The Effects of ultrasound transducer velocity on intramuscular tissue temperature across a treatment site

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THE EFFECTS OF ULTRASOUND TRANSDUCER VELOCITY ON
INTRAMUSCULAR TISSUE TEMPERATURE ACROSS A
TREATMENT SITE

by

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Bachelor of Science
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School of Allied Health Sciences
Division of Health Sciences

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The Effects of Ultrasound Transducer Velocity on Intramuscular Tissue Temperature Across a Treatment Site

by

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This purpose of this study was twofold: to determine whether ultrasound transducer velocity affected tissue temperature increase, and whether heating was uniform across the treatment site. Thermocouples were inserted 2.5cm below the skin surface at the center, edge of the ERA, and the edge of the treatment site that was the size of two times the soundhead. Each subject received three 10-minute treatments at each speed, letting tissue temperature return to baseline between treatments.

Repeated measures factorial ANOVA revealed no significant differences in the speed of application and no interaction between speed and location. However, the location of the thermocouples proved to be a factor, with pairwise comparisons showing a significant difference among the 3 locations. In conclusion, the speed at which ultrasound is applied has no effect on temperature rise; however, the size of the treatment area needs to be taken into account as uniform heating does not occur.
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There is no way I would have made it through the last two years without the amazing group of people I have the privilege of calling my friends. Thank you for providing me with constant laughter, endless support through the hardships and a lifetime of memories. I am truly grateful and forever indebted.
CHAPTER 1

INTRODUCTION

The Problem

Ultrasound is a deep-heating modality that has long been implemented in post-injury rehabilitation, particularly in chronic musculoskeletal conditions. The deep-heating action occurs through the use of high-frequency sound waves generated by the ultrasound machine, creating a thermal effect within the targeted tissue. With thermal ultrasound, a 3-4°C temperature increase from baseline, termed vigorous heating, is warranted to produce the effects of deep heating. Some of the many physiological effects of deep heating tissue include increasing collagen extensibility, increasing blood flow and circulation to the area, decreasing muscle spasms, and increasing range of motion. A great advantage of using ultrasound over other modalities that increase tissue temperature (i.e. heat packs or warm whirlpools) is the ability to target treatment to areas of high collagen content such as muscles, tendons, ligaments, joint capsules, menisci, and periosteum while bypassing adipose tissue.

During treatment it is important to keep the soundhead of the ultrasound machine moving at a constant linear or circular motion due to the beam nonuniformity ratio (BNR) of the crystal located in the soundhead. This ratio of peak spatial intensity to average spatial intensity is the variability of intensity within the effective radiating area (ERA), defined as the portion of the sound head that produces ultrasound waves. ERA varies
according to the manufacturer\textsuperscript{9} and between machines.\textsuperscript{10,11} Ideally, the BNR would have a ratio of 1:1 meaning the amount of heat distributed from the soundhead is uniform throughout the ERA, providing equal heating throughout the target tissue. Unfortunately this is not possible, so most machines will fall between the ratios of 2:1 and 5:1. With an increase in the BNR, there are greater chances of burn injuries due to “hot spots” in the tissue that are developed from too much energy being emitted from one area of the soundhead, such as in machines with BNRs of up to 8:1 where there is 8 times the amount of energy emitted at the peak than at the average intensity. Therefore, it is necessary to keep the soundhead moving at a constant speed to prevent uncomfortable temperature increases and possible burns to patients,\textsuperscript{1,2} assuming greater consistency in the distribution of heat occurs. Currently, the accepted soundhead speed during application is approximately 4-5 cm/s,\textsuperscript{1,2,4,5,8,12,13} however, there is limited clinical evidence to support this claim. There is an absence of data to support any suggested velocity of the transducer head during treatment. This should lead one to question where the recommendation of 4-5 cm/s originated.

In addition to BNR, it is important to be aware of each machines’ ERA since it varies with manufacturers.\textsuperscript{10} The ERA is the only part of the soundhead that emits acoustic waves and it is always smaller than the circumference of the soundhead. Since researchers recommend having a treatment area that is 2-3 times larger than the size of the ERA, it is expected that treatment areas not receiving continuous heat will have non-uniform temperature increases. Miller et al\textsuperscript{14} examined this theory while using intramuscular tissue temperature as the basis for whether or not uniform heating occurs. They found a 1.04°C temperature difference between the center and periphery of the
treatment site at the gastrocnemius, suggesting that uniform heating does not occur throughout the treatment area. However, there is debate about whether the placement of the thermocouples in the study were appropriate as one probe was placed 1-3 mm away from the periphery, so the ERA for that machine theoretically did not reach the temperature probe. To take away any concerns regarding thermocouple placement, it would be most beneficial for us to obtain temperature readings at the center of the treatment site and compare those results with the temperatures at the edge of the ERA and at the edge of the entire treatment area.

For ultrasound to be effective, it is important that both the treatment area and the speed of treatment be considered and altered to create the desired heating. Therefore, the purpose of this study was to determine if there are differences in intramuscular temperature change among the varying transducer head velocities at 2, 4, and 6 cm/s (4-5 cm/s is the “recommended speed”), and whether the same amount of heating occurs between the center, the periphery of the transducer head’s ERA, and the periphery of the treatment site. At the conclusion of this study, clinicians should have an understanding of how to better implement this widely-used modality in the rehabilitation of injuries.

Hypotheses

Null hypothesis: Varying transducer head velocities will not affect change in intramuscular tissue temperature at a fixed depth below the surface across the treatment site (with the size of the treatment area being constant at all three speeds). Alternate hypothesis: There will be a statistically significant difference in intramuscular temperature change when comparing the center of the treatment site to the peripheries of the ERA and the treatment site regardless of ultrasound transducer head velocity.
Delimitations

There are several delimitations that occurred with this study. First, the target population decreased dramatically with the inclusion criteria of 20-30mm of skinfold. We also needed to ensure that the subject has enough tissue to reach the desired depth for the thermocouples. Lastly, the amount of ultrasound gel utilized for each patient was dependent on patient comfort, with the addition of gel as the patient began to feel any type of “burning” sensation; therefore, that variable was not standardized.
CHAPTER 2

LITERATURE REVIEW

Major Concepts in Ultrasound Application:

Ultrasound

Therapeutic ultrasound is a deep-heating modality that transmits acoustic energy into tissue.¹ ² ⁸ ¹⁴-¹⁷ Its origins can be traced back as far as the 19th century when soldiers began to use ultrasound during World War II, ² ⁸ ¹⁵ and it has been extensively used in clinical settings since 1955¹⁸ for the treatment of chronic musculoskeletal injuries. Presently, it is one of the most commonly-used modalities by health care providers, more specifically, athletic trainers, physical therapists, occupational therapists and chiropractors.²

An ultrasound unit is made up of two parts: the generator (the largest part of the device that houses the controls) and the transducer head (the soundhead that transmits the acoustic waves). The acoustic energy that is produced with ultrasound is created by an alternating current flowing through a ceramic crystal in the transducer head. This crystal, located approximately 5 mm away from the surface of the soundhead,¹ is responsible for producing positive and negative electrical charges when it expands and contracts. This phenomenon is known as the reverse piezoelectric effect, and it is created from an alternating current passing through the crystal, causing mechanical vibration of the
transducer head. These vibrations result in the mechanical production of high-frequency sound waves.\textsuperscript{1, 2, 8, 19, 20}

The effects of ultrasound can be divided into thermal and non-thermal settings. Non-thermal ultrasound (or pulsed) is used to create a micromassage effect to promote tissue healing\textsuperscript{2} especially in instances where heat is contraindicated, such as acute injury.\textsuperscript{1} When thermal (or continuous) ultrasound is used in the rehabilitation of a chronic injury, it still has the effects of non-thermal ultrasound but the main goal is to increase intramuscular tissue temperature.\textsuperscript{3, 6, 7, 14, 16, 18, 19, 21-29} By increasing tissue temperature, this modality has the ability to produce a number of physiological effects. An increase in blood flow occurs to the area\textsuperscript{3, 5, 6, 29} due to vasodilation of blood vessels.\textsuperscript{29} This also increases the amount of cellular activity, or cell metabolism,\textsuperscript{30} which facilitates healing. The tissues that are heated increase in extensibility,\textsuperscript{5, 6, 24, 31, 32} which allows for greater range of motion in the tissue when combined with stretching.\textsuperscript{26, 31, 32} Because of these physiological effects, ultrasound is used to treat a multitude of conditions such as musculoskeletal pain,\textsuperscript{19, 33} soft tissue injury,\textsuperscript{34} the buildup of scar tissue\textsuperscript{31} and muscle spasms.\textsuperscript{30}

A great advantage of using ultrasound over other modalities that increase tissue temperature (such as hot packs, warm whirlpools, and diathermy) is its ability to specify treatment sites to areas of high collagen content. Draper and Sunderland\textsuperscript{5} examined this phenomenon, also known as the Law of Grotthus-Draper, in human subjects and found that subcutaneous fat (which has a very low collagen content and a high water content) does not attenuate ultrasound energy at a frequency of 1-MHz.\textsuperscript{5} In other words, similar effects of deep tissue heating can occur in people with varying thicknesses of
subcutaneous fat. Tissues of high collagen content such as muscles, tendons, ligaments, joint capsules, menisci, and periosteum are selectively heated – bypassing these areas of low collagen content completely.\textsuperscript{2, 5, 8, 13} Ultrasound, however, has different effects on different types of tissue as the amount of blood vessels in the area will affect the rate of heating and how much heat is retained.\textsuperscript{4} Chan et al\textsuperscript{24} discovered that rate of heating in the patellar tendon is 3 times faster than muscle,\textsuperscript{24} and these findings are likely due to tendon being less vascular in nature.

Effects of Deep Heating

One of the settings that can be adjusted on an ultrasound unit is the frequency. The frequency, measured in megahertz (MHz), is either 1-MHz or 3-MHz on most machines and selection depends on the desired depth of treatment and rate of tissue heating.\textsuperscript{2} Several studies\textsuperscript{18, 35} have examined rates of heating with varying frequencies at different set depths, as some people believe that increasing the intensity increases the depth of penetration, when in reality, it is the frequency. The output intensity, or the amount of power generated by the unit,\textsuperscript{1} merely sends more mechanical energy but at the same depth.\textsuperscript{2} The lower the frequency, the less energy is absorbed in the superficial tissues, and thus the deeper it penetrates.\textsuperscript{17} In 1995, Draper et al\textsuperscript{18} conducted the first in vivo study examining the rate of temperature increase and depth of penetration in the calf during 1-MHz and 3-MHz continuous ultrasound. They found that 1-MHz can reach tissues up to 5 cm deep, whereas 3-MHz can reach tissues up to 2.5 cm deep.\textsuperscript{18} These findings were supported by Hayes et al in 2004,\textsuperscript{35} in which they examined depth of penetration (described in terms of the half-value) at varying frequencies. In some studies, depth of penetration is described as the half-value, or the depth by which 50% of the
ultrasound beam is absorbed in tissue.\textsuperscript{2,18} Temperature effects are expected to be highest at the half-value layer and less at greater depths, meaning that if overall depth of penetration is 5 cm, according to the half-value layer principle, theoretically it should have a higher temperature at half that depth (2.5 cm).\textsuperscript{2}

Varying the frequency will not only change the depth of penetration, but it alters the magnitude of temperature increase within the tissue as well. Draper et al\textsuperscript{18} examined this rate of heating and the temperature differences that occurred with varying intensities (.5, 1.0, 1.5, and 2.0 W/cm\textsuperscript{2}) at frequencies of 1-MHz versus 3-MHz. By recording temperature changes every 30 seconds for 10 minutes,\textsuperscript{18} they were able to construct time versus temperature graphs, finding that with 1-MHz frequency the temperature increased 0.2°C per minute for every W/cm\textsuperscript{2} and with 3-MHz frequency the temperature increased much faster at 0.6°C per minute for every W/cm\textsuperscript{2}. This study gave clinicians a better idea of how they can change treatment time, intensity, and frequency to obtain desired therapeutic effects. These therapeutic effects are important to keep in mind because they vary depending on the amount of absolute temperature change. Lehmann et al\textsuperscript{30,36} found that with a baseline temperature of 36-37°C, an increase of 1°C (or “mild heating”) accelerates metabolic rate, an increase of 2-3°C, (or “moderate heating”) reduces muscle spasm, pain and chronic inflammation, and increases blood flow, and an increase of 4°C (or “vigorous heat”) decreases the viscoelastic properties of collagen and inhibit sympathetic activity.\textsuperscript{30,36} These findings have long been accepted as therapeutic goals during ultrasound, \textsuperscript{1,2,18,26,36} and they are important because failure to achieve these temperature increases will negate the thermal effects of the treatment.
Lehman et al\textsuperscript{30} was the first to describe an ideal window of treatment to allow for heat conductivity to occur in soft tissue. This 5-10 minute time span is long enough to produce a temperature increase depending on the frequency, intensity output, and type of soft tissue being treated. There is no ideal amount of time for an ultrasound treatment, so it must be determined based on factors such as depth of target tissue, size of the area, and the overall therapeutic goals of the treatment.\textsuperscript{2,17,18} The deeper the target tissue or the higher the desired temperature increase, the longer the treatment time.

Beam Non-Uniformity Ratio

The variability of intensity within an ultrasound beam is called the beam non-uniformity ratio (BNR). It is the ratio between the highest intensity emitted, called the spatial peak intensity, and the average intensity across the beam, called the spatial average intensity. This non-uniformity is expected between each machine and occurs due to the differences in the type and quality of the crystal (allowing some areas to transmit better than others) and manufacturing.\textsuperscript{1} Ideally, a 1:1 ratio is desired, meaning that a uniform beam is emitted throughout the ultrasound head, decreasing the probability of burning patients\textsuperscript{1,2,8} due to formation of “hot spots” or areas of peak intensity. Presently, ultrasound machines will have a BNR between 2:1 and 5:1, and the Food and Drug Administration ensures that all manufacturers report BNR on each unit\textsuperscript{37} to ensure patient safety. However, most machines only report the maximum average BNR of a sample of their units and it is not likely to be indicative of any single unit the clinician is using.\textsuperscript{3} Ultrasound beams should not have a BNR over 8:1\textsuperscript{1} as tissue damage may occur.

The non-uniform beam expressed by the BNR is the reason why the transducer head is kept moving at a constant motion throughout a treatment.\textsuperscript{12,17} If the transducer
head is held stationary, there will be an increased amount of heat emitted over the areas of peak intensities as compared to the other parts of the soundhead, therefore increasing the chance of burning patients due to “hot spots.”\textsuperscript{17} In the literature, the recommended speed at which to move the transducer is 4-5 cm/s. \textsuperscript{1, 2, 4, 5, 8, 12, 13, 20} However, there is an absence of studies to support this recommendation and there has been conflicting ideas as to what the ideal speed of the soundhead should be during a treatment. Draper\textsuperscript{17} stated that the 4-5 cm/s stemmed from the use of poor quality machines and that equipment with low BNRs allows for a slower stroking movement of the ultrasound transducer,\textsuperscript{17} therefore he recommends using a slower speed of 2 cm/s. However, new types of hands-free ultrasound devices are being manufactured that allow the clinician to apply ultrasound with an applicator that automatically moves the transducer head at the recommended rate of 4 cm/s.\textsuperscript{38} Presently, there is only one study known to examine the effects of altering transducer velocity during ultrasound. Weaver et al\textsuperscript{12} examined the effect of 3 transducer velocity conditions (2-3, 4-5, and 7-8 cm/s) on intramuscular temperature during a standardized ultrasound application at 3 cm below the adipose. They found a similar heating effect regardless of the transducer velocity with the amount of temperature increase used to quantify the effect. Their findings could support the claim that newer ultrasound machines are manufactured with better quality.

Effective Radiating Area

Within the transducer head lies the piezoelectric crystal responsible for converting electrical energy to acoustical energy by expanding and contracting. Because the crystal has to be small enough to fit in the soundhead and it is the part responsible for emitting the acoustic waves, it cannot be assumed that the entire surface radiates ultrasound
The effective radiating area (ERA) of a soundhead is the area on the surface of the transducer head that transmits soundwaves. According to the FDA, more specifically, ERA is the area consisting of all points of the effective radiating surface at which the intensity is 5% or more of the maximum intensity. This low 5% standard creates substantial variability when measuring and reporting true ERA for each soundhead, which also plays a role in why uniform heating does not occur throughout a treatment site. The ERA of a machine depends on the type of crystal used, the size, and the activity of the crystal.

Anecdotally, clinicians have used the idea of 2-3 times the area of the soundhead as treatment size. However, researchers have recommended treating an area that is 2-3 times the area of the ERA, since that is the only part of the transducer that emits the high frequency sound waves. This discrepancy poses a problem because it can lead to a treatment area that is too small (creating potential for burning the patient because there is not enough movement of the soundhead) or too large (therefore making the treatment ineffective due to the lack of temperature increase). Clinicians also need to keep in mind the pattern of energy emission, with most energy concentrated produced in the ERA and little to no energy being emitted in the outermost part of the soundhead outside of the ERA. If the clinician has a specific goal of temperature increase, it is crucial to heat the entire area evenly and effectively while still covering enough tissue to produce an effect.

Miller et al examined the idea of uniform heating by looking at the difference in intramuscular tissue temperature between the mid-point of the treatment and the periphery of the effective radiating area. Using implantable thermocouples, temperature recordings were taken at the two sites during a single ultrasound treatment (which was
the area of 2 soundheads). They reported that while using a frequency of 1 MHz, the periphery did not reach the desired therapeutic range of 3-4°C as compared to the center of the treatment area. However, there is some debate about whether or not the placement of the peripheral thermocouple was correct in the study design, as it was placed 1-3 mm from the outer edge (to estimate the edge of the ERA), but the actual ERA of the machine was not measured.

Because of the differences in the size of the crystal and the activity of the crystal, ERA not only varies among manufacturers, but it also varies among machines. Straub et al examined these differences by looking at 66 ultrasound machines from 6 different manufacturers (n=11 machines/manufacturer). The machines were calibrated and the ERA was calculated using a hydrophone, a device used to monitor sound underwater. They found that the measurements of ERA were highly varied, with a total of 15 transducers (23%) falling out of manufacturers’ reported guidelines (and thus FDA guidelines). Johns et al also tried to determine the degree of intra-manufacturer and inter-manufacturer variability in ERA using similar procedures. They also found large variability across manufacturers and within manufacturers, with XLTEK (XLTEK, Oakville, Ontario, Canada) and Mettler (Mettler Electronics Corp, Anaheim, CA) having higher variability as compared to the other manufacturers such as Omnisound (Accelerated Care Plus Corp, Sparks, NV) and Rich-Mar (Rich-Mar Corp, Inola, OK).

So why should knowing the ERA be a concern? Intramuscular tissue temperature changes differ across a treatment site, therefore, it is important that we understand how ultrasound will affect an injury and vary our treatment area as indicated. It is not
uncommon to see ultrasound administered on large areas, such as the quadriceps. However, we need to keep in mind what sort of heating we are actually producing. Also, clinicians purchase equipment assuming that the ERA reported is correct. However, these studies\textsuperscript{10,11} prove that variability exists, therefore we cannot truly base our treatment area on the ERA provided to us. We have to be aware of how we are treating our patients and whether or not our treatments are effective.

Optimizing the Ultrasound Treatment

Research has also shown that the coupling medium used during application has an effect on the magnitude of heating within a treatment area. A coupling medium is necessary to allow the ultrasonic energy to enter the target tissue by minimizing the amount of air between the skin and the transducer head and also to help decrease the amount of friction on the skin while moving the soundhead.\textsuperscript{7,16,17,22,39} There are 3 common types of ultrasound coupling mediums: gels for direct application, water for the immersion technique, and gel pads used for irregularly-shaped parts of the body. Although ultrasound gel is the most commonly seen coupling agent,\textsuperscript{16,20} the gel pad technique\textsuperscript{7} has also been proven to be an effective medium, while the immersion technique has shown to be comparatively ineffective.\textsuperscript{20} Bishop et al\textsuperscript{7} found similar increases in tissue temperature when comparing ultrasound gel and a gel/pad combination. On the other hand, Draper et al\textsuperscript{20} found that ultrasound only transmitted about 59.38\% of its power through distilled water, while 72.60\% of its power was transmitted through ultrasound gel, making the immersion technique seemingly less effective.
Some clinicians also mix ultrasound gel with topical analgesics, using the penetrating ultrasound waves as a means of driving pain relievers into the body. In 2001, Myrer et al\textsuperscript{22} found no difference in tissue temperature increase when comparing an ultrasound/analgesic mixture to a treatment using only ultrasound gel as the coupling medium.\textsuperscript{22} These results are in contrast to a previous study conducted by Ashton et al,\textsuperscript{16} where they found that intramuscular tissue temperatures were higher in treatments that used 100\% ultrasound gel, even though the Flex-All/gel mixture felt warmer to subjects.\textsuperscript{16} These differences can possibly be due to the differences in the types of analgesics used (one study tested Nature’s Chemist and Biofreeze\textsuperscript{22} and the other used Flex-all\textsuperscript{16}), or the differences in the frequencies of the treatments (1-MHz\textsuperscript{22} versus 3-MHz\textsuperscript{16}). Oshikoya et al\textsuperscript{39} studied whether or not the temperature of the medium had an effect on the treatment, but found that there were no additive benefits when using cooled or heated gel, and that room-temperature gel achieved maximal thermal effects at 5-cm below the skin.\textsuperscript{39}

Several studies\textsuperscript{21, 25, 40} have also examined the effects of using ice or heat as an additive treatment before ultrasound. The use of cold before a treatment may seem counterintuitive, but the theory behind it is that the application of cold before a treatment will increase the density of the tissue, therefore making ultrasound more effective because it is better transmitted through dense materials.\textsuperscript{19, 25} As stated previously, an advantage of using ultrasound is its ability to target treatment to areas of high-collagen content;\textsuperscript{2, 5, 8} the higher the collagen content, the higher the tissue density. Rimington et al\textsuperscript{25} were concerned about negating the effects of ultrasound by using ice beforehand, so they conducted a study investigating those effects. Their hypothesis was correct, and
they found that ultrasound preceded by 15 minutes of ice application did not increase
tissue temperature even to the original baseline level, whereas using ultrasound alone for
10 minutes increased tissue temperature 2°C on average.\textsuperscript{25} On the contrary to an ice
application, several authors\textsuperscript{21, 40} have hypothesized that the use of superficial heat (i.e. hot
packs) before ultrasound will increase effectiveness. Lehmann et al\textsuperscript{41} found no additive
effects on temperature when superficial heat was used before an ultrasound treatment.
This may be due to the fact that they only applied the hot pack for 8 minutes as opposed
to the standard 15 minute application. Therefore, Draper et al\textsuperscript{21} attempted to
reinvestigate the study using a 15 minute hot pack application and they found
contradicting results to those of Lehmann et al.\textsuperscript{41} They found that using superficial heat
before ultrasound increased overall temperature as compared to using ultrasound alone.
In addition, vigorous tissue heating (>4°C rise in tissue temperature) was reached 2-3
minutes sooner than using ultrasound alone.\textsuperscript{21} As a follow-up to that study, Holcomb et
al\textsuperscript{40} assessed whether or not using a heat pack before 1-MHz ultrasound will affect the
amount of temperature rise and decline at 3.75 cm below the surface. The depth of 3.75
cm below the surface was chosen because it is the mid-point of the depth of penetration
range for 1-MHz ultrasound, which has been reported to be 2.5-5 cm below the surface.\textsuperscript{18}
Their results showed an increase in temperature rise and also an increase in duration of
temperature elevation, which support the findings of Draper et al.\textsuperscript{21} It should be noted,
however, that there was no temperature increase at 3.75 cm below the surface with
superficial heat and that it was effective only as a type of insulation for the deeper target
tissue during the follow-up ultrasound treatment.\textsuperscript{40} As a result of these studies, it should
be noted that using ice before ultrasound will negate its effects, while using superficial
heat for 15 minutes before ultrasound will increase the overall rate of tissue temperature elevation, as well as maintain those increased temperatures for longer.

Another way to increase the efficacy of the ultrasound treatment is to take advantage of the “stretching window.” As previously stated, a physiological effect of deep heat is the increase of collagen extensibility. This extensibility allows the tissue to become more yielding and less resistant to stretch, therefore increasing the amount of motion in that area. However, as the tissue cools, the tissue becomes less pliable and begins to revert back to its original extensibility, becoming taut and fairly rigid. Research has shown that the use of ultrasound before stretching will greatly enhance its effects. Draper et al and Rose et al both investigated the effects of residual cooling after ultrasound on the triceps surae muscle group and found that the effects of “vigorous heating” only lasted 3.3 minutes after the treatment. This short time after the treatment where temperature elevation remains above 3°C is termed the “stretching window.” Draper et al also found that if the overall temperature increase was less than 5°C, the stretching window would last less than 2 minutes. It is important to point out, however, that their study was based off of a 3-MHz treatment. Rose et al conducted a similar study using a frequency of 1-MHz and concluded that muscle temperature increases above 3°C (which lasted about 2.5 minutes) followed by stretching produced a longer “stretching window,” therefore, an increase in tendon extensibility is more apt to occur. In 1998, Draper et al did a follow-up study and examined range of motion increases with respect to dorsiflexion to see if heating before stretching was more beneficial than stretching alone. They determined that the use of ultrasound for 7 minutes before stretching increased immediate range of motion more than just stretching.
alone, if the increase in tissue temperature increased more than 3°C. 32 If the overall goal of this modality is to increase range of motion, the clinician should make it a point to begin stretching the patient during the last minute of ultrasound and continue to do so immediately after the treatment because stretching anytime after this would not take advantage of the increased tissue extensibility.

Summary

Ultrasound is a deep heating modality that uses mechanical vibrations to increase tissue temperature in areas of high collagen. By adjusting the frequency and intensity, clinicians are able to vary the depth of treatment as well as the temperature increase to achieve a specific therapeutic effect in tissue. The BNR should not exceed 8:1 on a machine as it has a higher potential of burning patients. Because of the differences in BNR, it is important to keep the soundhead moving throughout the entire treatment time and the ERA of the machine should be known to ensure the clinician is hitting the target tissue and therapeutic goals are reached throughout the treatment area. It is important for clinicians to be familiar with ultrasound application to be able to maximize the benefits of this modality, such as using the right coupling medium, ensuring that the “stretching window” be utilized if needed, and being familiar with the machines’ BNR and ERA. In conclusion, it is important to pay attention to the correct application of ultrasound by being aware of the size of the treatment area, the desired depth of treatment, the amount of temperature increase in accordance to therapeutic goals and the type of ultrasound machine being used.
CHAPTER 3

METHODOLOGY

Design

This study was a 3 x 3 repeated measures design with the following independent variables: transducer speed (2 cm/s, 4 cm/s, and 6 cm/s) and location of treatment (center, periphery of ERA, or periphery of treatment site). The dependent variable was change in intramuscular tissue temperature.

Description of Subjects

Twelve healthy subjects (age = 24.25 ± 2.86; height = 171.29 ± 7.42 cm; weight = 81.46 ± 19.34; skinfold thickness = 25.08 ± 2.61 mm) were randomly assigned a treatment order based on transducer speed using a counterbalanced method. Subjects were excluded if they had a calf skinfold measurement outside of 20-30 mm range, impaired circulation, ischemia, areas with sensory deficits, deep vein thrombosis, an active infection over the treatment site, any type of known cancerous tumors, any known fractures or stress fractures over the treatment site, metal implants in the area, or if they are thought to be pregnant. All subjects signed an IRB approved consent form prior to exclusion and inclusion as subjects.

Instrumentation

The Omnisound 3000 (Accelerated Care Plus, Sparks, NV) was the ultrasound machine utilized for all of the treatments in this study. Holcomb et al\textsuperscript{9} found the
Omnisound 3000 to be more effective in raising intramuscular temperatures in tissues compared to a similar manufactured ultrasound unit. Omnisound is also the only manufacturer that performs ERA and BNR scans on each transducer. \(^3,^{10}\) Johns et al\(^{11}\) also found that Omnisound was the only manufacturer that did not show a significant difference between the reported and measured ERA values as compared with 5 other manufacturers. Room temperature ultrasound gel (Aquasonic Clear, Fairfield, NY) was used as the coupling medium. Intramuscular tissue temperature was measured by an IT Series Flexible Thermocouple Probe (Physitemp, Clifton, NJ) and the data were collected using the Iso-Thermex (Columbus Instruments, Columbus, OH) thermocouple thermometer. Prior to each data collection, the thermocouples were placed in a steam autoclave (Ritter M9 Series, Versailles, Ohio) and were sterilized for 5 minutes at 132º C under a 27.1 psi sterilization program with a 30 minute dry time.

Determining the Effective Radiating Area

Instead of using a watt meter and hydrophone to measure the ERA directly, we determined the ERA by finding the difference between the area of the transducer head, and the area of the crystal. When we contacted the manufacturer of the ultrasound unit, they stated that the ERA was 4.9 ± 0.2cm\(^2\) with a 5.0cm\(^2\) crystal (the size of the crystal was listed on the machine). To be safe, we decided to use 4.7cm\(^2\) as the ERA going off of the assumption that the temperature differences between there and the center of the treatment site would be at a minimum.

We determined the radius of the transducer head by measuring the diameter of the soundhead and dividing it by 2. We then determined the radius of the ERA by taking the area of 4.7cm\(^2\) and plugged it in to the formula \(A = \pi r^2\), which gave us a radius of
1.22cm. By subtracting 1.22cm from the radius of the soundhead, 1.8cm, we were able to indirectly calculate the difference between the two radii (5.8mm). This enabled us to figure out the exact placement of the thermocouple at the edge of the ERA. Figures 1 and 2 provide a visual of these calculations.

Figure 1. Birds-eye view of treatment area and ERA

Figure 2. Difference between radii of transducer head and ERA
Protocol

Subjects reported to the Athletic Training Research Laboratory to receive the ultrasound treatments. Skinfold thickness was measured with calipers at the thickest portion of the calf to make certain they were able to be included in the study. To ensure a homogeneous sample, subjects selected had to have between 10-15 mm of adipose and skin thickness (a skinfold measurement of 20-30 mm). Ambient temperature was recorded and monitored throughout each treatment session to ensure stability. The treatment area was the center of the triceps surae of the right limb, and all procedures and treatments were completed in one laboratory session lasting approximately 2 hours.

Subjects wore shorts and were positioned prone on a padded treatment table for the length of the treatment. The treatment area was the posterior aspect of the thickest portion of the right triceps surae (defined as the location with the greatest distance measured from the tibia to the posterior calf). An oval template approximately 7.4 cm in length and 3.7 cm in width (the shape of two ultrasound heads placed side by side) enclosed this area (Fig 3). After specifying the treatment area, we needed to determine the placement of each thermocouple. A second transparent template was put directly over the treatment template that contained small holes for marking where the 3 insertion points were going to be located (Fig 4). This template allowed us to keep the distance between the insertion points the same for each subject. The sites were determined by using the formula $A = \pi r^2$ where the area of the ERA was given by the manufacturers, therefore allowing us to calculate the radius. In addition, the subjects’ right tibia was palpated to ensure the needles did not hit bone prior to implantation.
An area 20 cm in diameter of the thickest portion of the posterior aspect of the right calf was shaved and cleansed with a Betadine swab in preparation for insertion of the thermocouples. Asceptic techniques were used while inserting and removing thermocouples to ensure subject safety. To ensure the thermocouples were working, they were first connected to the IsoThermex, which collected temperature data by converting the microvolts into a digital signal. The thermocouples were marked 2.5 cm from the tip and then placed in 21-gauge needles that allowed us to implant them. Using a level, the first needle was inserted directly into the posterior calf to a depth of 2.5 cm below the skin surface underneath the edge of the ERA. According to Draper et al\textsuperscript{18}, a frequency of 1-MHz reaches between 2.5-5 cm into the tissue, therefore, a depth of 2.5 cm was chosen as it is within the depth of penetration range for 1-MHz ultrasound.\textsuperscript{16} Once the desired depth was reached, the needle was removed while the thermocouple remained in the muscle and temperature readings were re-checked to ensure it was working. The second thermocouple was inserted at the same depth under the center of the treatment site on the right side of the first thermocouple. The third thermocouple was inserted at the same
depth under the edge of the treatment site to the right side of the second thermocouple (Fig. 5).

![Figure 5. Thermocouple placements](image)

After thermocouple implantation and before the onset of treatment, the thermocouples and treatment template were secured onto the skin to limit any movement. The subjects were then given time to reach a baseline tissue temperature by resting in the laboratory. After maintaining a stable baseline temperature (defined as no change in tissue temperature greater than 0.1 °C in 1 minutes), subjects received three treatments in random order with the transducer head moving at: 1) 2 cm/s, 2) 4 cm/s, and 3) 6 cm/s. To maintain consistency in speed, a metronome was used to monitor the pace of longitudinal movement of the soundhead set at: 1) 33 bpm, 2) 65 bpm, and 3) 97 bpm respectively. An adequate amount of ultrasound gel (about 20 mL in volume) was used as a coupling medium to allow the ultrasound head to move smoothly across the area and to help prevent discomfort from friction and burning. The application parameters followed those done by previous researchers,\textsuperscript{6,16} and are listed in Table 1.
Table 1. Application Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Duty Cycle</td>
<td>Continuous (100%)</td>
</tr>
<tr>
<td>Frequency</td>
<td>1-MHz</td>
</tr>
<tr>
<td>Intensity</td>
<td>1.5 W/cm²</td>
</tr>
<tr>
<td>Sound Head Size</td>
<td>5 cm²</td>
</tr>
<tr>
<td>ERA</td>
<td>4.9 ± .2cm²</td>
</tr>
<tr>
<td>BNR</td>
<td>3.5:1</td>
</tr>
</tbody>
</table>

Between applications, subjects rested comfortably while tissue temperatures returned to baseline. Temperatures were recorded every 10 seconds during each 10 minute treatment. At the conclusion of data collection for the third ultrasound application, the thermocouples were removed, the subject’s right limb was cleansed with 70% isopropyl alcohol and a bandage was placed over the injection site. Subjects were given instructions on how to clean the area treated and how to spot the signs and symptoms of infection, should that occur.

Data Analysis

At the conclusion of data collection, change in intramuscular tissue temperature that occurred during the 10-minute treatment was assessed for each speed, at each location for all 12 subjects. A repeated measures factorial ANOVA was used to test for significant main effects and interaction. Pairwise comparisons were used for post hoc tests in the case of a significant main effect. The significance level was set a priori at $\alpha = .05$ for all statistical tests. All statistical tests were conducted using the Statistical Package for Social Sciences (SPSS version 16.0, Chicago, IL).
CHAPTER 4

RESULTS

The mean baseline tissue temperature across all subjects was 35.77°C ± .66°C. The statistical analysis revealed a significant main effect for treatment site location ($F_{2, 22} = 112.01, p < .001$). The main effect for speed was not significant ($F_{2, 22} = .061, p = .941$) and the speed by location interaction was not significant ($F_{3.2, 35.3} = .313, p = .828$). Figure 6 shows the mean temperature change at each velocity and Figure 7 shows the mean temperature change at each location. Descriptive statistics showing overall intramuscular temperature change at each location for each transducer velocity are presented in Table 2.

Figure 6. Mean temperature change at each velocity with standard error bars
Figure 7. Mean temperature change at each location with standard error bars

Table 2. Mean temperature increase (mean ± SD °C) by transducer velocity and location

<table>
<thead>
<tr>
<th></th>
<th>2 cm/s</th>
<th>4 cm/s</th>
<th>6 cm/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERA</td>
<td>1.85 ± .73</td>
<td>1.87 ± .56</td>
<td>1.94 ± .91</td>
</tr>
<tr>
<td>Center</td>
<td>4.47 ± .97</td>
<td>4.33 ± .80</td>
<td>4.33 ± 1.18</td>
</tr>
<tr>
<td>Periphery</td>
<td>0.75 ± .45</td>
<td>0.71 ± .44</td>
<td>0.70 ± .43</td>
</tr>
</tbody>
</table>

Bonferroni post hoc tests were used to examine the nature of the significant main effect. The results revealed a significant difference in change in intramuscular tissue temperature between the ERA and the center (p < .001), the ERA and periphery of the treatment area (p < .001), and the center and periphery of the treatment area (p < .001). Figure 6 shows the average temperature change among speeds at the various locations.
With the data collapsed across all speeds, mean temperature increase at the edge of the ERA was 1.89 ± .17°C, the center of the treatment site increased 4.38 ± .08°C and the periphery of the treatment site increased 0.72 ± .03°C. Figure 7 shows the average change in temperature across the 10-minute treatment among the various locations.

Figure 8. Mean temperature change among speeds

Figure 9. Mean temperature change across time with standard error bars
CHAPTER 5

DISCUSSION

The purpose of this study was twofold: 1) to determine whether ultrasound transducer head velocity had an effect on overall tissue temperature change, and 2) to determine whether there was a significant difference in temperature rise between the center, the edge of the ERA, and the edge of the treatment area. Generally, the goal of therapeutic ultrasound is to increase tissue temperature to obtain a specific physiological goal. However, failure to achieve these temperature increases will likely render the treatment useless, but more importantly, delay the healing process. The findings of this study should allow clinicians to maximize the efficacy of their ultrasound treatments, thereby providing better overall patient care.

Our data revealed that transducer head velocity did not alter the heating effects during an ultrasound treatment. The speeds examined in this study were 2, 4, and 6 cm/s. The average amount of temperature rise at the center of the treatment area were as follows: at 2 cm/s the temperature rose 4.47°C ± 0.97°C, at 4 cm/s the temperature rose 4.33°C ± 0.79°C, and at 6 cm/s the temperature rose 4.33°C ± 1.17°C. The differences in tissue temperature increases among the speeds were not large enough to report a significant difference. Our average temperature increases were greater than the results of similar studies using the Omnisound 3000 unit where the average temperature increases ranged from 2.6-3.9°C. Previous authors have suggested using a speed of 4
cm/s because moving the soundhead too slowly may burn the patient. However, those authors also suggested that moving it too rapidly might cause the clinician to slip into treating too large an area. As the results show, as long as the intensity is set to patient tolerance and the treatment area is delineated, any of the three speeds tested are effective.

Even though transducer speed did not prove to be statistically different, there was an observed difference in temperature rise at the various locations within the treatment area. On average across all speeds, the center of the treatment site increased 4.39°C, the edge of the ERA increased 1.88°C, and the periphery increased 0.73°C. According to the findings of Draper et al, even though the center of the treatment site saw a greater increase than what was expected, the thermocouples at the ERA and the periphery did not reach the desired therapeutic goal of increasing tissue extensibility as temperatures did not increase 3-4°C. More specifically, tissue temperatures should rise about 3.3°C in 10 minutes with the parameters used in our study. These marked differences among the three locations may be due to the higher number of strokes across the mid-point of the treatment site versus the two peripheral thermocouples, therefore receiving twice as much ultrasonic energy in the center as compared to the other thermocouples. The temperature differences among the locations support the assumption that uniform heating does not occur within a treatment site regardless of the treatment area being only 2 times the size of the soundhead.

The results of this study support the findings of Weaver et al and Miller et al. Weaver et al reported similar increases in intramuscular tissue temperature regardless of ultrasound transducer head speed and their statistical analysis showed no significant difference among the speeds. The velocities they examined were 2-3, 4-5, and 7-8 cm/s.
which varied slightly from the velocities used in our study. Miller et al\textsuperscript{14} reported a significant difference in intramuscular tissue temperature rise between the mid-point and the periphery of the treatment area. Our results support those of Miller et al\textsuperscript{14} despite our observed differences in the amount of temperature rise in our study when comparing the center and the periphery of the treatment site (their temperatures increased approximately 2.62°C at the center and 1.58°C at the periphery, while we had an increase of 4.38°C at the center and 0.72°C at the periphery). Miller et al\textsuperscript{14} did not take temperature measurements at the edge of the ERA.

The methods utilized in this study were based off of those done by previous researchers.\textsuperscript{3, 5, 6, 12, 14, 16, 21, 25, 27, 35, 40} Due to its shape and the limited amount of overlying adipose, the calf is most often used as the treatment site in studies involving ultrasound.\textsuperscript{3, 5, 6, 12, 16, 21, 25, 35, 40} Also, the application parameters used in this study mimic those that were used in other studies,\textsuperscript{12, 14, 16, 25, 27} and were chosen as they were found to achieve the desired vigorous heating.\textsuperscript{18} Lastly, the Omnisound 3000 was chosen as it has been shown to be the superior unit as compared to similarly-manufactured ultrasound units.\textsuperscript{9} One significant difference between our methods and the methods used in previous studies, however, was the method of thermocouple implantation. To date, no known studies on ultrasound have utilized a direct insertion of the thermocouples into the treatment site. Instead, if the treatment site was the posterior calf, then the thermocouples were inserted horizontally into the medial aspect of that calf, therefore, increasing the probability of error due to its convex shape. Most researchers used a T-shaped ruler and a level as a guide for the insertion into the medial calf. In our study, we marked the thermocouples 2.5 cm from the tip, inserted them directly into the treatment site and
taped them down with a thin piece of porous tape. This method proved to be successful as there were no incidences of the thermocouples being shifted, removed or destroyed at any time during the treatments.

The results of this study support the assumption that uniform heating does not occur throughout a treatment site during the application of therapeutic ultrasound. This may be due to the quality of the crystal within the ultrasound head or the BNR of the ultrasound beam. Although past literature recommend treating an area that is 2-3 times the size of the soundhead, $^9$ or 2-3 times the ERA,$^4,18$ it may be more beneficial to treat a smaller area to maximize the effects of the modality. The template used in our study was the circumference of two soundheads placed side by side, which was found to consist of approximately three ERA. Therefore, utilizing a treatment area that is 2 times the size of the ERA (approximately the circumference of 1½ soundheads placed side by side) instead of 2 times the size of the soundhead will presumably be more beneficial due to the smaller treatment site. This is an area in which further research is necessary.

The main challenge that was encountered during the design of our study was that the exact shape and circumference of the ERA within the transducer head was originally unknown. In our study, the ERA of the transducer head was calculated using the difference between the radius of the transducer head and the radius of the ERA. The radius of the transducer head was measured directly, while the radius of the ERA had to be calculated using the formula $A = \pi r^2$, with the area of the ERA given by the manufacturer. Therefore, in order to maintain a treatment size that is no more than 2 times the size of the ERA, clinicians would have to either indirectly calculate the ERA themselves using the same methods as was used in this study, or use a watt meter and
hydrophone to measure it directly after it has been calibrated. Another assumption that was made was that the shape of the ERA was a circle. There has been no published literature that stated otherwise, therefore, we followed that assumption.

Recommendations for Clinicians

One strategy to decrease the amount of variability in heating throughout a treatment site is to purchase a high-quality ultrasound unit. Clinicians should ensure that the ERA covers as much of the area of the transducer head as possible to heat a larger amount of tissue, therefore making the treatment more efficient. Also, the clinician can ensure that the distribution of energy within the ultrasound beam is as uniform as possible by purchasing a machine with a low BNR. Although this issue was not specifically addressed in this study, it is still useful information for clinicians looking to purchase a machine.

Conclusion

If the goal of an ultrasound treatment is to achieve vigorous heating to increase tissue extensibility, then it is important that target tissue temperature is elevated by 3-4°C. As was shown, the speed at which ultrasound is applied has no effect on temperature rise, however, the size of the treatment area needs to be taken into account as uniform heating does not occur. Care should be taken to center the target tissue in the overall area that is treated so that significant heating in the target tissue is ensured. This will maximize the efficiency of this widely-used modality. In clinical practice, therapeutic ultrasound can be a very useful tool for clinicians in the rehabilitation of injury, if used correctly.
BIBLIOGRAPHY


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