THERAPEUTIC ULTRASOUND: THE EFFECTIVENESS OF ULTRASOUND AND THE IMPORTANCE OF PARAMETER SETTINGS

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Therapeutic Ultrasound: The Effectiveness of Ultrasound and the Importance of Parameter Settings

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The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

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ABSTRACT

Therapeutic ultrasound can be an important modality for clinician's use to heat tissue. Previous research has concluded that therapeutic ultrasound treatments may be ineffective. There are several options for parameters depending on type of treatment and desired goal. The purpose of this study was to determine if specific parameters for a specific desired treatment goal were correct. The parameters included 1.0 and 3.0 megahertz frequencies of continuous ultrasound treatment on 20 subjects. Tissue temperature was measured with thermocouples in the calf. Data analysis consisted of running a one way repeated measures ANOVA to compare sample means as well as running t-test's for each change in temperature for each setting. Some subjects reached a temperature which could be considered therapeutic and only a few subjects reached the temperature goal. This is important for clinicians to note that every patient is different and that parameters will differ with each machine.

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CHAPTER I. INTRODUCTION

Therapeutic ultrasound (US) is one of the most used modalities in sports medicine today.[4] It is documented that 79% of orthopedic specialists use US at least once a week in their clinical practice.[19] The US generator converts electrical energy to acoustic energy by passing electrical energy through a piezoelectric crystal located in a transducer.[4, 16] This acoustic energy generated by the crystal causes the molecules in the path of the ultrasound to collide. This vibration can cause a thermal and/or non-thermal response.[20] The amount of energy that is absorbed is based on the type of tissue being treated, the time of treatment, the frequency of the treatment and the intensity being given.[4] The absorption of this energy and the proper treatment parameters are necessary to have a positive effect on the tissue.

A physiological response to tissue can either be thermal or non-thermal. Thermal US causes tissue temperature increases that result in decreased pain, increased blood flow, reduction of muscle spasm, reduction of inflammation and increased collagen extensibility. These tissue temperature increases are associated with three levels of heating. To be considered a mild treatment, tissue temperature should be increased 1˚ Celsius (C) from normal body temperature. For a moderate treatment, an increase of 2˚-3˚C should be reached, and for more vigorous heating in order to increase extensibility, a temperature increase of 3˚-4˚C is needed.[8] The heating effect of US depends on the specific treatment parameters, the manufacture and the type of machine being used for that treatment.[8] The duration should be based on treatment goals which include the frequency, intensity, tissue temperature increase and the treatment area.[28]

Research on therapeutic US regarding its usage and effectiveness is important to pursue because there is limited data in athletic training. More specifically, there is very limited research

on the clinical use by athletic trainers (ATs). The only published article that tests specific US parameters from clinicians is by Demcheck and Stone.[28] Demcheck and Stone[28] performed a study observing the parameters used for therapeutic US from eight local clinicians and compared them to the recommended parameters. The recommended parameters used for this thesis are based on academic athletic training textbooks that are written for students to learn how to decide treatment duration based on the frequency and intensity for specific treatment goals.(Appendix A) A pilot study, by the researcher of this thesis, was performed in the spring of 2012. Athletic trainers were surveyed to determine the parameters they typically used with US on different injuries and conditions. The survey consisted of questions pertaining to the population of patients treated with US, the US units used, the conditions treated with US and the specific parameters used for each condition (Appendix B). The results of this pilot study are the tested parameters for this thesis, which were compared to the recommended parameters in the textbooks.

Statement of the Problem

There are several studies which test the effectiveness of therapeutic US and most have an outcome that concludes there is little clinical evidence to continue the use of US.[11] Most of these studies include randomized control trials with an active population as the subjects.[12] There is a lack of significant evidence for how US affects musculoskeletal tissue after injury. Despite this lack of evidence, US is still preferred for treatments, but is sometimes used incorrectly on patients. 11 Research is needed to find a protocol that can ensure a proper treatment using therapeutic US on patients.[11, 19, 5] The first step for research on this problem is to test on uninjured tissue to determine tissue temperature change with specific parameters.

Purpose of the Study

The purpose of this study was to determine if the most common parameters from the pilot study of US usage by ATs reached the recommended goal of increased tissue temperature for specific injuries.

Research Questions

1. Does a frequency of 3 MHz, intensity of 1.0 W/cm², and time of 5 minutes reach the goal of increasing the target tissue temperature 2˚ C for chronic inflammation?
2. Does a frequency of 1 MHz, intensity of 1.5 W/cm², and time of 5 minutes reach the goal of increasing the target tissue temperature 2 ˚C for reducing muscle spasm and trigger points?
3. Does a frequency of 1 MHz, intensity of 1.5 W/cm², and time of 7 minutes reach the goal of increasing the target tissue temperature of 3˚-4 ˚C for increasing range of motion and tissue extensibility?

Hypothesis Questions

1. There is no difference between the pilot study parameters of a frequency of 3 MHz, intensity of 1.0 W/cm², and time of 5 minutes and the recommended parameters of 3 MHz, intensity of 1.0W/cm^2 and a time of 3.5 minutes of for chronic inflammation.
2. There is no difference between the pilot study parameters of a frequency of 1 MHz, intensity of 1.5 W/cm², and time of 5 minutes and the recommended parameters of 1 MHz, intensity of 1.5 W/cm^2, and a time of 7 minutes for muscle spasm and trigger poin

3. There is no difference between the pilot study parameters of a frequency of 1MHz, intensity of 1.5 W/cm², and time of 7 minutes and the recommended parameters of 1MHz, intensity of 1.5 W/cm^2, and a time of 13.5 minutes for increasing range of motion and tissue extensibility.

Definitions of Terms

Absorption: The amount of energy from ultrasound that is taken in by tissues.[10]

AT: Athletic Trainer

Attenuated: Heat being reduced in density and force in the tissue. [10]

Continuous ultrasound: Increases the temperature of the soft tissue by increasing kinetic energy of tissue molecules and constantly increasing the production of unstable cavitation.[15]

Energy: This is contained within a sound beam during an ultrasound treatment and eventually diminishes.[10, 15]

Healing phases: Inflammatory, proliferative and remodeling stages in regards to human tissue.[10]

Intensity: A measure of the rate at which energy is being delivered per unit area.[29]

Reflected: The bending back of electromagnetic waves when they hit a substance. Angle of reflection is determined by angle of treatment.[29]

Refracted: The bending of electromagnetic waves when they pass through a substance.[29]

RCT: Randomized control trials. Subjects are randomly assigned to a treatment for an experiment.[12]

Therapeutic ultrasound: A therapeutic modality used for thermal or non-thermal effects and is currently used by health care professionals such as certified athletic trainers and physical therapists. [1, 4, 8]

Treatment parameters: Settings that are associated for a specific goal for ultrasound treatment that include time, intensity and frequency.[4]

Physiological response: Response from an agent or treatment that can be seen from within the body.[10]

Pulsed Ultrasound: Ultrasound which can facilitate healing in the inflammatory phase and proliferative phase following soft tissue injury.[10]

Importance of the Study

The importance of this study is to determine if the common US parameters from the survey are reaching the therapeutic goal. This could help ATs in providing information about the parameters needed to be used for treatments, as there is limited research in this area.

Assumptions

1. Ultrasound machines are all calibrated properly and therefore the outcome will be similar in most cases.
2. ATs use US correctly most of the time.
3. Some health care professionals consider US as ineffective because the correct parameters are not being used.

Limitations

1. Ultrasound machines used for this study may not be the same as those used by ATs who participated in the survey.
2. Patients who were tested by participating ATs completing the survey may not be similar in body mass as the participants for this study.
3. ATs perform US on injured patients, whereas, the subjects in this study will not be injured.
4. There will only be one area on the body being tested in this study.

Delimitations

1. Participants will be both male and female from the college population.
2. Participants may not have more than 1.5cm of adipose tissue on the gastrocnemius.
3. Participants will not be currently injured or have been injured in the previous six months before treatment.
4. The parameters that will be tested are the top three most listed frequently from the pilot study.
5. Testing will be completed on NDSU campus in one room with controlled temperature.

CHAPTER II. LITERATURE REVIEW

The purpose of this study was to determine if the most common parameters from the pilot study of US usage by ATs reached the recommended goal of increased tissue temperature for specific injuries This literature review will explore the use of therapeutic US on an active population and how it may, or may not be beneficial in their rehabilitation process**.** More specifically, the literature review will include the following: Application of US, physiologic properties, temperature change in tissue, ultrasound used for soft tissue pathology, effectiveness of therapeutic ultrasound and dose-response relationship.

Therapeutic US is commonly used in sports medicine clinics for the treatment of soft tissue injuries. A soft tissue injury can be defined as any injury resulting from excessive force to muscle tissue that can disrupt the surrounding tendons, fibers and ligaments.[1] Several studies have concluded that therapeutic US is being misused in clinical settings, or that it is ineffective.[1,2,3,4,5] Despite the lack of evidence, US is still one of the most widely used modalities today.[6] Clinicians in physical therapy and athletic training settings are still using therapeutic US as a heating agent for a variety of reasons including pain control, wound healing, stretching collagenous tissue, and reduction of trigger points.[7] Therefore, the current literature will be reviewed on the use of therapeutic US and how it is as a therapeutic modality in sports medicine.

Applications of Ultrasound

Therapeutic US has been implemented as a treatment for musculoskeletal conditions since 1955.[8] Ultrasound was first introduced into sports medicine as an alternative deep heating agent to diathermy and a hot pack.[8] The main uses for therapeutic US were as a modality for the treatment of musculoskeletal pain and soft tissue injury including osteoarthritis, bursitis, and tenosynovitis.[8]

Prevalence. According to a survey completed by physical therapists who were orthopedic certified specialists, 79% reported using therapeutic US at least once per week; another 45% reported using US more than ten times per week.[9] This survey was available to four hundred specialists from the northeast/mid-Atlantic regions of the United States in the year 2007.[9] The survey indicated that 83.6% of the physical therapists were mostly inclined to use US to decrease soft tissue inflammation, like bursitis and tendinitis. The second most common use for US was for tissue extensibility which was reported by 70.9% of clinicians.[11] Anecdotal evidence suggests that physical therapists who believe using therapeutic US is clinically important are more likely to use it more than those who do not believe it to be clinically important.[11] There is currently no literature on the prevalence and use of US by ATs.

Physiologic Properties

Therapeutic US refers to mechanical vibrations that are converted to acoustic energy through mechanical deformation. This deformation is possible with the transducer head that holds a piezoelectric crystal.[10] This crystal contracts and produces a polarity under the transducer which is described as direct piezoelectric effect. It then expands and reverses polarity which is indirect piezoelectric effect, and in turn produces US. When these acoustic waves are absorbed by the tissue, it results in oscillatory movements.[11] Oscillatory movements occur when the acoustic waves, or sound waves, move the molecules around creating heat or altering mechanical changes. Mechanical changes occur with thermal as well as non-thermal US depending on the parameter setting of continuous or pulsed, in addition to the intensity and time settings.[11] Continuous US has an intensity that remains constant over time and energy is produced 100% of the time which produces heat. On the other hand, pulsed US creates intensity

at which has an off time that produces no US. Overall, the average intensity is low during pulsed US which produces mechanical effects only.[29]

Thermal Ultrasound. The energy that is transported by an ultrasonic beam from the transducer head is attenuated as it passes through the skin and tissue.[10] When this energy is absorbed in the tissue, it can result in thermal heating from the collisions and vibrations. The effectiveness of continuous US vary according to the different types of tissue and their capacity to absorb US. Tissues with a higher protein content or collagen content will absorb US to a greater extent than tissues with higher water content (e.g. blood and fat).[15] When a clinician's goal for a treatment is to increase tissue temperature, the heating categories can be broken down into mild, moderate and vigorous heating. Mild heating is defined as an increase of tissue temperature of 1˚C, and is recommended to be used for mild inflammation and to accelerate the metabolic rate in tissue. An increase of 2˚-3˚C, or moderate heating, is thought to decrease muscle spasm and pain; increase blood flow; and reduce chronic inflammation. For vigorous heating and a goal to decrease viscoelastic properties of collagenous tissue, an increase of up to 3˚-4˚ C is recommended.[9, 12, 13, 16] The physiological response to heating depends on the maximum temperature achieved, rate of temperature increase, and length of treatment.[10] It has been reported that the thermal effects of therapeutic US can be expected if the tissue temperature increases at least 1˚C.[7] It has also been reported that an increase of 8˚C can cause tissue damage.[29] Since the treatment is temperature dependent, there is a formula to determine the treatment time based on the frequency, intensity, and goal of tissue temperature increase. The formula is the total temperature increase goal divided by the temperature per minute at the appropriate frequency. For example, if the goal of an US treatment was to decrease muscle spasm, this would be an increased tissue temperature goal of 2˚C. If the frequency was set at

3MHz and an intensity of 1.0 W/cm^2, the tissue would heat up 0.6˚C per minute. (Appendix B). Therefore, the total treatment time would be a little over three minutes (3.33 minutes).

Non-Thermal Ultrasound. While the thermal effects create tissue heating and mechanical effects, non-thermal US creates mechanical effects only which include tissue repair at the cellular level consisting of cell membrane alteration, vascular regeneration, wound healing, increased protein synthesis and increased calcium ion influx.[29] Cavitation is one of the processes that produced the mechanical effects during therapeutic US. The process of cavitation during an US treatment refers to activity of bubbles of gas undergoing movement due to an acoustic field. There are two types of cavitation; stable cavitation and transient cavitation. Stable cavitation occurs when the bubbles in the tissue are being moved and are oscillating at the exact frequency of the US treatment. This movement of the cells is not great enough to cause any damage to tissue, but still creates an effect that is considered the best for injured tissue. Transient cavitation refers to the process of the bubbles expanding to a larger size and then imploding violently, possibly causing tissue damage.[11] It is possible to change the violent pattern generated by US treatment by changing the applied frequency, as well as the beam uniformity ration (BNR).[11]

It would be most beneficial to use pulsed US during the inflammatory phase when the US can have a stimulating effect on the mast cells, platelets, and macrophages which have a phagocytic role. When these cells are increasing in activity, the therapeutic effects of US are reported to have a pro-inflammatory action rather than an anti-inflammatory action. Pro-inflammatory can be defined as an action or substance that promotes the process of inflammation rather than inhibit it.[10] These changes in the tissue are due to radiation forces within, which in turn may alter the concentration gradients in the extracellular membrane. This concentration affects the diffusion of ions across this membrane, creating changes in potassium and calcium,

which is helpful in the acute injury phase.[10] This is important for clinicians when deciding the parameters that need to be set in order to have a successful treatment.[15] If enough energy is absorbed, a process of tissue repair will most likely occur. During a soft tissue injury repair process, it is not advisable to use continuous US immediately following the injury.

Ultrasound Frequencies. The most common frequencies used for medical purposes range from 0.8 MHz to 3 MHz.[11] Most therapeutic US machines are set with frequencies of 1 MHz and 3 MHz. A lower frequency pushes sound waves to a greater depth in tissue, but the waves are less focused. Three MHz affects more superficial structures because of the attenuation of energy as it passes through the tissue. Attenuation is defined as the decrease in the energy of US as the distance it travels through increases.[3,4] Clinically, a frequency of 1 MHz is reported to be most beneficial for reaching tissues at 2.5-5 cm and is recommended for deeper tissue or on patients with more subcutaneous fat.[3] Whereas a frequency of 3 MHz is recommended for more superficial tissue at depths up to 2.5 cm.[3] Three MHz heats up tissue three times faster than 1MHz, therefore the treatment time should be a shorter duration than a 1 MHz treatment.[9] It has been reported that a frequency of 3 MHz is used most often because most of the tissue that the clinicians are trying to heat are more superficial.[12]

Half –Value Layer. It is especially important to discuss the half-value layer of therapeutic US treatments because of the way it can affect an US treatment. The half-value layer is the depth by which 50% of the US beam is absorbed in the tissue. For example, if a 1 MHz US treatment is delivered at intensity 1.0 W/cm^2; it will lose 50% of its energy at 2.3 centimeters and is now only 0.5 W/cm^2. A study by Draper et al.[9] has shown that only some US is absorbed in the tissue, and that only a portion of absorbed heat is aiding in the treatment of that tissue.

Draper also reported that there is no significant difference in maximum temperature increase between 1MHz and 3MHz frequencies.

Ultrasound Used for Soft Tissue Injuries

Ultrasound has been used for aiding rehabilitation of soft tissue injuries, and some studies have shown that the treatment was ineffective leaving the authors unsatisfied. Many treatment protocols include US for pain treatment in chronic conditions, chronic inflammation, trigger points and muscle stiffness.[5]

Lower Extremity Pathologies. With this in mind, a number of studies focused on the treatments of the ankle, knee, heel, and Achilles tendon pathologies.[5] After reviewing current literature, Shanks et al.[5] reported that there was no evidence available to support the use of therapeutic US for the treatment of heel pain. A limitation that could contribute to the results, is that the authors failed to list specific parameters in their treatments, so their conclusion may not be valid.[5] There were six placebo controlled trials that were cited in this study that failed to detect any statistically significant differences between true and sham US therapy for these particular soft tissue injuries.[5] Many of the studies were lacking in methodological quality which in turn affected the validity of the studies. Another quality that the research was lacking was well designed controlled experimental designs. The experimental design should have included the technical variables involved, and also the goals and objectives of the treatment.

Clinicians often use US on ankle injuries with respect to pain, swelling, and range of motion for dorsiflextion (DF), plantar flexion (PF) and postural stability. In addition, clinicians often use US for the treatment of ankle instability and pathology.[5] Ankle instability and soft tissue damage in the ankle are some of the most common pathologies of injury for the physically

active population. Lateral ankle sprains account for up to 95% of ankle injuries and 12% of all totally injuries of the entire body.[6] Since ankle injuries are so common, US is used frequently to treat them, although Zammit and Hennington[6] report there is no improvement between a placebo (sham) US group and a treatment US group.[6] However, the use of US along with ice led to a larger decrease in pain and swelling when compared to just compression and an US treatment. There were several flaws in the studies that were reviewed, including improper blinding of subjects, no control group and unclear US parameters. Three MHz was used for the first three treatments; with a treatment time of 10 min, an average spatial intensity of 1:4 and the intensity was continuous US at 0.25 W/cm^2. The spatial intensity is often used by clinicians to gauge therapeutic ultrasound dosage and it is measured in W/cm$^{2.}$ Three MHz was then used for treatments four through six with a treatment time of six minutes, an average spatial ratio of 1:2 with an intensity of 0.50 W/cm^2.[6] It should be noted that the patients were advised to apply ice three times a day, wear a compressive sleeve, and also partake in exercises for stabilization of the ankle after US treatments. The authors attributed their results to possibly having incorrect treatment parameters for the particular injury they wanted to correct.[6,7,8] Also, it is unknown how much the ice and compression sleeves impacted the results of this study or if the range of motion results and pain are based solely on the US treatment. This is due to the subjects using ice and having compression sleeves on after the US treatments. It is unclear as to why the authors chose to incorporate a continuous US treatment. Some athletic training textbooks recommend that in order to minimize the thermal effects and maximize non-thermal effects, an intensity of 0.1-0.2 W/cm^2 with continuous US should be used.[29] Also, the use of additional modalities for the ankle injury impacted the conclusion of US not being effective.

A literature review by Brosseau et al.[3] used therapeutic US to treat patella femoral issues in athletes. The goal for this treatment is often associated with decreasing the amount of pain and also increasing the extensibility of the patellar tendon. This author only found one methodologically sound article that could be used to assess the effectiveness of US. The authors concluded that there was a greater trend toward a greater pain reduction and strength increase with the US treatment as compared to the control. However, the controls varied from the use of ice massage to phonophoresis and therefore, the data were inconsistent.[3] Brosseau et al.[3] concluded that there is not sufficient evidence to recommend US treatment as part of a treatment regimen for patella femoral issues. Thus, the authors came to the conclusion that it is possible the positive outcomes for this study could have been attributed to the use of ice, not the US treatment.

Similarly, US has been reported to be the best treatment for plantar fasciitis.[17] Yet, Stuber et al.[1] found that US had unsatisfactory results when used as a therapy for this pathology. One limitation of this review is that the authors came to a conclusion after reviewing one study which used pulsed US. The parameters were 0.5 W/cm^2 with a frequency of 3 MHz for 8 minutes compared to a sham US treatment performed two times a week for three weeks. The results of this study indicated that both groups experienced a decrease in pain and stiffness in the affected area, with the US group leading with a 30% decrease in symptoms, and the sham US group with a 25% decrease.[17] The decrease in pain with the sham US group could possibly be attributed to a placebo effect. These results were not statistically significant, therefore the authors concluded that US did not make a difference.[1, 17] The use of pulsed US can have very little or no thermal effects for the treatment parameters. This was reported knowing that a 2° C temperature increase for chronic inflammation is indicated. Therefore, using pulsed US would be an incorrect

parameter to use for plantar fasciitis.[17,4,9,18,20] The authors concluded that US was not effective for this particular injury and that it should not be implemented into a therapy protocol. It can, however, be implemented if used concurrently with another form of treatment such as stretching, orthotics, splinting or by using the correct US paramters.[1] This should be taken into consideration for clinicians. This information should assist clinicians in effectively increasing joint ROM for adhesive capsulitis, tendinitis, and joint contractures by using proper protocols.[13]

Upper Extremity Pathologies. Soft tissue disorders in the upper extremity which may be treated with US include bicipital tendinosis, rotator cuff tendinitis and subacromial bursitis.[19] Sauers[19] focused on shoulder soft tissue pathologies, to evaluate whether US, when combined with hot packs and interferential current (IFC), enhances the outcomes of intervention.[14,19] Subjects in this study had chronic soft tissue disorders of the shoulder for at least four weeks prior to the study. Subjects were then randomly assigned to receive a true US or a sham US. The parameters for the true US group were 1 MHz at an intensity of 1.5 W/cm^2 and a treatment duration of 10 minutes. According to the recommended formula (Appendix B), the treatment duration should be 7 minutes to reach a 2˚C increase in tissue temperature. The use of hot packs and IFC were also used because the authors believed US would not have any effect without additional interventions.[19] This is a limitation of the study because the results could simply be from the interventions of a hot pack for 10 minutes or the IFC treatment for 15 minutes. Based on the results, the authors concluded that there were pre-intervention-post-intervention differences for pain and range of motion.[14,15,19] There was an increase in range of motion in the true US group, but the authors could not conclude that this outcome was purely due to the use of US. This may lead to confusion about US being ineffective because the results were so similar and could have been caused by other conditions.

In addition, there are several types of treatment options for patients experiencing subacromial impingement syndrome (SAIS). There should be careful consideration when choosing the correct intervention when trying to produce a successful rehabilitation program. It has been reported that the use of US was not a proper treatment for this particular pathology.[21] Sauers[21] investigated the need for surgical intervention for SAIS, versus more traditional forms of rehabilitation including stretching, strengthening and the use of other modalities.[19] Multiple treatments may need to be administered in order to alleviate any problems. The results indicated that US was not effective in two of the treatments which focused on the rehabilitation of SAIS; one containing pulsed US with no parameters listed, and one which failed to list what type of US was used.[19]

Osteoarthritis. The use of US is not deemed ineffective by all research. Srbely et al.[23] critically reviewed research investigating the use of therapeutic US in the treatment and management of osteoarthritis. Osteoarthritis is considered to be one of the most common rheumatologic diseases and affects more than 80% of the population approximately 55 years of age.[23] This degenerative condition can be characterized by joint pain, stiffness, tenderness, in association with articular cartilage and bone mass. Many clinicians choose therapeutic US as a treatment for the patients with this condition.[23] Unlike previous studies, the author of this literature review paid closer attention to parameters and the technical details of the studies being reviewed. Of the 16 methodologically sound papers, two reported positive effects of decreased pain and increased range of motion in their subjects.[23] Two of these research papers concluded US was ineffective and one paper reported it was inconclusive. There was evidence that US had reduced pain and increased range of motion for acute inflammation of osteoarthritis patients which could be potentially helpful for the patients experiencing this condition.

Trigger Points. Draper et al.[21] investigated US applied over trigger points to decrease stiffness and tension. The definition of a trigger point was defined as hypersensitive areas in the muscle and fascia which were discrete and painful. There were two groups in this study, one receiving US and a control group receiving no treatment. The parameters for the US group was a frequency of 3 MHz continuous US at an intensity of 1.4 W/cm^2 for 5 minutes. Compared to the recommended parameters, these settings would be sufficient in creating 4˚ tissue temperature increase to decrease trigger points. Each subject received the treatments twice during the study. The authors analyzed the data and came to the conclusions based on the change in intramuscular temperature, pre to post, with all treatments. Retention of the treatment effects between sessions were also taken into consideration.[21] The results from this study support the idea that the use of US to produce heat in the muscle relaxed the trigger point, allowing the patient to experience less pain and have an increase in range of motion in their muscle. This study was more conclusive with the evidence because of the experimental design, and the control of the treatments that they administered. This supports the treatment of heating a trigger point and relieving the patients' pain.[21]

Effectiveness of Therapeutic Ultrasound

A literature review by Robertson and Baker[24] concluded that there was little to no evidence to support the use of US for treating patients with musculoskeletal disorders. They included 22 articles that were methodologically adequate to the author's standards, but after careful examination of the studies, only 10 were reviewed. There were several issues the authors came across when reviewing the articles based on how parameters were set. These included where US was being administered on the body and the different types of US machines being used for the studies.[11] Most of the studies were thrown out, because of those potential problems,

so the authors ultimately only reviewed two articles of the original 22 articles. This literature review is a good example of how inconclusive findings can affect US research and how it can be perceived by clinicians. There were many research articles that included US with their treatment regiment, yet only a few were methodologically sound. This poses a question as to whether or not researchers actually know the correct way to use US. Interestingly enough, US is still being used just as much as many other therapeutic modalities, yet much of the evidence is viewed as being ineffective.[1,3,24] The literature supports US is being used, however there is inconsistency of parameters, and methodological rigor of studies.

Mistakes Associated With Ultrasound Use. It is assumed that clinicians who use US on a regular basis have been using it correctly on their patients. However, from the literature reviewed, there are some discrepancies within the parameters of treatments. These discrepancies could be the reason why some of the random controlled trials (RCT's) were flawed and US was deemed an ineffective treatment. There are several mistakes that occurred which lead to inaccurate US use. Some of the most common mistakes include; having too large of a treatment area, inappropriate treatment duration, incorrect frequency, ignoring the stretching window and moving the transducer head too quickly.[4,5,24] A general rule of thumb for a clinician planning to use US is that any adjustment in the treatment intensity must be countered with an adjustment in treatment duration. Therefore, thermal US treatment should always be temperature dependent, not time dependent.[7]

Treatment Size. The application of US should be limited to an area 2-3 times the size of the effective radiating area (ERA) of the crystal. The ERA is the portion of the transducer head that transmits ultrasonic energy which is the size of the piezoelectric crystal.[4] If the ERA rule is not followed correctly, the temperature goal may not be reached no matter if the treatment area is

deep or superficial. Depth of the tissue being heated may not reach the desired level if this goal is not considered. The ERA is always smaller than the transducer surface, so the size of the transducer is not indicative of the radiating surface.[5] Other heating modalities, such as a hot pack or a warm whirlpool, will heat a larger area than US will, but the downside of using these modalities is that the heat will not penetrate as deep as US. Therefore, choosing the appropriate modality is important.

Another common mistake is using an inappropriate treatment time for US which can yield ineffective results. From previous research, clinicians have been using US for either 5 minutes, or 10 minutes, which may be too short or too long of time and the authors do not specify the desired intensity.[5] Ultrasound treatment time should be based on the tissue temperature goal, frequency, and intensity.

Incorrect Frequency. Using the incorrect frequency for US is another issue that can lead to unsuitable results for research. Using a frequency of 3 MHz should be done to reach up to 2.5cm below the surface of the skin. One MHz penetrates from 2.5 cm up to 5.0 cm, and possibly to the depth of bone.[9] It would be assumed that most clinicians use 3 MHz because many times the depth being treated is more superficial.[5] Using a high frequency would be more beneficial for structures such as the patellar tendon, and a lower frequency would be best used on structures such as the hamstring muscles because there is more muscle to heat at a greater depth.[4,5,12] This information needs to be considered when making appropriate choices and treatment variables for the patient. However, it can be assumed that US machines are not all created equal, and the frequencies of the treatment may not always be the same.

Stretching. It is common for a clinician to use US on a patient or athlete and then send them right out to practice or competition without any further treatment. There is a false

assumption that the heating effects from US can last up to an hour.[13] If the goal for using a heating modality is to heat the structure in order to stretch out collagenous tissue, then stretching should be done immediately after the conclusion of the treatment. If tissue is left to cool down or if the stretch is done incorrectly, it could damage the tissue if the force is too great.[4] Draper et al[4] studied how fast the tissue cooled after an US treatment with 1 MHz and 3 MHz frequencies.[4,5,13] The stretching window is defined by Draper[4] as the time period of vigorous heating when tissues will undergo the greatest extensibility and elongation. The results of this study showed that the stretching window for collagenous stretching was only 3.3 minutes for a 3 MHz frequency and five minutes for a 1 MHz frequency. Therefore, stretching, joint mobilization or friction massage should be performed immediately after an US treatment. [4, 13]

Speed. The final reason that could cause discrepancies within the use of US is how fast clinicians move the transducer head during a treatment. If equipment for US is not properly maintained or calibrated properly, the clinician may be inclined to move the transducer faster than necessary. This is done because older or non-calibrated machines can sometimes create hot spots and could potentially burn the patient. The correct rate that the US applicator should be moved is 4cm per second and the movement is dependent on the beam nonuniformity ratio (BNR).[4] The BNR is an indicator of the variability of intensity within an US beam. Typically, if periosteal irritation is occurring, the transducer needs to be moved faster and the intensity needs to be decreased.[4,6] Heating an area that is too large may also cause the movement of the sound head to be too rapidly. This will not allow enough US waves to be absorbed and sufficient heating will not occur in the tissues. If these actions occur, it could affect the results of the clinician goals such as the dose-response relationship.

Dose-Response Relationship

If a treatment intervention is needed, there should be a relation between the dosage and the response outcome. The goal for researchers is to find this relation, so that clinicians do not have to guess what parameters they should use for US. The problem is that there are several variables that need to be established in order to figure out the correct dosage for each treatment.[27] Robertson[24] examined the relevance of dosage responses in RCT's. The first step was to establish if there was a dose-response relationship for US in clinical studies.[27]Several of the studies used US from 5 minutes up to 40 minutes. This makes it difficult to establish any conclusions since other parameters, goal of tissue temperature change, intensity and frequency were not revealed.[25] Calibration of US units is important to ensure that the output indicated is the actual output from the applicator.[24,25] Schabrun et al.[25] reported that there is no information about calibrations of US machines. The lack of information about calibrations is more than likely due to the fact that a way to test the reliability of US machines was devised as recently as 2008.[11,25]

Summary

In conclusion, it was difficult to establish whether US is an effective or ineffective heating therapeutic modality. Based on several studies and reviews, it seems that there are many discrepancies in the way researchers use US on a regular basis.[1,2,3,8,9,23,26] It is not, however, appropriate to come to a conclusion that US is not effective overall for its heating effects. Although many of the studies reviewed concluded that US was not effective for a specific injury, there seems to be a pattern in the reason why these conditions were reached. There is not one set of parameters that should be used for a specific treatment. There should be an established dose-response relationship based on the patient and the goal that is trying to be reached.

Therapeutic US creates a heating effect that warms up tissue in a set amount of time, based on the frequency and intensity and tissue depth. There is a window of time after US is used for collagenous stretching and tissue elongation, but there may be a problem with clinicians ignoring that stretching window.[9,13] There is also an issue with the amount of time that US is used in a treatment session. All of these factors lead to research pointing to the conclusion that US is effective in very few domains of rehabilitation. The real issue is that US is not being used correctly and is why it is important to compare study parameters to the recommended parameter. Therefore it is possible that patients are not getting the appropriate treatment. When trying to reach a goal for rehabilitation of soft tissue, it is important for the clinician to take the time to pay attention to the parameters being set, making sure to be consistent with treatments and keeping in mind the reason for why US is being applied.

CHAPTER III. METHODOLOGY AND PROCEDURES

The purpose of this study was to determine if the most common parameters from the pilot study of US usage by ATs reached the recommended goal of increased tissue temperature for specific injuries. Therapeutic US was used for the treatment, and thermocouples were used to measure intramuscular temperature change during treatment. This chapter focuses on: pilot study, experimental design, population, instruments, procedures, and data analysis to test different settings for the use of therapeutic ultrasound treatment.

Pilot Study

A pilot study was carried out in the spring of 2012 which consisted of a survey (Appendix B) for ATs to answer questions regarding the clinical use of therapeutic US. The most frequent parameters answered for the questions about specific injuries or conditions were the basis for this research project. The survey consisted of demographic questions about how long they've been certified, where they work, and what kind of setting in which they currently work. There were also questions pertaining to the US machines used (types, calibrations, etc), yes or no questions asking if they use US on specific conditions (ie: hematoma, muscle spasm, chronic injury), and the parameters used for the specific conditions (Appendix B). The survey was conducted through SurveyMonkey™, an online program in which surveys can be created and analyzed. Before the survey was sent out, it was sent to clinical and faculty ATs at North Dakota State University to determine face, content, and construct validity. No reliability measures were taken due to the fact that only 2 of the 8 individuals filled out the survey. The pilot study was accepted by the North Dakota State University Institutional Review Board (IRB) (Appendix C).

The Research Education Foundation (REF) of the National Athletic Trainer's Association (NATA) was contacted in order to send the survey out. The NATA was able to send 1000 emails out to ATs across the country. Included in the email sent was a cover letter (Appendix

D), as well as a link to the survey. (Appendix B). If subjects chose to participate in the survey, they were given a total of 5 weeks to complete the survey. Reminders to complete the survey were sent out every week until the end of the 5 week deadline (Appendix E).

The response rate for this survey was 48 out of 1000 ATs, where 39 of them responded that they were currently working in a clinical AT setting, 19 in a high school, 21 in a university/college setting and 11 in a clinic/rehabilitation facility. The average age of patients treated with US was 19-24 years of age and the second highest range was 14-18 years. When participants were asked if they use US on certain conditions, the percentage of participants who answered yes were as follows: chronic soft tissue injury 85.4%, muscle spasm/trigger point 52.1%, and tissue extensibility 52.1%. Specific parameters for these conditions were calculated and the mode number reported for chronic soft tissue injury was 3 MHz at an intensity of 1.0 W/cm^2 for 5 minutes, muscle spasm/trigger point was 1 MHz at an intensity of 1.5 W/cm^2 for 5 minutes, and for increasing range of motion and tissue extensibility was at 1 MHz at an intensity of 1.5 W/cm^2 for 7 minutes.

Experimental Design

A crossover study design was used for this experiment. The treatment conditions depended on the results based on the pilot study completed by ATs and their use of therapeutic US. Three treatment parameters from the pilot study were tested and used as the treatment condition and time which include the following: a frequency of 3 MHz, intensity of 1.0 W/cm^2, and time of 5 minutes; a frequency of 1 MHz, intensity of 1.5 W/cm^2, and time of 5 minutes; and a frequency of 1 MHz, intensity of 1.5 W/cm^2, and time of 7 minutes. The dependent variable was the gastrocnemius muscle temperature change at a depth of 2.5 cm with no more than 1.5 cm adipose tissue.

Population

A sample of participants between the ages of 18-30 year old males and females from North Dakota State University were used for this study. A convenient sample of 20 subjects, with no injuries to the gastrocnemius bilaterally within the previous six months were selected. The subjects' dominant leg was used for testing. This was based on what the subjects use as a dominant leg. In addition, subjects had no more than 1.5 cm adipose tissue. Subjects were excluded if they were currently injured, have been injured in the past six months, or had any contraindications to US. Contraindications for a thermal US treatment include acute and postacute conditions, vascular insufficiency, thrombophebitis, treatment over the eyes, reproductive organs, pregnancy, pacemaker, malignancy or infection.[29] Subjects were randomly assigned to three different groups in order to counter threats to internal validity. Groups were balanced using a Latin square, which helped minimize order effects.

Instruments

The Terason t3200™ Diagnostic Ultrasound (MedCorp LLC., Tampa, FL) was used to image and measure the adipose thickness of the target tissue area. This method has been previously tested by Selkow et al.[30] in a subcutaneous thigh fat assessment, comparing skinfold calipers and US imaging. Aquasonic® 100 (Parker Laboratories, Inc., Fairfield, New Jersey) ultrasound gel was applied to the 15L4 Linear (4.0-15.0 MHz) (MedCorp LLC., Tampa, FL) diagnostic US transducer. The transducer with gel was placed over the target treatment area. For the therapeutic US treatment, a recently calibrated (August 12, 2012) Dynatron Solaris® 700 Series ultrasound unit (Dynatronics Corporation, Salt Lake City, UT) with an ERA of 5cm² and a BNR of 6:1 was used. A 20 gauge x 1.16 in. needle catheter (Cardinal Health) was used in order to insert the 21 gauge, 1 foot thermocouple (Physitemp Instruments, Clifton, NJ). The

thermocouple was connected to the Iso Thermex electronic thermometer (Columbus Instruments, Columbus, OH) which recorded and saved the intramuscular temperature data. Each thermocouple was cleansed in Cidex Plus™ 28 day solution, which is a gluteraldehyde solution, for at least 24 hours between each treatments. In order to treat the area that was twice the size of the ERA, a template for the US treatment was used. This template was used for all participants.

Procedures

The parameters used for therapeutic US in a clinical setting are varied among different ATs. A pilot study was performed which allowed ATs to report the different types of therapeutic US (continuous/pulsed), frequencies, intensities and treatment times used for different pathologies and injuries. The top 3 parameters that were reported from the pilot study included 3 MHz @ 1.0 W/cm² for 5 min, 1 MHz @ 1.5W/cm² for 5 min, and 1 MHz @ 1.5 W/cm² for 7 min. These settings were tested and compared to the recommended parameters. The recommended parameters consisted of the same frequency and intensity as the pilot study parameters; however, the time was determined by the appropriate formula based on the treatment goal and condition. (Appendix A) All testing was completed on the North Dakota State University campus in the Bentson Bunker Field House Athletic Training Research Laboratory (ATRL). The room temperature was controlled and was the same for each treatment. Each subject reported to the ATRL dressed in shorts, or pants that were able to be pulled up to expose the gastrocnemius. The subjects read and signed the informed consent form. The subjects laid prone for the entire treatment. The Terason t3200™ diagnostic US was used to determine adipose thickness in all subjects before testing begins. Aquasonic ® 100 ultrasound gel was applied to the 15L4 transducer and then the transducer was applied to the target treatment area. The diagnostic US screen was frozen and the skin and adipose tissue thickness was measured

using the caliper button. After adipose thickness was measured, the tissue underneath was scanned to look for any abnormalities that would contraindicate thermocouple insertion or thermal US.

The treatment area and thermocouple insertion site was shaved to remove any body hair (if necessary) and thoroughly cleaned with Betadine and then swabbed with 70% isopropyl alcohol. The muscle was observed to identify the greatest girth for the center of the treatment area. A carpenter's square was placed flush against the lateral muscle belly so it was level and a mark was placed in line laterally with the level at 2.5cm. The 21 gauge flexible implantable thermocouple was sterilized with Cidex Plus™ 28 day solution for 24 hours before use. Before inserting the thermocouple, it was removed from the Cidex Plus™ solution, dried off and then marked at 2.5 cm and at 5cm and cleaned with 70% isopropyl alcohol prior to insertion. A 20 gauge x 1.16 in needle catheter was inserted parallel to the carpenter's square and treatment area at a depth of 2.5 cm. (Figure 1)

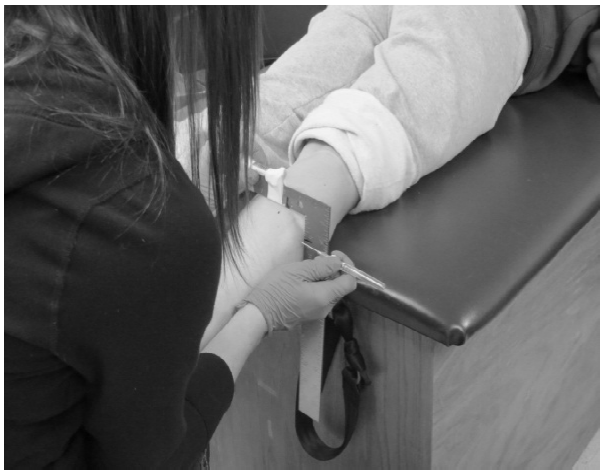

Figure 1. Thermocouple insertion technique with carpenter square

Once in place, the spring loaded needle was retracted and the 21 gauge thermocouple was threaded into the catheter to a depth of 2.5 cm and then the catheter was removed. The thermocouple was secured to the leg with medical tape to prevent movement. (Figure 2)

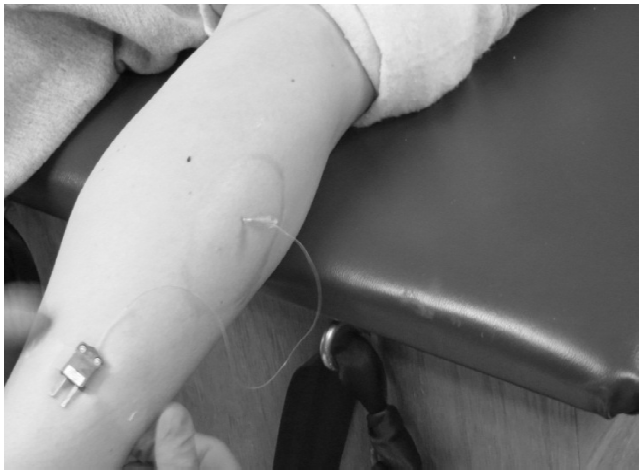

Figure 2. Catheter and thermocouple in muscle belly

The thermocouple was connected to the Iso Thermex electronic thermometer (Columbus Instruments, Columbus, OH), which measured and recorded intramuscular temperature from the tip of the thermocouple. The thermocouples were calibrated before the study began. The subjects were instructed to relax, and to remain still so that the muscle temperature was able to reach a stable temperature before the treatment began. Once the temperature was stable for three minutes, the treatment began by performing one of the three pilot study parameters over the target tissue which was on the posterior side of the gastrocnemius. (Figure 3)

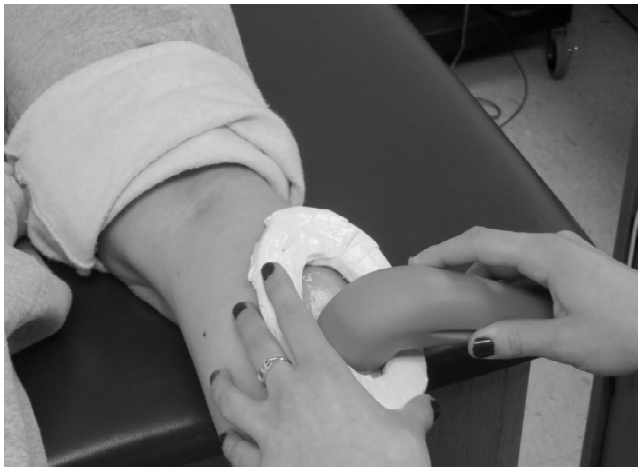

Figure 3. Ultrasound treatment with template

Each subject received each of the three treatments, which were performed on three different days. In order to counter threats to internal validity, a chart in which the subjects were counterbalanced was made which helped minimize order effects. After the treatment, the subjects were again instructed to remain prone to record the tissue temperature. The treatment was complete when subjects reached their baseline intramuscular temperature. After the treatment was complete, the template and thermocouple were removed, the subject's leg was cleaned and a bandaid was applied to the insertion area. The thermocouples were immediately placed in the Cidex Plus™ solution for at least 24 hours before the next treatment. The subject was instructed when to return for their second and third treatments. There were no more than 7-10 days between each of the three testing days for each subject for a total of 3 weeks.

Data Analysis

Descriptive statistics were used for each treatment condition post-treatment temperatures. The descriptive statistics of mean and standard deviation of the temperature change for each of the three settings was calculated. Three one-sample t-tests were run for each treatment testing the null hypothesis that the change in temperature was equal to the treatment goal. A repeated measures ANOVA was run to test whether the changes among the treatments within each subject

were equal. All analyses were conducted using SPSS (20th edition; Pearson Education Inc., Upper Saddle River, NJ).Significance was accepted at $p<0.05$.

CHAPTER IV. JOURNAL OF ATHLETIC TRAINING-MANUSCRIPT

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Context: Therapeutic ultrasound is mainly used in order to heat tissue for different musculoskeletal conditions. Research on therapeutic ultrasound has shown mixed results for the overall effectiveness based on the variety of parameters used, machines used, and treatment areas. This study was based on parameters used clinically versus recommended parameters based on textbook information. **Objective:** The purpose of this study was to determine if the most common parameters, from a survey of ultrasound usage by athletic trainers (ATs), reach the recommended goal of increased tissue temperature for specific injuries. **Design:** Crossover Study**. Setting:** Athletic Training Research Laboratory-NDSU **Patients or Other Participants:** Twenty healthy volunteers (11 females, 9 males) **Interventions:** Thermocouples were inserted 2.5 cm deep into the lateral gastrocnemius. Ultrasound was delivered at the following settings: 3 MHz, 1.0 W/cm² for 5 minutes, 1 MHz, 1.5 W/cm^2 for 5 minutes, and 1 MHz, 1.5 W/cm^2 for 7 minutes. All settings were continuous. **Main Outcome Measures:** Intramuscular temperature was recorded every 5 seconds for 5 or 7 minutes. **Results:** Treatment one was the parameters of 3 MHz at 1.0 W/cm^2 for 5 minutes which produced a mean ending temperature of 36.64 ˚C ±1.22 with a mean change in temperature of 0.60˚C ±0.69. Treatment two was the parameters of 1 MHz at 1.5 W/cm^2 for 7 minutes which produced a mean ending temperature of 36.67˚C±1.08 with a mean change in temperature of 0.74˚C±0.61. Treatment three was the parameters of 1 MHz at 1.5 W/cm^2 for 5 minutes which produced a mean ending temperature of 36.44˚C ±1.90 with a mean change in temperature of 0.68˚C ±0.55. **Conclusions:** Some of the subjects reached a temperature which could be considered therapeutic and only a few subjects reached the temperature goal. This is important for clinicians to note that every patient is different when it comes to tissue heating. Also the issue arises that not every ultrasound machine produces the same result so parameters will differ with each machine.
Key words: therapeutic modalities, therapeutic ultrasound, tissue temperature, thermocouple, parameters, heat, treatment

Therapeutic ultrasound (US) is one of the most used modalities in sports medicine today.[4] Research on therapeutic US and its usage and effectiveness is important to pursue because there is limited data in athletic training. More specifically, there is very limited research on clinical use by athletic trainers. The only published article that tests specific US parameters from clinicians is by Demcheck and Stone[28]. Demcheck and Stone[28] performed a study observing the parameters used from therapeutic US from eight local clinicians and then compared them to the recommended parameters. To determine the parameters to be examined, we surveyed the

athletic training population on clinical US usage in the spring of 2012. Athletic trainers were surveyed to determine the parameters they typically used on different injuries and conditions. The survey consisted of questions pertaining to the population of patients treated with US, the US units used, the conditions treated with US and the specific parameters used for each condition. The most common parameters used were noted and were the basis for this study.

There are several studies which test the effectiveness of therapeutic US and most have an outcome that concludes there is little clinical evidence to continue the use of US.[1,2,4,5,10,11] Most of these studies include randomized control trials of an active population as the subjects.[12] There is a lack of significant evidence for how US affects musculoskeletal tissue after injury. Despite this lack of evidence, US is still preferred for treatments, but is used incorrectly on patients.[11] Research is needed to find a protocol or protocols that can ensure proper treatment using therapeutic US on patients.[11, 19, 5] The purpose of this study was to determine if the most common parameters from the survey of US usage by ATs reached the recommended goal of increased tissue temperature for specific injuries. The research questions included: Does a frequency of 3 MHz, intensity of 1.0 W/cm², and time of 5 minutes reach the goal of increasing the target tissue temperature 2˚ C for chronic inflammation?, Does a frequency of 1 MHz, intensity of 1.5 W/cm², and time of 5 minutes reach the goal of increasing the target tissue temperature 2 ˚C for reducing muscle spasm and trigger points?, and Does a frequency of 1 MHz, intensity of 1.5 W/cm², and time of 7 minutes reach the goal of increasing the target tissue temperature of 3˚-4 ˚C for increasing range of motion and tissue extensibility? We hypothesized that there would be no difference between the survey parameters and the recommended tissue temperature goal.

Methods

Study Design. A crossover study design was used for this experiment. Treatment conditions depended on the results based on the survey completed by athletic trainers and their use of therapeutic US. Three treatment parameters from the survey were tested and used as the treatment parameters which included the following: 3 MHz, 1.0 W/cm² for 5 minutes; 1 MHz at 1.5 W/cm², for 5 minutes; and 1 MHz at 1.5 W/cm² for 7 minutes.

Participants. A sample of 20 subjects male and female, ages 18-30, with no injuries to the gastrocnemius bilaterally within the previous six months, were selected for this. The subjects' dominant leg was used for testing. Only 19 subjects' data were used and 2 of the subjects' data from 2 treatment parameters were removed due to a possible malfunctioning thermocouple. In addition, subjects had no more than 1.5 cm of adipose tissue. None of the subjects for this study were currently injured or had been injured during the past six months and no subjects had any of the contraindications for thermal US. The contraindications included acute and postacute conditions, vascular insufficiency, thrombophebitis, treatment over the eyes, reproductive organs, pregnancy, pacemaker, malignancy or infection.[29] Subjects were randomly assigned to three different groups in order to counter threats to internal validity. Groups were balanced using a Latin square, which helped minimize order effects. The study was approved by North Dakota State University's Institutional Review Board and participants gave written informed consent.

Instruments. The Terason t3200™ Diagnostic Ultrasound (MedCorp LLC., Tampa, FL) was used to image and measure the adipose thickness of the target treatment area. This method has been previously tested by Selkow et al.[30] in a subcutaneous thigh fat assessment, comparing skinfold calipers and US imaging. Aquasonic® 100 (Parker Laboratories, Inc., Fairfield, New

Jersey) ultrasound gel was applied to the 15L4 Linear (4.0-15.0 MHz) (MedCorp LLC., Tampa, FL) diagnostic US transducer. The transducer, with gel, was placed over the target treatment area. For the therapeutic US treatment, calibrated in August 2012, a Dynatron Solaris® 700 Series ultrasound unit (Dynatronics Corporation, Salt Lake City, UT) with the manufacture reported ERA of 5cm² and a BNR of 6:1 was used. A 20 gauge x 1.16 in. needle catheter (Cardinal Health) was used to insert the 21 gauge, 1 foot thermocouple (Physitemp Instruments, Clifton, NJ). The thermocouple was connected to the Iso Thermex electronic thermometer (Columbus Instruments, Columbus, OH) which recorded and saved intramuscular temperature data. Each thermocouple was cleansed in Cidex Plus™ 28 day solution, a gluteraldehyde solution, for at least 24 hours between each treatment. In order to treat the area that was twice the size of the ERA, a template for the US treatment was used. This template was used for all participants.

Procedures. Each subject reported to the testing site dressed in shorts, or pants that were able to be pulled up to expose the gastrocnemius. The subjects read and signed the informed consent form and then laid prone for the entire treatment. The Terason t3200™ diagnostic US was used to determine adipose thickness in all subjects before testing began. Aquasonic ® 100 ultrasound gel was applied to the 15L4 transducer and then the transducer was applied to the target treatment area. The diagnostic US screen was frozen and the skin and adipose tissue thickness was measured using the caliper button. After adipose thickness was measured over the treatment site, the tissue underneath was scanned to look for any abnormalities that would contraindicate thermocouple insertion or thermal US.

The treatment area and thermocouple insertion site was shaved to remove any body hair (if necessary) and thoroughly cleaned with Betadine, and then swabbed with 70% isopropyl

alcohol. A carpenter's square was placed flush against the lateral muscle belly so it was level and a mark was placed in line with the level at 2.5cm. The 21 gauge flexible implantable thermocouple was sterilized with Cidex Plus™ 28 day solution for 24 hours before use. Before inserting the thermocouple, it was removed from the Cidex Plus™ solution, dried off and then marked at 5cm as well as at 2.5 cm and cleaned with 70% isopropyl alcohol prior to insertion. A 20 gauge x 1.16 in. needle catheter was inserted perpendicular to the carpenter's square and treatment area at a depth of 2.5 cm. (Figure 1) Once in place, the spring loaded needle was retracted and the 21 gauge thermocouple was threaded into the catheter to a depth of 2.5 cm and then the catheter was removed. (Figure 2) The thermocouple was secured to the leg with medical tape to prevent movement. The thermocouple was connected to the Iso Thermex electronic thermometer (Columbus Instruments, Columbus, OH), which measured and recorded intramuscular temperature from the tip of the thermocouple. The thermocouples were calibrated before the study began. The subjects were instructed to relax, and to remain still so that the muscle temperature was able to reach a stable temperature before the treatment began. All of the subjects' baseline temperatures were stable within the first three minutes. Therefore, each treatment was started after three minutes of rest. Each subject received each of the three treatments from the survey parameters which were performed on three different days. After the treatment, the subjects were again instructed to remain prone to record the time for the tissue to return to baseline. After the treatment was complete, the template and thermocouple were removed, the subject's leg was cleaned and a bandaid was applied to the insertion area. The thermocouples were immediately placed in the Cidex Plus™ solution for at least 24 hours before the next treatment. The subject was instructed when to return for their second and third treatments. There were no more than 7-10 days between each of the testing days for each subject for a total of 3 weeks.

Statistical Analysis. The descriptive statistics of mean and standard deviation of the temperature change for each of the three settings was calculated. The a priori alpha value was set at 0.05. A one-sample t-test was run for each treatment testing the null hypothesis that the change in temperature was equal to the treatment goal. A repeated measures ANOVA was run to test whether the temperature changes among the treatments within each subject were equal. All analyses were conducted using SPSS (20th edition; Pearson Education Inc., Upper Saddle River, NJ).

Results

Treatment one used the settings of 3 MHz at 1.0 W/cm^2 for 5 minutes which produced a mean ending temperature of 36.64 ˚C and a standard deviation ±1.22 with a mean change in temperature of 0.60 ±0.69˚C. Treatment two used the settings of 1 MHz at 1.5 W/cm^2 for 7 minutes which produced a mean ending temperature of 36.67 ±1.08˚C with a mean change in temperature of 0.74 ±0.61˚C. Treatment three used the settings of 1 MHz at 1.5 W/cm^2 for 5 minutes which produced a mean ending temperature of 36.44 ±1.90˚C with a mean change in temperature of 0.68 ±0.55˚C. The one-sample t-test for treatment one testing the null hypothesis that the temperature change from this study equaled 2 ˚C (from the recommended temperature change) which resulted in a t-value of $t(19)=-8.69$ ($p<.001$). The one-sample t-test for treatment three tested the null hypothesis that the temperature change from this study equaled 2˚C as well which resulted in a t-value of $t(19)= -10.892$ ($p<.001$). The one-sample t-test for treatment two tested the null hypothesis that the temperature change would equal 4˚C resulted in a t-value of $t(19)=-28.35$ ($p<.001$). The repeated measures ANOVA provided no evidence to suggest there were changes among the treatments within subjects ($F_{2, 18}=.063$, $p=.939$). The overall change in

temperature for each subject after each treatment is displayed below (Figure 4). Average tissue increase per minute was 0.18˚C for treatment one, 0.15˚C for treatment two and 0.14˚C for treatment three. The average adipose tissue thickness for all subjects was less than 1 cm±0.14 (Figure 5).

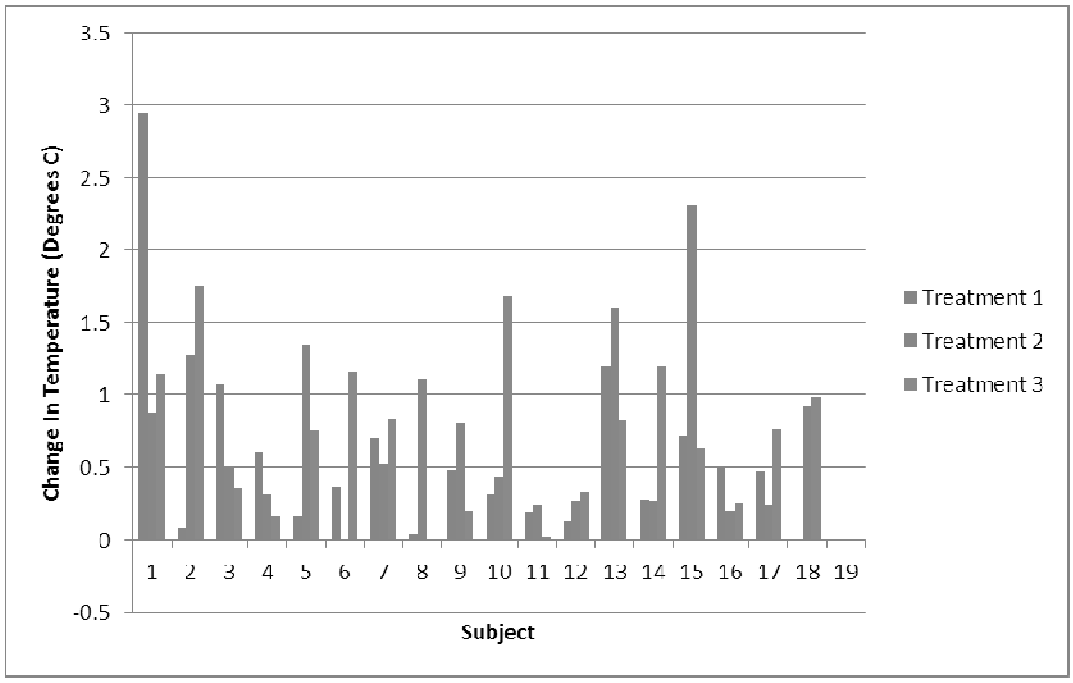

Figure 4. Change in temperature after each treatment for each subject {Treatment 1: 3MHz 1.0W/cm^2 for 5 minutes; Treatment 2: 1 MHz 1.5 W/cm^2 for 7 minutes; Treatment 3: 1 MHz 1.5 W/cm^2 for 5 minutes.}

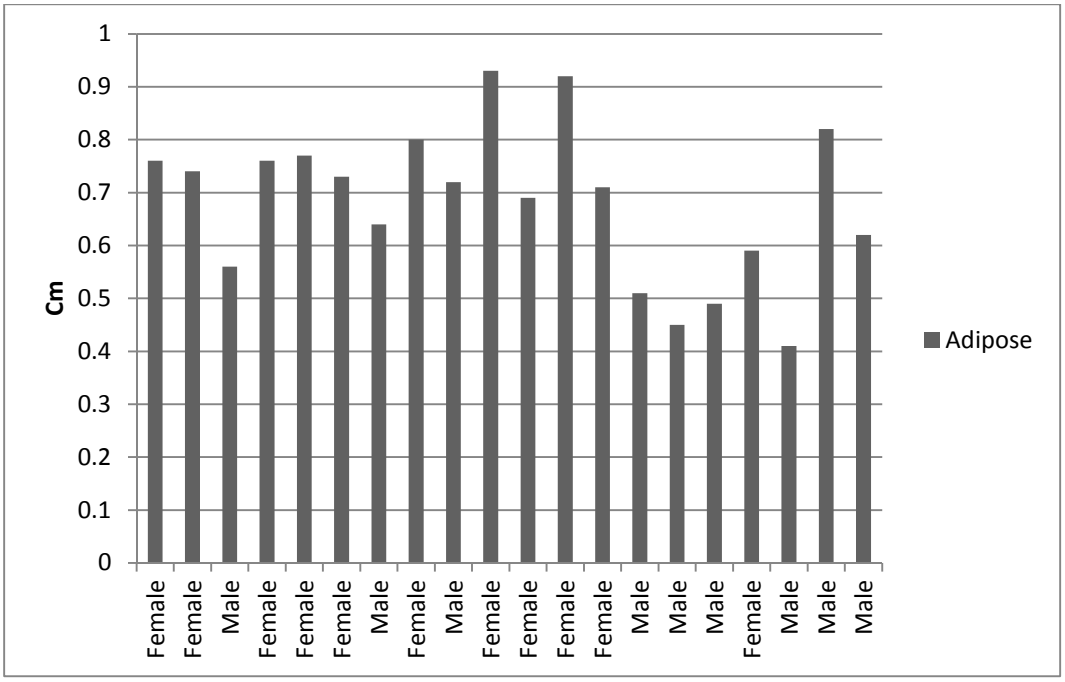

Figure 5. Average adipose thickness for all subjects

Discussion

The three settings used in this study were based on a survey of therapeutic ultrasound use by athletic trainers. Based on this survey, it was concluded that athletic trainers are indeed using therapeutic ultrasound quite frequently with a wide variety of settings. Clinically, a frequency of 1 MHz is reported to be beneficial for reaching tissues at 2.5-5 cm and is generally recommended for deeper tissue or on patients with more subcutaneous fat.[29] A frequency of 3 MHz is recommended for more superficial tissue at depths up to 2.5 cm and will heat up tissue three times faster than 1 MHz.[29] Previous research has concluded that clinicians are using therapeutic ultrasound on several different pathologies, however ultrasound is still deemed as being an ineffective treatment.[24] Many of these studies base their conclusions on how the ultrasound treatment affects the severity of the condition or injury, not on tissue temperature increase.[4,9,13,24] Several factors may be the reason for this initial conclusion including incorrect

treatment parameters, having too large of a treatment area, moving the transducer head too quickly and an ultrasound machine that produces different outputs than what the manufacture reports.[4] In this study, a template was used for the treatment area which was measured to be 2 times the size of the ERA. Although we were using treatment parameters which were not individualized for each person, they still did not reach the temperature goal change of 2˚ and 4˚ C. In this study, we made sure to account for adipose tissue thickness because it is an important factor in how quickly tissue may heat up, but it didn't seem to be an issue in this study based on the average amount of adipose tissue for the subjects used. This brings up the question as to why only a few subjects met the tissue temperature goal and if this was a result of a machine that is not working properly, if a thermocouple was not reading correctly, the process of inserting the thermocouple by the researcher or if the parameters for each treatment were just not appropriate for the subjects.

Previous research by Schabrun et al.[25] tested the power accuracy, timer accuracy as well as reliability of different machines used in physiotherapy practice. It was concluded that a total of 13 US machines were found to produce inaccurate power outputs on all settings that were tested. Schabrun et al. concluded that there is a widespread level of machine inaccuracy, suggesting that approximately one in every two patients will receive an inaccurate dose than what was originally intended.[25] The authors suggested that the reason for such high and widespread levels of US machine inaccuracy may be due to the machine design. Another study by Johns et al.[31] conducted an experiment which measured clinical values that describe ultrasound transducers and the difference in ERA, power and SAI at 3 MHz.[31] They tested several different machines, one of which was the machine used in our study. The authors concluded that there is a 16% to 35% intramanufacturer difference and a 61% difference for SAI

values among 66 different transducers.[31] The process for testing SAI included dividing the experimental power (W) by the experimental ERA (cm^2) which was then compared with the reported SAI in the digital display of the ultrasound generator. The conclusion for the Dynatron model for a 3MHz transducer was that it produced one of the largest ranges of normalized spatial intensities of 0.88 to 1.19 W/cm^2. The transducers for this machine emitted ultrasound over approximately 45%-48% of the transducer surface.[31] Clinically, this is important because the amount of energy being emitted may not be what is indicated on the machine and changing the amount of time that an US treatment should be performed. This suggests that clinicians need to pay close attention to the characteristics of each individual unit, regardless of the manufacture. This is also important to our study because although our Dynatron Solaris® 700 Series ultrasound unit (Dynatronics Corporation, Salt Lake City, UT) was calibrated at an appropriate time, it may not have been calibrated correctly, therefore skewing our results. Although is it unclear if the machine used for this study was the cause for the results, there is still the possibility that the settings are just inappropriate and should have more closely reflected the recommended parameters.

The thermocouple insertion protocol for this study was based off a previous study[28] and was controlled for each subject and treatment. The process for thermocouple insertion has not been studied a great deal and the researcher performing the insertion did not have an extended amount of experience, therefore possibly having a negative result on the reading of tissue temperature. However, each time a thermocouple was removed after the treatment it was measured how far into the muscle it was inserted and was then recorded. The average length for treatment one was 2.52± 0.226 cm, treatment two was 2.59± 0.297 cm and the third treatment was 2.58 ± 0.278 cm.

Recommended parameters are important in this study because it reflects what the end results of a treatment should be and was the basis for the original research questions. The recommended parameters should be the total temperature increase goal divided by the temperature per minute at the appropriate frequency.[29] The average temperature increases for this study were less than the recommended parameters which made each of the time parameter settings incorrect for the subjects (Figure 6). The 12 subjects who did reach an intramuscular temperature that could be considered therapeutic had a mean baseline intramuscular temperature of 36.16±1.05˚C whereas the rest of the subjects had a mean of 36.03±0.86˚C for treatment 1, and average baseline temperature of 35.87±0.93˚C for treatment 2 and an average baseline temperature of 35.75±0.79˚C for treatment 3 (Figure 7). It is clear that the US machine was increasing tissue temperature, yet it was at a much slower rate than it should have been in order for the treatment to be effective. More importantly, this should change clinician's settings when using this particular machine, not completely disregard it as a treatment option.

The rate of tissue temperature increase is important for clinicians to remember when treating patients based on the type of machine being used. The recommended parameters are based on the Omnisound ultrasound machine and because this machine tends to have the better BNR of 1:8:1 and an ERA of 5.0 cm^2.[29] Based on a study by Johns et al.,[31] Five ultrasound machines were tested including Chattanooga, Dynatron, 2 Omnisounds and XLTEX.

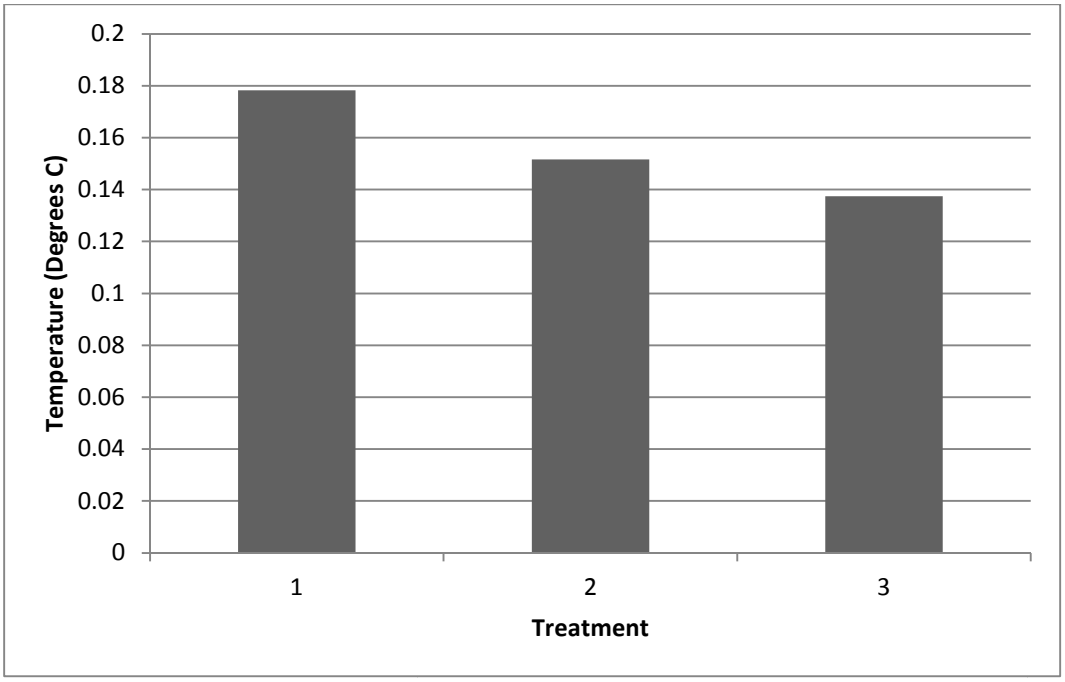

Figure 6. Average overall temperature change per minute
Treatment 1: 3MHz 1.0W/cm^2 for 5 minutes; Treatment 2: 1 MHz 1.5 W/cm^2 for 7 minutes; Treatment 3: 1 MHz 1.5 W/cm^2 for 5 minutes

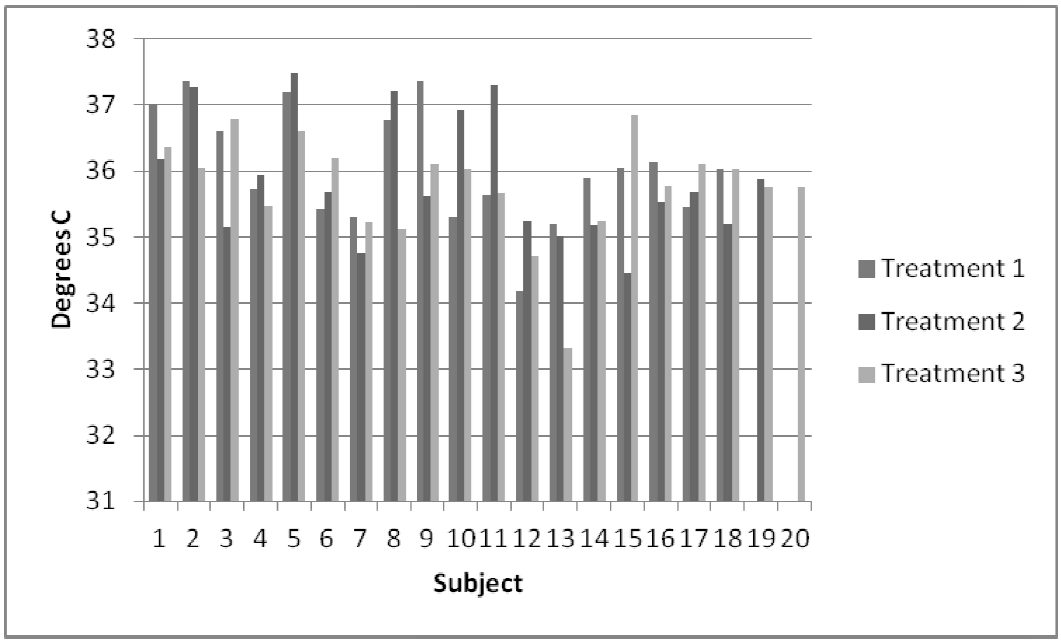

Figure 7. Baseline intramuscular temperature treatment for each subject
Treatment 1: 3MHz 1.0W/cm^2 for 5 minutes; Treatment 2: 1 MHz 1.5 W/cm^2 for 7 minutes; Treatment 3: 1 MHz 1.5 W/cm^2 for 5 minutes

When the Omnisounds were used at 3MHz at 1.5 or 1.0 W/cm^2, it produced a heating rate per minute of 0.58˚-1.00˚C. The Dynatron produced an average of 0.63˚C per minute. The machine with the lowest heating rate per minute was Chattanooga with 0.39˚C per minute. With regards to our results, in order to reach our target tissue temperature we would have needed more time for the treatments. Treatment 1 would have reached the tissue temperature goal at 11.1 minutes, treatment 2 at 26.2 minutes and treatment 3 at 13.3 minutes. This is based off taking our tissue temperature goal of either 2˚C or 4˚C divided by the average increase in temperature based on our results at the appropriate frequency used. With these results alone, it is clear that using recommended parameters based off just one machine is not beneficial for clinicians and may be the reason for ultrasound being deemed ineffective in research. Further research is needed based on the results concluding that there are obvious differences within therapeutic machines and research which uses them. This study makes it clear that each person that receives ultrasound will need different settings in order to reach the temperature goal. Research should be conducted in testing all ultrasound machines for all settings to find the difference in temperature increase and thus changing parameters based on the fact some may not increase temperature at the same rate as others.

CHAPTER V. DISCUSSION, CONLUSION AND FURTHER RESEARCH

The purpose of this study was to determine if the most common parameters from the pilot study of US usage by ATs reached the recommended goal of increased tissue temperature for specific injuries. The data for this research allowed the following research questions to be answered: Does a frequency of 3 MHz, intensity of 1.0 W/cm², and time of 5 minutes reach the goal of increasing the target tissue temperature 2˚ C for chronic inflammation? Does a frequency of 1 MHz, intensity of 1.5 W/cm², and time of 5 minutes reach the goal of increasing the target tissue temperature 2 ˚C for reducing muscle spasm and trigger points? And does a frequency of 1 MHz, intensity of 1.5 W/cm², and time of 7 minutes reach the goal of increasing the target tissue temperature of 3˚-4 ˚C for increasing range of motion and tissue extensibility? The tissue temperature was recorded every 5 seconds at 2.5 cm depth. This study was essential to determine if these parameters are appropriate for the desired temperature increase for chronic inflammation, muscle spasm and trigger points, as well as range of motion and tissue extensibility.

Summary

It is difficult to establish whether or not US is an effective or ineffective therapeutic modality based on previous research. There seems to be too many discrepancies in how clinicians use US and the way it is studied to come to one conclusion. It is recognized that there is not one set of parameters that should be used for a specific treatment, yet results from a pilot survey for the use of US by ATs yielded results which concluded the same parameters were used for several of the same conditions. This creates an issue when using US on patients in that they may not be receiving the appropriate treatments. In order to test these parameters that were being used, a study was conducted using healthy subjects to test them and determine if they were

reaching appropriate temperature increases. With 2˚ and 4˚ C as the temperature increase goal, three different settings were used on 20 healthy subjects. Results of this study indicated no significant differences between the three settings as well as significance with regards to these three settings not reaching the temperature goals of 2˚ and 4˚C. Fourteen of the subjects reached a tissue temperature increase which could be considered therapeutic, yet performing any type of joint mobilizations could cause damage to the tissue, and therefore should be avoided.

Conclusions

The results from this study indicated that the three particular settings tested did not significantly increase tissue temperature to the desired goal. There is limited research on tissue temperature increase over time with US, but clinicians should be aware that a frequency of 1 MHz is reported to be beneficial for reaching tissues at 2.5-5 cm and is generally recommended for deeper tissue or on patients with more subcutaneous fat.[29] A frequency of 3 MHz is recommended for more superficial tissue at depths up to 2.5 cm and will heat up tissue three times faster than 1 MHz.[29] One aspect from several previous research studies is that the Ominsound 3000 (Accelerated Care Plus Corp. Reno, NV) was the predominantly used machine to test effectiveness and temperature increase on patients. The Ominisound is regarded to be a high powered machine which produces significantly higher heating rates than other US machines.[29, 31] Since this study used a different machine, it is important to note this may produce different results. Based on these results, clinicians using US to treat patients should be aware of the particular machine and settings used in correlation with the specific conditions they are trying to treat. There are several possible factors as to why these three treatments did not reach the temperature increase goal including the Dynatron Solaris® 700 Series ultrasound unit itself (Dynatronics Corporation, Salt Lake City, UT), incorrect parameters for these particular subjects,

incorrect reading by the Iso Thermex electronic thermometer (Columbus Instruments, Columbus, OH) or the procedure for thermocouple insertion being incorrect. In this particular study, the question remains as to whether or not the US machine was causing the insignificant temperature change which is important for clinicians to note regarding the machine they use in their daily practice.

With regards to ultrasound machine accuracy, there has been previous research by Schabrun et al.[25] which tested the power accuracy, timer accuracy as well as the reliability of different machines used in physiotherapy practice. Power accuracy was determined by testing 12 different settings with a "resting" period in between each session. It was concluded that a total of 13 US machines were found to produce inaccurate power outputs on all settings that were tested. This is important to our research in regards that it is critical that the amount of power being delivered to the tissues and the overall time exposed is accurate. Schabrun et al.[25] concluded that there is a widespread level of machine inaccuracy, suggesting that approximately one in every two patients will receive an inaccurate dose than what was originally intended. It was suggested that the reasoning for such high and widespread levels of US machine inaccuracy may be due to the machine design. Clinically this is important because the amount of energy being emitted may not be what is indicated on the machine and changing the amount of time that an US treatment should be performed. This could potentially be the reason why the subjects in this study did not reach the goal intramuscular temperature.

Another study by Johns et al.[31] conducted a study which had the objective to measure clinical values that describe ultrasound transducers and the difference in ERA, power and SAI at 3 MHz. They tested several different machines, including the Omnisound 3000 (Acclerated Care Plus Corp, Reno NV) and the Dynatron 300-5 (Dynatron Corp, Salt Lake City , UT) . The

authors concluded that there is a 16% to 35% intramanufacturer difference and a 61% difference for SAI values among 66 different transducers.[31] The authors speculated that the differences in the peak area of maximum BNR between different transducers contributed to heating rates. When the transducers were tested for intensity output, results for Chattanooga transducers were emitting 0.85 ±0.05 W/cm^2 whereas the Omnisound 3000 transducers were emitting 0.99±0.11 W/cm^2. This would result in the conclusion that the Chattanooga group was delivering an average of 14% less energy than the Omnisound 3000.[31] When compared to another study by Holcomb and Joyce,[33] the Omnisound 3000 produced greater heating than both an XLTEX and Dynatron 950, but based on SAI values it would be thought that the Dynatron would produce higher heating rates.[33] The Omnisound delivered 10.1 W over a treatment area of 19.2 cm^2, whereas the Dynatron delivered 7.5 W over a treatment area of 25.2 cm^2, making the Omnisound to have a greater effect on heating rate over the Dynatron. Conclusions of these research studies are that there is variability within the different machines with regards to the reported ERA, the BNR and SAI, which in turn results in different heating rates and machine reliability.[31,33] These results would suggest that clinicians need to pay close attention to the characteristics of each individual unit, regardless of the manufacturer. This also suggests that more research needs to be performed to determine the rate of tissue temperature increase for each type of machine so that clinicians can adequately make changes to their parameters depending on the model/manufacturer of their machine they are using.

The thermocouple insertion protocol used in this study is based off previous studies.[23,28] These studies provided information in how to insert the thermocouple using a level which is based on depth of supposed heating, as well as where the treatment will take place. In this study, the depth at which the thermocouple was inserted was based off the overlap depth between

1MHz and 3 MHz US frequencies. The amount of the thermocouple that was in the muscle belly was based off where the treatment would be on top of the skin. It was important to make sure each subject received the same thermocouple insertion protocol each treatment session. Each time the thermocouple was removed, the length at which the thermocouple was inserted was measured and noted in the data log. The average length at which the thermocouple was inserted was close to the 2.5 cm goal and more than likely is not a factor in the low temperature increases.

Although it may not have made a large difference in the results, the baseline temperature of each of the subjects before the US treatments began could have been a reason for the low increase in temperature during the US treatments. The 12 subjects who did reach an intramuscular temperature which could be considered therapeutic had an overall average baseline temperature before US treatment of. 36.16±1.05˚C. For treatment one, only two subjects reached a therapeutic increase in temperature and the average baseline temperature for these subjects was 36.10±0.65˚C. This is compared to the rest of subjects for treatment one who had an average baseline temperature of 36.03±0.86˚C. For treatment two the four subjects who reached a therapeutic increase in tissue temperature had an average baseline of 36.60±1.43˚C with the remainder of subjects having an average baseline temperature of 35.87±0.79˚C. Treatment three had six subjects reach a therapeutic tissue temperature increase and had an average baseline temperature of 35.89±0.68˚C while the rest of the subjects had an average baseline temperature of 35.75±0.79˚C. It is unlikely that the baseline temperature for any of the subjects had an impact in tissue temperature increase after any of the US treatments.

Recommended parameters are important in this study because it reflects what the end results of a treatment should be and were the basis for the original research questions. The recommended parameters should be the total temperature increase goal divided by the

temperature increase per minute at the appropriate frequency. The recommended parameters are based on textbooks written for clinicians who plan to use US in their practice. Currently the recommended parameters are based on the Omisound only so the parameters may be different for those using other types of US machines. The average temperature increase per minute for treatment one (3MHz at 1.0w/cm^2 for 5 minutes) was 0.18 ±0.21˚C. Based on the recommended parameters, these settings should have increased the tissue temperature 0.6˚C and should have only taken 3.33 minutes to do so. Due to the tissue temperature increase per minute from this study, the treatment should have lasted a little over 11 minutes in order to reach the goal temperature increase of 2˚C. For treatment two (1 MHz at 1.5 w/cm^2 for 7 minutes), the average temperature increase per minute was 0.15 ± 0.12˚C. These parameters should have increased tissue temperature 3˚-4˚C and would have taken 13.33 minutes to be successful according to the recommended parameters. For this study, the treatment should have lasted about 20 minutes for the tissue temperature to reach at least 3˚C. Not only did this not reach this goal, it is an incorrect setting to use for this treatment goal. This is important because the clinicians who used this parameter setting for their treatments depend on which machine they were using for treatments and the accuracy of that specific machine. For the third setting (1 MHz at 1.5w/cm^2 for 5 minutes), the average increase in temperature per minute was 0.14± 0.13˚C. Recommended parameters state that the tissue temperature should have increased at 0.3˚C per minute and the treatment would have been a total of 6.33 minutes. In order for this to be effective with the Solaris though, the treatment should have lasted 16 minutes to reach a temperature increase goal of 2˚C. Many of the subjects who responded to the pilot study survey reported using the Omnisound 3000 in their practice and they may be able to use the recommended parameters. Yet there should be established recommended parameters for each specific machine used in each

setting because it is clear that using the recommended parameters for the Solaris machine used in this study was not beneficial.

Regardless of the reason behind the low amount of temperature increase for type (model) of machine to come up with average increases, based off the means and standard deviations from the results these settings/parameters were not correct. The results for the temperature increase per minute indicate more attention should be paid to the amount of time that a treatment should be and therefore changing parameters. The outcomes of this research should not change clinician's view of US, but make them aware that the settings that they may be using for a large amount of their patient population may not be effective in heating up the tissue for their particular treatment goal. This is not to say that every US machine heats up at the same rate as the one used in this study, so caution should be taken when deciding parameters for each patient respectively. This could be an implication to test each US machine with regards to how fast it heats up tissue, therefore making recommended parameters for each individual US machine. Further research should incorporate more testing and examination of US machines looking at machine inaccuracy and how prevalent it actually is. There is no doubt that therapeutic US machines increase tissue temperature, but at what rate and accuracy they do this is the question clinicians need to keep in mind and should be the basis for future research. Further research should also incorporate testing US parameters with thermocouples being inserted at different depths and on different parts of the body because of the difference in adipose tissue and other anatomical structures possibly changing the outcome of US treatments. There also should be research which tests the frequencies and intensities used in this study and perform the US treatment until a therapeutic temperature increase is reached and determine the heating rate for that machine model.

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APPENDIX A. RECOMMENDED PARAMETERS

Intensity (W/cm^2)	1MHz	3MHz
.5˚C	.04˚C	.3˚C
1.0˚C	.2˚C	.6˚C
1.5˚C	.3˚C	.9˚C
2.0˚C	.4˚C	1.4˚C

$$\text{Treatment Time} = \frac{\text{Total Intramuscular Temperature Increase (C˚)}}{\text{Temperature/Minutes at appropriate MHz}}$$

APPENDIX B. SURVEY

***1. How many years have you been a Certified Athletic Trainer?**

***2. Are you currently a faculty memeber within a professional or post-professional athletic training education program?**

- ◯ Yes
- ◯ No

Other (please specify)

3. If you answered YES, to the previous question, have you worked in a clinical setting in the past 5 years?

- ◯ Yes
- ◯ No

***4. Are you currently performing clinical work as an ATC?**

- ◯ Yes
- ◯ No

Other (please specify)

***5. Please select your current work setting or previous clinical work setting in the past 5 years.**

- ☐ High School
- ☐ University/College - D1
- ☐ University/College - D2
- ☐ University/College - D3
- ☐ Clinic/Rehab facility
- ☐ Hospital
- ☐ Other
- ☐ N/A

Other (please specify)

***6. What is the average age of the population you treat with ultrasound?**

- [ ] N/A
- [ ] 14-18
- [ ] 19-24
- [ ] 25-35
- [ ] 35-55
- [ ] 55+

***7. Please provide the information for the ultrasound unit(s) that you use in your current work setting.**

1.Name	
Manufacture	
Model	
ERA	
BNR	
2.Name	
Manufacture	
Model	
ERA	
BNR	
3.Name	
Manufacture	
Model	
ERA	
BNR	
4.Name	
Manufacture	
Model	
ERA	
BNR	
5.Name	
Manufacture	
Model	
ERA	
BNR	
6.Name	
Manufacture	
Model	

ERA

BNR

***8. How often do you calibrate your ultrasound unit?**

- ◯ Monthly
- ◯ Yearly
- ◯ Every other year
- ◯ Never
- ◯ Other (please specify)

***9. For the following condition/injury, please indicate if you use ultrasound or not. If you select YES, please include the parameters for the types of treatment including frequency, intensity, time, continuous or pulsed.**

	Yes	No
Acute Soft Tissue Injury (Sprain, Strain, Contusion)	◯	◯

Specific Condition(s) and Parameters

***10. For the following condition/injury, please indicate if you use ultrasound or not. If you select YES, please include the parameters for the types of treatment including frequency, intensity, time, continuous or pulsed.**

	Yes	No
Chronic Soft Tissue Injury (sprain, strain, contusion)	◯	◯

Specific Condition(s) and Parameters

***11. For the following condition/injury, please indicate if you use ultrasound or not. If you select YES, please include the parameters for the types of treatment including frequency, intensity, time, continuous or pulsed.**

	Yes	No
Muscle spasm/Trigger point	◯	◯

Specific Condition(s) and Parameters:

*** 12. For the following condition/injury, please indicate if you use ultrasound or not. If you select YES, please include the parameters for the types of treatment including frequency, intensity, time, continuous or pulsed.**

	Yes	No
Hematoma	○	○

Specific Condition(s) and Parameters:

*** 13. For the following condition/injury, please indicate if you use ultrasound or not. If you select YES, please include the parameters for the types of treatment including frequency, intensity, time, continuous or pulsed.**

	Yes	No
Acute Inflammation (acute injury, bursitis)	○	○

Specific Condition(s) and Parameters:

*** 14. For the following condition/injury, please indicate if you use ultrasound or not. If you select YES, please include the parameters for the types of treatment including frequency, intensity, time, continuous or pulsed.**

	Yes	No
Chronic Inflammation	○	○

Specific Condition(s) and Parameters:

*** 15. For the following condition/injury, please indicate if you use ultrasound or not. If you select YES, please include the parameters for the types of treatment including frequency, intensity, time, continuous or pulsed.**

	Yes	No
Increase Tissue Extensibility (scar tissue, adhesions)	○	○

Specific Condition(s) and Parameters

***16. On which type of conditions/injuries do you use other modalities IN ADDITION to therapeutic ultrasound?**

	Pathology	Modality
1		
2		
3		
4		

Other (please specify)

17. Which conditions/injuries do you perform manual therapy (Stretching, trigger point release, tissue extensibility) on a patient after the use of ultrasound?

18. What is the number of ultrasound treatments performed before switching to another modality or ending the treatment?

19. How do you stay up to date on therapeutic ultrasound literature/research?

- [ ] Read Literature
- [ ] Perform Studies
- [ ] Attend Conferences
- [ ] I do not actively stay up to date

Other (please specify)

APPENDIX C. IRB APPROVAL FOR SURVEY

NDSU NORTH DAKOTA STATE UNIVERSITY

Institutional Review Board
Office of the Vice President for Research, Creative Activities and Technology Transfer
NDSU Dept. 4000
1735 NDSU Research Park Drive
Research 1, P.O. Box 6050
Fargo, ND 58108-6050

701.231.8995
Fax 701.231.8098

Federalwide Assurance #FWA00002439

Friday, March 30, 2012

Dr. Kara Gange
Health, Nutrition & Exercise Sciences

Re: IRB Certification of Human Research Project:

"Therapeutic Ultrasound Survey"
Protocol **#HE12165**

Co-investigator(s) and research team: **Marika Londeen**

Study site(s): **varied** Funding: **n/a**

It has been determined that this human subjects research project qualifies for exempt status (category # 2) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, *Protection of Human Subjects*). This determination is based on the protocol form received 3/20/2012 and consent/information sheet received 3/20/2012.

Please also note the following:

- This determination of exemption expires 3 years from this date. If you wish to continue the research after 3/29/2015, the IRB must re-certify the protocol prior to this date.
- The project must be conducted as described in the approved protocol. If you wish to make changes, pre-approval is to be obtained from the IRB, unless the changes are necessary to eliminate an apparent immediate hazard to subjects. A *Protocol Amendment Request Form* is available on the IRB website.
- Prompt, written notification must be made to the IRB of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
- Any significant new findings that may affect the risks and benefits to participation will be reported in writing to the participants and the IRB.
- Research records may be subject to a random or directed audit at any time to verify compliance with IRB policies.

Thank you for complying with NDSU IRB procedures; best wishes for success with your project.

Sincerely,
Kristy Shirley
Kristy Shirley, CIP, Research Compliance Administrator

APPENDIX D. EMAIL CONSENT FOR SURVEY

Email Consent Form

North Dakota State University
Health, Nutrition, and Exercise Sciences
Benson Bunker Fieldhouse, 1A
Fargo, ND 58102

Therapeutic Ultrasound Survey

Dear Certified Athletic Trainer,

You are being invited to participate in a research study concerning the use of therapeutic ultrasound by certified athletic trainers. This survey is being conducted by Kara Gange and Marika Londeen out of North Dakota State University and the college of Health, Nutrition and Exercise Science. The objective of this research is to attempt to understand how certified athletic trainers are using therapeutic ultrasound in their clinical practice. Although you may not be currently working in a clinical setting, we invite you to participate in this survey if you have worked at a clinical site in the past five years.

Your participation is entirely voluntary and you may withdraw from participating at any time without penalty. There are no risks if you choose to participate in this survey nor are there any costs for participating. You are being asked to participate in this survey so that the data may be used to better understand what pathologies and injuries are being treated with therapeutic ultrasound and what specific parameters are being implemented. This survey should take between 5-10 minutes for you to complete.

This study is anonymous. If you do choose to participate, please do not disclose your name or any other contact information. You will have a total of 5 weeks to finish the survey, and reminders will be sent out every week during that time. No one will be able to identify you, or determine who you are based on your responses to the survey. This survey is voluntary and you are not obligated to participate. Answers will only be seen by the first and second researcher and will be stored on a computer in a locked office.

This study has been accepted by the NDSU Institutional Review Board. If you have any questions about the rights of human research participants, or if you would like to report a problem, please contact the NDSU IRB Office at (701) 231-8908 or email NDSU.IRB@ndsu.edu. In addition, if you have any questions regarding this study, you can contact Dr. Kara Gange at (701) 231-5777 or kara.gange@ndsu.edu, or Marika Londeen at (952) 270-0699 or marika.londeen@ndsu.edu.

Thank you for your time and participation.

Survey Link: www.surveymonkey.com/
Sincerely,

Marika Londeen, ATC

APPENDIX E. EMAIL REMINDER FOR SURVEY

Email Reminder

North Dakota State University
Health, Nutrition, and Exercise Sciences
Benson Bunker Fieldhouse, 1A
Fargo, ND 58102

Dear Certified Athletic Trainer,

This is a notice to remind you to please take the time to take the therapeutic ultrasound survey that was previously sent to you. This is only a reminder and if you have already taken the survey, please disregard this message. Your participation would be greatly appreciated.

Your participation is entirely voluntary and you may withdraw from participating at any time without penalty. There are no risks if you choose to participate in this survey nor are there any costs for participating.

This study has been accepted by the NDSU Institutional Review Board. If you have any questions about the rights of human research participants, or if you would like to report a problem, please contact the NDSU IRB Office at (701) 231-8908 or email NDSU.IRB@ndsu.edu. In addition, if you have any questions regarding this study, you can contact Dr. Kara Gange at (701) 231-5777 or kara.gange@ndsu.edu, or Marika Londeen at (952) 270-0699 or marika.londeen@ndsu.edu.

Survey Link: www.surveymonkey.com/

Sincerely,

Marika Londeen, ATC

APPENDIX F. IRB APPROVAL FOR STUDY

NDSU NORTH DAKOTA STATE UNIVERSITY

Institutional Review Board
Office of the Vice President for Research, Creative Activities and Technology Transfer
NDSU Dept. 4000
1735 NDSU Research Park Drive
Research 1, P.O. Box 6050
Fargo, ND 58108-6050

701.231.8995
Fax 701.231.8098

Federalwide Assurance #FWA00002439

November 26, 2012

Kara Gange
Department of Health, Nutrition & Exercise Sciences
BBFH

IRB Approval of Protocol **#HE13086**, **"Therapeutic Ultrasound: The Effectiveness of Ultrasound and the Importance of Parameter Settings"**
Co-investigator(s) and research team: **Marika Londeen**

Approval period: 11/26/2012 to 11/25/2013 **Continuing Review Report Due: 10/1/2013**

Research site(s): **NDSU** Funding agency: **n/a**
Review Type: Full Board, meeting date – 11/9/2012
Risk Level: No more than minimal risk
IRB approval is based on original submission, with revised: protocol (received 11/16/2012) and recruitment email and consent form (received 11/26/2012).

Additional approval is required:

- prior to implementation of any proposed changes to the protocol (*Protocol Amendment Request Form*).
- for continuation of the project beyond the approval period (*Continuing Review/Completion Report Form*). A reminder is typically sent two months prior to the expiration date; timely submission of the report is your responsibility. To avoid a lapse in approval, suspension of recruitment, and/or data collection, a report must be received, and the protocol reviewed and approved prior to the expiration date.

A report is required for:

- any research-related injuries, adverse events, or other unanticipated problems involving risks to participants or others within 72 hours of known occurrence (*Report of Unanticipated Problem or Serious Adverse Event Form*).
- any significant new findings that may affect risks to participants.
- closure of the project (*Continuing Review/Completion Report Form*).

Research records are subject to random or directed audits at any time to verify compliance with IRB regulations and NDSU policies.

Thank you for cooperating with NDSU IRB procedures, and best wishes for a successful study.

Sincerely,
Kristy Shirley

Kristy Shirley, CIP
Research Compliance Administrator

Last printed 11/26/2012 2:57:00 PM

APPENDIX G. INFORMED CONSENT FOR STUDY

INFORMED CONSENT

NDSU North Dakota State University
Health, Nutrition and Exercise Science
Benson Bunker Fieldhouse, 1A
Fargo, ND 58102

Title of Research Study: Therapeutic Ultrasound: The Effectiveness of Ultrasound and The Importance of Parameter Settings

This study is being conducted by:
Marika Londeen-MS student in Advanced Athletic Training Program (Advisee)
Kara Gange-Faculty in Athletic Training Programs (Advisor)

Why am I being asked to take part in this research study? You are being asked to participate in this study if you are male or female, are between the ages of 18-30 and are a student at North Dakota State University. You will not be allowed to participate in this study if you have more than 1.5 cm of fat on top of either your right or left calf muscle, currently have a calf injury, have been had a calf injury in the past six months. In addition, if you have the following conditions, you will not be allowed to participate in the study: decreased blood flow to the calf, blood clots in the calf, decreased feeling/sensation in the calf, tumors in the calf, infection in the calf, or a fracture of the bones of the lower leg. I If any tissue abnormalities in the calf muscles are seen on the diagnostic ultrasound, you will not be allowed to continue with the study.

What is the reason for doing the study?
The purpose of this study is to determine if the most common parameters from a pilot study of ultrasound use by athletic trainers (AT's) reach the recommended goal of increased tissue temperature for specific injuries. This could help athletic trainers in providing information about the parameters needed to be used for treatments, as there is limited research in this area.

What will I be asked to do?
You will come to the Bentson Bunker Fieldhouse, room 14 wearing shorts or pants that are able to be pulled up to expose the calf. Once you have read the consent form, asked any questions you may have and signed the consent form, you will lie on your stomach on a treatment table. A diagnostic ultrasound will be placed on the skin of the calf to determine the amount of fat tissue sitting on top of the calf muscle and to see if there are any abnormalities in your calf muscle. If you are cleared to continue, the treatment area and needle insertion area will be shaved to remove any body hair (if necessary). The needle insertion area will then be disinfected with Betadine and alcohol.

A needle catheter (similar to a flu shot needle) will be inserted into the inside of the calf muscle. The needle is retracted so the very small catheter is still in the tissue. A thermocouple (very small flexible temperature probe) is inserted through the catheter into the calf muscle and the catheter is removed. Tape will be applied on top of the skin to hold the

Revised November 2012

Who will see the information that I give?
We will keep private all research records that identify you. Your information will be combined with information from other people taking part in the study. When we write about the study, we will write about the combined information that we have gathered. We may publish the results of the study; however, we will keep your name and other identifying information private. Your name and other sensitive information will be kept in the athletic training faculty's locked file cabinet during the study and destroyed when the research is complete.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. The results from your ultrasound testing will be kept under an assigned number, not your name. For example, your name will be kept separate from your research records and these two things will be stored in different places under lock and key.

Can my taking part in the study end early? You have the option of ending your participation early. If you fail to show up to all sessions you may be removed from the study. You will not receive full compensation if you fail to finish the entirety of the study.

Will I receive any compensation for taking part in this study? If you choose to participate in all three study sessions, you will receive $30.00 cash. Compensation will be pro-rated. For instance, if you only participate in one session, you will receive $10.00 cash.

What happens if I am injured because of this research?
If you happen to get injured because of this research study, you should contact the primary investigator, Kara Gange at (701)231-5777 regarding the injury. The primary investigator will assess the injury and provide proper treatment or refer you to Student Health Services for further treatment. Treatment for the injury will be available including first aid, emergency treatment and follow-up care as needed. Payment for this treatment must be provided by you and your third party payer (such as health insurance or Medicare). This does not mean that you are releasing or waiving any legal right you might have against the researcher or NDSU as a result of your participation in this research.

What if I have questions?
Before you decide whether to accept this invitation to take part in the research study, please ask any questions that might come to mind now. Later, if you have any questions about the study, you can contact the researchers, Marika Londeen at (952)270-0699 marika.londeen@my.ndsu.edu or and Dr. Kara Gange at (701) 231-5777 or kara.gange@ndsu.edu.

What are my rights as a research participant?
You have rights as a participant in research. If you have questions about your rights, or complaints about this research or to report a research-related injury, you may talk to the researcher or contact the NDSU Human Research Protection Program by:

- Telephone: 701.231.8908
- Email: ndsu.irb@ndsu.edu
- Mail: NDSU HRPP Office, NDSU Dept. 4000, PO Box 6050, Fargo, ND 58108-6050.

The role of the Human Research Protection Program is to see that your rights are protected in this research; more information about your rights can be found at: www.ndsu.edu/irb .

Documentation of Informed Consent:
You are freely making a decision whether to be in this research study. Signing this form means that

1. you have read and understood this consent form
2. you have had your questions answered, and
3. you have decided to be in the study.

You will be given a copy of this consent form to keep.

_____ _____
Your signature Date

_____
Your printed name

_____ _____
Signature of researcher explaining study Date

_____
Printed name of researcher explaining study

Institutional Review Board
North Dakota State University
PROTOCOL #: HE13086
APPROVED: 2/14/13
EXPIRES: 11/8/13

Revised November 2012