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Heat Penetration into Soft Tissue with 3 MHz Ultrasound

Jared Franson

A thesis submitted to the faculty of
Brigham Young University
in partial fulfillment of the requirements for the degree of

Master of Science

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ABSTRACT

Heat Penetration into Soft Tissue with 3 MHz Ultrasound

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Context: Therapeutic ultrasound is a deep heating modality often used to produce vigorous heating (≥4°C Δ) in tissues. The vigorous heating effects of 3 MHz therapeutic ultrasound have only been tested to a 2.5 cm depth, but its maximal depth of producing vigorous heating has yet to be established. Objective: To investigate the tissue temperature change produced by a 3 MHz ultrasound treatment at depths of 3 and 3.5 cm in the human triceps surae muscle group. Design: Randomized control design. Setting: Therapeutic modalities research laboratory. Patients or Other Participants: Twenty healthy college-aged participants (male = 13, female = 7; age = 23.4 ± 1.31; calf subcutaneous fat thickness= 0.6 cm ± 0.2 cm). Participants were randomized into treatment (n = 15) and sham (n = 5) groups. Participants were blinded to their group assignment. Interventions: Two MT-26/6 needle thermocouples were inserted into the left posterior triceps surae at depths of 3.0 ± 0.1cm and 3.5 ± 0.1cm from the skin's surface. Participants in the treatment group received a continuous 3 MHz ultrasound treatment at 1.4 W/cm^2 for 8 minutes with 10mL of 100% ultrasound gel as a coupling medium. Participants in the sham group received the same treatment parameters, but the ultrasound device was not turned on. The Omnisound 3000 ultrasound device (ERA = 4.2cm^2, BNR = 3.0:1) was used for all treatments. A 15cm^2 template was used to ensure a constant and proper treatment size. Baseline temperature (T_B) was established by taking a mean of intramuscular tissue temperature (T_{IM})for five minutes before the treatment and T_{IM} were recorded every 10 seconds throughout the experiment session. Participants marked a visual analog scale (VAS) indicating heat sensation at pre-treatment and post-treatment. Main Outcome Measures: A 2 x 2 x 2 (probe depth x condition x time) ANCOVA with T_B used as a covariate analyzed the difference in T_{IM}. We only used the time points of baseline and final T_{IM} for our analysis as we are only interested in the change in T_{IM} from beginning to end of the ultrasound treatment. Descriptive statistics for T_{IM} and VAS for heat sensation were computed as post-treatment minus pre-treatment for each condition and probe depth. Results: There was a significant difference in T_{IM} between the conditions at the different probe depths from the beginning and end of the ultrasound treatment ($F_{1,15} = 7.35$, $p = 0.016$). The mean changes in T_{IM} for each condition at each probe depth were: sham 3cm = -0.4 ± 0.3°C, sham, 3.5cm = -0.2 ± 0.3°C, treatment, 3cm = 4.4 ± 0.2°C, treatment, 3.5cm = 3.5 ± 0.2°C. Mean VAS scores for each group were: sham = 0 ± 0mm and treatment = 71.8 ± 11.8mm. Conclusions: At 3cm deep into the posterior calf, the Omnisound 3000 using a 3 MHz treatment produced vigorous heating (≥4°C Δ). Moderate heating (2-3°C Δ) occurred at 3.5cm deep into the calf. Three MHz ultrasound may be used to heat tissues deeper than previously theorized, but it does, however, create a moderately high level of heat sensation for the patient.

Keywords: therapeutic ultrasound, 3 MHz frequency, intramuscular temperature change

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Introduction

Thermotherapy is the therapeutic use of heat. Therapeutic ultrasound, an acoustic vibration occurring at frequencies too high to be perceived by the human ear[1] is a source of thermotherapy that has been used for over 50 years for the benefit of a variety of soft tissue injuries.[2-4] To receive thermal effects with therapeutic ultrasound, tissue temperature must be raised 2-4°C.[2,5-8] A 2-3°C temperature increase characterizes moderate heating,[6,9] which has been shown to decrease muscle spasm and pain, increases blood flow, and reduces chronic inflammation.[4,9-11] However, if the goal is to increase the viscoelastic changes in collagen, then vigorous heating of $\geq$ 4°C is warranted.[1,2,6,9]

Therapeutic ultrasound commonly has two traditional frequencies to treat different depths of soft tissue injuries, 1 MHz[2,12] and 3 MHz.[2,5,6,12,13] A 1 MHz ultrasound frequency is used to treat deeper tissues from 2.5-5 cm in depth, while the 3 MHz frequency ultrasound is used to treat more superficial tissues of 0.8 to 2.5 cm deep.[5,14,15] Additionally, the 3 MHz frequency's energy is absorbed three times faster than the 1 MHz ultrasound's which results in an increase of tissue temperature three times faster than when using 1 MHz frequency.[5,6] Thus, using 3 MHz ultrasound may increase the efficiency of the treatment by decreasing application time by one-third.

Hayes et al[5] used a 3 MHz ultrasound frequency with an intensity of 1.5 W/cm^2 and found vigorous heating in 3.35±1.23 min at a depth of 2.5 cm into the triceps surae muscle group. Due to the rapid rate at which vigorous heating was achieved at this depth, we theorized that 3 MHz ultrasound may actually heat tissues to a vigorous level deeper than

2.5 cm. Thus, our purpose was to test the depth of penetration of a 3 MHz ultrasound at an intensity of 1.4 W/cm^2 by measuring the intramuscular tissue temperature change in tissues at 3 and 3.5 cm.

Methods

This study was reviewed and approved by the Institutional Review Board for Human Subjects before participants were enrolled into the study. Each participant was informed of study procedures, risks, and benefits and provided written informed consent prior to participation; each participant rights were protected through the study. A 2 x 2 x 49 factorial, randomized control design was implemented. The dependent variable was intramuscular tissue temperature of the triceps surae muscle. The independent variables were treatment group, probe depth and time. The treatment group had two levels, a treatment group (n = 15) that received a 3 MHz ultrasound treatment and a sham group (n = 5) where the ultrasound head was moved, but the device was not turned on. All temperatures were measured at two depths, 3.0 cm and 3.5 cm from the ultrasound application surface. Intramuscular tissue temperature was measured and recorded at baseline and at every 10-second intervals over the course of an 8 min ultrasound treatment yielding 49 time measurements. A heat sensation modified visual analog scale (VAS) was recorded at the beginning and end of the treatment (Table2). The VAS was to determine whether or not the heat sensation level became too hot and if it is beneficial to continue treatment. The patient was instructed that a 0 on the VAS scale was “no heat” and 10 was “intense heat that is too hot to withstand.”

Participants

Twenty healthy college-aged student volunteers (male = 13, female = 7; age = 23.4 ± 1.31; calf subcutaneous fat thickness = 0.6 cm ± 0.2 cm) participated in this study. An *A priori* analysis for sample size was completed ($\alpha = 0.05$, $\beta = 0.2$, power = 0.08) using data from Hayes et al[5] and determined that we needed 15 participants to show a difference in temperature. Before being enrolled in this study, each participant was screened for the following excluding factors: blood-borne disease, recent history of left leg ecchymosis, infection, edema, metal implants in the lower extremity, a history of lower extremity injury within the past six months or subcutaneous fat thickness of the triceps surae muscle greater than 15 mm. All participants were assessed with ultrasound imaging to ensure at least a 5 cm tissue depth from the posterior aspect of the triceps surae muscle group to the tibia of at least 5 cm. This is to ensure that the tibia would not be hit when inserting the temperature probe.

Instruments

The recently calibrated Omnisound 3000 Pro (Accelerated Care Plus LLC, Reno NV) ultrasound device was used to apply the treatments. The device was equipped with a 5 cm^2 ultrasound head, which has an effective radiating area (ERA) of 4.2 cm^2 and a beam non-uniformity ratio of 3.0:1.

Two 26-gauge needle microprobe thermocouples (Model: MT 26/6, Physitemp Instruments, Inc., Clifton, NJ) were used to measure tissue temperature at 3.0 cm and 3.5 cm. Prior to their use each needle microprobe was tested to be reliable and valid in a 42.0°C water bath using methods described previously.[16] The needle microprobes were interfaced with a computer through an Iso-Thermex electrothermometer (Iso-Thermes, Columbus Instruments, Columbus, OH) in order to record temperatures in real time. The reliability and validity of the Iso-Thermex electrothermometer were reported previously.[17]

A Doppler Imaging ultrasound (Model: LogiQ 5e, General Electric Company, Fairfield, CT) was used to measure and ensure that the needle microprobe was inserted to the proper depth.

Procedures

Using aseptic technique and universal precautions, two thermocouples were inserted into the medial aspect of the triceps surae horizontally to the ultrasound treatment surface at a depth of 3.0 and 3.5 cm from the treatment surface. This was performed by the same investigator to ensure consistency.

With the participant lying prone, we shaved a 10 cm diameter area on the medial side of the left triceps surae. From the posterior surface of the skin, we measured 3.0 and 3.5 cm from the posterior aspect of the triceps surae muscle group and marked this with a felt marker on the medial side of that same muscle group. The insertion area was then thoroughly cleaned using an iodine swab. The two needle microprobes were inserted horizontally into the triceps surae muscle at the marked depths (Figure 1 and 2). To ensure and confirm the microprobes were inserted to the depth of 3.0 and 3.5 cm, Doppler imaging ultrasound was used to visualize and measure the needle tips from the ultrasound application surface on the triceps surae. To ensure reliability the needle microprobes were deemed at an acceptable depth if they were inserted within a 0.1 cm of the desired depth. The actual average depths of insertion of the two needle microprobes were 3.0 ± 0.1 cm and 3.5 ± 0.0 cm.

A 15 cm^2 treatment area template was taped to the skin directly above the inserted needle microprobes on the triceps surae. This was to ensure that the area between ultrasound treatments was consistent and the ultrasound treatment area was an appropriate size. A 10 mL of ultrasound gel (Omnisound gel, Accelerated Care Plus, LLC, Reno NV) was applied to the treatment area. The baseline temperature was then determined by measuring the mean tissue temperature of both probes over a 5-minute period. At the end of the 5-minute period a baseline heat sensation VAS was recorded. The patient was instructed that a 0 on the VAS scale was "no heat" and 10 was "intense heat that is too hot to withstand." They placed a dash vertical line on a 10 cm scale. The clinician then measured the patients marking and measured it in mm to give a VAS score between 0 and 100.

Participants received either an ultrasound treatment or a sham treatment. Participants were randomly assigned, via a random number generator, into the ultrasound treatment group (n = 15) or sham (n = 5). Participants in the treatment group received a continuous 3 MHz ultrasound treatment at an intensity of 1.4 W/cm^2. For the sham treatment, the transducer head was moved over the area, but the ultrasound device was not turned on and no acoustic energy was delivered. The ultrasound transducer moved in a superior to inferior in a back and forth direction within the template at a rate of 3 to 4 cm/sec. Each treatment, ultrasound or sham, was 8 min and instantaneous intramuscular temperatures were recorded at 10 sec intervals (Figure 3). At the end of the treatment the participant was instructed to complete another heat sensation VAS of the hottest point of the treatment.

Once the ultrasound application was completed, the needle microprobes were removed, the insertion area was cleaned using isopropyl alcohol, and an adhesive bandage was applied over the needle insertion sites.

Data Analysis

Descriptive statistics for intramuscular tissue temperature and heating perception VAS scores for heat sensation were computed as post-treatment minus pre-treatment for each condition and probe depth (Table 2).

We used 2 x 2 x 2 (probe depth x condition x time) mixed model ANCOVA with baseline temperature used as a covariate to analyze the difference in intramuscular tissue temperatures. We only used the time points of baseline and final for our analysis as we are only interested in the change in intramuscular tissue temperature from beginning to end of the ultrasound treatment.

With change in VAS scores from post-treatment minus pre-treatment a two sample t-test was used to analyze differences between treatment groups. All statistical analyzes was performed with JMP 9.0 (SAS Inc., Cary, NC), and the *a priori* α level equal to 0.05.

Results

There was a significant difference in intramuscular temperature change between the two conditions at the two different probe depths from the beginning and end of the ultrasound treatment ($F_{1,15} = 7.35$, $p = 0.016$). At 3 cm deep into the posterior calf, the Omnisound 3000 using a 3 MHz treatment produced vigorous heating of 4.4 ± 0.9°C. Moderate heating of 3.5 ± 1.2°C occurred at 3.5 cm deep in the triceps surae (Table 1, Figure 4). During the study, all participants were fully compliant and there was no reason for early termination of an ultrasound treatment. The modified VAS had an average of

71.2 ± 11.2 mm on a 100 mm scale, but this was not high enough that any of the participants wanted to discontinue the treatment (Table 2).

Discussion

Depth of 3 MHz Ultrasound

The purpose of our study was to evaluate the penetration of 3 MHz ultrasound by measuring the tissue temperature increases at the depths of 3.0 and 3.5 cm in the triceps surae muscle. In the past, 3 MHz ultrasound was theorized to only heat superficial tissues to the depth of 1 to 2 cm.[18,19] Hayes et al[5] found that 3 MHz ultrasound actually heated tissues vigorously (≥4°C) to the depth of 2.5 cm and this heating occurred at a fairly rapid rate of 3.35 minutes. Thus we theorized that 3 MHz ultrasound may actually heat tissues vigorously to the depths of 3.0 and 3.5 cm, but over a longer time than the 3.35 min reported by Hayes et al.

Our results showed a slight difference in what we hypothesized. With a 3 MHz ultrasound treatment there was an average tissue temperature change at 3 cm of 4.4 ± 1.2°C and at 3.5 cm a change of 3.5 ± 0.9°C. At 3 cm vigorous heating was achieved but at 3.5 cm only moderate heating was achieved, which is still beneficial for decreasing muscle spasm and pain, increasing blood flow, and reducing chronic inflammation.[4,6,9,10]

The difference in the results and what we hypothesized may be due to attenuation. Attenuation is a measure of the decrease in ultrasound intensity as the ultrasound wave travels through tissue.[19,20] As the ultrasound waves travel through the surface and into the soft tissue it is absorbed and heat is produced. With different frequencies of ultrasound the waves are absorbed to different depths.[6] Our results show that absorption begins to diminish between 3.0 cm and 3.5 cm. Thus the ultrasounds waves are not as intense at that range. Another reason for the difference is due to conduction.[21] As the superficial tissues are heated with the 3 MHz frequency the soft tissues conduct heat to their surrounding tissues, but the ultrasound treatment may have not been long enough to affect the deeper tissues as greatly.

Comparison with Hayes et al. and Ultrasound Devices

The main purpose of Hayes et al[5] study was to determine whether the 1 MHz or the 3 MHz ultrasound frequency was more effective at increasing intratissue temperature at a depth of 2.5 cm. It was found that the 3 MHz ultrasound frequency produced vigorous heating at 2.5 cm. There were some main differences between our study and the Hayes et al study. In the Hayes et al study they used the Theratouch 7.7 ultrasound device (Rich-Mar, Inola, OK) with a Therapy Hammer transducer.[5] In the study that we performed we used the Omnisound 3000 (Accelerated Care Plus, Reno NV) ultrasound device. Both the effective radiating area (ERA) and the beam non-uniformity ratio (BNR) were not determined for the Theratouch 7.7 device used, but the manufacture reported an ERA of 5 cm^2 and a BNR of 5.5:1.[5] The Omnisound 3000 that we used had an ERA of 4.2 cm^2 and a BNR of 3.0:1. Because there is not much difference between the ERA's, the treatment area is about the same size but there is a difference between the BNR's. The Optimal BNR would be a ratio of 1:1;[20] indicating a smooth, uniform sound emission without any peaks or valleys. Because this ratio is impossible due to the crystal not vibrating uniformly[21] the closer the ratio is to 1:1 the better the uniform heating properties of the ultrasound device.[6] This is one of the main reasons that we used the Omnisound 3000 for our particular study. According to

Holcomb et al. the Omnisound 3000 is more effective than the Forte 400 in raising tissue temperatures due to its lower BNR.[22]

Rate of Heating

When performing an ultrasound treatment it is important to consider the rate of heating as it will indicate to the clinician the appropriate time necessary to reach the goal temperature of either moderate or vigorous heating. Hayes et al found that vigorous heating with 3 MHz continuous ultrasound ($\geq 4°C\ \Delta$) was achieved on an average of 3.35 ± 1.23 min at 2.5 cm deep. Thus, the rate of heating was 1.19°C/min.[5] In comparison to our study, vigorous heating was achieved at 5.9 ± 2.2 min at 3.0 cm deep with a rate of heating of 0.66°C/min, while moderate heating was achieved at 5.3 ± 1.7 min at 3.5 cm deep with a rate of heat increase of 0.66°C/min. These results do not contradict the findings of Hayes et al because it can be assumed that it takes longer to reach vigorous heating at a deeper depth.

The difference in the rate of heating between the two studies may be due to a few different factors. The first of these reasons may be due to conduction. During a 3 MHz ultrasound treatment the superficial tissues are being heated first and as the tissue temperature increases it conducts heat to the surrounding tissues thus increasing their temperature, but at a slower rate.[10,21,23] Another factor would be the rate of absorption is decreased at deeper depths due to attenuation of the sound waves thus requiring a longer time to achieve the desired heating level.[23] The last of these reasons may be due to probe placement reliability. In Hayes et al they were not using any type of imaging to ensure that the probe placement was exactly 2.5 cm. Because of this, it is unknown that the probes were actually at 2.5 cm or less. If the probes in fact were not as deep as planned then the rate of heating would be much higher and faster. In our study we had the benefit of having ultrasound imaging to ensure that the probes were within 0.01 cm of their intended depth.

Temperature Increase for Viscoelastic Effects

Tissue temperatures must be raised 2-4°C in order to receive a therapeutic effect.[2,5-7] An increase of 2-3°C (moderate heating)[6,9] can decrease muscle spasms and pain, increase blood flow, and reduce chronic inflammation.[4,6,9,10,24] However, if the goal is to increase the viscoelastic changes in collagen to better allow for stretching or joint mobilization, then vigorous heating of ≥ 4°C is warranted.[1,2,9,14]

We were able to determine that the 3 MHz ultrasound heated tissues vigorously at 3.0 cm deep and also heated tissues moderately at 3.5 cm deep. With this information we can now say that 3 MHz ultrasound frequency heats vigorously at 3.0 cm, which is deeper than originally theorized.

Coupling Medium

Draper et al. described coupling mediums as solutions that are placed between the skin and sound head of an ultrasound unit that are used to deliver the sound energy to the target tissues while preventing reflection of the ultrasonic energy to the treatment field.[11] The coupling medium allows for energy to enter the target tissue by minimizing the air between the transducer head and the target tissue.[25] It has been shown that commercial ultrasound gel allows for the greatest amount of heating when compared to other coupling mediums[11] such as distilled water, lotion, creams, mineral oils, and gel pads.[11,25,26]

For our ultrasound treatment, 10 ml of ultrasound gel was placed on the skin inside a template that was cut to 15 cm^2. As the treatment progressed the movement of the transducer head pushed some of the ultrasound gel under the template, therefore losing some of the gel. When this happened and the amount of gel was minimized and the subjects reported that they could feel intense heat. After adjusting the gel by regathering it to the proper area, the intense heat dissipated and the subjects reported the heat was tolerable. It is suggested that when performing an ultrasound treatment to be generous with ultrasound gel or to periodically adjust the gel by regathering it to the proper area so it is directly over the treatment area and not spread too thinly.

Conclusion

The results of our study indicate that 3 MHz ultrasound heats tissues vigorously to the depths of 3 cm and moderately to 3.5 cm, which is further than previously thought.[5] Because the 3 MHz ultrasound frequency heats soft tissues three times faster than the 1 MHz ultrasound frequency is beneficial to the clinician to use the 3 MHz ultrasound for soft tissue to 3 cm deep for vigorous heating and 3.5 cm for moderate heating.

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Table 1: Mean temperature increase

Treatment	Depth	Δ temp (°C)
Control	3.0 cm	-0.4 ± 0.2
	3.5 cm	-0.2 ± 0.2
Treatment	3.0 cm	4.4 ± 0.9
	3.5 cm	3.5 ± 1.2

Table 2: Visual Analog Scale (VAS); Descriptive statistics

Treatment Group	Number	Mean	Std Dev	Std Err Mean	Lower 95%	Upper 95%
Control	5	0	0	0	0	0
Treatment	15	71.2	11.2517	2.9052	64.969	77.431

Figure 1. Thermocouple Insertion

Figure 2. Treatment Site

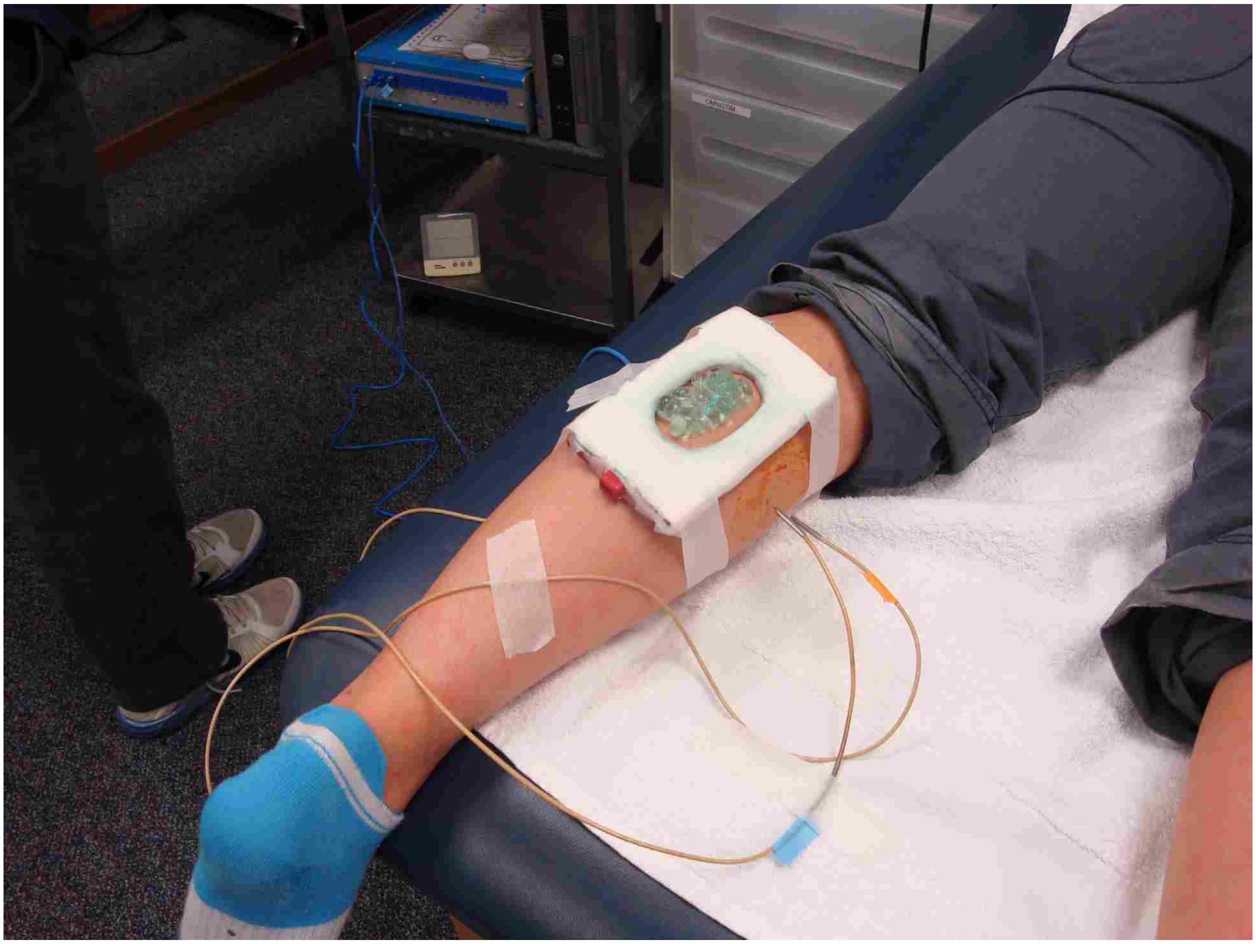


Figure 3. Treatment Procedure

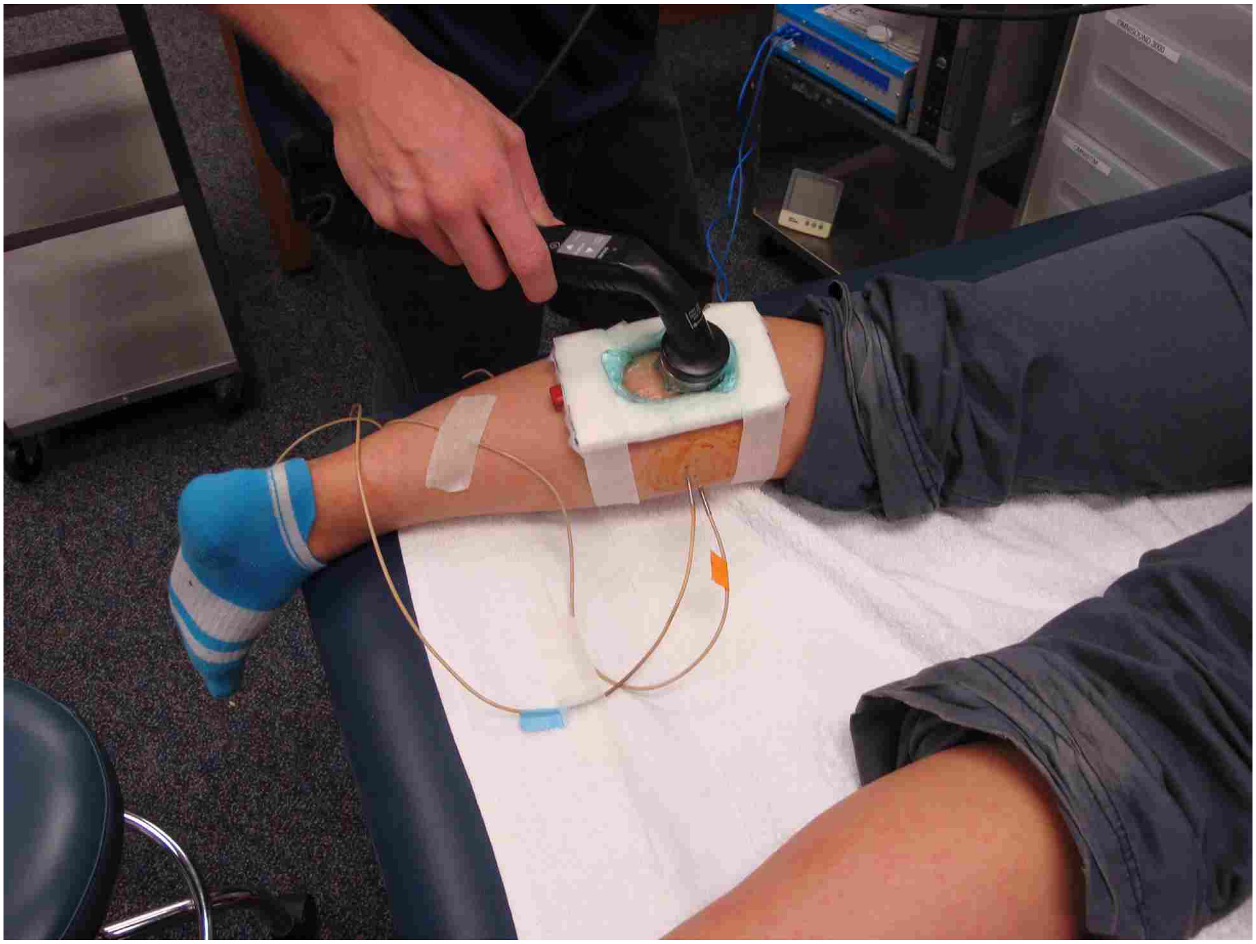
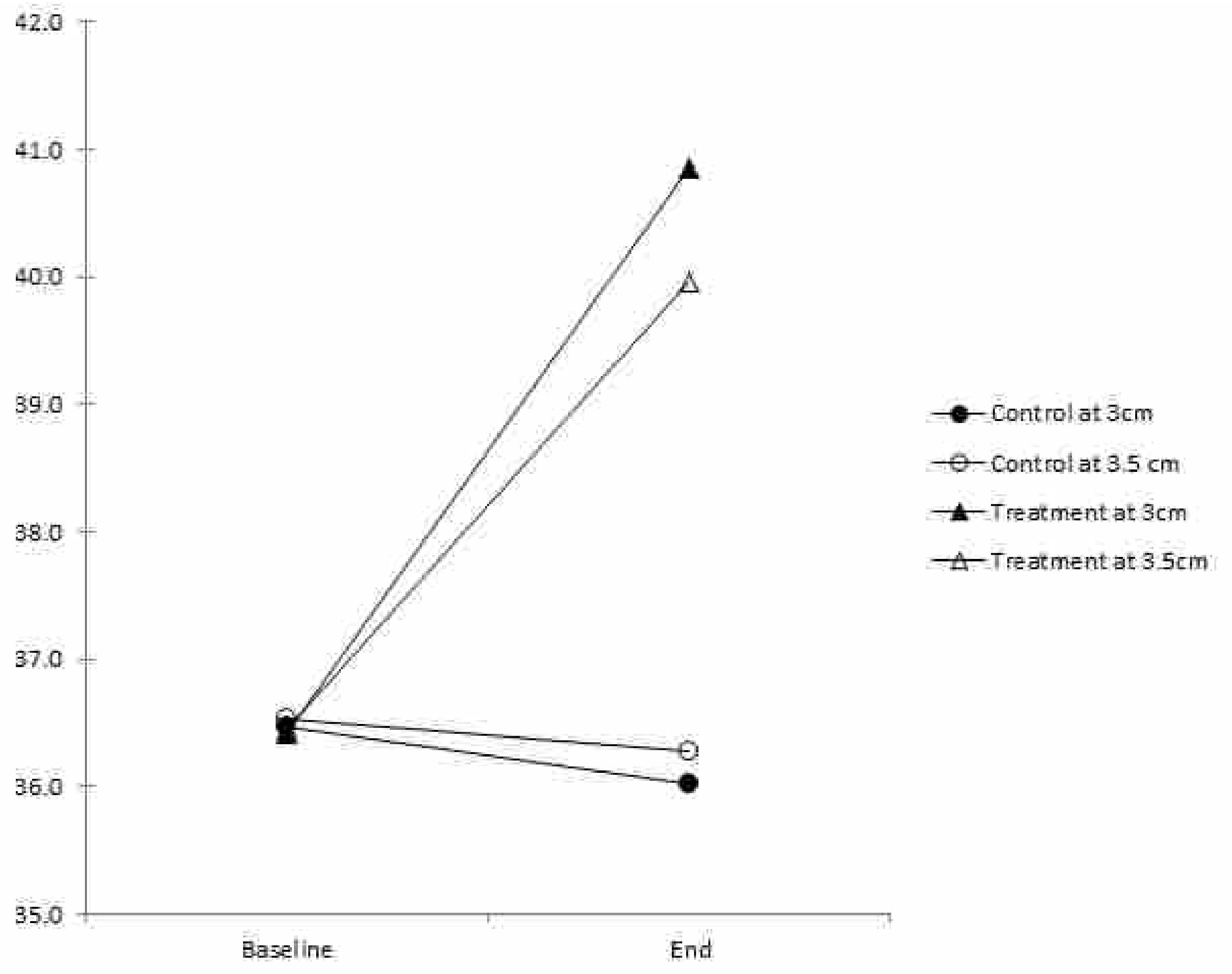


Figure 4. 3 cm and 3.5 cm Temperature Increases



Appendix A

Prospectus

Chapter 1

Introduction

Therapeutic ultrasound has been used for many years for the benefit of a variety of injuries.[2-4] It has been documented that ultrasound's clinical effect is to decrease joint stiffness,[9,10,25] reduce muscle spasm,[5,22,27] increase soft tissue extensibility,[2,8,9,11,14] decrease pain [6,9,22,23,25] and soften scar tissue.[6,28] The baseline temperature of a muscle is 36°C to 37°C [2,5,9] and in order to receive any significant heating effect the tissue temperature must be raised 2-4°C;[1,5,23,26] with 4°C being considered as vigorous heating.[6,29]

There are typically two different frequencies used in therapeutic ultrasound to treat soft tissue injuries, 1 MHz and 3 MHz[2,5,6,12] During a therapeutic ultrasound treatment, the frequency determines the depth to which the sound waves travel and the rate at which the energy is absorbed into the underlying tissues[6]. A 1 MHz continuous ultrasound is typically used to treat deeper tissues from 2.5 to 5 cm in depth,[5,14] while the 3 MHz continuous ultrasound is used to treat more superficial tissues of 0.8 to 2.5 cm in depth.[5,14] Due to its higher frequency, the 3 MHz frequency allows for its energy to be absorbed 3 times as fast than 1 MHz ultrasound resulting in an increase of tissue temperature that is also 3 times faster than 1 MHz ultrasound.[6] Thus, utilizing the 3 MHz ultrasound may increase the efficiency of the treatment by decreasing application time by one third.

The heating effects of a 3 MHz therapeutic ultrasound treatment have only been tested to 2.5 cm in depth where the temperature increase of 4°C was achieved at 3.35 minutes during a 10-minute treatment with an intensity of 1.5 W/cm^2. [5] We theorize that the 3 MHz ultrasound may actually heat tissues by 4° C at a depth of 3 cm and that it may even have moderate heating (2-3°C) at 3.5 cm. Therefore, the primary purpose of this study is to test the depth of penetration of a 3 MHz ultrasound by measuring the temperature change of tissue at 3 and 3.5 cm of depth. In our pilot study we found an increase of 4°C at 3 cm of depth.

Statement of the problem

The purpose of this study is to evaluate the penetration depth of 3 MHz ultrasound by measuring tissue temperature increases at predetermined depths of 3.0 and 3.5 cm in the triceps surae muscle. There has only been one study that evaluated the depth of 3 MHz ultrasound penetration up to 2.5 cm.[5]

Null hypothesis

A 3 MHz, 8 minute ultrasound treatment administered to the triceps surae muscle will not produce vigorous heating at 3.0 and 3.5 cm.

Hypothesis

A 3 MHz, 8 minute ultrasound treatment administered to the triceps surae muscle will produce vigorous heating at 3.0 and 3.5 cm.

Assumptions

Ultrasound treatment will not be affected by differences in subcutaneous fat tissue.[30,31] The ultrasound machines will work properly throughout the treatments. The thermocouples will remain at the same depth throughout the treatment and their readings will be accurate.

Limitations

The results of this study will be limited to the Omnisound device at 1.4 W/cm^3 (parameters). The patients demographics will be limited to Utah County, UT. The subjects' ages will range from 18 to 35. The treatment will be limited to only the triceps surae muscle group.

Delimitations

Adipose tissue depth of greater than 15 mm in the triceps surae muscle group.

Operational Definitions

Ultrasound- a therapeutic modality used to heat soft tissue by using sound waves.

Vigorous heating- temperature increase of 4°C or more.

Significance of study

If we find that 3 MHz ultrasound will elicited vigorous heating at 3.0 or 3.5 cm it will increase utilization of 3 MHz ultrasound in clinical practice.

Chapter 2

Review of Literature

Literature Searched

Literature articles were found through searching the following databases: U.S. Department of Education Resource Information Center (ERIC), SPORTDiscus, Web of Science, Academic Search Premier, MEDLINE, and ProQuest. Keywords searched include the following: ultrasound, 3 MHz, 1MHz, pulsed ultrasound, continuous ultrasound, heat modalities, tissue heating.

Ultrasound

Ultrasound is defined as an acoustic vibration occurring at frequencies too high to be perceived by the human ear.[1] Therapeutic ultrasound is a tool that clinicians have used for over 50 years for the treatment and rehabilitation of many soft tissue injuries.[4] Therapeutic ultrasound commonly utilizes 1 and 3 MHz frequencies.[5,6] Tissue temperature must be raised 2-4°C in order to receive a therapeutic effect.[2,5-7] An increase of 2° to 3° C (moderate heating)[6,9] decreases muscle spasm and pain, increases blood flow, and reduces chronic inflammation.[4,6,9,10] However, if the goal is to increase the viscoelastic changes in collagen, then vigorous heating of $\geq 4°$ C is warranted.[1,2,6,9]

When choosing a tissue heating modality the user has to consider two criteria, size of the area treated and depth of the tissue being targeted.[3] Ultrasound is effective in increasing tissue temperature when treating an area of approximately twice the size of the ultrasound soundhead,[3,4,10] or more specifically effective radiating area (ERA).[3] The ERA is approximately slightly smaller than the size of the crystal.[3] If a larger treatment area is used it will dilute the dose so that the thermal effects on the tissue will be minimal.[6] Researchers have shown the heating effects of a 2-ERA (two times the ERA) and a 4-ERA (four times the ERA) treatment area on the patellar tendon. It showed that both the 2- and 4-ERA treatment areas increased patellar tendon temperatures but the 2-ERA size produced a higher temperature increase of 8.3°C than the 4-ERA, which only increased the tissue temperature to 5.0°C.[3,4,10] The 2-ERA treatment maintained vigorous heating (≥ 4°C increase[6,9]) for 4 minutes post treatment, while the tissues treated with the 4-ERA treatment maintained vigorous heating for only 2 minutes post treatment.[10]

Ultrasound emits sound waves that are never completely uniform, they have small peaks and valleys within the wave.[20] The beam nonuniformity ratio (BNR) is the measurement of these peaks and valleys. The optimal BNR would be 1:1 ratio;[20] indicating a smooth, uniform emission without any peaks or valleys. Unfortunately, this is not possible because the crystal that generates the ultrasound does not vibrate uniformly.[21] The crystal is located in the transducer head where the waves are produced. The waves are inaudible high-frequency mechanical vibrations that are created by a generator and produces electrical energy and converts it to acoustic energy.[24] The best clinically possible BNR is between 2 and 5 to reduce the chance of hot spots.[20] The lower the ratio the less peaks; the waves created are more uniform. Hot spots are areas the tissue that are being overheated from high peaks within the ultrasound's beam, where the sound waves are concentrated on that area.[20] Scientists reported 3 subjects out of 16 received blisters on their shins after a 1 MHz, 1.5 W/cm^2 ten-minute ultrasound treatment. The clinicians theorized that one of the reasons that the subjects received blisters was because the BNR of the ultrasound device caused irregular heating and produced hot spots.[13]

Another reason for hotspots is when the ultrasound head is stationary too long during the treatment. There are two types of treatment techniques, static and moving. A treatment is considered static when the ultrasound head is stationary; it is considered moving when the ultrasound head is moved across the treatment area at a given rate, often determined by a metronome.[5,9,13,25] In the clinic it is standard practice to keep the ultrasound head moving. Because the piezoelectric element (crystal) within the transducer head does not vibrate uniformly it is important to keep the transducer head moving to avoid hot spots.[21] To avoid any hot spots we will use the moving technique within an ERA two times the soundhead.

3 MHz Ultrasound Frequency

Ultrasound at 3 MHz is typically used to target the more superficial tissues of 0.8 to 2.5 cm depth, whereas the 1 MHz ultrasound treatments is used to heat deeper tissues of 2.5 to 5.0 cm depth.[5,6] A recent study has shown that the 3 MHz ultrasound can be effective in heating intermediate as well as superficial tissues.[5]

It has been shown that a 3 MHz ultrasound with an ERA of two times the soundhead, heats tissue temperature 1.2 cm depth 3-4 times faster than the 1 MHz ultrasound.[2,6]

1 MHz Ultrasound Frequency

One of the greatest benefits of therapeutic ultrasound is its ability to heat deeper tissues without heating the skin.[20] One *in vivo* study evaluating continuous ultrasound applied to the hip joint of a pig showed that after only 1 minute of treatment with 1 MHz at 2.5 W/cm^2 the anterior aspect of the fibrous capsule increased temperature from 39.8°C to 41°C. After 2 and 3 minutes the temperature had a significant increase and reached 43°C and 44°C respectively.[23]

Draper and colleagues[6] tested the rate of heating of 1 MHz ultrasound at four different doses of 0.5, 1.0, 1.5, and 2.0 W/cm^2.[6] They hypothesized that the 3 MHz ultrasound will heat three times the rate of the 1 MHz ultrasound. The per minute rates of increase were .04°C at 0.5 W/cm^2, 0.16°C at 1.0 W/cm^2, 0.33°C at 1.5 W/cm^2, and .38°C at 2.0 W/cm^2.[6] In theory 2.0 W/cm^2 treatment in theory should have heated the tissue twice as fast as the 1.0 W/cm^2 but, in fact it heated the tissue 2.3 times faster. It also should have heated approximately 25% faster than the 1.5 W/cm^2 but it only heated 15% faster. However, the tissue temperature rate and rise of each of the subjects were consistent at these dose levels.[6] It was found that at 0.5 W/cm^2 the thermal effects were insufficient, but there was a significant difference between the other intensities.[6]

Rate of Temperature Increase

Therapeutic ultrasound has been shown to be very beneficial in heating tissue at a specific depth in a relatively short amount of time. Holcomb et al.[22] tested the rate of temperature increase in two separate ultrasound units, the Omnisound 3000 (Accelerated Care Plus, Reno NV) and the Forte 400 Combo (Chattanooga Group, Inc, Hixson, TN) They found that the mean rate of temperature increase was 0.58°C/min at 1.0 w/cm^2 with the Omnisound 3000 and 0.39°C/min with the Forte 400 Combo.[22] There results show that there is a considerable change in temperature increase when comparing two different ultrasound machines. Therefore it is important to take into consideration which ultrasound machine to use to provide the most beneficial rate of heating.

There is a relationship between the time needed to heat a tissue to a significant therapeutic level and the size of the treatment area.[6] The larger the treatment area the longer it takes to heat the tissue.[3,10] It is suggested that the size of the treatment area should be about two times the size of the sound head.[3,4,10,32] Researchers compared the difference of muscle temperature between a 2-ERA and a 6-ERA ultrasound treatment with the intensities of 1.5 W/cm^2 and 2.0W/cm^2 for a 10-minute period. The mean temperature change from the 2-ERA treatment was 3.5°C, compared with only 1.3°C for the 6-ERA.[3,32] Therefore the smaller the treatment area or ERA the shorter the time necessary to produce a significant tissue temperature increase.

Coupling Mediums and Ultrasound Gels

Sound waves travel through fluids and solids more efficiently than through air. In order to achieve optimal tissue heating it is important to consider the medium or material through which the sound waves travel including the interface between the sound probe and the skin. Common practice when using both diagnostic and therapeutic ultrasound is to use a coupling medium to enhance the interface between the sound probe and skin. Coupling mediums are solutions that are placed between the skin and sound head and are used in delivering the sound energy to the target tissues while preventing reflection of the ultrasonic energy to the treatment field.[11] The coupling medium allows the energy to enter the target tissue by minimizing the air between the transducer head and the tissue.[25] There are different types of coupling mediums used by clinicians including distilled water, lotion, creams, mineral oils, gels, and gel pads[11,25,26] or it can be applied under water.[23] In order to make the coupling medium effective it needs to have three characteristics. First, it needs to be viscous so that an adequate amount of the medium stays in between the transducer head and the skin (or the ultrasound treatment needs to be applied in water). Second, the medium should have a high water content. This allows the sound waves to be transmitted without much attenuation. Lastly, is must have low susceptibility to bubble formation so that the sound energy is not reflected but instead is absorbed by the target tissue.[11] In our study we will use commercial ultrasound gel as this is standard practice in the clinical setting and has been shown to allow greater heating than a gel pad.[11]

Temperature Probes

Thermistors, a type of temperature probe, are commonly used to measure temperature changes within a muscle or soft tissue.[2,5,22] A thermistor consists of a small needle with a temperature-measuring device placed in the tip and/or at different levels along the needle. Thermistors allow for a direct measure of temperature within the muscle during administration.[26] It is very important that the probes generate reliable and valid measurements. In a pilot study we confirmed that the thermistors were reliable and valid in measuring temperature of a water bath when compared to a calibrated thermometer.

Conclusion

Ultrasound has proven to be a convenient tool to use in therapeutic rehabilitation when the goal is to raise tissue temperature, but there are many areas that still need to be elucidated. One of those areas is tissue penetration of the specific ultrasound frequencies. Hayes et al. theorized that 3 MHz ultrasound using 3 MHz actually heated deeper tissues than previously claimed.[5] In the past, 3 MHz ultrasound was theorized to only heat superficial tissues to the depth of 1.6 cm. Hayes et al. found that 3 MHz ultrasound actually heated to the depth of 2.5 cm.[5] Unfortunately their thermocouples only reached 2.5 cm deep into the tissue. In the study we are proposing we will address this issue as our thermocouples will reach 3.5 cm deep into the tissues and will measure the temperature at

3.0 and 3.5 cm. We theorize that the 3 MHz ultrasound will reach tissues deeper than 2.5 cm.

Chapter 3

Methods

Design

We will use a 2 x 2 x 49 factorial, repeated measures design. The independent variables are treatment group, probe depth and time. Ultrasound Frequency has two fixed levels: 3 MHz and a control where a treatment will be given but the machine will not be turned on. All temperatures will be measured at two depths: 3.0 cm and 3.5 cm from the ultrasound application surface. Time is measured and recorded every 10 seconds and a baseline measurement over the course of an 8-minute ultrasound treatment yielding 49 measurements. The dependent variable is intramuscular tissue temperature of the triceps surae muscle.

Subjects

Twenty healthy college-aged student volunteers will participate in this study. Five will serve as the no treatment control and 15 for the actual ultrasound treatment. A brief health status questionnaire will be used to collect subjects' demographic data and to rule out any excluding factors which are: blood-borne disease, recent history of left leg ecchymosis, infection, edema, metal implants in the lower extremity, or a history of lower extremity injury within the past six months. All subjects will be assessed with Doppler (LOGIQ P5, GE Health Care, Fairfield, CT)) imaging to ensure at least 5 cm tissue thickness of the posterior calf region. All subjects will be informed of possible risks associated with participation in the study and will provide written informed consent for their participation. The university's institutional review board will approve the study prior to any data collection. *A priori* analysis for sample size was done (alpha=0.05, beta=0.2, power=0.08) and determined that we needed 15 subjects to show a difference in temperature.

Instruments

A calibrated Omnisound 3000 (Accelerated Care Plus, Reno NV) ultrasound device with a 3 MHz setting will be used to apply the treatments.

Two 26-gauge microprobe needles (Physitemp MT 26/6, Physitemp Instruments, Inc., Clifton, NJ), with temperature sensors in the tip will be used to measure tissue temperature at 3.0 cm and 3.5 cm.

A General Electric LOGIQ P5 Doppler Ultrasound (Fairfield, CT), will be used to measure and ensure the proper depth of the probe insertion. Ultrasound gel (Aquasonic, Fairfield, NJ) will be used to prevent reflection of ultrasound energy.

Procedures

We will conduct this study according to an estimated protocol.[2,5,6,11] Using aseptic technique and universal precautions, two thermocouples will be inserted into the medial aspect of the triceps surae horizontally 6 cm to the ultrasound treatment surface at a depth of 3.0 and 3.5 cm from the treatment surface on the posterior aspect of the triceps surae muscle group. All thermocouple insertions will be performed by the same investigator as follows: A 10-cm-diameter thermocouple insertion area on the left triceps surae muscle group will be shaved. With the subject laying prone Doppler (LOGIQ P5) imaging will be used to measure adipose tissue depth to ensure that it is under 15mm. The thermocouple insertion areas will be thoroughly cleaned using a Betadine swap and wiped clean with a 70%

isopropyl alcohol prep pad. The two thermistors will be inserted approximately 6 cm horizontally into the triceps surae muscle, one at 3.0 cm and the other at 3.5 cm. A carpenter's square will be used to measure those depths from the posterior aspect. To ensure and confirm the needles are inserted to the exact depth of 3.0 and 3.5 cm, Doppler (LOGIQ P5) imaging will be used to visualize and measure the needle tips from the ultrasound application surface.

A template cut to twice the area of the transducer head of the ultrasound applicator will be placed onto the skin overlying the treatment area. This will ensure that the area between ultrasound treatments is consistent.

After we implant the thermistors, we will wait until the tissue temperature does not change more than 0.2°C for one minute and then record the baseline temperature as an average of measured temperatures for one minute. All baseline and treatment temperature measurements will be taken at 10-second intervals.

All ultrasound treatments will be administered with the subject prone using 5-mL of room temperature ultrasound gel as the coupling agent. Subjects in the treatment group will receive a 3 MHz ultrasound with the intensity set at 1.4 W/cm^2 with a continuous duty cycle. For the control treatment, the transducer head will be moved over the area, but the ultrasound unit will not be turned on, and no acoustic energy will be delivered. The ultrasound transducer will be moved in a superior to inferior direction within the template at a rate of 3 to 4 cm/s. A 8 minute ultrasound treatment will be delivered with instantaneous temperature recorded every 10 seconds during the application. Once the ultrasound application is completed, the thermocouple will be removed, the insertion area will be cleaned using 70% isopropyl alcohol, and an adhesive bandage will be applied to the needle-insertion site.

Data Analysis

To analyze peak temperature change and time to peak temperature change we will use two 2 x 2 x2 mixed model ANCOVA's. The covariate for this study will be adipose tissue thickness and baseline temperature. Differences in individual baseline temperatures will be accounted for through the model. Statistical analyses will be performed with JMP 9.0 (SAS Inc., Cary, NC), and the *a priori* alpha level equal to 0.05.

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Appendix B

Statistical Tables

2 x 2 x 2 ANCOVA, Intra-muscular Temperature

Fixed Effect Tests

Source	Nparm	DF	DFDen	F Ratio	Prob > F
Condition	1	1	17.77	98.1565	<.0001
Time	1	1	18.6	70.9071	<.0001
Condition*Time	1	1	18.6	100.2859	<.0001
Probe	1	1	20.46	2.0068	0.1716
Condition*Probe	1	1	18.14	10.287	0.0048
Time*Probe	1	1	18.05	4.0509	0.0593
Condition*Time*Probe	1	1	18.05	9.4014	0.0066
Temp baseline	1	1	27.11	32.7705	<.0001

Least Squares Means Table

Level	Time	Probe	Least Sq Mean	Std Error	Difference (end-baseline)
Control	Baseline	3	36.5	0.3	-0.4
Control	End	3	36.0	0.3	
Control	Baseline	3.5	36.5	0.3	-0.2
Control	End	3.5	36.3	0.3	
Treatment	Baseline	3	36.4	0.2	4.4
Treatment	End	3	40.9	0.2	
Treatment	Baseline	3.5	36.5	0.2	3.5
Treatment	End	3.5	40.0	0.2	

VAS Score

Means and Std Deviations

Level	Number	Mean	Std Dev	Std Err Mean	Lower 95%	Upper 95%
Control	5	0	0	0	0	0
Tx	15	71.2	11.2517	2.9052	64.969	77.431

t Test

Difference	71.2	t Ratio	13.89476
Std Err Dif	5.1242	DF	18
Upper CL Dif	81.9656	Prob > |t|	<.0001
Lower CL Dif	60.4344	Prob > t	<.0001
Confidence	0.95	Prob < t	1