55
Range-of-motion (ROM).....	55
Shoulder Muscle Strength (MVIC).....	55
Between-Group Comparisons: Primary Outcome Measures.....	56
Secondary Outcome Measures.....	59
Between-Group Comparisons: Primary Outcome Measures Main Effects.....	61
5 DISCUSSION.....	62
Within-Group Comparisons: Primary Outcome Measures.....	63
Secondary Outcome Measures.....	65
Between-Group Comparisons: Primary Outcome Measures.....	66
Secondary Outcome Measures.....	67
Exercise-Induced Injury Model.....	68
Evidence-Based TENS Considerations.....	69
Study Limitations.....	71
Conclusions.....	72
APPENDIX	
A IRB CONSENT FORM.....	73
B IRB PROTOCOL.....	77

C DATA COLLECTION FORM.....	81
LIST OF REFERENCES.....	88
BIOGRAPHICAL SKETCH.....	97

LIST OF FIGURES

<u>Figure</u>	<u>page</u>
1-1. Gate control theory of pain (Melzack and Wall 1965).....	3
3-2. Fischer algometer.	39
3-3. Positioning of subject during ER ROM measurements.	41
3-4. Position of subject during resting IR measurement.	42
3-5. Three sites for MPT testing over the supraspinatus and infraspinatus muscles and the tip of the acromion.....	43
3-6. Subject position for IR/ER testing on the Kin-Com.	44
3-7. Flow chart of single blind randomized control trial of three groups (control, placebo, treatment) to measure the efficacy of TENS.	46
4-8. Significant increase in self-reported shoulder pain on a visual analogue scale after exercise-induced injury.....	53
4-9. Increase in upper extremity dysfunction as measured by the DASH questionnaire after exercise-induced injury of the shoulder.	54
4-10. Increase in point tenderness at three sites of the shoulder after exercise-induced injury.	54
4-11. Active and passive ROM decrease after exercise-induced shoulder injury.....	55
4-12. External rotation MVIC decrease after exercise-induced injury of the shoulder.....	56
4-13. Increase in pain among the three groups after exercise-induced injury of the shoulder.	57
4-14. Increase in dysfunction of the upper extremity in the three groups after exercise- induced injury.....	57
4-15. Increase in point tenderness of the tendon insertion of the rotator cuff and the supraspinatus trigger point after exercise-induced injury of the shoulder.	58

4-16. Increase in point tenderness of the infraspinatus trigger point after exercise-induced injury of the shoulder.....	58
4-17. Loss of IR and ER active and passive ROM after exercise-induced injury of the shoulder.....	59
4-18. Decrease in passive IR and ER ROM after exercise-induced injury.....	60
4-19. Decrease in resting IR ROM after exercise-induced injury of the shoulder.....	60
4-20. Between-group strength differences after exercise-induced injury in the shoulder.....	61

Abstract of Dissertation Presented to the Graduate School
of the University of Florida in Partial Fulfillment of the
Requirements for the Degree of Doctor of Philosophy

MULTIPLE DAILY TENS TREATMENTS FOR THE SHOULDER AFTER
EXERCISE-INDUCED INJURY

By

Geoffrey Dover

August, 2005

Chair: Paul Borsa

Major Department: Applied Physiology and Kinesiology

Pain is the most common reason why people seek medical attention. In addition, pain is the most common symptom of injury and disease. Studies that evaluate pain relief are needed to find effective modalities to decrease pain. Our study evaluated the efficacy of a new Transcutaneous Electrical Nerve Stimulation (TENS) device for treating pain in the shoulder. Our study was a single-blind, randomized controlled trial measuring the efficacy of TENS for providing pain relief and improved function in the shoulder after exercise-induced injury of the shoulder. Thirty-six healthy subjects volunteered for this study. We measured how much the subjects could move their shoulder and how strong their shoulder was in the external rotation direction. In addition we measured point tenderness around their shoulder and had all subjects fill out a functional questionnaire that measured activities of daily living.

After baseline testing all subjects underwent a rigorous shoulder exercise protocol on Day 1, then returned for three more days for follow-up testing. Follow-up testing

included the same measures as Day 1 (including movement, point tenderness, filling out the functional questionnaire, and strength). For the three days after the exercise protocol, 12 subjects received no treatment, another 12 subjects received TENS treatment and 12 subjects received a sham treatment. The TENS treatment consisted of 90 minutes of high-frequency current designed to reduce pain. All subjects experienced a significant increase in pain ($F(4,132)=36.99, p<.01$) and dysfunction ($F(3,99)=45.75, p<.01$) and a decrease in movement ($F(3,99)=48.66, p<.01$) and strength ($F(3,99)=10.79, p<.01$) in their shoulder after the exercise protocol. The TENS group did not experience less pain ($F(8,132)=0.75, p=.64$) or dysfunction ($F(6,99)=1.36, p=.24$) compared to the other two groups. TENS is not effective in reducing pain or dysfunction in the shoulder after a rigorous exercise bout. The exercise protocol used in our study is effective for inducing pain in the shoulder and can be used for future studies to evaluate pain management. Future studies are warranted to identify pain-relief modalities for the upper extremity.

CHAPTER 1 INTRODUCTION

Reducing a patient's level of pain is a high priority for clinicians treating acute musculoskeletal injuries. Recognition of pain as a causative agent in functional impairment and disability has grown enormously over the past decade both nationally and internationally. Pain has garnered so much attention in the United States that initiatives have been undertaken with the purpose of classifying pain as "the fifth vital sign" (along with blood pressure, temperature, heart rate, and respiration)(Turk and Melzack 2001). Pain is the most common symptom of musculoskeletal injuries (Denegar and Donley 2003) and the treatment of pain has cost the U.S. an estimated \$215 billion a year (Praemer et al. 1999). Musculoskeletal injuries and disorders involve trauma to bone, muscle, tendon, and ligament; and may also include bone and joint damage from degenerative arthritis and osteoporosis (Cherry and Woodwell 2002).

Transcutaneous Electrical Nerve Stimulation (TENS) is a commonly used therapeutic modality for treating musculoskeletal-related injuries. However, evidence supporting the efficacy of TENS is equivocal (Chesterton et al. 2003; Koke et al. 2004; Price and Pandyan 2001; Reeve et al. 1996; Snels et al. 2002); to positive (Ada and Foongchomcheay 2002; Bjordal et al. 2003; Chabal et al. 1998; Morgan et al. 1995; Walsh et al. 1995); to not effective for treating certain conditions (Brosseau et al. 2002; Carrol et al. 1996; Craig et al. 1996; Herman et al. 1994). In one study subjects suffering from chronic pain who were treated by TENS reported a 55% decrease in pain medication and a 69% decrease in physical or occupational therapy (Chabal, et al. 1998).

Another meta-analysis reported that 15 of 17 studies did not indicate significant pain relief using TENS compared to a placebo (Carrol et al. 1996). Methodological differences among studies have prevented researchers from drawing strong conclusions supporting TENS use in a clinical setting (Carrol et al. 1996; Johnson 2001). These methodological differences include blinding (or masking) and randomization procedures, selection bias, and the dosage or amount of TENS delivered (Johnson 2001). Improper blinding, randomization, and dosage can significantly alter the results of a study (Altman and Bland 1999a; Altman and Schulz 2004; Carrol et al. 1996; Grimes and Schulz 2002; Schulz and Grimes 2002b; Schulz and Grimes 2002c; Schulz and Grimes 2002a). Proper blinding and randomization are necessary in order to not artificially inflate the treatment effect. Carrol et al. completed a meta-analysis that identified 46 reports studying TENS but noted that only 17 of them were randomized control trials, resulting in a paucity of well-designed, properly blinded, and randomized studies measuring the effectiveness of TENS (Carrol et al. 1996).

Most TENS units provide a variety of application protocols for both acute and chronic pain relief. The type of pain perceived by the patient (e.g. sharp pain vs. dull ache) dictates which treatment protocol should be used. Treatment dosage is determined by the frequency (once/twice a day), intensity (amplitude of current), mode (continuous/pulsed), duration (minutes), and length of treatments (days/weeks). Results of various studies on TENS are difficult to compare because of the multitude of treatment dosages prescribed.

The mechanism by which high-frequency TENS relieves acute pain is based on gate control theory (Figure 1-1)(Melzack and Wall 1965). According to the theory,

stimulating large diameter (A- β) afferent fibers in the body using TENS application results in pain reduction (Denegar and Donley 2003). Neural signals from large diameter afferent fibers stimulate 2nd order neurons in the spinal cord that ultimately inhibit (or close the gate) on pain impulses transmitting from a cluster of nociceptors (A- δ and C).

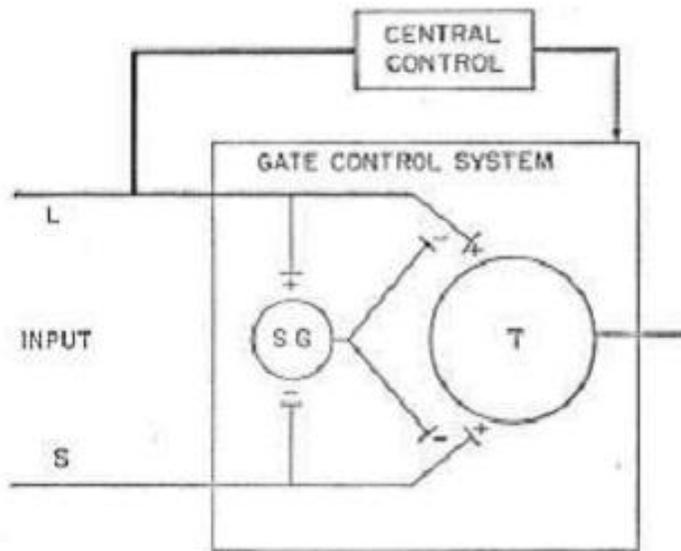


Figure 1-1. Gate control theory of pain (Melzack and Wall 1965)

Pain signals that transmit along both large A- δ and small C fiber pathways are diminished; as a result, the subject perceives less pain (Denegar and Donley 2003). Based on this theory, a patient will only experience pain relief for as long as high frequency treatment is being applied with no residual effects (Denegar and Donley 2003; Johnson 1997). A short treatment time may not provide enough current and pain relief to effect the subjects overall pain or function.

Craig et al. used TENS to treat musculoskeletal pain with one 20-minute session per day for four days and concluded that TENS was ineffective in providing pain relief or function (Craig et al. 1996). During the other 23 hours and 40 minutes of the day the subjects were not allowed to treat any pain they may have been experiencing. The short

treatment time may have confounded the results by not providing an adequate dose for the subjects to experience pain relief or improve function (Johnson 1997).

No study to date has measured the efficacy of TENS for treating acute pain using multiple daily treatments. Multiple daily TENS treatments allow for repeated exposures, thus increasing the therapeutic dose for the patient. Multiple daily treatments increase the amount of time during the day subjects will experience pain relief, which may translate to an overall decrease in symptoms and an increase in function. TENS is easy to use, safe, noninvasive, non-addictive, and cost-effective compared to other therapeutic agents (such as prescription pain medication, injections and acupuncture) making TENS a desirable therapeutic modality for pain management. Additionally TENS has no harmful side effects, and there is no potential for toxicity or overdose (Johnson 2001).

TENS treatment can be used on most anatomical locations on the body and is a popular treatment modality for joint injuries such as those of the ankle, knee, spine and shoulder. Specifically, pain and dysfunction in the shoulder is a problem for individuals who rely heavily on upper-extremity function for work, movement or regular activities of daily living. Approximately 12 million visits were made to physicians' offices due to shoulder problems in 2000 (Cherry and Woodwell 2002). This high volume of shoulder injuries requires new studies that focus on pain relief and improve function of the glenohumeral joint.

Exercise-induced muscle injury is a condition that appears 12–48 hours after eccentric or strenuous exercise to a localized area (Leadbetter 1994). The pathophysiology of induced injury has been shown experimentally to be similar to the traditional acute musculoskeletal injury inflammation model that includes a local vascular

and cellular response in and around the damaged tissues. Moreover, the signs and symptoms of exercise-induced injury are pathologically similar to those of acute injury (persistent pain, swelling and edema, loss of function, and signs of healing at approximately 72 hours)(Smith 1991; Toumi and Best 2003). Most research on exercise-induced injury used the bicep brachii model, inducing injury through repeated eccentric muscle actions (Borsa and Sauer 2000; Byrne et al. 2004; Craig et al. 1996; Lee et al. 2003; Myers et al. 1999; Saxton et al. 1995; Vincent et al. 2000). Researchers commonly use the biceps because it is large, biarticular, superficial, and easily identifiable muscle with few agonists for elbow flexion; all of which make the elbow joint useful for measuring differences in joint range of motion, pain perception, and muscular force production. However, pain relief has been found to vary depending on the anatomical location and tissues involved (Denegar and Donley 2003; Hartley 1997). No study to date has evaluated or treated exercise-induced injury in the shoulder. This is alarming, given the fact that the shoulder is so important for upper-extremity function especially for individuals involved in overhand activities.

Muscle and tendon-related injuries are common in the shoulder; especially injuries involving the rotator cuff. Overhand athletes (such as baseball pitchers, tennis players and swimmers) can suffer from acute or insidious types of shoulder injuries most of which include symptoms such as pain (Wilk and Arrigo 1993). Stroke survivors often have associated pain and shoulder problems due to the motor deficits after an ischemic attack (Ada and Foongchomcheay 2002; Price and Pandyan 2001; Snels et al. 2002; Turner-Stokes and Jackson 2002; Vuagnat and Chantraine 2003). Relieving shoulder pain is of special concern to health care professionals and no study yet has been able to identify

viable modalities for providing pain relief and improved glenohumeral function after musculoskeletal trauma. Therefore, the grand objective of this study was to determine the efficacy of multiple daily TENS treatments compared to placebo TENS, and a control group for reducing acute shoulder pain and improving functional status after exercise-induced injury.

Primary Specific Aims

1. To test the hypothesis that multiple daily TENS treatments would provide significantly more symptomatic (pain) relief and improved function compared to sham and control treatments after shoulder exercise-induced injury across days. Following the eccentric exercise bout, the perceived pain levels among the three groups were compared using a Visual Analogue Scale (VAS) and the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire.

2. To test the hypothesis that multiple daily TENS treatments would significantly lower point tenderness (MPT) after exercise-induced injury compared to sham and control treatments across days. This was achieved by measuring mechanical pain threshold using an algometer.

Secondary Specific Aims

1. To test the hypothesis that multiple daily TENS treatments would significantly improve glenohumeral joint range-of-motion after exercise-induced injury compared to sham and control treatments across days. This was achieved by measuring active, passive, and resting glenohumeral joint range-of-motion (IR/ER) using a standard goniometer.

2. To test the hypothesis that multiple daily TENS treatments would significantly improve glenohumeral muscular force production after exercise-induced injury compared

to sham and control treatments across days. This was achieved by measuring the maximal voluntary isometric force production of the shoulder external rotators using a dynamometer.

CHAPTER 2 BACKGROUND AND SIGNIFICANCE

TENS

Transcutaneous electrical nerve stimulation (TENS) is a popular modality for pain relief (Johnson 2001; Melzack and Wall 1965; Walsh 1997). Treatment is administered by electrical currents, which are generated by a controlled stimulating device and delivered across the intact surface of the skin via electrodes. Use of TENS has increased because of the noninvasive nature of the treatment, ease of use, few side effects and no drug interaction. There is no potential for toxicity, or overdose. Patients can administer the treatment and titrate the dosage themselves. Moreover, TENS may be an economical and effective alternative to prescription medication (Chabal et al. 1998; Walsh 1997).

Historically TENS has been defined as a modality that delivers electricity to the intact surface of the skin, which would include current or shocks from electrogenic fish (Walsh 1997). Today the definition includes any stimulation from a standard TENS device. A standard TENS device generates a biphasic or monophasic pulsed current in a repetitive manner with a pulse duration between 50 microseconds and 1000 microseconds, and pulse frequencies between 1 and 250 pulses per second (pps)(Johnson 2001). Pulses are typically delivered in a repetitive and continuous pattern, although most new devices include burst and modulation settings. Most differences between TENS devices on the market are minor and would not significantly vary treatment outcome. Treatment differences include the amplitude of current selected by the user, the application procedure, and the dosing regimen.

Pain is an integral part of life and plays an important protective function (Turk and Melzack 2001). In addition, pain is the primary symptom that prompts us to seek medical attention. Recognition of pain is growing and there is a movement in the United States to consider pain “the fifth vital sign” (along with blood pressure, temperature, heart rate, and respiration). In January 2001, then President Bill Clinton signed into law a bill declaring the decade 2001–2010 as the Decade of Pain Control and Research. Pain medications are the third most frequently prescribed medications (after cardiac and renal drugs)(Schappert 1996). Each year, in the US, 23 million surgical procedures are performed for which pain is a common symptom afterwards(Peebles and Schneiderman 1991). In addition there are approximately 50 million trauma injuries each year, which are often associated with a high level of pain (Schappert 1996). However, these are only the reported cases. Many people treat their own pain by buying over-the-counter drugs or seeking alternative and complementary forms of treatment. Costs for direct and indirect treatment of pain may be near \$125 billion annually (Turk et al. 1999). Because of the prevalence of musculoskeletal and neuro-degenerative pain, we need better and economical ways to treat pain.

Pain has three major psychological dimensions: sensory-discriminative, motivational-affective, and cognitive-evaluative (Turk and Melzack 2001). The underlying theory suggests that these categories interact to provide perceptual information on the location, magnitude, and spatiotemporal properties of the noxious stimuli. This has been described as a motivational tendency toward escape or attack, coupled with cognitive information based on past experience and probability of outcome of different response strategies.

The purpose of TENS is to activate select populations of nerve fibers, to produce a specific physiological outcome (Denegar and Donley 2003). TENS can be classified into three types: conventional, brief intense, and acupuncture-like or noxious. The variety of TENS applications have evolved from knowledge about the ability of various nerve fibers to activate differing analgesic mechanisms in the body. Evidence from axonal studies in vitro suggests that excitability varies according to the characteristics of the applied current (Garrison and Foreman 1994). To sell more TENS units, manufactures regularly make new treatment parameters for their devices. These units are sold based on the idea that their TENS units can provide treatment that was not previously available. New parameters are based on theory and most have not been tested clinically. Manufacturers are able to produce devices with new parameters faster than researchers can evaluate them. Another reason why there is no definitive answer regarding the efficacy of TENS is the large number of treatment parameters that are present. Most studies that evaluate TENS use different treatment parameters including time of treatment, frequency, and current duration. Clinicians may be more interested in changing the output or treatment parameter as opposed to changing the physiological nature of the treatment. Another factor that leads to the breakdown of TENS is the non-homogenous nature of the tissue underlying the electrodes. To further discuss this point, the mechanism of TENS is explained next.

The purpose of conventional TENS is to selectively activate the large diameter A- β fibers without activating the small-diameter A-sigma, C fibers, or muscle efferents. Theoretically, high-frequency (10–250 pps), low-intensity (non-painful), currents with a pulse duration between 100 and 200 microseconds would be most effective for

stimulating the A- β fibers (Denegar and Donley 2003; Walsh 1997). In practice, A- β afferent activity is recognized by the patient reporting strong but comfortable and non-painful electrical paraesthesia or tingling locally under the electrodes. Animal and human studies show that TENS-induced A- β activity inhibits ongoing nociceptive information in the spinal cord and this produces segmental analgesia with a rapid onset and offset (Garrison and Foreman 1994; Garrison and Foreman 1996). They measured dorsal horn cell activity during noxious stimuli in an anesthetized cat by using microelectrodes that measured the extracellular action potentials in 83 cells in the dorsal horn while a pinch or muscle clamp was applied to the left upper and lower extremity. During application of conventional TENS, dorsal horn cell activity decreased in 56% of the cells; and the decrease in activity occurred only while the TENS was being applied (Garrison and Foreman 1994).

Amplitude or intensity is important for A- β stimulation (Johnson 2001). Patients are instructed to use a high enough amplitude to generate a non-noxious paraesthesia perceived as a comfortable tingling or buzzing sensation without pain (activating the A-sigma and C fibers). Previous studies suggest that the magnitude of analgesia achieved during conventional TENS depends partly on pulse frequency, but findings are inconsistent (Johnson et al. 1989; Sjolund 1985; Sjolund 1988; Walsh 1997). While one of the earliest studies (Sjolund 1985) advocated using 80 pps, later results indicated no difference in pain relief using any frequency between 20 and 80 Hz (Johnson et al. 1989).

Low-frequency TENS may use two other mechanisms to decrease pain, including the release of endogenous opioids and modifying descending inhibition. Discovery of endogenous opioids in the 1970's significantly contributed to the theory of pain relief

(Denegar and Donley 2003). The theory proposes that increased neural activity in A-alpha and A- β primary afferent pathways triggers a release of enkephalin from enkephalin interneurons found in the dorsal horn of the spinal cord. These neuroactive amines inhibit synaptic transmission in the A- δ and C fiber afferent pathways. The end result is a decrease in pain transmission. In addition, another analgesic mechanism includes descending inhibition. This theory suggests that higher centers of the nervous system may affect the dorsal horn gating process (Denegar and Donley 2003). Impulses from the thalamus and brain stem are carried into the dorsal horn of efferent fibers in the dorsal or dorsal lateral tracts. These higher center impulses act to close “the gate” (as mentioned above) blocking the transmission of the pain message at the dorsal horn synapse. This theory originates from the higher centers of the brain, which can be influenced by various factors. Previous experiences, emotional influences, and sensory perception can influence higher brain centers and can alter pain perception-making measuring pain a challenge. Each person having a different background and life experiences may experience pain differently, given the same stimulus.

A form of TENS that targets opioid release is “acupuncture-like” TENS. The purpose of acupuncture like TENS is to generate activity in the small diameter muscle afferents A- σ or Group III arising from ergoreceptors that respond from muscle contraction (Fargas-Babjak et al. 1992). This is achieved by delivering currents at low frequencies with high but not painful intensities over motor points in order to activate Alpha efferents resulting in a forceful but non-painful muscle twitch-like responses (Eriksson et al. 1979). The subsequent volley of impulses from muscle afferents mediates an extrasegmental antinociceptive mechanism and the release of endogenous opioid

peptides in a manner similar to acupuncture (Anderson et al. 1973; Sjolund and Eriksson 1979; Sjolund et al. 1977).

The purpose of intense TENS is to activate the A- σ cutaneous afferents by delivering current over peripheral nerves arising from the site of pain at an intensity that is barely tolerable to the patient. Currents are applied at high frequencies (up to 150 pps) to prevent phasic muscle twitches that would be too forceful for the patient to tolerate. Cutaneous A- σ afferent activity has been shown to block transmission of nociceptive information in peripheral nerves and to activate extrasegmental antinociceptive mechanisms (Chung et al. 1984; Ignelzi and Nyquist 1976; Ignelzi and Nyquist 1979; Woolf et al. 1980). These mechanisms can include a slowing of conduction velocity, an increase in electrical threshold, and a decrease in response by the afferent fibers (Ignelzi and Nyquist 1979).

Summary

Pain is a symptom that can be treated by using TENS. Various mechanisms and pathways are responsible for the reduction of pain by using TENS (Denegar and Donley 2003). The study of the reduction of pain is important due to the number of people that seek medical attention every year for pain relief (Cherry and Woodwell 2002).

Efficacy

Several studies have reported that TENS treatments can provide relief for chronic pain (Bates and Nathan 1980; Brosseau et al. 2002; Chabal et al. 1998; Fargas-Babjak et al. 1989; Koke et al. 2004; Reeve et al. 1996). Study design is important in determining the efficacy of treatments. In the discussion section of these studies, the authors emphasize the methods of the study and how the design influences the results. Brosseau et al. completed a meta-analysis on the treatment of chronic low back pain using TENS

(Brosseau et al. 2002). The authors commented on the difficulty of completing the study because they only found 5 randomized clinical trials to include in the analysis. Although the result of the study was that TENS was not effective for treating chronic low back pain, the authors concluded that the lack of effectiveness could be explained by the differences in the methods of the clinical trials included in the analysis. Not all of the studies consistently reported the characteristics of the TENS device and the parameters of the treatment used. In addition, the lack of standardized outcome variables made performing the analysis difficult. The authors concluded by stating future studies measuring the effectiveness of TENS should address the type of application, site of application, treatment duration, optimal frequencies and optimal intensities. Moreover, controlling patient pathology is sometimes a confounding variable in clinical trials. Patients with different injuries may suffer from different levels of pain, increasing the error between groups (Brosseau et al. 2002). As mentioned by Brosseau et al. TENS effectiveness may be better measured with another outcome variable such as medication cost (Brosseau et al. 2002). Chabal et al. randomly selected 376 patients undergoing TENS treatments for pain and reported a significant decrease in pain medication taken for chronic pain subjects (Chabal et al. 1998). Costs were reduced by up to 55% for medication and 69% for physical and occupational therapy treatment (Chabal et al. 1998). In addition, the same authors reported a significant decrease in pain, interference with work, home, and social activities with TENS (Fishbain et al. 1996).

Several authors have suggested that the amount of pain relief generated by TENS may be site and condition specific (Brosseau et al. 2002; Denegar and Donley 2003; Walsh 1997). Studies measuring TENS should be completed on various joints and

conditions in the body including arthritis in the knee. Osteoarthritis is one of the most common chronic pain conditions in the knee. A specific form of TENS referred to as codetron significantly reduced pain compared to a group of subjects who received a sham treatment with osteoarthritis in the knee (Fargas-Babjak et al. 1989). Subjects receiving TENS reported a 74% reduction in pain compared to 25% in the sham group (Fargas-Babjak et al. 1989). This study suggests that TENS is effective for pain relief of osteoarthritis in the knee.

Injury heterogeneity may be an important factor in determining the efficacy of TENS. Researchers have difficulty measuring the effectiveness of TENS on various injuries because the perceived pain level may be different for each injury. A previous study reported no significant benefit with using TENS on patients with a wide range of pathology (Bates and Nathan 1980). Subjects were diagnosed with injuries or signs and symptoms ranging from postherpetic neuralgia, chronic back pain, spinal pain, amputation stump pain, a painful scar, and atypical facial pain (Bates and Nathan 1980). The main outcome measure in this study was the length of time patients kept their TENS units, before returning them to the clinic. This is not an objective measure of pain relief rather, the authors assumed the longer the subjects had the device the more pain relief they required. A group of subjects who suffer from a wide range of injuries most likely experience different levels of pain, which would make identifying a significant reduction in pain more difficult. Between the varying levels of pain suffered by the patients, and measuring a subjective variable such as time keeping the TENS unit, the authors could not recommend using or not using TENS (Bates and Nathan 1980).

Two reports proposed that patients develop a tolerance to TENS over time, which may refer to the treatment time, or over multiple treatments (Bates and Nathan 1980; Loeser et al. 1975). Current devices have modulation parameters to counteract the nervous system habituation to the repetitive monotonous stimuli over one treatment or multiple treatments. Tulgar et al. have fluctuated the pulse frequency and observed a reduction in pain (Johnson et al. 1989; Tulgar et al. 1991b; Tulgar et al. 1991a). Although there is no evidence to date to suggest that altering the pulse frequency can affect the tolerance to TENS. Another option is to deliver a random pulse or burst which may provide effective pain relief (Johnson et al. 1991). Johnson et al. has described Codetron as a TENS-like device that delivers low-frequency 2–4 pps in a square wave form with a pulse duration of 1 ms in a random order to one of 6 electrode placements (Herman et al. 1994; Johnson 2001). For this type of application, six pads are placed over acupuncture points, which may work in a similar manner to electro-acupuncture (Fargas-Babjak et al. 1992; Fargas-Babjak et al. 1989; Herman et al. 1994). These authors reported a decrease in reported pain, which suggests that varying pulse frequency and intensity can help reduce pain and prolong the tolerance effect.

Two previous studies evaluated the efficacy of TENS for alleviating pain from exercise-induced injury of the biceps (Craig et al. 1996; Walsh 1997). Craig et al. measured 24 male and 24 female volunteers who never experienced TENS before. The subjects non-dominant elbow flexors were fatigued and they received a control, placebo, low TENS (200 usec 4Hz), or High TENS (200 usec 110Hz) treatment. Subjects reported on three consecutive days and measurements were made on elbow extension, flexion, resting angle, mechanical pain threshold (algometer), a visual analog scale, and the

McGill pain questionnaire. The authors noted significant improvement using the high TENS only for increasing the flexion range of motion and decreasing the resting angle range of motion for the elbow. The authors concluded that TENS was not effective for treating exercise-induced injury but did mention they wanted to measure the results again over a 72-hour duration. This is another example of the results of the study being brought into question by examining the study design.

While exercise-induced injury is an excellent model for evaluating the efficacy of a pain relief modality, ischemic pain has also been examined (Walsh et al. 1995). Walsh et al. used a method referred to as the sub-maximum effort tourniquet technique (SETT) to approximate the duration and severity of clinical pain (Walsh et al. 1995). The technique involves wrapping a sphygmomanometer pressure cuff around the upper limb and quickly inflating the cuff to over 200 mm Hg followed by a series of hand gripping exercises to induce ischaemic pain. The authors used the SETT on 32 females and subjects received either a control, sham, low TENS, or high TENS treatment. The results indicated that the low frequency TENS provided more pain relief compared to the other 3 groups. However, the authors mentioned that there were no differences between groups for the pain scores from the McGill Pain Questionnaire.

Another model used to evaluate pain is pressure pain thresholds applied at the hand (Chesterton et al. 2003). The authors used an algometer to apply force to the first dorsal interosseous muscle until the subject reported that they perceived pain. Walsh et al. randomly assigned subjects into 8 groups that included high frequency TENS, low frequency TENS, A segmental application, extrasegmental application, a combined treatment, a control, and a sham group (Walsh et al. 1995). The high frequency TENS,

high intensity segmental, and combined groups showed significant hypo-analgesia compared to the other groups. Although the high frequency TENS group experienced a significant reduction in pain relief compared to the sham group, the authors claimed that a clinically significant level of pain relief was not achieved. They reported a difference of up to 15 Newtons of force was required to elicit pain in the group using high frequency TENS compared to the control, but the authors claimed this was not a clinical level of pain relief. In addition to applying TENS to the painful area, the authors applied TENS to the neck using a segmental treatment to a separate group. We used a similar application in our proposed study. Four electrodes were applied around the shoulder joint at known acupuncture points in order to reduce pain. In addition, our study provided a good example of using a sham treatment group. Having a sham treatment group is necessary for randomized clinical trials so we know if the difference is due to a placebo effect. The sham group was blinded and received the same instructions as all the other treatment groups in order to limit experimenter influence for the outcome. A previous study noted lower pain scores in the sham group compared to the control group at all time periods, although the findings were not statistically significant (Chesterton et al. 2003).

Researchers have experienced difficulty measuring the efficacy of TENS on an injured population, because each injury may elicit a different amount of pain. Subjects suffering from a mild injury may report less pain than subjects diagnosed with more serious injuries. While researchers would prefer to use injured subjects versus their healthy counterparts, the difference in pain levels would significantly affect the results of the study. However, Morgan et al. used subjects who were receiving distension arthrography for a 'frozen shoulder' (Morgan et al. 1995). Distension arthrography is an

effective but painful treatment for the 'frozen shoulder'. In this study, all subjects were undergoing the same treatment for their 'frozen shoulder'. The same surgical procedure for each subject may be less variable than separate injuries suffered by different patients. This study used TENS in conjunction with medication to increase analgesia for patients undergoing the distension arthrography. The procedure involves using a large needle to distend the shoulder joint with air. The TENS group reported a significant reduction in pain versus the control group. The authors concluded that TENS is a safe modality that can be used to reduce pain in various settings. However, the authors did not include a sham treatment group as part of the study design. The exclusion of a sham treatment group may artificially inflate the pain relief of the TENS treatment. The authors stated that they could not blind the surgeon during the TENS treatments. Morgan et al. have no way of knowing if a sham treatment group in this case would have felt significantly less pain compared to the treatment group (Morgan et al. 1995).

Bjordal et al. measured pain relief after surgery and also concluded TENS was beneficial (Bjordal et al. 2003). The purpose of this study was to determine if TENS or acupuncture like TENS could reduce analgesic consumption after surgery. This study was a meta-analysis that included any randomized placebo controlled trials that measured medication request after various surgeries. The surgeries ranged from caesarean sections to inguinal hernias. The meta-analysis demonstrated a significant decrease in analgesic consumption versus the placebo (Bjordal et al. 2003). The difference was 26.5% reduction in request for medications for the patients after their respective surgeries. When the authors recalculated the analysis with what was considered the optimal treatment dosage for the TENS the difference was 35.5% compared to the placebo group. Although

they did not measure pain relief directly, they assumed the reduction in medication and pain scores from a VAS would correlate. The subjects after their respective operations had free access to the medication. If they needed more, they would request additional medication. Because the subjects who received a TENS treatment in cooperation with medication requested medication less, they may have experienced less pain.

Another study measuring the effects of TENS on chronic pain found favorable results with no placebo group (Koke et al. 2004). Koke et al. measured the reduction in pain while using three frequency settings of TENS for chronic pain sufferers (Koke, et al. 2004). Subjects had pain from various conditions such as failed back surgery, cervical dysfunction, or neuropathic injury. No placebo group was used, and the study incorporated a single blind design. There were no differences in the VAS pain scores among the three TENS settings. However, all treatment groups reported significantly less pain compared to the control group. Surprisingly, the authors did not conclude that TENS was useful in reducing pain. In addition the authors reported no conclusion could be drawn about the effectiveness of pain relief because there was no placebo group in the abstract of the study. This is another example of a possible positive finding for TENS that cannot be used in a meta-analysis because the study lacks a sham treatment group.

As mentioned earlier researchers experience difficulty measuring the effectiveness of analgesic treatments on injured humans because of the various levels of pain experienced by the subjects. Researchers can be more invasive inducing injury in animals compared to humans. This allows researchers to induce the same injury to all animal subjects. The overall pain experienced by all the animal subjects may have less variation than the reported pain scores in humans who suffer various injuries in the athletic

population. Gopalkrishnan et al. induced a painful injury by injecting carrageenan into the paw of rats (Gopalkrishnan and Sluka 2000). After the injection, Gopalkrishnan et al. noted that high frequency TENS (100 Hz) significantly reduced primary hyperalgesia to heat and mechanical stimuli for up to one day after treatment (Gopalkrishnan and Sluka 2000). Unfortunately conclusions cannot be generalized to a human population. This study is a good example of controlling the extent of injury between subjects. By controlling the extent of injury, one can assume that the amount of pain experienced by each rat was controlled. Controlling the amount of pain felt by each subject is important to reduce the amount of within group error. A condition that has been used in humans in the past is exercise-induced injury.

Summary

Despite the wide use of TENS, debate still exists about the efficacy of pain relief from TENS treatment. While some studies claim TENS is effective and some studies do not, one point that is discussed in all articles is the importance of randomizing and blinding. Lack of blinding or improper randomization can lead to an inflated treatment effect (Altman and Bland 1999a). Studies that measure the effectiveness of TENS that are properly controlled are warranted.

Exercise-Induced Injury

Exercise-induced injury has been described as high force eccentric contractions resulting in muscle damage that can be observed at the cellular level (Clarkson 1997). Signs and symptoms can include Z-line streaming and myofibrillar disruption, muscle soreness, prolonged deficits in muscle strength, range of motion, changes in substrate levels, swelling, increases in muscle proteins in the blood, and decrements in motor control (Borsa and Sauer 2000; Byrne et al. 2004; Toumi and Best 2003). After the

eccentric bout, the first cells to enter are the neutrophils, followed by macrophages, and finally white blood cells (Toumi and Best 2003). Researchers are unsure how soreness is produced, but discomfort exists, and peaks around 24–48 hours after the exercise (Borsa and Sauer 2000; Clarkson 1997). Eccentric muscle actions are important in inducing Delayed Onset Muscle Soreness (DOMS) because more force is generated eccentrically than concentrically and a large number of fibers need to be recruited in order for the weakest ones to break down. The decreased strength noted after DOMS could be attributed to a change in the length tension relationship. When the muscle is trying to contract while being forced into a lengthened position, there are fewer number of cross bridges that can connect (Clarkson 1997). Stiffness and the inability to fully contract the muscle cause a decrease in Range of Motion (ROM), which is an important sign of exercise-induced injury (Byrne et al. 2004).

Exercise-induced injury and fatigue have been used previously in the shoulder to measure proprioception but not pain. Myers et al. evaluated proprioception and neuromuscular control after an exercise bout in the shoulder (Myers et al. 1999). The authors demonstrated a significant decrease in joint position sense after the exercise bout. In this study, the shoulder was fatigued in the internal and external rotation ROM direction. The subjects were deemed fatigued when their peak MVIC dropped to 50% of the subject's baseline MVIC. Using 50% of the baseline MVIC as an indication of fatigue in the shoulder has been used in previous studies (Carpenter et al. 1998; Myers et al. 1999; Voight et al. 1996).

Exercise-induced injury is a common model used today to evaluate strength and performance, however the exact mechanism that causes DOMS is theoretically based. In

addition, researchers are uncertain whether women are more susceptible to DOMS than men. To answer this question, levels of Creatine Kinase (CK) are commonly measured to evaluate exercise-induced injury between genders (Byrne et al. 2004). Creatine kinase has been used less as a marker for exercise-induced injury because of fluctuations during exercise (Ebbeling and Clarkson 1989). However, women have lower resting blood CK levels and an attenuated blood CK response after prolonged endurance exercise (Clarkson and Hubal 2001). This has led researchers to believe that women may be protected from exercise-induced muscle damage due to circulating estrogen. Studies using laboratory models to examine gender differences in exercise-induced injury have not documented consistent results (Clarkson and Hubal 2001). In addition, research examining exercise-induced injury on women with different levels of circulating estrogen has not found a correlation between the estrogen and indicators of muscle damage. The recovery time after injury may be different in women warranting a between-gender comparison. Therefore, the PI completed a pilot study that compared males and females ROM, pain, and strength after exercise-induced injury in the shoulder. The PI noted that there was no significant difference between males and females who were not actively engaged in resistance training or exercise.

However, a previous study suggested females experience more pain and dysfunction after exercise-induced injury (Borsa and Sauers 2000). Borsa and Sauers compared ROM, pain, and function after an eccentric exercise protocol in the biceps brachii of males and females (Borsa and Sauers 2000). The authors noted that there was a significant difference in strength and perceived pain between males and females after the exercise protocol. Females reported more pain after the same exercise protocol than the

males. More studies are needed comparing functional outcomes between males and females after eccentric exercise.

Summary

Exercise-induced injury provides an excellent model to measure the effects of a pain relief modality. The reduction in ROM and the increase in pain and dysfunction are well documented (Clarkson 1997; Ebbeling and Clarkson 1989). The amount of pain and dysfunction reported within a group of subjects with exercise-induced injury of the shoulder present with more consistent signs and symptoms than a group of subjects with various shoulder pathologies. Using the exercise-induced injury model compared to using injured subjects will reduce the amount of within group error.

Outcome Measures

Clinicians evaluate outcome measures including pain, impairment, strength, and ROM to assess the significance of injury or the efficacy of a treatment (Turk and Melzack 2001). These outcome measures are recorded using tools or equipment such as Visual Analogue Scales, isokinetic dynamometers, goniometers, questionnaires, and algometers. These instruments and their respective measures need to be valid and reliable for clinicians to make conclusions about their treatments.

Visual Analogue Scales

The visual analogue scale (VAS) is a tool used to measure perceived pain (Turk and Melzack 2001). The VAS usually consists of a 10cm line with “no pain” on one end and “pain as bad as it could possibly be” on the opposite end. Subjects are instructed to draw a line that most accurately describes their perceived level of pain. Some previous authors have evaluated the VAS further. Bolton measured perceived pain in 200 patients diagnosed with back injuries (Bolton 1999). The author compared their daily recordings

of pain to once a week sessions of “average pain” for the week. The results indicated that estimating patient’s pain ‘on average’ was an accurate measure of ‘actual pain’ experienced by the subjects. Bolton et al. calculated the ICC between ‘on average pain’ and ‘actual pain’ to be 0.82. This study suggests that asking patients “on average how was your pain today” is a valid measure. The specific question of “How much pain are you in now” may be a less accurate measure. This may be due to the numerous factors that can control the level of perceived pain by a subject at any moment. Pain ratings of usual pain, or pain on average are gaining popularity because they are more realistic measures of pain than a single snapshot of current pain (Bolton 1999).

While the VAS is an accurate measure of pain, the key component to research is measuring the change in reported pain over multiple sessions. Two authors stated the actual amount of pain experienced by a patient is not as important measure as the reliability of the change in reported pain between sessions (Turk and Melzack 2001). For example if two subjects start with different levels of pain and improve the same amount from a single treatment researchers would need the VAS to accurately reflect the change. As long as the measure of pain correlates with the change, then the VAS can be an effective tool for measuring pain. That is why we need a pain-measuring tool, to measure the change in pain for treatments and clinical effectiveness for interventions. The VAS can accurately report the differences in pain between sessions.

Price et al. completed a study that measured the ratio scaling properties of the VAS during the application of a noxious stimulus (Price et al. 1983). In this study the authors applied a thermal stimuli at various degrees to the forearm (43, 45, 47, 48, 49, and 51°C) and measured the difference in pain perception with a VAS. The power

functions were predictive of estimated ratios of sensation. This suggested that the levels of pain and direct temperature were internally consistent. This makes the VAS a good measure of treatment effects, comparing the control group to the treatment group's pain levels. Another advantage is having the scale in mm. This means there are 101 response levels, much more compared to a verbal questionnaire. The VAS in other words may be more sensitive to changes than other types of scales. In addition to reported pain values point tenderness is a symptom of musculoskeletal pain, which can be evaluated by an algometer.

The DASH

The DASH (disability of the arm, shoulder and hand) questionnaire is a region specific measure of functional status designed to assess upper extremity disability and symptoms (Atroshi et al. 2000; Beaton et al. 2001; Beaton and Schemitsch 2003; Gummesson et al. 2003; Hudak et al. 1996; Turchin et al. 1998; Turk and Melzack 2001). Patients rate their ability to perform 30 different physical function tasks on a five-point scale. The scale ranges from 0 = no difficulty to 5 = unable. The tasks range from ability to prepare a meal, recreational activities, and writing. Symptom questions and self-image and social functioning questions are included. A larger score would indicate a healthier or less disabled patient. The DASH is a valid and reliable measure of upper extremity pain and disability (Atroshi et al. 2000; Beaton and Schemitsch 2003; Gummesson et al. 2003). Previous authors have noted that the DASH may be the most reliable and valid measure of upper extremity dysfunction (Bot et al. 2004). A previous study has reported high internal consistency and test-retest reliability (Beaton et al. 2001). After upper extremity dysfunction, performance measures as well as activities of daily living might be affected.

The DASH enables researchers to evaluate the performance of the upper extremity outside the research lab.

Algometry

A Fischer algometer was used in this study (Fischer 1986; Fischer 1987; Fischer 1988). The algometer is a calibrated gauge that delivers a measurable amount of linear force through an applicator. The algometer is commonly used in conjunction with a VAS to quantify the amount of pain elicited. There are two common measures with the algometer including mechanical pain threshold (MPT) and pressure pain threshold (PPT). Mechanical pain threshold is determined from a standardized amount of pressure from the algometer, and a change in pain perception is noted on the VAS. The final measure is in mm and the difference between baseline and treatment is used in the analysis. Pressure pain threshold is a measure of kg/cm^2 that the examiner applies until the subject verbalizes they are experiencing pain. The end result will be a measure of kg/cm^2 . A tool will only be used if the measures are reliable, so some previous authors have evaluated the reliability of the algometer and the MPT and PPT measures.

The best way to measure the reliability of a measure is to make the measurement over subjects on consecutive days and compare between and within subjects. Persson et al. examined whether the PPT's of 2 shoulder muscles (the trapezius and the deltoid muscles) vary in a test-retest situation in (a) a few minutes, (b) long term including days, (c) within subjects, (d) between subjects, (e) between right and left side, (f) within examiners (intra-rater), and (g) between examiners (inter-rater) (Persson et al. 2004). The authors reported high ICC's ranging from 0.7–0.94 over a four-day testing period (Persson et al. 2004). This study suggests that the algometer is a reliable instrument for measuring point tenderness in the shoulder.

Nussbaum and Downes studied the reliability of clinical pressure-pain algometric measurements obtained on consecutive days (Nussbaum and Downes 1998). This study measured (a) normal pain pressure threshold (PPT), (b) the reliability over three days, (c) the reliability between examiners, and (d) the number of measurements required to make the best estimates. The authors noted that an algometer is a tool, which can provide a quick and safe marker of pain recovery versus other invasive procedures. In addition, Nussbaum and Downes noted that marking test sites could increase reliability between sessions (Nussbaum and Downes 1998). The authors indicated good reliability for the Fischer algometer with ICC's for intrarater reliability ranging from 0.93–0.96. Moreover, intertester reliability ranged from 0.81–0.88. These authors concluded that the Fischer algometer is a reliable tool for evaluating point tenderness.

A previous study has measured PPT in the painful shoulder of women (Persson et al. 2003). The authors evaluated PPT in the shoulders of females who were suffering from shoulder pain. All subjects had been suffering from shoulder pain for over a year, and their PPT was measured before and after a static abduction endurance test. Persson et al. reported interesting findings by noting an increase in PPT after the fatigue protocol (Persson et al. 2004). The subjects needed more pressure applied to indicate they perceived pain. This is one of the few articles that report an increase in PPT after fatigue in the shoulder. Most studies that measure acute pain induced by eccentric exercise report a significant increase in pain after the exercise-induced injury (Fischer 1987).

Isokinetic Evaluation

The Kin-Com is an isokinetic dynamometer that can evaluate muscle force production in the shoulder (Dauty et al. 2003; Hartsell 1998; Mandalidis and Donne 2001; Mayer et al. 1999; Mayer et al. 2001; Noffal 2003; Plotnikoff and MacIntyre 2002;

Tis and Maxwell 1996). A previous study has demonstrated that isokinetic evaluation of peak torque in the shoulder is a reliable measure with ICC's ranging from 0.81–0.94 (Mayer et al. 2001). Another use for the dynamometer other than measuring force production is for inducing fatigue via isokinetic eccentric and concentric muscle contractions. When inducing fatigue, previous research has suggested using 50% of the MVIC as the indication of fatigue (Borsa and Sauers 2000; Carpenter et al. 1998; Mayer et al. 2001; Myers et al. 1999; Voight et al. 1996). In order to have fewer fluctuations in strength during testing the torso should be stabilized and the opposite arm fixed (Mayer et al. 2001). Some subjects try and to compensate while one limb is being tested by swinging the rest of the body to generate more force. In addition, overhand athletes should not be used in conjunction with a healthy population because they can recruit individual muscle groups in a much more selective and coordinated way compared to untrained individuals (Mayer et al. 2001). In addition, recording the peak torque value for the middle three trials of a five trial set is the most reliable method for identifying peak torque (Mayer et al. 1999).

Body position during isokinetic testing is a key factor when measuring the shoulder and was examined in a few studies (Hartsell 1998; Mandalidis and Donne 2001; Plotnikoff and MacIntyre 2002). The most effective testing position for the shoulder is in the scapular plane (Hartsell 1998; Tis and Maxwell 1996). Testing should be completed at 45° abduction and 30° horizontal flexion, in the scapular plane. Testing the arm at 45° abduction and 30° horizontal cross flexion reduces stress placed on the anterior capsuloligamentous structures, enhances vascularity of the supraspinatus tendon, and prevents impingement of the greater tuberosity under the acromion (Dauty et al. 2003;

Plotnikoff and MacIntyre 2002; Tis and Maxwell 1996). This position also provides better congruency between the articular surfaces of the glenohumeral joint, optimum length-tension relationship of the rotator cuff muscles, and more comfort for the subject (Dauty et al. 2003; Plotnikoff and MacIntyre 2002). In addition, more strength is generated in the scapular plane for the same reason (Tis and Maxwell 1996). Test re-test reliability for strength scores in the shoulder was high in a few of studies ranging from 0.76–0.98 (Dauty et al. 2003; Hartsell 1998; Mandalidis and Donne 2001; Plotnikoff and MacIntyre 2002). Specifically, strength measures in the external rotation direction were more reliable compared to internal rotation strength measures (Mandalidis and Donne 2001). This means that external strength measures are preferred when evaluating shoulder strength because they are more reliable. In addition, evaluating the shoulder in the seated position is more reliable than measuring shoulder strength in the standing position (Dauty et al. 2003). Testing in the seated position avoids compensation by rotation of the trunk and participation of the lower limbs, which can raise peak torque (Dauty et al. 2003).

Summary

Pain and function for this study was evaluated by using a VAS, the Fischer algometer, Kin-Com isokinetic dynamometer, and the DASH. All of these measures are valid and reliable tools for measuring point tenderness, muscle strength, and ability to perform activities of daily life (Bolton 1999; Dauty et al. 2003; Fischer 1986; Hartsell 1998; Mandalidis and Donne 2001; Nussbaum and Downes 1998; Plotnikoff and MacIntyre 2002). These measures were made daily to compare pain and performance between groups.

Hemiplegic Shoulder Pain

Treating shoulder pain is of special concern to the hemiplegic population. Between 60%–75% of hemiplegic patients suffer from shoulder pain (Van Ouwenaller et al. 1986; Wanklyn et al. 1996). In addition, up to 81% of stroke sufferers experience a shoulder subluxation (Ada and Foongchomcheay 2002). Cerebrovascular accident is frequently associated with poor upper limb function. When subjects have more movement in their upper extremity, they experience less subluxations (Ada and Foongchomcheay 2002). After stroke, as a result of the paralysis, the gravitational pull on the humerus can be enough to sublux the glenohumeral joint. The weight of the arm can stretch the capsule and soft tissue structures around the glenohumeral joint, which may result in pain and impairment. Stroke patients with upper limb pain have been associated with having a decrease in upper limb power, reduced shoulder shrug strength, atrophy, glenohumeral subluxation, sensory inattention, and sensory loss (Price and Pandyan 2001). In addition to subluxation, there are two causes of hemiplegic shoulder pain, distant sources or referred pain (neck muscles, visceral pain), or local problems (rotator cuff, subluxation, adhesive capsulitis)(Snels et al. 2002). Shoulder pain can be a marker for stroke severity and can contribute to negatively affecting rehabilitation and recovery (Price and Pandyan 2001). Stroke patients with shoulder pain remain hospitalized longer, which complicates the rehabilitation process (Snels et al. 2002). Part of the rehabilitation process can involve TENS, but researchers are unclear as to whether TENS is beneficial or not.

Hemiplegic shoulder pain may involve coordinated multidisciplinary management to minimize interference with rehabilitation and optimize outcome (Turner-Stokes and Jackson 2002). Identifying the best treatment for hemiplegic shoulder pain has been

difficult for the same reason why TENS has not been proven effective, methodological concerns with existing literature (Snels et al. 2002). One analysis evaluated 14 studies that measured hemiplegic shoulder pain treatment and concluded that because of the poor quality of collected studies no definite conclusion can be drawn about the most effective method of treatment (Snels et al. 2002). However, of the existing treatments, TENS may be effective (Ada and Foongchomcheay 2002; Snels et al. 2002; Turner-Stokes and Jackson 2002; Vuagnat and Chantraine 2003).

A previous meta-analysis examined the prevention and treatment of shoulder subluxations using electrical stimulation (Ada and Foongchomcheay 2002). While 67 articles were found using the search strategy, only 7 trials met the inclusion criteria. This relates back to the previous point that most studies have inadequate experimental design and test protocols. After analyzing the 7 trials the authors concluded that electrical stimulation was effective in preventing glenohumeral subluxation. However, another meta-analysis could not conclude positive or negative findings with regards to treating post stroke shoulder pain with TENS (Price and Pandyan 2001). Twenty-two studies were identified in the search, but only 4 were used in the analysis, citing the same reason as above. Trials were not included if they were not a randomized control trial.

Randomization is an important factor in clinical trials. Although the authors concluded there was no significant difference in pain treating the shoulder with TENS, there was a significant decrease in the incident of shoulder subluxations and an increase in passive range of motion.

Summary

With the growing age of our population and the potential increase in stroke sufferers, a treatment for hemiplegic shoulder pain is becoming more important.

Identifying a pain relief modality specifically for the shoulder will benefit the large number of people who suffer from shoulder pain in the stroke population.

General Summary

Many early TENS studies were completed without the necessary blinding and randomization required in the experiments. Therefore the reductions in pain experienced by subjects in early studies of TENS were due to the patient's expectation of the modality reducing pain. In addition some trials lacked randomization, which can lead to the overestimation of the effects of TENS (Altman and Bland 1999b; Altman, Schulz et al. 2001; Altman and Schulz 2001; Altman and Schulz 2004; Bland and Altman 1986; Carrol et al. 1996; Schultz et al. 1995; Vickers and Altman 2001). The reason why conclusive evidence does not exist with regards to TENS is that randomized control trials using TENS are rare and difficult to conduct. Researchers have difficulty finding subjects that do not suffer from any exclusion criteria such as: neuromuscular disorders, cardiac disorders, peripheral neuropathy, history of trauma or surgery to shoulder, current medication for pain, history of epilepsy, diabetes, or pregnancy, or any altered sensation may affect the results (Johnson 2001; Walsh 1997). A control group of subjects who receive no treatment must be included in the design so a conclusion can be based on the results found in the treatment group, not on the expectation of the patient.

A letter published in *Pain* commented on a previous study and the importance of the amount of treatment delivered in a particular TENS study (Johnson 1997). Craig et al. noted no significant relief of pain using TENS when treating DOMS (Craig et al. 1996). However, Johnson replied in a letter and stated the reason for the lack of findings was due to an inappropriate treatment intervention (Johnson 1997). The theory of pain relief while applying high frequency TENS is that the analgesia is generated only while the

current is being delivered. While high frequency TENS is being delivered, the current stimulates the A- β 's fibers and closes the gate so the C fibers cannot deliver the pain signal. That is the theory of acute pain relief for high frequency TENS. In theory, if the patients are getting pain relief for 20 minutes a day, that may not be enough time to reduce the subjects pain or dysfunction. A 20-minute treatment leaves 23 hours and 40 minutes that day with no chance to treat the subject's pain. In fact, during these studies additional treatments such as ice and NSAIDS are prohibited in order to control for extraneous variables, which may alter the treatment effect. In addition, if the subjects have ever experienced pain before the induction of experimental DOMS, the pain generated by the experimental DOMS may be more painful because the subjects are not allowed to treat the pain themselves. People who are experiencing pain usually seek medical attention in the form of a doctor visit or medication to reduce their pain (Cherry and Woodwell 2002). Subjects who participate in a study measuring pain who are not allowed to treat the pain they are experiencing may report a higher level of pain. Therefore an ideal study would included a group that receives TENS treatments more than once a day who are allowed to treat themselves as necessary. Subjects will receive more pain relief and may experience less pain and dysfunction.

Randomization is a key factor in TENS studies. Carrol et al. indicated that most studies that were not randomized properly indicated a positive result where as 15 of the 17 "appropriately randomized" trials demonstrated no difference with TENS (Carrol et al. 1996). Moreover, in the 19 studies that were not properly randomized, 17 demonstrated a positive analgesic effect (Carrol et al. 1996). There are even studies where the authors state in the abstract that no conclusion could be based on the results due to the methods of

the study (Koke et al. 2004). All the data collected indicated that using TENS can reduce pain, but a conclusion could not be made based on the lack of a sham treatment group.

The popularity of TENS is becoming based on hear say. Early research was not done properly, and cannot catch up with new TENS devices. New TENS devices are being entered into the business world faster than studies can be done to measure the effectiveness of the new devices. Salesmen often sell new devices based on “new” parameters that the particular device offers without substantial research supporting positive findings. Therefore current research is needed to examine new devices.

CHAPTER 3 RESEARCH DESIGN AND METHODS

Study Population

Men and women of any racial/ethnic background were considered for inclusion. 36 subjects volunteered for a four-day treatment trial. 18 Men (height = 178.8 ± 10.1 cm, mass = 77.6 ± 14.4 Kg, age = 20.6 ± 1.9 years) and 18 women (height = 164.5 ± 6.3 cm, mass = 63.2 ± 16.0 Kg, age = 19.8 ± 1.2 years) participated in the study. The number of subjects was based on a power analysis using the change in force and VAS pain scores from a pilot study completed by the PI. The power analysis was completed using the G power program (GPOWER Version 2.0 Bonn, Germany). Effect sizes were calculated prior to subject recruitment using means and standard deviations from the pilot study that ranged from 0.55 – 0.8. The power was set at 0.8, resulting with an n of 12 in each group for a three group (control, placebo, treatment) clinical trial. The PI made verbal announcements in various classrooms on the University of Florida campus in order to inform students of the study and the necessary inclusion criteria. The PI contacted subjects who were interested in participating and meet the inclusion criteria. In addition, the PI answered any questions and explained in greater detail to the candidate what was involved with the study and what the subject was required to do. If the candidate volunteered to participate the PI then scheduled the initial appointment.

Entry criteria included having no previous history of shoulder injury that required rehabilitation, surgery, or any significant alterations in activities of daily living. Subjects were unaware of their group allocation and were instructed that a new device was being

evaluated for treating their shoulder. We excluded any subjects if they presented with any sensorimotor impairments of the shoulder and/or cervical region. Moreover we excluded subjects if they regularly participated in upper extremity weight training, have previously received a TENS treatment, regularly take pain medication, or if they had any plans of activity that may interfere with the study over the four days of testing. Regular upper extremity weight training refers to any weight (resistance) training more than once a week in the past six months. Based on results of our pilot study, subjects who are less physically active are preferred due to their reaction to the eccentric exercise. Preliminary data indicated that subjects who were less active might experience more general shoulder pain, loss of strength, and decreased ROM after the exercise protocol. None of the subjects used participated in regular exercise and have not trained with weights in the six months prior to their completion of the study.

Instrumentation

Visual Analogue Scale (VAS)

The Visual Analogue Scale (VAS) is a tool that can measure pain perception in human subjects (Turk and Melzack 2001). The VAS is a 10cm line with “No pain at all” denoted on the left side of the line and “Worst pain ever experienced” on the right side. We instructed the subjects to make a single pen slash through the line indicating the overall amount of pain they felt in their shoulder over the course of the day. The score is calculated by measuring the distance from the left side of the line to the pen slash in millimeters. The higher the score, the more pain the subject perceives. The VAS is a valid and reliable tool for measuring true and experimental pain in human subjects (Bolton 1999; Koke et al. 2004; Price et al. 1983). Moreover, the VAS is a robust tool for

measuring the change in pain within subjects and between treatments (Koke et al. 2004; Turk and Melzack 2001; Fischer 1986; Fischer 1987; Pontinen 1998).

Disabilities of the Arm, Shoulder, and Hand (DASH) Questionnaire

The Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire (Institute for Work & Health, Toronto, Ontario, Canada) is a 30-item self-report questionnaire designed to measure symptoms, functional limitations and disability across a range of upper extremity musculoskeletal disorders (Solway et al. 2002). Subjects rated their symptoms and ability to perform specific daily tasks using a 5-pt. hierarchical likert scale. The sum of the 30 scores is then divided by the number of responses and multiplied by 25 to generate the final disability score. The DASH has demonstrated excellent psychometric properties; test/retest reliability and SEM (ICC = 0.92, SEM = 7.6), internal consistency (Cronbach's alpha = 0.96), convergent and construct validity, and responsiveness to treatment (SRM 1.13 and 0.70)(Atroshi et al. 2000; Beaton et al. 2001; Beaton and Schemitsch 2003; Gummesson et al. 2003; Hudak et al. 1996; Navsarikar et al. 1999; Turchin et al. 1998).

Fischer Algometer

The Fischer algometer (Pain Diagnostics and Thermography Inc., Great Neck, NY) is a manually operated device that administers focal pressure to an area of the body for the purpose of measuring point tenderness. The algometer is a force gauge calibrated in kilograms that is capable of applying force or pressure through a rubber disc attached to the gauge by a lead pole (Figure 3-2). The disc surface is exactly 1 cm² so force applications will read in kg/cm². The accuracy of the dial is reported to be +/- 0.05 kg. The pressure is applied manually perpendicular to the surface of the skin at a constant rate. The Fisher algometer is a valid and reliable tool for assessing pain threshold in

human subjects (Fischer 1986; Fischer 1987; Fischer 1988; Nussbaum and Downes 1998; Pontinen 1998).



Figure 3-2. Fischer algometer.

Kin-Com

The Kin-Com 500 H isokinetic testing and exercise device (Chattecx Corp., Chattanooga, TN) is an electromechanical dynamometer that measures muscular force production in a variety of modes (isometric, isotonic, and isokinetic). We used the Kin-Com to induce musculoskeletal injury as well as measure maximum voluntary isometric contractions (MVIC). We positioned each subject on the Kin-Com based on the manufacture's specifications. The Kin-Com is a reliable tool for measuring shoulder strength (Dauty et al. 2003; Mandalidis and Donne 2001; Mayer et al. 2001; Noffal 2003; Plotnikoff and MacIntyre 2002). We positioned the subjects so their glenohumeral joint is in the scapular plane. The scapular plane is a more reliable position for determining shoulder strength and in this position there is less chance of the head of the humerus

impinging the rotator cuff musculature under the acromial arch (Hartsell 1998; Mandalidis and Donne 2001; Tis and Maxwell 1996).

TENS Device

A CT1 TENS device (Cyclotec Advanced Medical Technologies, Inc., Lauderhill, FL) was used for all TENS treatments for all subjects in the treatment group. The CT1 is a new device developed by Cylotec for the sole purpose of providing pain relief. The CT1 was developed through extensive research supported by the NIH (Grant Number = 1R41DA016547-01). The CT1 can deliver current with varying frequency, intensity, amplitude, and pulse duration. The TENS treatment involved applying current at 85 Hz at an amplitude high enough to generate a comfortable tingling sensation but not strong enough to generate a muscle contraction. Four pads were used for the application located at pre-selected sites around the shoulder joint. These sites were identified to two research assistants who were observed by the PI placing the device on several subjects. The pads were placed in pairs at the tendon insertion of the supraspinatus and the insertion of the deltoid muscle, as well as anterior and posterior to the acromion by the research assistants. The subjects in the treatment and placebo groups reported to the biomechanics lab (151 FLG) for all treatment sessions. The two research assistants supervised all treatment and placebo sessions. All treatments consisted of two 45-minute sessions separated by at least 15 minutes.

Clinical Measures

Range of Motion (ROM)

The subjects' glenohumeral range of motion (ROM) was measured using a universal goniometer (Baseline Diagnostic and Measuring Instruments, Paris, TX). The measurements included active internal and external rotation ROM, passive internal and

external rotation ROM and a resting internal rotation ROM for the glenohumeral joint. The active internal and external ROM measurements were made while the subject was lying supine on a table with their elbow flexed to 90° and their shoulder abducted to 90° (Figure 3-3). The subject was positioned so the distal portion of their humerus was off the edge of the table. The subject was in the same position for the passive internal and external rotation ROM measurements. The final measurement was resting internal rotation (Figure 3-4). Subjects allowed their forearm to passively relax in the internally rotated position while supine and the angle was recorded. This angle represents the resting tension on the external rotators of the shoulder.

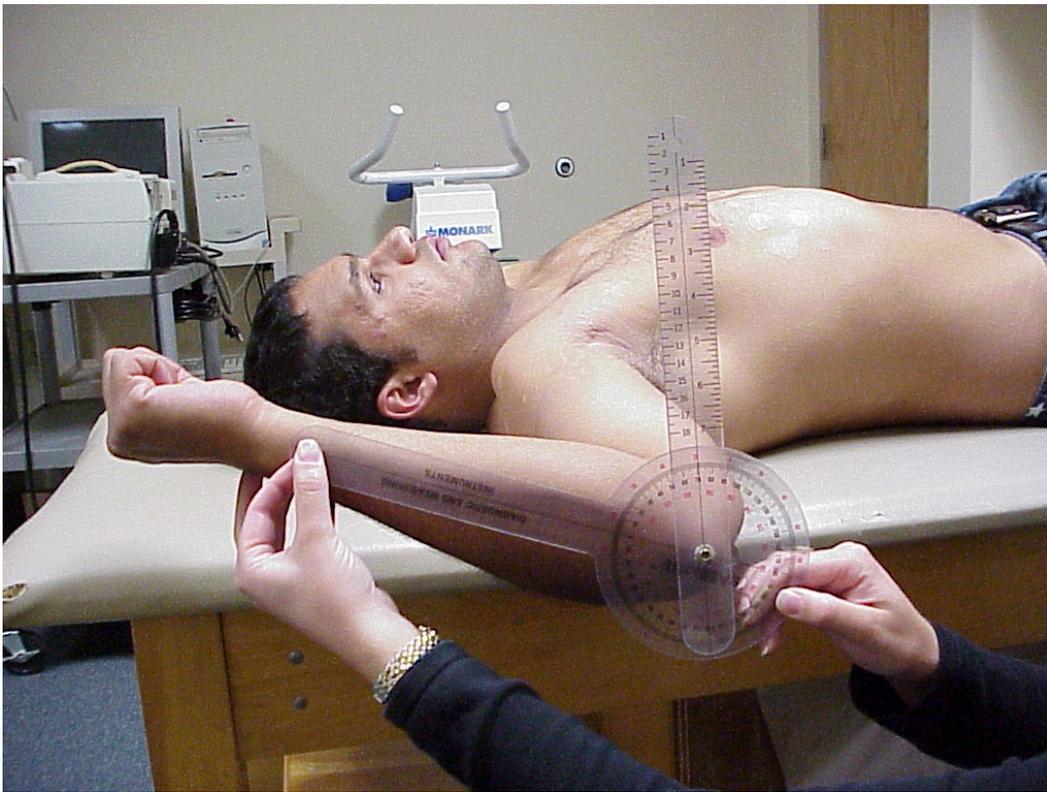


Figure 3-3. Positioning of subject during ER ROM measurements.



Figure 3-4. Position of subject during resting IR measurement.

Assessment of Pain and Functional Impairments

Shoulder pain was evaluated by a VAS and the DASH questionnaire. For the VAS, subjects were presented with a single line representing overall pain today for their shoulder. They made a single pen slash through the line that represented their overall pain felt that day in their shoulder. The PI and a research assistant recorded these measures before and after the exercise session, and once a day for the three sessions after the exercise bout. In addition, subjects filled out the DASH questionnaire each day (Day 0, Day 2, Day 3, and Day 4). These pain perception and functional measures were compared among the three groups to determine if TENS treatments can significantly reduce shoulder pain and dysfunction after exercise-induced injury.

Mechanical Pain Threshold (MPT)

Mechanical Pain Threshold (MPT) is a subjective measure of pain perception while a standard force is applied to the injured area using an algometer. While the force is being applied, the subjects would make a pen slash on the VAS indicating how much

pain the algometer was causing. The MPT was recorded at baseline and 4 occasions after the exercise bout on three locations around the shoulder. The locations were the tendon insertion of the supraspinatus just inferior to the acromion process, the trigger point of the supraspinatus (mid belly), and the trigger point of the infraspinatus (mid belly) (Figure 3-5). The testing order of the three sites was randomized. Trigger points have been used previously for algometer studies (Fischer 1987; Pontinen 1998). Trigger points for this study were identified using traditional Chinese acupuncture points (Hartley 1997). The three points were tested randomly at baseline (Day 0), post-exercise (Day 1), and Day 2 through 4. The research assistant showed a separate VAS scale to the subject for each location and asked the subject to make a pen slash at the point that best represents the pain experienced for each point.



Figure 3-5. Three sites for MPT testing over the supraspinatus and infraspinatus muscles and the tip of the acromion.

The PI applied 9 kg/cm² of pressure and instructed the subjects to mark the line while the pressure was being applied. During the treatment and sham treatment days, the MPT was measured at the end of the treatment.

Maximum Voluntary Isometric Contraction (MVIC)

All subjects were baseline tested (Day 0) for their Maximum Voluntary Isometric Contraction (MVIC). The shoulder external rotators were tested for their ability to produce a maximal static or isometric force. The infraspinatus is the prime external rotator of the glenohumeral joint (Kelly et al. 1996). In addition, the teres minor muscle and the posterior fibers of the deltoid assist in external rotation. All participants were secured in the Kin-Com using manufacture's specifications with their shoulder in the scapular plane. Testing the shoulder in the scapular plane is reliable and decreases the chance of compression between the muscle-tendon unit of the rotator cuff and the subacromial arch (Hartsell 1998). The subjects were seated, strapped into the chair and their forearm faced forward in the neutral position (Figure 3-6). Each subject attempted 5 trials of externally rotating the arm of the Kin-Com isometrically with maximal effort. All subjects received verbal encouragement during testing. The middle three trials were recorded and averaged for the MVIC, which is the most reliable method of measuring shoulder MVIC (Dauty et al. 2003; Mandalidis and Donne 2001). For the purpose of data analysis, all strength scores were converted to a percent of the baseline or healthy MVIC (Day 0).



Figure 3-6. Subject position for IR/ER testing on the Kin-Com.

Research Design

This study used a placebo-controlled randomized before and after design (Figure 3-7). We randomly assigned subjects to either a treatment, sham (placebo) or control group by picking numbers out of a hat. The number 1 indicated the control group, 2 indicated the placebo group, and 3 represented the treatment group. This has been described as an effective method of randomization (Altman and Bland 1999b). The treatment consisted of locally applied TENS, the sham consisted of locally applied inactive TENS (the electrodes were either not plugged in or the intensity was set at zero), and the control group received no treatment. Subjects were instructed not to engage in any other form of treatment for his/her shoulder impairment. This included other therapeutic modalities, rehabilitative exercises, stretching, and anti-inflammatory or pain medications. There was an upper extremity activity restriction placed on the patient for the duration of the study. Participants were instructed to only use their extremity in activities of daily living. Subjects were required to complete a four-day treatment trial. The treatment trial was used to determine the effectiveness of TENS therapy for the treatment of symptoms and functional limitations related to exercise-induced injury.

Experimental Procedures

All subjects reported to the Sports Medicine Research Laboratory (SMRL) for four separate test sessions on consecutive days. On Day 1 subjects read and signed the informed consent approved by the University Institutional Review Board (Appendix A and B). After their signed agreement to voluntarily participate in the study, subjects completed a short questionnaire that requests demographic information and

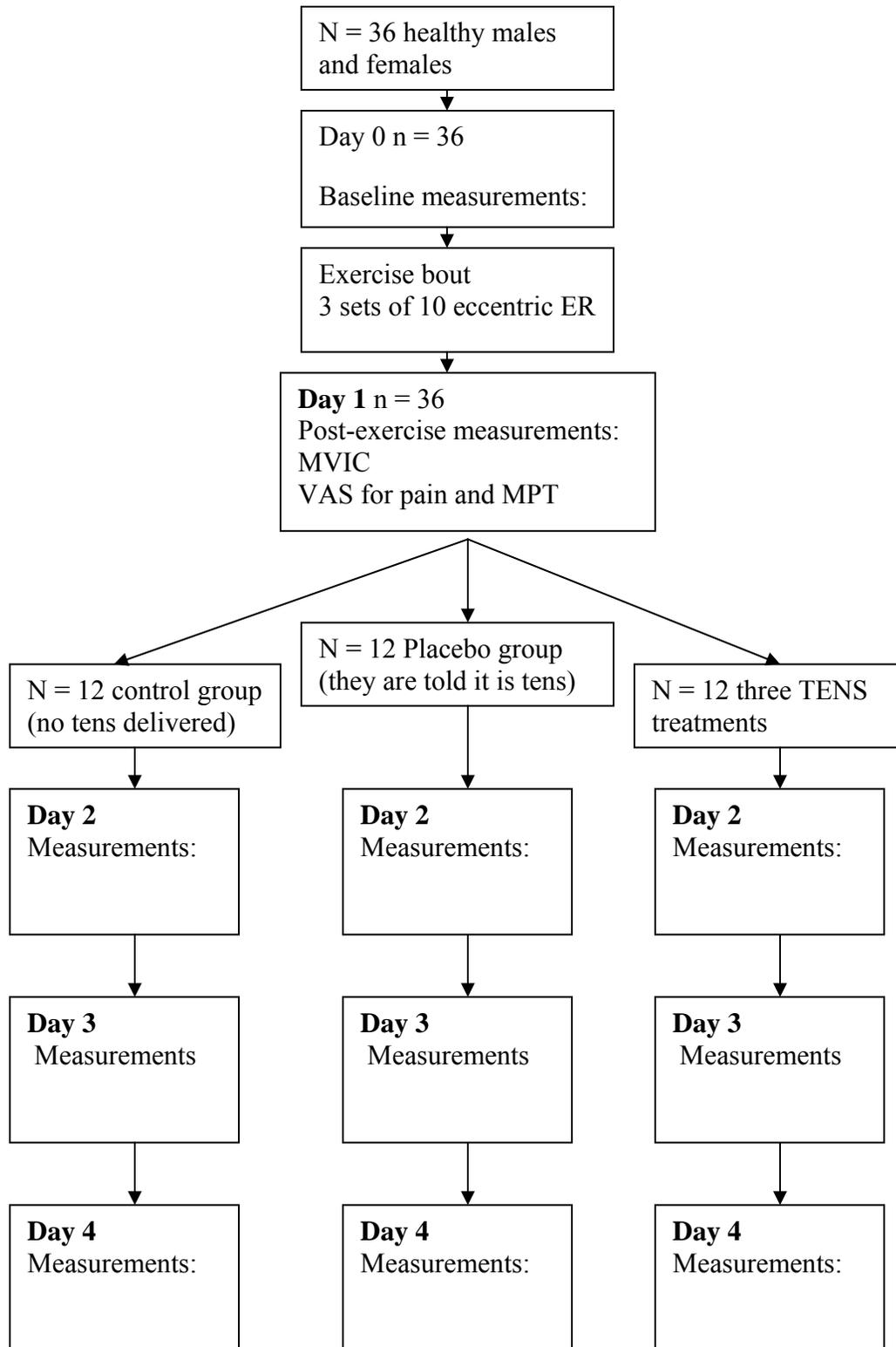


Figure 3-7. Flow chart of single blind randomized control trial of three groups (control, placebo, treatment) to measure the efficacy of TENS.

contains all inclusion criteria for the study (Appendix C). The PI questioned the subjects' closely about their level of physical activity over the 4 days of the study. Physical activity, stretching, or a warm-up for an event may have interfered with the internal validity. In addition, all subjects were instructed to avoid other extraneous factors including participation in HHP activity classes or related daily recreational activities, out-of-town travel, and pain medication. Each testing session the PI and a research assistant reminded the subjects only to use their dominant limb for activities of daily living.

After the questionnaire and signed consent, clinical measures including ROM, pain perception, and muscular strength were made on Day 0 by the PI and a research assistant. Active and passive internal and external rotation ROM were recorded followed by the resting internal rotation on the dominant limb. All testing was performed on the dominant limb. After the ROM measurements, the subjects were seated on the edge of a table and their shoulder exposed for the MPT testing. A clipboard with the four VAS's (overall pain, and three MPT sites) was placed in front of them by the research assistant. The participants made a pen slash on the line representing their "overall shoulder pain today" on the first line. The PI instructed the subjects that he would "Press down on their shoulder, while you mark the line representing how much pain you feel while the pressure is being applied". The PI used the algometer to apply 9 kg/cm^2 of pressure at a constant rate at the three sites while the subject marks the line after all of them. As soon as 9 kg/cm^2 is reached with the algometer the PI stated "now" so that each subject marked the line when 9 kg/cm^2 of pressure was being applied. The order of testing was randomized for the three sites for each testing session. The three sites included the trigger

point for the supraspinatus muscle, trigger point for the infraspinatus muscle, and the tendon insertion for the rotator cuff.

We familiarized each subject with the Kin-Com for the MVIC and exercise portion of the testing. The PI and research assistant positioned the subject on the Kin-Com using the manufacture's specifications for shoulder internal and external rotation. The tip of the olecranon process was placed at the axis of rotation of the dynamometer. The PI demonstrated on the non-dominant limb what direction they are going to push with their dominant arm, and how their arm will not move during the MVIC testing in order to familiarize them with the procedure. The PI placed the subject's limb in the neutral position while they pushed the arm of the dynamometer with their maximum amount of force in the ER direction. Testing in the neutral position ensured that the force was not negatively affected by the length tension curve (Borsa and Sauers 2000). After the MVIC, the Kin-com was programmed for the exercise protocol. Again the PI demonstrated on the subjects' non-dominant limb what to expect during the exercise protocol. The protocol included approximately 3 sets of eccentric and concentric external rotation repetitions. The number of repetitions was based on the subjects force output. A speed of 100°/sec was used to familiarize the subjects with the device and the speed was lowered each set to a minimum of 45°/sec during the last set making the exercise progressively harder. Exercise continued until the subject could only generate 50% of their original MVIC isometrically. Previous studies have used 50% MVIC as a level indicating fatigue in the shoulder (Carpenter et al. 1998; Myers et al. 1999; Voight et al. 1996).

After the eccentric protocol, the subjects overall shoulder pain and the MPT of the three sites were measured again. Each subject was randomly placed in one of three groups at the end of Day 1. They were placed into a control, placebo, or TENS treatment group.

Control Group

Subjects in the control group reported to the Sports Medicine research laboratory (SMRL) for 3 testing sessions on consecutive days after the exercise bout. The control subjects arrived on Day 2 and had their shoulder ROM measured as described above. Measurements included active and passive IR and ER, and the resting IR measure. Then the subjects recorded their overall shoulder pain that day on the VAS. After the VAS the subjects filled out the DASH questionnaire, the subjects exposed their shoulder and their point tenderness was randomly tested at three sites. For the last part of the test session the PI and the research assistant evaluated their MVIC in the ER direction. The key factor with the control group was to make sure they altered their schedule so they did not participate in any activity that would affect their perceived pain during the three days, which included taking medication, applying ice, or stretching. Test sessions on Day 3 and Day 4 were the same as described above.

Placebo Group

After the exercise bout all subjects who were randomly assigned to the placebo group reported to the biomechanics lab (151 FLG). An additional two research assistants scheduled the sham treatment sessions for all placebo subjects for the three days. The sham treatment included multiple treatment sessions throughout the day based on the subjects class schedule. Each subject received a total sham treatment of 90 minutes over the course of the day. The PI instructed the two research assistants on the use of the

TENS device and the specific instructions for all subjects. Instructions included describing the TENS device as a pain relief modality. In addition, subjects' were instructed that they may or may not feel the treatment. Moreover, during the sham treatment, the research assistants would ask each subjects how the treatment felt and pretend to turn up the intensity of the TENS device if desired. All placebo and treatment subjects received the same instructions with regards to the TENS application. Sham units provided no current, because either the electrodes were not plugged in, or the intensity was not turned up maintaining the illusion that the subjects were receiving treatment. After the sham treatment the subjects were tested in a similar fashion as the control group. All ROM, VAS scores, the DASH, and MVIC measurements were made after the subject has received a total of 90 minutes of sham TENS treatment.

TENS Group

The TENS group received multiple TENS treatment sessions throughout the day based on their class schedule. Each subject received a total of 90 minutes of TENS over the course of the day. The treatment sessions were administered by the same two research assistants that coordinated the sham treatments in the biomechanics lab (151 FLG). The parameter for the treatment was a high frequency TENS 85 Hz and 75us pulse width at a voltage (0–80ma) high enough to generate a strong but comfortable tingling or buzzing sensation with no muscle contraction as used in previous studies (Craig et al. 1996; Denegar and Donley 2003). The PI instructed the two research assistants to give the same instructions to the placebo group including “You may or may not feel anything during the treatment”. The placebo subjects were told that they would receive some electric current that will provide pain relief. In addition, the instructions indicated that after a few minutes subjects may get used to the voltage and the current can be turned up according

to their comfort level. After a total 90 minutes of treatment all subjects in the treatment group reported to the SMRL for post testing. Testing was the same for the control, placebo, and TENS groups. First their ROM was measured, followed by the over all pain and DASH questionnaire. Subjects were seated with their shoulders exposed for the MPT evaluation before the PI and a research assistant evaluated their MVIC in the ER direction. Each subject in this group received three days of treatments after the eccentric exercise bout.

Statistical Procedures and Analyses

Primary Outcome Measures: Overall Shoulder Pain

A 3 X 5 repeated measures ANOVA was used to determine differences among the pain (VAS) scores. The two factors group (control, placebo, TENS) and day (Day 0, Day 1, Day 2, Day 3, Day 4) were included in the analyses. The group by day interaction has one more level than the ROM data because an additional measurement was made after the exercise bout before they left the first day (Day1).

DASH Questionnaire

A 3 X 4 repeated measures ANOVA was used to identify differences among the groups. The two factors group (control, placebo, TENS) and day (Day 0, Day 2, Day 3, Day 4) were included in the analyses.

MPT

One three-way repeated measures ANOVA (3 X 5 X 3) was used to identify differences with the MPT data. The three factors are group (control, placebo, TENS), day (Day 0, Day 1, Day 2, Day 3, Day 4), and site (supraspinatus trigger point, infraspinatus trigger point, and tendon insertion).

Secondary Outcome Measures: ROM

Five separate two-way ANOVA's were used to determine significance with the ROM data. The 3 X 4 two factors, group (control, placebo, TENS) and day (Day 0, Day 2, Day 3, Day 4), were included in the analyses.

MVIC Data

The difference or change in muscular force production between the pre-injury (Day 0) MVIC trial and all subsequent post-injury trials (Day 1 through 4) were used for the data analysis. All strength values were converted from Nm's to a percent of pre-injury MVIC. All strength data were analyzed by separate 3 X 5 ANOVA's (group: control, placebo, TENS and day: Day 0, Day 1, Day 2, Day 3, Day 4) to determine mean differences among the percentage scores. Data were analyzed using SPSS for windows version 13.0. Alpha level was preset at 0.05 for all analyses.

CHAPTER 4 RESULTS

Primary Outcome Measures Within-Group Comparisons

After exercise-induced injury, subjects experienced a significant increase in pain and dysfunction with several significant main effects (collapsed across groups) being observed.

Pain and DASH scores

Subjects experienced an increase in self reported pain (as measured by the VAS) ($F_{(4,132)} = 36.99, p < .01$) and upper extremity dysfunction (as measured by the DASH questionnaire) ($F_{(3,99)} = 45.75, p < .01$) (Figure 4-8 and 4-9 respectively). Pain and dysfunction increased significantly from Day 0 to Day 1 (indicated by the *) and then decreased from Day 3 to Day 4 (indicated by the †) as identified by the Tukey test.

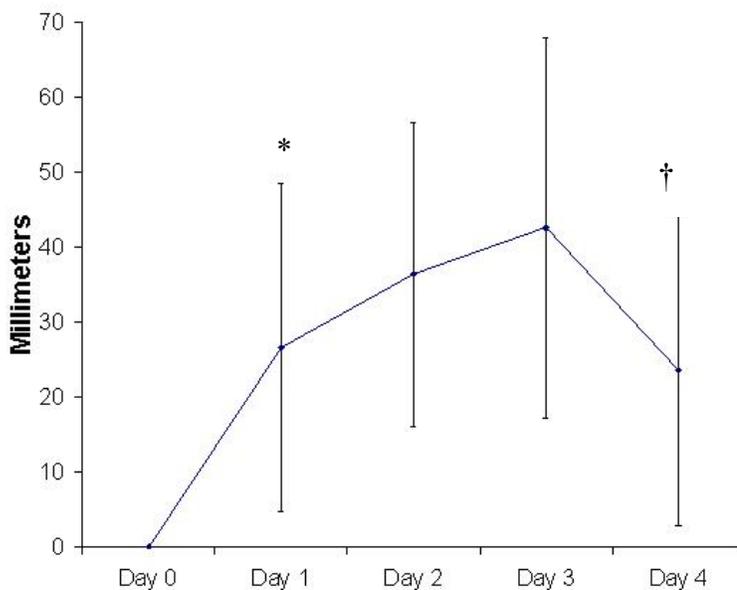


Figure 4-8. Significant increase in self-reported shoulder pain on a visual analogue scale after exercise-induced injury.

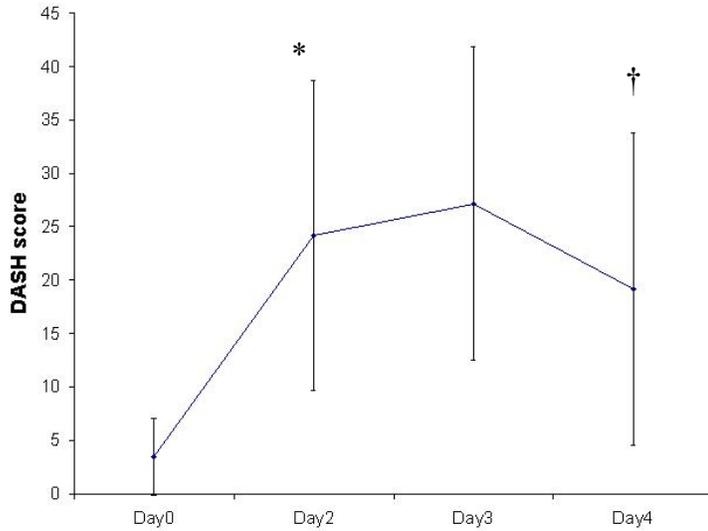


Figure 4-9. Increase in upper extremity dysfunction as measured by the DASH questionnaire after exercise-induced injury of the shoulder.

Point Tenderness

Subjects experienced a significant increase in point tenderness at all three targeted sites on the shoulder ($F_{(6,198)} = 2.88, p < .02$). Point tenderness significantly increased from Day 1 to Day 2 for all three sites as indicated by the Tukey test. In addition, point tenderness significantly decreased at the supraspinatus and infraspinatus trigger point from Day 3 to Day 4 (Figure 4-10).

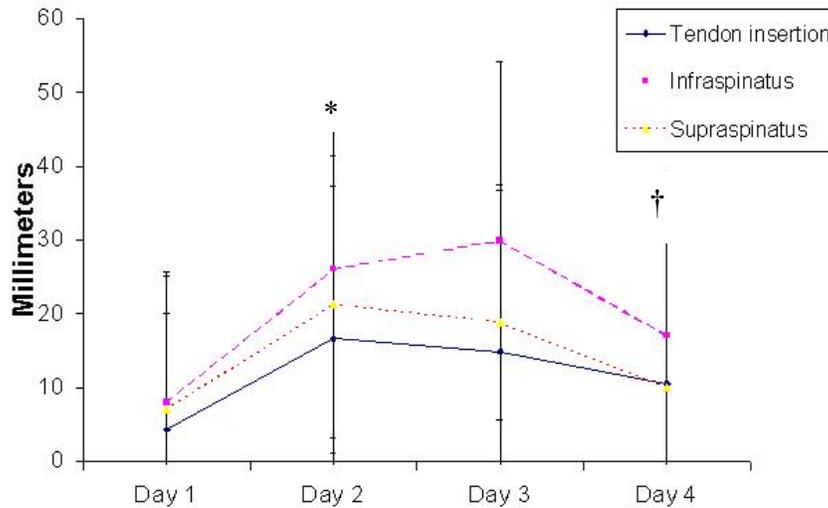


Figure 4-10. Increase in point tenderness at three sites of the shoulder after exercise-induced injury.

Secondary Outcome Measures

After exercise-induced injury, subjects experienced a significant decrease in shoulder range-of-motion (ROM) and muscular strength with several significant main effects (collapsed across groups) being observed.

Range-of-motion (ROM)

Subjects experienced a decrease in active IR ROM ($F_{(3,99)} = 39.62, p < .01$), active ER ROM ($F_{(3,99)} = 12.08, p < .01$), passive IR ROM ($F_{(3,99)} = 88.65, p < .01$), passive ER ROM ($F_{(3,99)} = 10.87, p < .01$), and resting IR ROM ($F_{(3,99)} = 48.66, p < .01$) from Day 0 to Day 2 as indicated by the Tukey test (Figure 4-11).

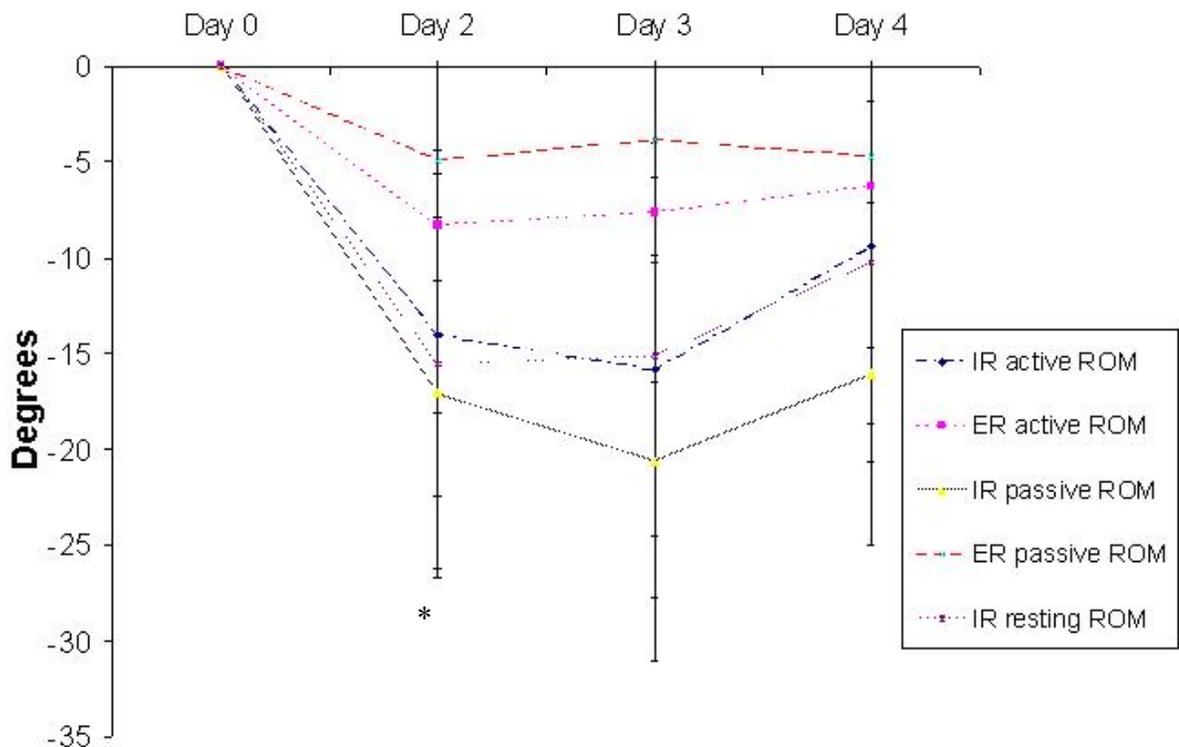


Figure 4-11. Active and passive ROM decrease after exercise-induced shoulder injury.

Shoulder Muscle Strength (MVIC)

Subjects experienced a decrease in MVIC post-injury ($F_{(3,99)} = 10.79, p < .01$) (Figure 4-12).

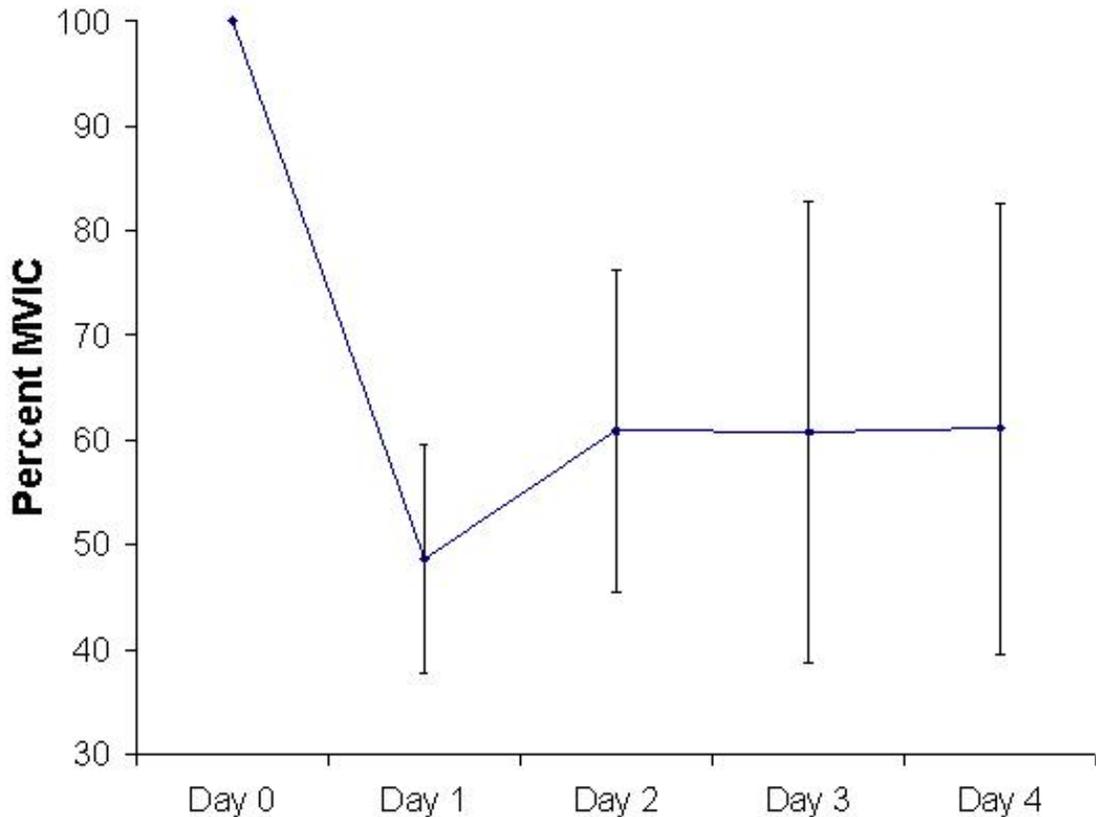


Figure 4-12. External rotation MVIC decrease after exercise-induced injury of the shoulder.

Between-Group Comparisons: Primary Outcome Measures

There were no significant differences between groups for self-reported pain ($F_{(8,132)} = 0.75$, $\eta^2 = 0.551$, $p = .64$) or upper extremity dysfunction (DASH) ($F_{(6,99)} = 1.36$, $\eta^2 = 0.043$, $p = .24$) (Figures 4-13 and 4-14 respectively). In addition there were no significant differences among the groups for point tenderness after exercise-induced injury ($F_{(12,198)} = 0.79$, $\eta^2 = 0.188$, $p = .68$) (Figures 4-15 and 4-16).

Secondary Outcome Measures

There were no significant differences between groups for any of the dependent measures with the exception of shoulder muscular strength (MVIC).

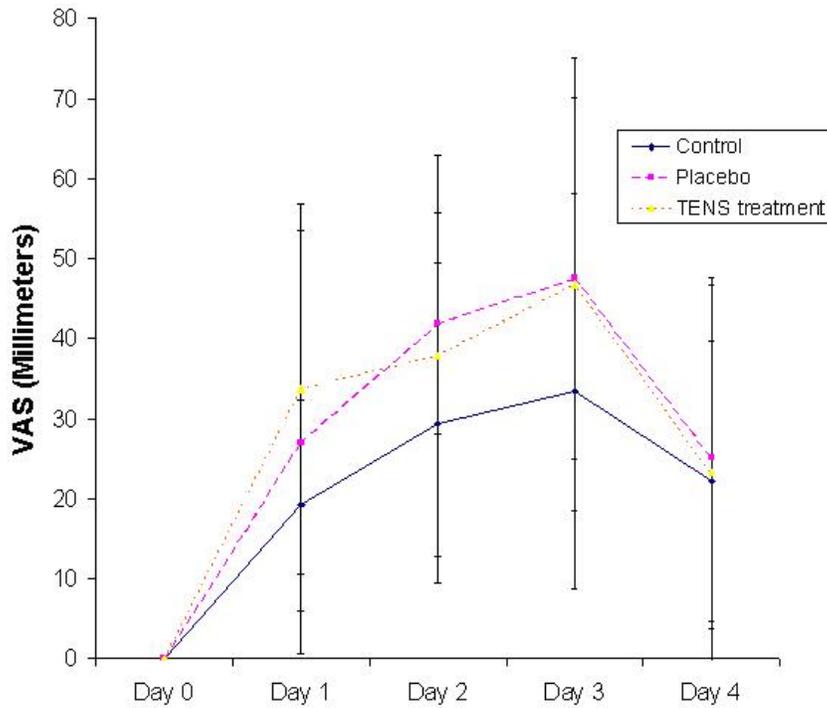


Figure 4-13. Increase in pain among the three groups after exercise-induced injury of the shoulder.

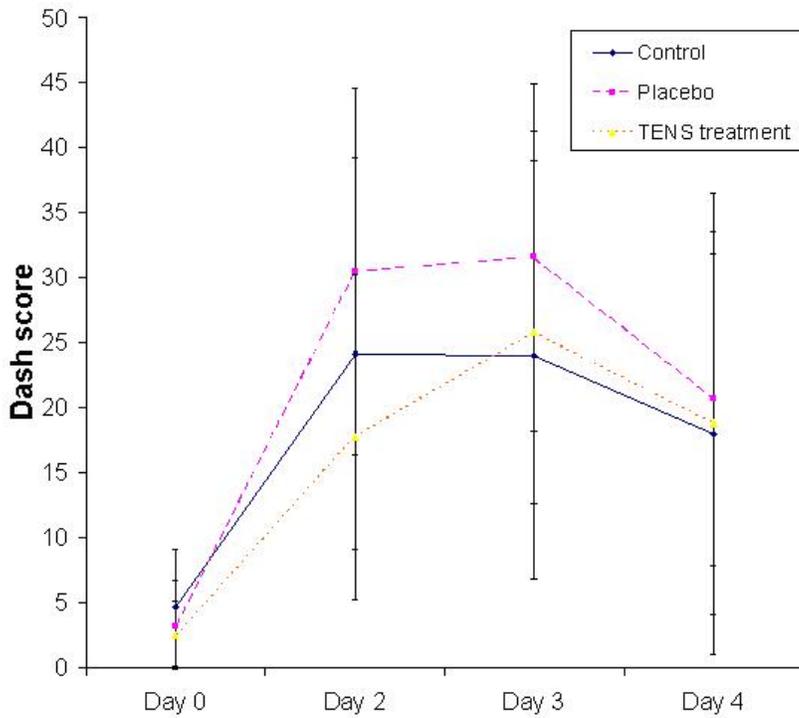


Figure 4-14. Increase in dysfunction of the upper extremity in the three groups after exercise-induced injury.

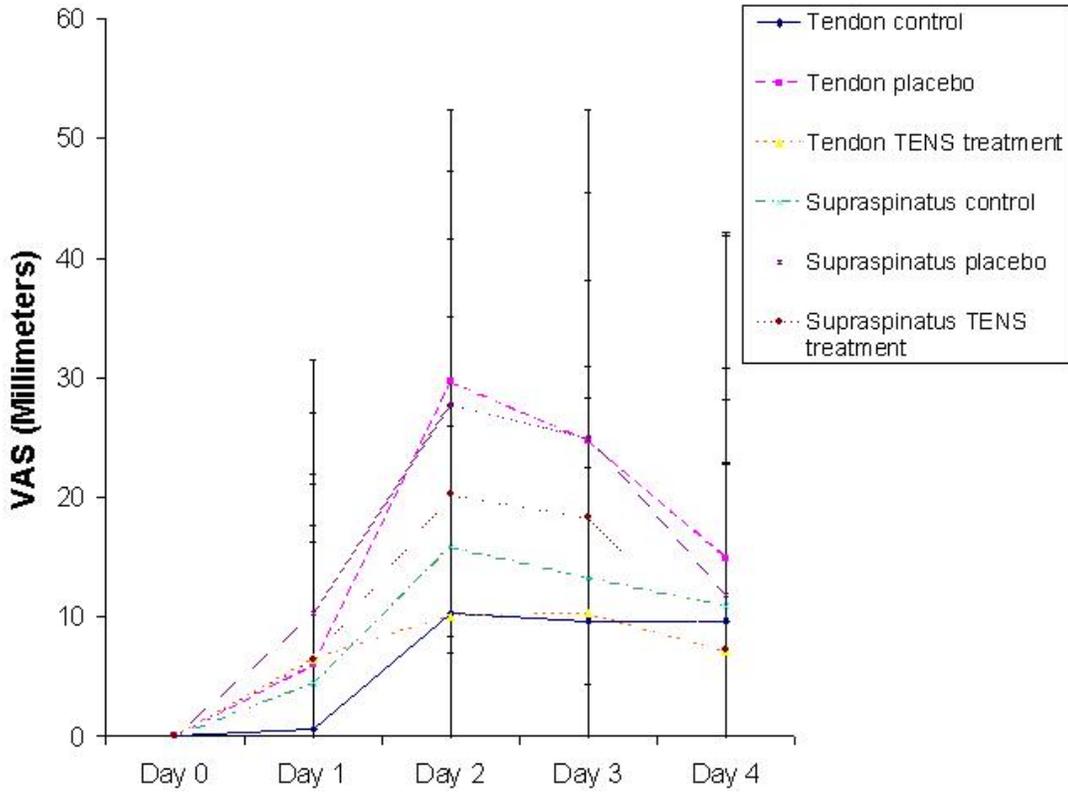


Figure 4-15. Increase in point tenderness of the tendon insertion of the rotator cuff and the supraspinatus trigger point after exercise-induced injury of the shoulder.

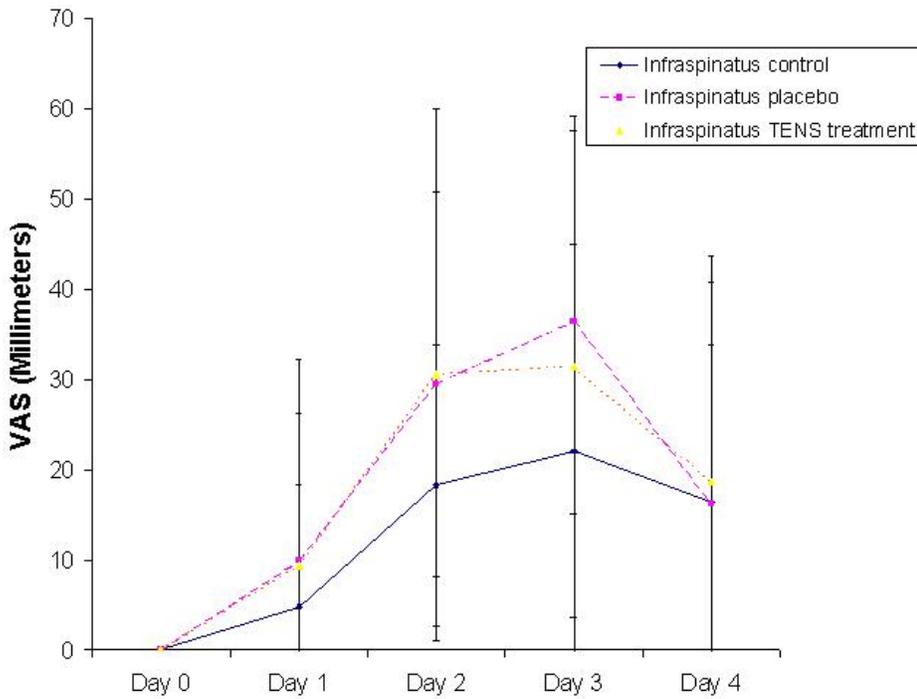


Figure 4-16. Increase in point tenderness of the infraspinatus trigger point after exercise-induced injury of the shoulder.

There were no significant differences in ROM (IR active, $F_{(6,99)} = 1.03$, $\eta^2 = 0.11$, $p = .41$), ER active ($F_{(6,99)} = 0.59$, $\eta^2 = 0.003$, $p = .73$), IR passive ($F_{(6,99)} = 1.68$, $\eta^2 = 0.062$, $p = .14$), ER passive ($F_{(6,99)} = .93$, $\eta^2 = 0.12$, $p = .48$), or IR resting ROM ($F_{(6,99)} = 0.81$, $\eta^2 = 0.071$, $p = .57$) (Figures 4-17, 4-18, and 4-19).

The control group experienced a significant increase in shoulder muscular strength on Day 3 compared to the placebo and treatment group (as indicated by *) and on Day 4 compared to the placebo group (as indicated by †) ($F_{(6,99)} = 2.55$, $p < .05$) as identified by the Tukey test (Figure 4-20).

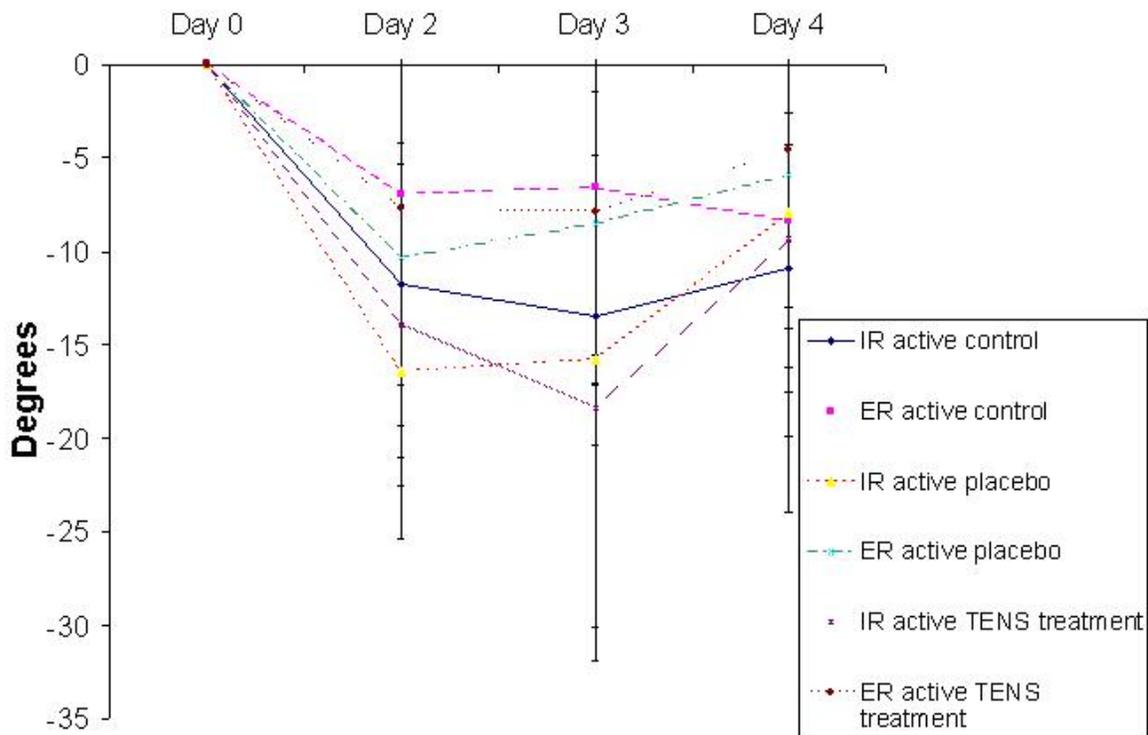


Figure 4-17. Loss of IR and ER active and passive ROM after exercise-induced injury of the shoulder.

Between-Group Comparisons: Primary Outcome Measures Main Effects

There were no main effect differences between groups for pain ($F_{(2,33)} = 1.19$, $p = .32$), function ($F_{(2,33)} = 0.92$, $p = .41$), and point tenderness ($F_{(2,33)} = 1.24$, $p = .30$) (Table 4-1).

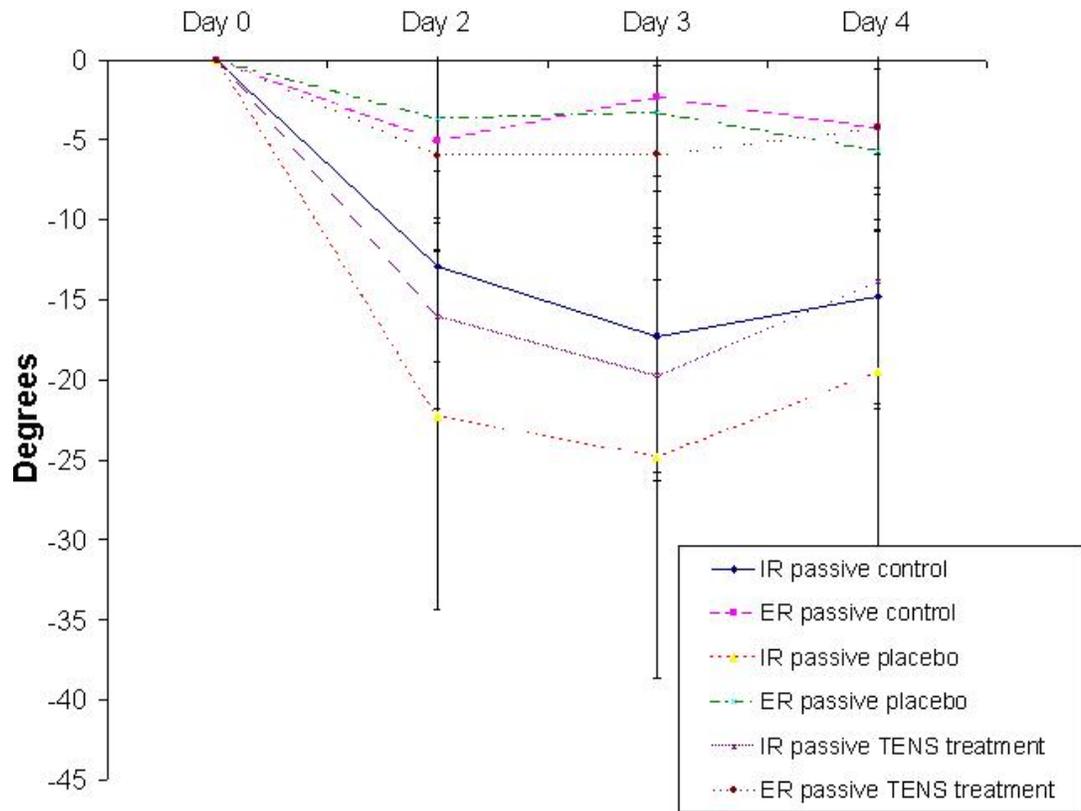


Figure 4-18. Decrease in passive IR and ER ROM after exercise-induced injury.

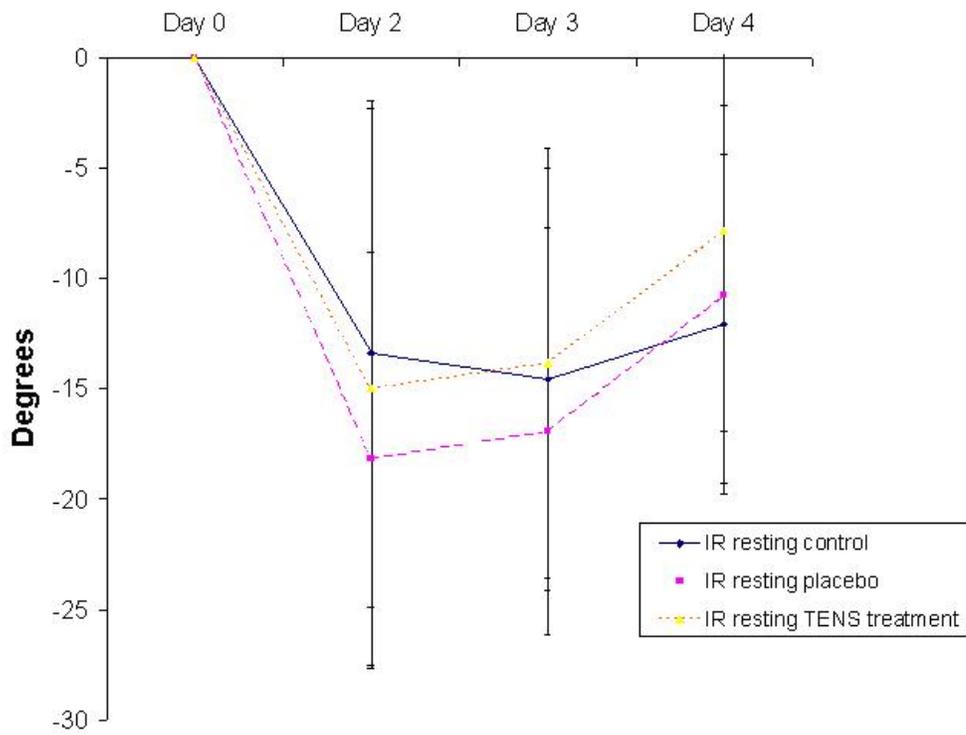


Figure 4-19. Decrease in resting IR ROM after exercise-induced injury of the shoulder.

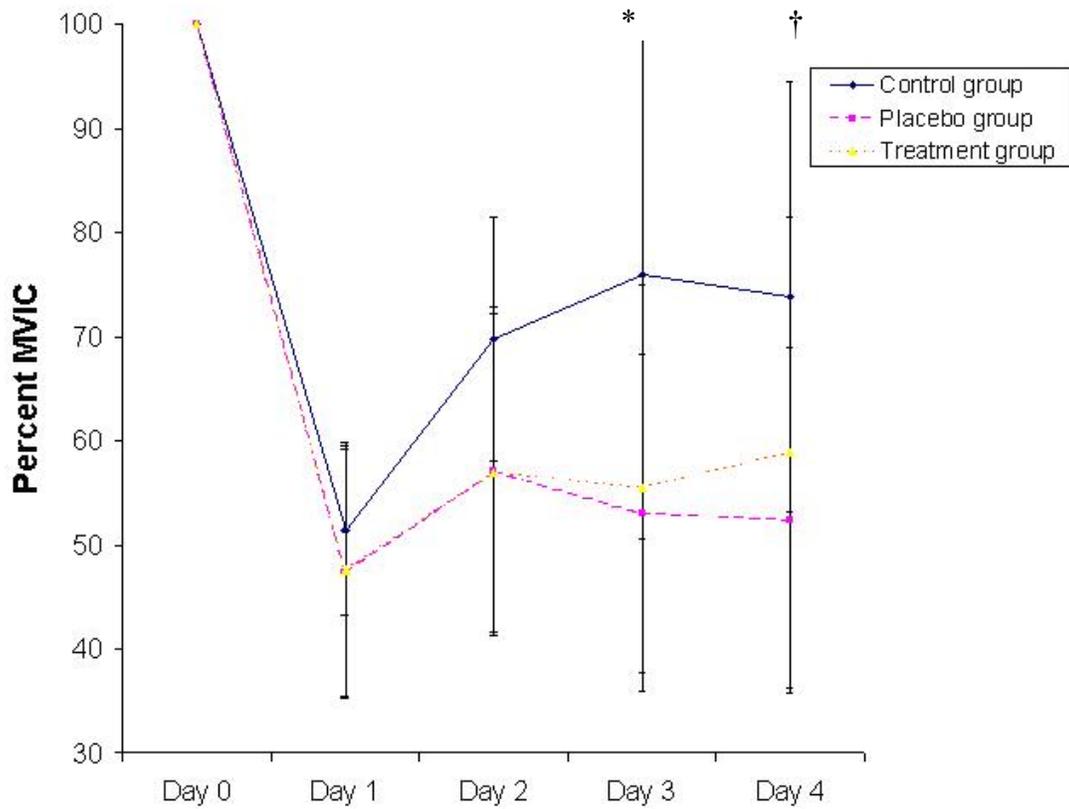


Figure 4-20. Between-group strength differences after exercise-induced injury in the shoulder.

Table 4.1 Main effects for pain, function, and point tenderness.

Group	Pain (mm)	Function (DASH)	MPT (mm)
Control	20.8 ± 12.9	17.7 ± 9.2	11.3 ± 7.2
Placebo	28.3 ± 18.5	21.5 ± 13.1	20.2 ± 12.1
TENS treatment	28.3 ± 17.3	16.2 ± 9.8	14.3 ± 10.1

CHAPTER 5 DISCUSSION

Subjects who received multiple, daily TENS treatments did not experience a significant reduction in overall shoulder pain, upper extremity dysfunction, point tenderness or an improvement in muscular strength or ROM compared to the placebo or control group after exercise-induced muscle injury. Overall subjects in all 3 groups experienced a similar amount of shoulder pain and upper extremity dysfunction post-injury. Therefore, our results suggest that multiple, daily TENS treatments of approximately 90 minutes are not effective in reducing clinical signs and symptoms related to exercise-induced injury of the shoulder.

Our study was properly blinded, controlled and randomized which is critically important when conducting a clinical trial. According to Carrol et al. most studies that were properly blinded, controlled and randomized did not find TENS to be effective for treating pain and/or function after musculoskeletal injury (Carrol et al. 1996). In addition, Carrol et al. identified 46 reports measuring the efficacy of TENS but could only include 17 in their analysis due to improper blinding and randomization techniques. Many of the published TENS studies were not conducted properly according to Carrol et al. indicating that a paucity of properly blinded and randomized studies exist regarding the therapeutic use of TENS as a treatment in a clinical trial. To ensure that our study would be considered for future TENS meta-analyses we followed the suggestions made by previous authors regarding blinding and randomization (Altman and Bland 1999b; Altman and Schulz 2004). A research assistant was used in our study to record all data

and was blinded to group assignment. Moreover the research assistants who applied the TENS and sham treatments were not involved with the data collection process. We performed our randomization procedures for group allocation according to recommendations by Bland et al. (Altman and Bland 1999b). This ensured no artificial treatment effect due to improper randomization previously suggested by these authors (Altman and Bland 1999a). In summary, our study was well designed and conducted using a single blind method, was properly randomized, used appropriate treatment parameters, reliable pain model, and evaluated appropriate outcome measures. As a result we were not able to find TENS to be clinically effective at treating pain and dysfunction after exercise-induced injury of the shoulder.

Within-Group Comparisons: Primary Outcome Measures

All subjects experienced a significant increase in overall shoulder pain as indicated on a VAS. The self-reported pain score in millimeters increased 20–30 mm after induced injury from Day 2 to 4. Dannecker et al. noted a similar increase after an eccentric exercise bout in the elbow of approximately 30mm (Dannecker et al. 2005). This increase is similar to amount of pain experienced during experimentally induced ischaemia (~30 mm increase from baseline)(Walsh et al. 1995). Walsh et al. induced ischaemic pain by applying a sphygmomanometer to the biceps brachii, inflating the cuff to 200 mm Hg and instructing subjects to perform hand-gripping exercises. The amount of experimentally induced pain and injury was shown to be sufficient to find a treatment effect using a pain relief modality.

We used the DASH questionnaire to measure shoulder dysfunction. Subject's scores increased from 0 to 17–31 (higher score indicating more dysfunction) although there were no statistically significant differences among the three groups (Figure 4-13).

Subjects' DASH scores on average, increased by approximately 20 from baseline (Day 0) and peaked at Day 3. Researchers have suggested that a 10-point change in the DASH score may be considered the minimum for a clinically significant finding (Gummesson et al. 2003). The peak DASH scores in our subjects were similar to the amount of discomfort and dysfunction as seen in post-operative shoulder patients (Gummesson et al. 2003). Similar to the findings of Craig et al. our subjects experienced an increase in upper extremity dysfunction after the exercise-induced injury at a level high enough to measure a treatment effect for a pain relief modality (Craig et al. 1996).

Our subjects experienced an increase in point tenderness ranging from 5–30 mm as indicated on a VAS scale (Figure 4-9). Persson et al. noted a 103–120% increase in pain pressure threshold in their subjects after a shoulder endurance test (Persson et al. 2003). Our subjects tended to experience more point tenderness over the infraspinatus motor point compared to the tendon insertion and supraspinatus motor point (Figure 4-9). The subjects Mechanical Pain Threshold (MPT) VAS scores for the infraspinatus peaked on Day 3 at around 30 mm, almost 10 mm more than the most painful day for the supraspinatus and 13 mm more painful than the most painful day for the tendon insertion. Our exercise injury protocol involved several sets of repeated eccentric external rotation actions. The infraspinatus is used primarily in external rotation more so than the supraspinatus (Kelly et al. 1996). Anecdotally, the PI noted, although no direct measures were taken, that the infraspinatus appeared swollen after the exercise protocol. The infraspinatus appeared to have been affected more by the exercise-induced injury protocol than the supraspinatus, mainly because the infraspinatus contributes more to external rotation than the supraspinatus. Moreover, after the exercise-induced injury, the

PI subjectively noted that the head of the humerus could shift in the glenoid fossa easier than before the exercise protocol. No direct GH joint translation measures were recorded, however the PI noted that the head of the humerus would sublux in the majority of patients during the force application using the algometer during the tendon insertion point tenderness testing. We speculate that the rotator cuff may have been fatigued to the point where the musculature could not dynamically stabilize the humeral head on the glenoid fossa during the tendon insertion algometer testing. Therefore, instead of the algometer pressure being applied to the tendon insertion, the force was being used to translate the head of the humerus and may have resulted in a lower point tenderness score.

Secondary Outcome Measures

Our subjects experienced a significant decrease in shoulder ROM and strength similar to other studies that used exercise to induce injury in the upper extremity (Borsa and Sauers 2000; Craig et al. 1996; Dannecker et al. 2005; Reeser et al. 2005). Collectively, our subjects experienced a 5–24° loss in active, passive, and resting IR and ER ROM of the shoulder, while Craig et al. noted a similar 5–25° loss in resting and active ROM at the elbow (Craig et al. 1996) and Reeser et al. observed a 5–12° loss of resting and active ROM of the elbow (Reeser et al. 2005). The decrease in ROM, strength and increase in pain and dysfunction we observed in the shoulder are similar to other studies at the elbow. No study to date that we are aware of has measured ROM, strength, pain, point tenderness, and dysfunction in the shoulder after an exercise-induced muscle injury.

Passive IR ROM decreased the most compared to the other ROM measures and from our data appears to be the best ROM indicator of impairment. The mean loss of passive IR ROM peaked at 20° on Day 3 compared to the other ROM measurements,

which only ranged from 4–15°. The exercise-induced injury protocol we used included multiple repetitions of eccentric external rotation movements, utilizing predominantly the external rotators (infraspinatus) of the shoulder. During our measurements of passive IR the external rotator musculature, primarily the infraspinatus, was put on stretch. Muscle stiffness, secondary to intramuscular edema and pain, is a common symptom of exercise-induced injury and has been mentioned in other studies (Borsa and Sauers 2000; Craig et al. 1996; Dannecker et al. 2005). Our exercise-induced injury protocol produced a similar amount of muscular stiffness as was observed in previous studies of the elbow (Borsa and Sauers 2000; Craig et al. 1996; Dannecker et al. 2005).

Between-Group Comparisons: Primary Outcome Measures

Our results are consistent with other studies that found TENS to be ineffective for treating pain and dysfunction associated with injuries to the elbow, low back and post-surgery (Brosseau et al. 2002; Carrol et al. 1996; Craig et al. 1996). Brosseau et al. noted in their meta-analysis on low back pain that there was an approximate 4mm decrease in pain (based on a 100mm visual analogue scale) in the TENS treatment group compared to the placebo group (Brosseau et al. 2002). The 4 mm decrease was not statistically significant, where as previous researchers have suggested that a 10mm change on the VAS regarding pain would be clinically significant (Bolton 1999; Price et al. 1983). We found similar results as Brosseau et al. regarding pain in our study. Subjects in each of the three groups reported a similar amount of pain regardless of condition. Subjects in the TENS group did not experience a significant change in their pain levels compared to the placebo or control group. This suggests that multiple TENS treatments do not reduce pain in the shoulder after exercise-induced injury.

Although not statistically significant but worth noting, the TENS group did experience less pain and dysfunction, while having more IR active, ER active, IR passive, and IR resting ROM on Day 2. This improvement, while not statistically significant, may advocate the immediate and acute application of sensory level TENS to a musculoskeletal related injury. Sensory level TENS application is indicated primarily for pain relief of acute injuries. Day 2 of our model represents the initial 24–48 hours post exercise-induced injury, which is where acute phase pain relief is primarily indicated. TENS has additional settings for chronic pain relief and these settings may be better indicated for Days 3 and 4, which may represent a more sub acute or chronic stage post-injury.

Subjects in the TENS group did not experience an increase in upper extremity function or point tenderness as compared to the placebo and control group which is also consistent with previous studies (Carrol et al. 1996; Craig et al. 1996). Craig et al. measured dysfunction by using the short form McGill Pain (MPQ-SF) questionnaire. Carrol et al. and Craig et al. evaluated the efficacy of TENS to reduce pain in four groups (control, placebo, low frequency TENS, and high frequency TENS) after exercise-induced injury of the biceps. Their subjects Pain Rating Index (PRI) scores ranged from 18–26mm after injury. Although some of the PRI scores were higher in the control and placebo groups compared to the treatment groups, none of the differences were statistically significant (Craig et al. 1996).

Secondary Outcome Measures

There were no differences in ROM between groups although the control group did experience an increase in strength compared to the placebo and treatment groups during Days 3 and 4. We have no plausible explanation as to why this effect occurred, however we may speculate that subjects in the control group had less muscle damage after the

eccentric exercise protocol than did the treatment and placebo groups. In addition, the treatment and placebo group may have been affected by the knowledge they were receiving treatment for their shoulder. Psychologically knowing that they are being treated for their pain may make subjects more aware of their dysfunction. The control group knew they were not going to receive any treatment and therefore they might not think about the pain as much as the other two groups.

Exercise-Induced Injury Model

Exercise-induced injury is a popular model used to measure pain and dysfunction. The cause of the pain and dysfunction has been attributed to the primary and secondary injury mechanisms associated with acute phase inflammation, cytokine response and oxidative stress (Borsa and Sauers 2000; Dannecker et al. 2005; Saxton et al. 1995; Toumi and Best 2003; Vincent et al. 2000). Exercise-induced injury is a popular model because eccentric contractions has been shown to generate a local and systemic connective tissue and hormone response with similar signs and symptoms to an acute musculoskeletal injury (Byrne et al. 2004; Toumi and Best 2003). The inflammation response includes a large neutrophil release within the first 24–48 hours followed by macrophage infiltration on Day 3 and lasting several days up to a week. Although neutrophils and macrophages are needed for phagocytosis, some researchers believe that the increase in cytokines and leukocytes cause additional muscle damage after the primary injury (Toumi and Best 2003). In fact, a previous study that measured an antibody that blocked a neutrophil burst demonstrated that myofiber damage could significantly be reduced 24 hours after injury (Toumi and Best 2003). Moreover, there seems to be a preservation of intermediate myofilaments desmin and dystrophin, suggesting that oxygen free radicals may operate directly on these proteins. The

inhibition of desmin and dystrophin has been attributed to the prolonged strength deficit after exercise-induced injury. The increase in neutrophil activity may cause secondary muscle damage to occur after the initial injury was induced. This secondary muscle damage that occurs hours after the initial injury may explain why the strength measures remained impaired 4 days after exercise-induced injury. The average percent MVIC for all subjects on Day 4 was around 63%. All subjects were significantly weaker three days after the exercise bout. This weakness that was observed over the three days suggests that the eccentric exercise protocol induced a significant amount of muscle damage that may have been exacerbated by leucocyte activity and resulted in prolonged strength deficits.

Evidence-Based TENS Considerations

High frequency, sensory level TENS treatments alone may not provide enough pain relief to evoke an analgesic response for this type of injury. High frequency TENS only provides pain relief when electrical current is being delivered. Additional therapeutic agents may be necessary along with TENS to reduce acute inflammation and facilitate healing at the lesion site. Pain relief using sensory level TENS is based on the gate control theory (Johnson 2001; Melzack and Wall 1965). According to the gate control theory, stimulation of large diameter (A- β) afferent fibers in the body from TENS application results in pain reduction (Denegar and Donley 2003). Neural signals from large diameter afferent fibers stimulate 2nd order neurons in the spinal cord that ultimately inhibit (or close the gate) on pain impulses transmitting from a cluster of nociceptors (A- δ and C). Pain signals that transmit along both large A- δ and small C fiber pathways are diminished and as a result the subject perceives less pain (Denegar and Donley 2003). Based on this theory, a patient will only experience pain relief for as long as high frequency treatment is being applied (Denegar and Donley 2003; Johnson 1997). It

appears from the results of our study that multiple daily TENS treatments is not sufficient to create prolonged pain relief from the exercise-induced injury. In addition, treatment of musculoskeletal conditions rarely consists of one intervention alone especially in the shoulder. In the real world a combination of treatments would most likely be used. Treatment of musculoskeletal injuries usually encompasses multiple treatments at the various phases of tissue healing (Denegar and Donley 2003; Prentice 1999; Wilk and Arrigo 1993). In the acute phase of tissue healing, treatments can include ice, rest, and NSAIDS (Prentice 1999). The combination of treatments may be the reason for the significant decrease in pain and increase in function that clinicians expect after musculoskeletal injury. Clinicians rarely use TENS treatments alone to care for an acutely injured patient.

Multiple treatments create a challenge for researchers attempting to assess treatment effectiveness for a given impairment. Multiple variables increase the difficulty of measuring the treatment effect; this is a common problem when evaluating a combination of treatments in a research study. Previous studies that measured the effectiveness of TENS did not allow patients to receive additional treatment during the course of the study. Based on the results of our study and others, TENS treatments alone may not be enough to significantly decrease patient pain and dysfunction. However, if researchers provide multiple treatments during the course of the study, the treatment effect may be harder to detect. Clinicians will not know if the desired effect was from the treatment of interest or a combination of the other treatments. This is a question every researcher needs to address before starting any treatment trial. The choice is between

using multiple treatments because it is more similar to real life rehabilitation, or limit the number of treatments in order to better measure the treatment effect in isolation.

Johnson suggested that the typical 20-minute treatment time for TENS might not be enough to observe a measurable treatment effect (Johnson 1997). We hypothesized that a longer (~90-minute) treatment time would be necessary to produce noticeable therapeutic effects. Longer treatment times are common in high frequency TENS treatments of acute musculoskeletal injuries (Denegar and Donley 2003). This treatment, although not a combination treatment, is more comparable to what clinicians use in the real world for treating injuries. Rarely will a clinician treat an injured athlete or patient for 20 minutes alone using a single treatment. We postulated that an increase in treatment time would provide more pain relief and result in a measurable treatment effect for the patient. However this was not the case, and our subjects did not experience any significant pain decrease using TENS.

Study Limitations

Limitations of this study include the lack of invasive procedures to directly quantify the magnitude of muscle damage and inflammation with our exercise-induced injury model and the timing of our reported pain data collection. We were only able to infer the magnitude of muscle damage and inflammation from our subjective and objective clinical measures. Previous studies have used blood markers such as creatine kinase (CK) and imaging techniques such as MRI to quantify muscle damage and inflammation (Armstrong 1990; Byrne et al. 2004). However, some researchers have questioned the accuracy of CK as a marker of tissue damage (Ebbeling and Clarkson 1989). In addition our data collection on Day 2 – Day 4 occurred only after the final treatment session for that day. The theory of sensory level TENS treatment is that pain

relief is only going to be experienced while the electric current is being applied. A measure of how much pain relief was experienced during the TENS session for those subjects in the placebo and TENS groups would have been appropriate to determine if subjects experienced more pain relief while subjects were receiving the treatment. We measured reported pain by asking the subjects how much overall shoulder pain they experienced that day which might not have been sensitive enough to pain relief during the treatment session.

Our results can only be generalized to college-aged subjects since older individuals may react differently to exercise-induced injury and for treating the shoulder since other joints may react differently to TENS treatments and pain relief.

Conclusions

Multiple daily TENS treatments alone are not effective in relieving pain and dysfunction after exercise-induced injury of the shoulder compared to placebo and control groups. In addition, the exercise model of inducing injury to the shoulder is effective at generating pain, loss of ROM, upper extremity dysfunction, and point tenderness as observed in other exercise-induced injury studies. The best indicators of exercise-induced injury after an external rotation eccentric exercise protocol are infraspinatus point tenderness, IR passive ROM, and ER strength. After exercise-induced injury, infraspinatus point tenderness significantly increased, while IR passive ROM, and ER strength significantly decreased.

Future studies should include combined treatments to more accurately reflect real clinic-based treatments. Moreover, further clinical trials that are properly blinded and randomized for evaluating pain relief at the shoulder are warranted.

APPENDIX A
IRB CONSENT FORM

Informed Consent Agreement

Project Title: Shoulder treatment after an exercise bout.

Investigators: PI: Geoffrey Dover, MS, CAT(C), ATC, Doctoral Candidate,
Department of Applied Physiology and Kinesiology.

Co investigators: Paul Borsa, PhD, ATC, Associate Professor, Department of
Applied Physiology and Kinesiology.

**Please read this consent agreement carefully before you decide to participate
in this study.**

Purpose of the research study:

The purpose of this investigation is to monitor or treat the shoulder after an
exercise session.

What you will do in the study:

You have been asked to volunteer to participate in this study because you have not
suffered any injuries lately to your shoulder. If you have a history of an arm or shoulder
injury that could prevent you from safely participating, you should not volunteer for this
study. If you have any decreased sensation or if you have a pacemaker you should not
participate in this study. If you are unsure that you can safely participate, please consult
your doctor before participating. In the event you can participate, immediately before
beginning testing, your demographic data including age, gender, height (cm), and weight
(kg) will be recorded.

The first step is measuring how much rotation movement you have in your shoulder. We will measure how much movement you have in the internal (arm in) and external (arm out) rotation of your shoulder. Then, you will sit on a chair and we will strap your arm to a machine called a Kin-Com. This machine will not provide any resistance too you, the arm of the machine will not move while you push against it. Then you will be asked to perform 3 sets of exercises for the shoulder in the external rotation direction. Following the exercise, you will fill out a form that asks questions about your performance of the exercise bout. At the end of the session, you will be asked to come back on three other occasions to fill out more information about the exercise session. During those three test sessions you may or may not be able to apply some treatment to your shoulder. The treatment consists of using a small battery operated device referred to as a TENS device. TENS stands for transcutaneous electrical nerve stimulation. The amount of current you will receive is minimal considering the device is operated by a 3V battery. You may or may not feel anything during the 90 minute treatment. If you do feel anything it will be a comfortable buzzing like a vibrating cell phone.

As far as the exercise goes you will only perform the exercise once during the first session. On the three other sessions you will either receive the treatment or just report how you are feeling.

Time required:

Four sessions total. Each requiring 30 minutes for a total of 2 hours.

Risks:

There is a chance that some discomfort and soreness in the shoulder will be experienced following the bout of eccentric exercise. As with any type of resistance exercise, there is a slight risk muscle injury. In the unlikely event that an injury may occur, a National Athletic Trainers Association athletic trainer (ATC) will be present for all the testing sessions.

Benefits/Compensations:

There are no benefits or any type of compensation for participating in this study.

Confidentiality:

Data will be kept confidential to the extent provided by law. Your information will be assigned a code number. The list connecting your name to this number will be kept in a locked file. When the study is completed and the data have been analyzed, the list will be destroyed. Your name will not be used in any report.

Voluntary Participation:

Your participation in the study is completely voluntary. There is no penalty for not participating.

Right to withdraw from the study:

You have the right to withdraw from the study at anytime without penalty.

Payment:

You will receive no payment for participating in the study.

Who to contact if you have questions about the study:

Geoffrey Dover, MS, CAT(c), ATC, Department of Applied Physiology and Kinesiology, (352) 392-0584 *1297 and Paul Borsa, PhD, ATC, Department of Applied Physiology and Kinesiology, 149 FLG, (352) 392-0584 x 1261

Who to contact about your rights in the study:

UFIRB Office, Box 112250, University of Florida, Gainesville, FL 32611-2250,
(352) 392-0433

Agreement:

I have read the procedure described above. I voluntarily agree to participate in the procedure and I have received a copy of this description.

Participant: _____

Date:

Principal Investigator: _____

Date: _____

APPENDIX B
IRB PROTOCOL

UNIVERSITY OF FLORIDA INSTITUTIONAL REVIEW BOARD

1. Title of Protocol: Shoulder treatment following an exercise bout.

2. Principal Investigator:

Geoffrey C. Dover, MS, CAT(C), ATC

University of Florida

Department of Applied Physiology and Kinesiology

148 Florida Gymnasium

PO Box 118207

Gainesville, FL 32611-8207

H: (352) 871-4636

W: (352) 392-0584 *1297

Fax: (352) 392-5262

E-mail: gdover@hhp.ufl.edu

3. Supervisor:

Paul Borsa, PhD, ATC

University of Florida

Department of Applied Physiology and Kinesiology

149 Florida Gymnasium

PO Box 118205

Gainesville, FL 32611-8205

(352) 392-0584, ext. 1261

Fax: (352) 392-5262

E-mail: pborsa@hhp.ufl.edu

4. Dates of Proposed Protocol: November 1st 2004 to December 20th 2005.

5. Source of Funding for Protocol: There is no funding for this protocol.

Scientific Purpose of the Investigation: The purpose of this investigation is to evaluate a treatment for the shoulder following an exercise bout. This is a follow up study to the UFIRB 2004 – 4 – 471 (copy of protocol is included) where we induced shoulder fatigue, now we are treating that fatigue with a small watch battery operated device.

Research Methodology: All subjects will undergo four testing sessions that will be held on four separate days. During the first test session, participants will read and sign the informed consent approved by the UF IRB. Then subjects will fill out some demographic data including age, weight, and if they have suffered an upper extremity injury lately followed by having selected baseline measurements taken. The amount of external (rotating arm out) and internal rotation (rotating the arm in) of the shoulder will be measured using a goniometer, which is a hand held plastic device placed beside the shoulder during the movement of the participant. Following the range of motion measurements, their shoulder isometric strength will be assessed in the external rotation direction. All participants will sit in a chair and their arm secured to a machine called the Kin-Com (Chattecx Corp., Chattanooga, TN). The Kin-Com is a computerized device for measuring muscular strength. The machine will not apply any force to the subject. The arm will remain stationary while the subject pushes against it. This one repetition max will be assessed and used to determine exercise intensity. All participants will then

perform 3 sets of 10 eccentric (muscle lengthens while it contracts, otherwise known as a negative) repetitions. Participants will only perform the 3 sets of 10 repetitions during the first session; all subsequent sessions will involve the same measurements as the pre-exercise session. The subjects will then fill out a questionnaire concerning their perceived level of performance. Then subjects will be randomly placed in three groups (control, treatment, and placebo). The treatment consists of a 90 minute application of TENS. TENS stands for transcutaneous electrical nerve stimulation. The amount of current that is applied is minimal because the device operates with a small 3 V power source. The participants may or may not feel anything. If they do feel something it will be a comfortable buzzing sensation similar to a vibration of cell phone. The placebo group will be treated with a sham device that provides no current but they will be told that current is being applied. The control group will receive nothing. All participants will be asked to return 24, 48, and 72 hours after initial testing to provide subjective (self-report) information regarding the exercise bout.

Potential Benefits and Anticipated Risk: There will be no direct benefits to the subjects for taking part in this study. There is a chance that some discomfort and soreness in the shoulder will be experienced following the bout of eccentric exercise. As with any type of resistance exercise, there is a slight risk muscle injury. In the unlikely event that an injury may occur, a National Athletic Trainers' Association Board-certified athletic trainer (ATC) will be present for all testing sessions.

Participant Recruitment, Number and Age of Participants, and Compensation: Participants will be recruited from the university community. A total of 36 subjects (18 male and 18 female approximately) will be selected. Students from

Geoffrey Dover's class or Paul Borsa's class will not be used. Subjects will be excluded from participation if they have suffered any injury to their shoulder in the past six months. In addition, subjects who have decreased sensation, or a pacemaker will not be considered for this study. Subjects' demographic data including age, gender, height (cm), and weight (kg) will be taken prior to testing. There will be no compensation for participation.

Informed Consent: Each subject will be asked to read and sign an informed consent form providing them with all the information about the study. This document will present an overview of the study and instructions on what will be done, as well as associated risks and benefits for participation.

Principal Investigator's Signature

Supervisor's Signature

I approve this protocol for submission to the UFIRB:

Dept. Chair / Date

APPENDIX C
DATA COLLECTION FORM

Shoulder fatigue and force output

Name: _____ ID #: _____

Age: _____ Ht (cm): _____ Wt (kg): _____
(2.54 x in) (4536 x lbs)

Date: _____ DOB: _____ Dominant limb _____

History questions: (dates)

Hx of shoulder pain Yes No Date:

Rotator cuff/Biceps tendonitis Yes No Date:

Last time you worked your out upper extremity Yes No Date:

Had TENS before? Yes No Date:

Prior surgery Yes No Date:

Current Symptoms:(tested shoulder) Right - Yes No

Left - Yes No

Day 1

DOM IR active –

ER active-

IR passive -

ER passive -

IR resting -

MVIC 1st -1st -2nd -2nd -3rd -3rd -MVIC after fatigue 1st -1st -2nd -2nd -3rd -3rd -

How is your pain today?

No Pain _____ Unbearable Pain

How painful is spot #1

No Pain _____ Unbearable Pain

How painful is spot #2

No Pain _____ Unbearable Pain

How painful is spot #3

No Pain _____ Unbearable Pain

Day 1

After fatigue

How is your pain now?

No Pain _____ Unbearable Pain

How painful is spot #1

No Pain _____ Unbearable Pain

How painful is spot #2

No Pain _____ Unbearable Pain

How painful is spot #3

No Pain _____ Unbearable Pain

Day 2

DOM IR active – ER active- IR passive - ER passive -

IR resting -

How is your pain today?

No Pain _____ Unbearable Pain

How painful is spot #1

No Pain _____ Unbearable Pain

How painful is spot #2

No Pain _____ Unbearable Pain

How painful is spot #3

No Pain _____ Unbearable Pain

MVIC 1st -

1st -

2nd -

2nd -

3rd -

3rd -

Day 3

DOM IR active – ER active- IR passive - ER passive -

IR resting -

How is your pain today?

No Pain _____ Unbearable Pain

How painful is spot #1

No Pain _____ Unbearable Pain

How painful is spot #2

No Pain _____ Unbearable Pain

How painful is spot #3

No Pain _____ Unbearable Pain

MVIC 1st -

1st -

2nd -

2nd -

3rd -

3rd -

Day 4

DOM IR active – ER active- IR passive - ER passive -

IR resting -

How is your pain today?

No Pain _____ Unbearable Pain

How painful is spot #1

No Pain _____ Unbearable Pain

How painful is spot #2

No Pain _____ Unbearable Pain

How painful is spot #3

No Pain _____ Unbearable Pain

MVIC 1st -

1st -

2nd -

2nd -

3rd -

3rd -

LIST OF REFERENCES

- Ada,L. and Foongchomcheay,A., Efficacy of electrical stimulation in preventing or reducing subluxation of the shoulder after stroke: A meta-analysis, *Australian Journal of Physiotherapy*, 48 (2002) 257-267.
- Altman,D.G. and Bland,J.M., Treatment allocation in controlled trials: why randomise?, *British Medical Journal*, 318 (1999a) 1209-1209.
- Altman,D.G. and Bland,J.M., How to randomise, *British Medical Journal*, 319 (1999b) 703-704.
- Altman,D.G. and Schulz,K.F., Concealing treatment allocation in randomised trials, *British Medical Journal*, 323 (2001) 446-447.
- Altman,D.G. and Schulz,K.F., Turning a blind eye, *British Medical Journal*, 328 (2004) 1135.
- Altman,D.G., Schulz,K.F., Moher,D., Egger,M., Davidoff,F., Elbourne,D., Gotzsche,P.C., and Lang,T., The revised consort statement for reporting randomized trials: Explanation and elaboration, *Annals of Internal Medicine*, 134 (2001) 663-694.
- Anderson,S.A., Ericson,T., Holmgren,E., and Lindqvist,G., Electro-acupuncture. Effect on pain threshold measured with electrical stimulation of teeth, *Brain Research*, 63 (1973) 393-396.
- Armstrong,R.B., Initial events in exercise-induced muscular injury, *Medicine and Science in Sports and Exercise*, 22 (1990) 429-435.
- Atroshi,I., Gummesson,C., Andersson,B., Dahlgren,E., and Johansson,A., The disabilities of the arm, shoulder, and hand (DASH) outcome questionnaire, *Acta Orthopaedic Scandinavia*, 71 (2000) 613-618.
- Bates,J.A.V. and Nathan,P.W., Transcutaneous electrical nerve stimulation for chronic pain, *Anaesthesia*, 35 (1980) 817-822.
- Beaton,D.E., Davis,A.M., and Hudak,P., The DASH (Disabilities of the arm, shoulder, and hand) outcome measure: What do we know about it now?, *British Journal of Hand Therapy*, 6 (2001) 109-118.

Beaton,D.E. and Schemitsch,E., Measures of health-related quality of life and physical function, *Clinical Orthopaedics and Related Research*, 413 (2003) 90-105.

Bjordal,J.M., Johnson,M.I., and Ljunggreen,A.E., Transcutaneous electrical nerve stimulation (TENS) can reduce postoperative analgesic consumption. A meta-analysis with assessment of optimal treatment parameters for postoperative pain, *European Journal of Pain*, 7 (2003) 181-188.

Bland,J.M. and Altman,D.G., Statistical methods for assessing agreement between two methods of clinical measurement, *Lancet*, 1 (1986) 307-310.

Bolton,J.E., Accuracy of recall of usual pain intensity in back pain patients, *Pain*, 83 (1999) 533-539.

Borsa,P.A. and Sauers,E.L., The importance of gender on myokineic deficits before and after microinjury, *Medicine and Science in Sports and Exercise*, 32 (2000) 891-896.

Bot,S.D.M., Terwee,C.B., van der Windt,D.A.W.N., Bouter,L.M., Dekker,J.H.M., and de Vet,H.C.W., Clinimetric evaluation of shoulder disability questionnaires: a systematic review of the literature, *Annals of the Rheumatic Diseases*, 63 (2004) 335-341.

Brosseau,L., Milne,S., Robinson,V., Marchand,S., Shea,B., Wells,G., and Tugwell,P., Efficacy of the transcutaneous electrical nerve stimulation for the treatment of low back pain: a meta-analysis, *Spine*, 27 (2002) 596-603.

Byrne,C., Twist,C., and Eston,R., Neuromuscular function after exercise-induced muscle damage, *Sports Medicine*, 34 (2004) 49-69.

Carpenter,J.E., Blasier,R.B., and Pellizzon,G.G., The effects of muscle fatigue on shoulder joint position sense, *American Journal of Sports Medicine*, 26 (1998) 262-265.

Carrol,D., Tramer,M., McQuay,H., Nye,B., and Moore,A., Randomization is important in studies with pain outcomes: Systematic review of transcutaneous electrical nerve stimulation in acute postoperative pain, *British Journal of Anaesthesia*, 77 (1996) 798-803.

Chabal,C., Fishbain,D.A., Weaver,M., and Heine,L.W., Long-term transcutaneous electrical nerve stimulation (TENS) use: Impact on medication utilization and physical therapy costs, *Clinical Journal of Pain*, 14 (1998) 66-73.

Cherry, D.K., and Woodwell, D.A., National ambulatory medical care survey: 2000 Summary, *Advance Data from Vital and Health Statistics*, 328 (2002) 1-32.

Chesterton,L.S., Foster,N.E., Wright,C.C., Baxter,G.D., and Barlas,P., Effects of TENS frequency, intensity, and stimulation site parameter manipulation on pressure pain thresholds in healthy human subjects, *Pain*, 106 (2003) 73-80.

Chung,J.M., Fang,Z.R., Hori,Y., Lee,K.H., and Willis,W.D., Prolonged inhibition of primate spinothalamic tract cells by peripheral nerve stimulation, *Pain*, 19 (1984) 259-275.

Clarkson,P.M., Eccentric exercise and muscle damage, *International Journal of Sports Medicine*, 18 (1997) S314-S317.

Clarkson,P.M. and Hubal,M.J., Are women less susceptible to exercise-induced muscle damage?, *Current Opinion in Clinical Nutrition and Metabolic Care*, 4 (2001) 527-531.

Craig,J.A., Cunningham,M.B., Walsh,D.M., Baxter,G.D., and Allen,J.M., Lack of effect of transcutaneous electrical nerve stimulation upon experimentally induced delayed onset muscle soreness in humans, *Pain*, 67 (1996) 285-289.

Dannecker,E.A., Hausenblas,H.A., Kaminski,T.W., and Robinson,M.E., Sex differences in delayed onset muscle pain, *Clinical Journal of Pain*, 21 (2005) 120-126.

Dauty,M., Delbrouck,C., Hugue,D., and Rousseau,B., Reproducibility of concentric and eccentric isokinetic strength of the shoulder rotators in normal subjects 40 to 55 years old, *Isokinetics and Exercise Science*, 11 (2003) 95-100.

Denegar,C.R., Donley,P.B., Managing pain with therapeutic modalities. In: W.Prentice (Ed.), *Therapeutic modalities for sports medicine and athletic training*. New York NY, McGraw-Hill, 2003, pp. 32-52.

Ebbeling,C.B. and Clarkson,P.M., Exercise-induced muscle damage and adaptation., *Sports Medicine*, 7 (1989) 207-234.

Eriksson,M., Sjolund,B.H., and Nielzen,S., Long term results of peripheral conditioning stimulation as an analgesic measure in chronic pain, *Pain*, 6 (1979) 335-347.

Fargas-Babjak,A., Pomeranz,B., and Rooney,P., Acupuncture-like stimulation with codetron for rehabilitation of patients with chronic pain syndrome and osteoarthritis, *Acupuncture and electro-therapeutics res.Int.J.*, 17 (1992) 95-105.

Fargas-Babjak,A., Rooney,P., and Gerecz,E., Randomized trial of codetron for pain control in osteoarthritis of the hip/knee, *The Clinical Journal of Pain*, 5 (1989) 137-141.

Fischer,A.A., Pressure tolerance over muscles and bones in normal subjects, *Archives of Physical Medicine and Rehabilitation*, 67 (1986) 406-409.

Fischer,A.A., Pressure algometry over normal muscles - standard values, validity and reproducibility or pressure threshold, *Pain*, 30 (1987) 115-126.

Fischer,A.A., Documentation of myofascial trigger points, *Archives of Physical Medicine and Rehabilitation*, 69 (1988) 286-291.

Fishbain,D.A., Chabal,C., Abbott,A., Heine,L.W., and Cutler,R., Transcutaneous electrical nerve stimulation (TENS) treatment outcome in long-term users, *Clinical Journal of Pain*, 12 (1996) 201-214.

Garrison,D.W. and Foreman,R.D., Decreased activity of spontaneous and noxiously evoked dorsal horn cells during transcutaneous electrical nerve stimulation (TENS), *Pain*, 58 (1994) 309-315.

Garrison,D.W. and Foreman,R.D., Effects of transcutaneous electrical nerve stimulation (TENS) on spontaneous and noxiously evoked dorsal horn cell activity in cats with transected spinal cords , *Neuroscience Letters*, 216 (1996) 125-128.

Gopalkrishnan,P. and Sluka,K.A., Effect of varying frequency, intensity, and pulse duration of transcutaneous electrical nerve stimulation on primary hyperalgesia in inflamed rats, *Archives of Physical Medicine and Rehabilitation*, 81 (2000) 984-990.

Grimes,D.A. and Schultz,K.F., Bias and causal associations in observational research, *Lancet*, 359 (2002) 248-252.

Gummeson,C., Atroshi,I., and Ekdahl,C., The disabilities of the arm, shoulder, and hand (DASH) outcome questionnaire: longitudinal construct validity and measuring self-rated health change after surgery, *BMC Musculoskeletal Disorders*, 4 (2003) 1-6.

Hartley,A., A pain control manual, Etobicoke, Ontario, Anne Hartley Agency, Canada, 1997.

Hartsell,H.D., The effects of body position and stabilization on isokinetic torque ratios for the shoulder rotators, *Isokinetics and Exercise Science*, 7 (1998) 161-170.

Herman,E., Williams,R., Stratford,P., Fargas-Babjak,A., and Trott,M., A randomized controlled trial of transcutaneous electrical nerve stimulation (codetron) to determine its benefits in a rehabilitation program for acute occupational low back pain, *Spine*, 19 (1994) 561-568.

Hudak,P.L., Amadio,P.C., Bombardier,C., Beaton,D.E., Cole,D., Davis,A.M., Hawker,G., Katz,J.N., Makela,M., Marx,R.G., Punnett,L., and Wright,J., Development of an upper extremity outcome measure: the DASH (Disabilities of the Arm, Shoulder, and Hand), *American Journal of Industrial Medicine*, 30 (1996) 372-372.

Ignelzi,R.J. and Nyquist,J.K., Direct effect of electrical stimulation on peripheral nerve evoked activity: Implications in pain relief, *Journal of Neurosurgery*, 45 (1976) 159-165.

Ignelzi,R.J. and Nyquist,J.K., Excitability changes in peripheral nerve fibers after repetitive electrical stimulation, *Journal of Neurosurgery*, 51 (1979) 824-833.

Johnson, M.I. Comments on Craig et al. PAIN, 67 (1996) 285-289, 1997.

Johnson, M.I., Transcutaneous electrical nerve stimulation (TENS) and TENS-like devices: Do they provide pain relief?, Pain Reviews, 8 (2001) 121-158.

Johnson, M.I., Ashton, C.H., Bousfield, D.R., and Thompson, J.W., Analgesic effects of different frequencies of transcutaneous electrical nerve stimulation on cold-induced pain in normal subjects, Pain, 39 (1989) 231-236.

Johnson, M.I., Ashton, C.H., Bousfield, D.R., and Thompson, J.W., Analgesic effects of different pulse patterns of transcutaneous electrical nerve stimulation on cold-induced pain in normal subjects, Journal of Psychosomatic Research, 35 (1991) 313-321.

Kelly, B.T., Kadrmas, W.R., and Speer, K.P., The manual muscle examination for rotator cuff strength. An electromyographic investigation., American Journal of Sports Medicine, 24 (1996) 581-588.

Koke, A.J.A., Schouten, J.S.A.G., Lamerichs-Geelen, M.J.H., Lipsch, J.S.M., Waltje, E.M.H., Kleef, M.V., and Patijn, J., Pain reducing effect of three types of transcutaneous electrical nerve stimulation in patients with chronic pain: a randomized crossover trial, Pain, 108 (2004) 36-42.

Leadbetter, W.B., Soft tissue athletic injury. In: F.H. Fu and D.A. Stone (Eds.), Sports Injuries. Williams and Wilkins, Baltimore, MD, 1994, pp. 839-888.

Lee, H., Liao, J., Cheng, C., Tan, C., and Shih, J., Evaluation of shoulder proprioception following muscle fatigue, Clinical Biomechanics, 18 (2003) 843-847.

Loeser, J.D., Black, R.G., and Christman, A., Relief of pain by transcutaneous stimulation, Journal of Neurosurgery, 42 (1975) 308-314.

Mandalidis, D.G. and Donne, B., Reliability of isokinetic internal and external rotation of the shoulder in the scapular plane, Isokinetics and Exercise Science, 5 (2001) 65-72.

Mayer, F., Bilow, H., Horstmann, T., Martini, F., Niess, A., Rocker, K., and Dickhuth, H.H., Muscular fatigue, maximum strength and stress reactions of the shoulder musculature in paraplegics, International Journal of Sports Medicine, 9 (1999) 487-493.

Mayer, F., Horstmann, T., and Baurle, W., Diagnostics with isokinetic devices in shoulder measurements - potentials and limits, Isokinetics and Exercise Science, 9 (2001) 19-25.

Melzack, R. and Wall, P.D., Pain mechanisms: A new theory, Science, 150 (1965) 973-979.

- Morgan,B., Jones,A.R., Mulcahy,K.A., Finlay,D.B., and Collett,B., Transcutaneous electrical nerve stimulation (TENS) during distension shoulder arthrography: A controlled trial, *Pain*, 64 (1995) 265-267.
- Myers,J., Guskiewicz,K., Schneider,R., and Prentice,W., Proprioception and neuromuscular control of the shoulder after muscle fatigue, *Journal of Athletic Training*, 34 (1999) 362-367.
- Navsarikar,A., Gladman,D.D., Husted,J.A., and Cook,R.J., Validity assessment of the disabilities of arm, shoulder, and hand questionnaire (DASH) for patients with psoriatic arthritis, *Journal of Rheumatology*, 26 (1999) 2191-2194.
- Noffal,G.J., Isokinetic eccentric-to-concentric strength ratios of the shoulder rotator muscles in throwers and nonthrowers, *American Journal of Sports Medicine*, 31 (2003) 537-541.
- Nussbaum,E.L. and Downes,L., Reliability of clinical pressure-pain algometric measurements obtained on consecutive days, *Physical Therapy*, 78 (1998) 160-169.
- Peebles,R.J. and Schneiderman,D.S., Socioeconomic fact book for surgery American College of Surgeons, Chicago, 1991.
- Persson,A.L., Brogardh,C., and Sjolund,B.H., Tender or not tender: Test-retest repeatability of pressure pain thresholds in the trapezius and deltoid muscles of healthy women, *Journal of Rehabilitation Medicine*, 36 (2004) 17-27.
- Persson,A.L., Hansson,G., Kalliomaki,J., and Sjolund,B.H., Increases in local pressure pain thresholds after muscle exertion in women with chronic shoulder pain, *Archives of Physical Medicine and Rehabilitation*, 84 (2003) 1515-1522.
- Plotnikoff,N.A. and MacIntyre,D.L., Test-retest reliability of glenohumeral internal and external rotator strength, *Clinical Journal of Sport Medicine*, 12 (2002) 367-372.
- Pontinen,P.J., Reliability, validity, reproducibility of algometry in diagnosis of active and latent tender spots and trigger points, *Journal of Musculoskeletal Pain*, 6 (1998) 61-71.
- Praemer,A., Furner,S., and Rice,D.P., Musculoskeletal conditions in the united states, American Academy of Orthopaedic Surgeons, Rosemont IL, 1999.
- Prentice,W., Rehabilitation techniques in sports medicine, WCB/McGraw-Hill, Boston, MA, 1999.
- Price,C.M. and Pandyan,A.D., Electrical stimulation for preventing and treating post-stroke shoulder pain: a systematic Cochrane review, *Clinical Rehabilitation*, 15 (2001) 5-19.

- Price,D.D., McGrath,P.A., Rafii,A., and Buckingham,B., The validation of visual analog scales as ratio scale measures for chronic and experimental pain, *Pain*, 17 (1983) 45-56.
- Reeser,J.C., Smith,D.T., Fischer,V., Berg,R., Liu,K.J., Untiedt,C., and Kubista,M., Static magnetic fields neither prevent nor diminish symptoms and signs of delayed onset muscle soreness, *Archives of Physical Medicine and Rehabilitation*, 83 (2005) 565-570.
- Reeve,J., Menon,D., and Corabian,P., Transcutaneous electrical nerve stimulation (TENS): A technology assessment , *International Journal of Technology Assessment in Health Care*, 12 (1996) 299-324.
- Saxton,J.M., Clarkson,P.M., James,R., Miles,M., Westerfer,M., Clark,S., and Donnelly,A.E., Neuromuscular dysfunction following eccentric exercise, *Med Sci.Sports Exerc.*, 27 (1995) 1185-1193.
- Schappert,S.M., Ambulatory care visits to physicians offices, hospital outpatient departments, and emergency departments: United States, *Vital and Health Statistics*, 13 (1996) 1-80.
- Schulz,K.F., Chalmers,I., Hayes,R.J., and Altman,D.G., Empirical evidence of bias, *JAMA*, 273 (1995) 408-412.
- Schulz,K.F. and Grimes,D.A., Allocation concealment in randomised trials: Defending against deciphering, *Lancet*, 359 (2002a) 614-618.
- Schulz,K.F. and Grimes,D.A., Sample size slippages in randomized trials: Exclusions and the lost and wayward, *Lancet*, 359 (2002b) 781-785.
- Schulz,K.F. and Grimes,D.A., Blinding in randomised trials: Hiding who got what, *Lancet*, 359 (2002c) 696-700.
- Sjolund,B.H., Peripheral nerve stimulation suppression of c-fiber-evoked flexion reflex in rats. Part 1: Parameters of continuous stimulation, *Journal of Neurosurgery*, 63 (1985) 612-616.
- Sjolund,B.H., Peripheral nerve stimulation suppression of c-fiber-evoked flexion reflex in rats. Part 2: Parameters of low-rate train stimulation of skin and muscle afferent nerves, *Journal of Neurosurgery*, 68 (1988) 279-283.
- Sjolund,B.H. and Eriksson,M., The influence of naloxone on alagesia produced by peripheral conditioning stimulation, *Brain Research*, 173 (1979) 295-301.
- Sjolund,B.H., Terenius,L., and Eriksson,M., Increased cerebrospinal fluid levels of endorphins after electro-acupuncture, *Acta physiol.scand.*, 100 (1977) 382-384.

Smith,L.L., Acute inflammation - the underlying mechanism in delayed onset muscle soreness, *Medicine and Science in Sports and Exercise*, 23 (1991) 542-551.

Snels,I.A.K., Dekker,J.H.M., Van der Lee,J.H., Lankhorst,G.J., Beckerman,H., and Bouter,L.M., Treating patients with hemiplegic shoulder pain, *American Journal of Physical Medicine and Rehabilitation*, 81 (2002) 150-160.

Tis,L.L. and Maxwell,T., The effect of positioning on shoulder isokinetic measures in females, *Medicine and Science in Sports and Exercise*, 28 (1996) 1188-1192.

Toumi,H. and Best,T.M., The inflammatory response: friend or enemy for muscle injury?, *British Journal of Sports Medicine*, 37 (2003) 284-286.

Tulgar,M., McGlore,F., Bowsher,D., and Miles,J.B., Comparative effectiveness of different stimulation modes in relieving pain. Part II. A double-blind controlled long-term clinical trial, *Pain*, 47 (1991b) 157-162.

Tulgar,M., McGlore,F., Bowsher,D., and Miles,J.B., Comparative effectiveness of different stimulation modes in relieving pain. Part I. A pilot study, *Pain*, 47 (1991a) 151-155.

Turchin,D.C., Beaton,D.E., and Richards,R.R., Validity of observer-based aggregate scoring systems as descriptors of elbow pain, function, and disability, *Journal of Bone and Joint Surgery*, 80A (1998) 154-162.

Turk,D.C. and Melzack,R., *Handbook of pain assessment*, The Guilford press, New York, 2001.

Turk,D.C., Okifuji,A., Kalauokalani,D., Clinical outcome and economic evaluation of multidisciplinary pain centers. In: A.R.Block, E.F.Kremer, and E.Fernandez (Eds.), *Handbook of pain syndromes: Biopsychosocial perspectives*. Erlbaum, Mahwah NJ, 1999, pp. 77-98.

Turner-Stokes,L. and Jackson,D., Shoulder pain after stroke: A review of the evidence base to inform the development of an integrated care pathway, *Clinical Rehabilitation*, 16 (2002) 276-298.

Van Ouwenaller,C., Laplace,P.M., and Chantraine,A., Painful shoulder in hemiplegia, *Archives of Physical Medicine and Rehabilitation*, 67 (1986) 23-26.

Vickers,A.J. and Altman,D.G., Analysing controlled trials with baseline and follow up measurements, *British Medical Journal*, 323 (2001) 1123-1124.

Vincent,H.K., Carlson,C., Hyatt,J.P., Yihua,L., and Vincent,K.R., Alterations in bilateral force judgment following strenuous eccentric exercise, *Research Quarterly for Exercise and Sport*, 71 (2000) 340-348.

Voight,M.L., Hardin,J.A., Blackburn,T.A., Tippett,S., and Canner,G.C., The effects of muscle fatigue on and the relationship of arm dominance to shoulder proprioception, *J Orthop.Sports Phys Ther.*, 23 (1996) 348-352.

Vuagnat,H. and Chantraine,A., Shoulder pain in hemiplegia revisited: Contribution of functional electrical stimulation and other therapies, *Journal of Rehabilitation Medicine*, 35 (2003) 49-56.

Walsh,D.M., *TENS Clinical applications and related theory*, Churchill Livingstone, New York, 1997.

Walsh,D.M., Liggett,C., Baxter,D., and Allen,J.M., A double-blind investigation of the hypoalgesic effects of transcutaneous electrical nerve stimulation upon experimentally induced ischaemic pain, *Pain*, 61 (1995) 39-45.

Wanklyn,P., Forster,A., and Young,J., Hemiplegic shoulder pain (HSP): Natural history and investigation of associated features, *Disability and Rehabilitation*, 18 (1996) 497-501.

Wilk,K.E. and Arrigo,C., Current concepts in the rehabilitation of the athletic shoulder, *J Orthop Sports Phys Ther.*, 18 (1993) 365-378.

Woolf,C.J., Mitchell,D., and Barrett,G.D., Antinociceptive effect of peripheral segmental electrical stimulation in the rat, *Pain*, 8 (1980) 237-252.

BIOGRAPHICAL SKETCH

Born in Canada, I grew up and attended high school in Toronto. After high school I earned my Bachelor of Science degree in human kinetics from the University of Guelph. In 1996 I attended Sheridan College for my athletic therapy training. Since 1999 I have been at the University of Florida as a graduate student, teaching assistant, doctoral student, lab coordinator, and faculty member. Currently I serve as the graduate director of athletic training here in the department of Applied Physiology and Kinesiology.