

TISSUE TEMPERATURE INCREASE USING IMMERSION THERAPEUTIC
ULTRASOUND AT 3MHZ, 10 MINUTES, 1.5CM DEPTH, WITH VARYING INTENSITIES
OF 1.0W/CM², AND 1.5W/CM²

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TISSUE TEMPERATURE INCREASE USING IMMERSION
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ABSTRACT

The purpose of this study was to examine the thermal effects of both $1.0\text{W}/\text{cm}^2$ and $1.5\text{W}/\text{cm}^2$ at 3MHz with continuous US while the triceps-surae is immersed in 37°C water. Intramuscular tissue temperature increases observed through the thermocouples at $1.5\text{W}/\text{cm}^2$ was compared to $1.0\text{W}/\text{cm}^2$. The study is needed to determine which intensity was most efficient at increasing intramuscular tissue temperature in the triceps-surae at a 1.5cm depth. Twenty college students, 10-males and 10-females ($M=23.45 \pm 1.986$ -years), participated in 2 sessions. A thermocouple measuring intramuscular temperature was inserted into the gastrocnemius muscle. There were no significant differences in intramuscular temperature increases at 0-minutes ($M=0.1320$, $SE=0.5617$), 5-minutes ($M=-0.3570$, $SE=0.5617$), and 10-minutes ($M= -0.6885$, $SE=0.569$). This study indicated no significant difference between intensities $1.0\text{W}/\text{cm}^2$ and $1.5\text{W}/\text{cm}^2$ throughout a 10-minute treatment. Clinically selecting appropriate parameters should be done to best treat patients. This study provides evidence that increasing intensity does not always increase tissue temperature.

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CHAPTER 1. INTRODUCTION

Therapeutic ultrasound (US) is a widely used modality in the sports medicine field for treating orthopedic injuries.¹ Various orthopedic injuries benefit from therapeutic US. For example, soft tissue injuries, musculoskeletal pain, tenosynovitis, and bursitis.² Indications for US include: increased blood flow, increased tissue extensibility, calcium deposit elimination, plantar wart treatment, decreased joint stiffness, reduced muscle spasms, increased tissue repair, wound healing, edema reduction, pain reduction, and scar tissue treatment.²⁻⁵ The sports medicine field commonly performs therapeutic US because of the aforementioned indications.

In addition, thermal effects of therapeutic US are commonly desired for athletic injuries. Vigorously heating injured intramuscular tissue with US increases tissue extensibility of collagen fibers, resulting in increased range of motion.⁴ Therapeutic US also increases metabolic rate by 13% for each 1°C intramuscular increase.⁶ Both 1 MHz and 3 MHz US frequencies produce significant blood flow increases, resulting from thermal effects.^{3,7} Conversely, excessive heating can damage tissue. It is reported in the literature that an increase of 8°C from the baseline intramuscular tissue temperature, or an overall increase above 45°C, can potentially damage tissue.^{8,9}

The most effective and common form of US is the direct method.^{1,10,11} The direct method is when the transducer remains in full contact with the skin, with only a thin layer from a coupling medium between the transducer and the skin. The gold standard of coupling mediums is US gel.¹² Ultrasound gel provides significant intramuscular temperature increases and is the most common US application.¹² While the direct method is effective, it is not always applicable in smaller or bony areas of the body.¹¹

The indirect method of US is preferred when full contact with the transducer and skin cannot be made. The indirect method allows for the transducer to remain in contact with the skin using a coupling medium, such as water or gel pad. The indirect coupling mediums make full contact with the small or bony area, and create an area for the transducer to evenly transmit the US. The most cost efficient and significantly relevant coupling medium is tap water.¹³ When using water with the indirect method, or water immersion US, the transducer should remain consistently 1cm away from the skin as suggested by the athletic training textbooks.^{1, 10} The 1cm distance from the skin however, does cause impedance.¹⁴ The impedance reduces the intensity of the treatment and the amount of US delivered to the underlying muscle.¹⁴

The intensity, or the rate of energy transmitted into the tissue, is an important parameter to consider, especially with the indirect method.¹⁰ Athletic training textbooks suggest that when using the indirect method, the intensity should be increased by 50% greater than the intensity used with the direct method.¹ One athletic training textbook recommends a 50% increase of intensity for water immersion US because the separation of the transducer and the skin can allow for a portion of the US waves to disperse in the water.^{1, 14} This athletic training textbook's recommendation for the 50% increase is based upon an unpublished pilot study referenced in the discussion section of a research article by Draper et al.¹⁴ There is no other research supporting or refuting this claim.

Statement of the Problem

Draper and Prentice¹ report that when using tap water as a coupling medium for the indirect method, the intensity should be increased 50% greater than the intensity used with the direct method. Draper and Prentice¹ based the 50% increase on an unpublished pilot study conducted by Draper.¹⁴ Since there has been no subsequent research supporting or refuting this

claim, the importance of this research was to examine the intensity for water immersion therapeutic US and determine whether or not this claim is clinically applicable.

Purpose of Study

The purpose of this study was to examine the thermal effects of both 1.0 watts per centimeter squared (W/cm^2) and 1.5 W/cm^2 at a frequency of 3 megahertz (MHz) with continuous US while the triceps surae was immersed in 37°C water. Any intramuscular tissue temperature increases observed through the thermocouples at 1.5 W/cm^2 were compared to the control group of 1.0 W/cm^2 . The study was needed to determine which intensity would be most efficient at increasing intramuscular tissue temperature in the triceps surae at a depth of 1.5 cm.

Research Questions

The following research questions guided this study:

1. What is the overall tissue temperature increase with the parameters of 3 MHz, continuous US, 1.5 cm depth, treatment time of 10 minutes, 37°C water, at the intensity of 1.0 W/cm^2 , using the Dynatron Solaris Therapeutic Ultrasound Machine?
2. What is the overall tissue temperature increase with the parameters of 3 MHz, continuous US, 1.5 cm depth, treatment time of 10 minutes, 37°C water, at the intensity of 1.5 W/cm^2 using the Dynatron Solaris Therapeutic Ultrasound Machine?
3. Is there a statistical difference in the overall tissue temperature increase with the parameters of 3 MHz, continuous US, 1.5 cm depth, a treatment time of 10 minutes, with 37°C water, with the intensities of 1.0 W/cm^2 and 1.5 W/cm^2 , using the Dynatron Solaris Therapeutic Ultrasound Machine?

Definition of Terms

Frequency – oscillations a molecule experiences from sound waves of US in 1 second; expressed in megahertz(MHz).¹¹

Megahertz (MHz) – 1 million cycles per second or 1 million hertz.¹¹

Ultrasound – high frequency, acoustic vibrations, capable of producing both thermal and non-thermal physiological effects.¹⁰

Intensity – the strength of an US beam, determining the rate energy is delivered per unit area; expressed in watts per centimeter squared (W/cm^2).¹¹

Duration – amount of time the US current is flowing.¹⁰

Effective Radiating Area (ERA) – total surface area that the soundhead is able to efficiently transmit sound waves from the crystal to the tissue.¹⁰

Coupling medium – a facilitating substance that transmits US energy by decreasing impedance at the air-skin interface.¹⁰

Calibration – accuracy of the instrument, frequently by measurement of its variation from the factory standard, and to ascertain necessary correction factors.¹⁵

Continuous duty cycle – the US intensity remains constant, or continuous throughout the treatment, and there is 100% energy produced all of the time.¹⁰

Transducer – also commonly known as the soundhead on the US machine, or the applicator.¹⁰

Beam non-uniformity ratio (BNR) –the ratio between the highest intensity of an ultrasonic beam and the recorded intensity on the machine.¹⁰

Thermal – used when the desired outcome is tissue temperature increases.¹⁰

Non-Thermal – mechanical effects of US occur with pulsed output at standard treatment intensities, or with continuous output at lower level intensities. Non-Thermal US is indicated when a temperature increase is not desired.¹⁰

Therapeutic – having healing properties.¹⁰

Direct Coupling Mediums – direct application of US involving actual contact between the applicator and the skin, with a thin film of coupling medium between.¹

Indirect Coupling Mediums – application of US where the transducer head does not have actual contact with the skin, due to the coupling medium.¹

Importance of the Study

There is currently a lack of research on water immersion US. This is a method used clinically with little evidence supporting the parameters. The only supporting evidence was based upon a 1993 unpublished pilot study. The clinical parameters for the intensity of water immersion US are based the unpublished pilot study, which only had 3 subjects.¹⁴ Since the pilot study, no other literature has been published supporting or refuting the pilot study.¹⁴ Studying the effects of intensity on water immersion US will enable clinicians to better treat their patients.

Limitations

- The only machine that was used is a Dynatron 708 Series.
- Only uninjured subjects were used.
- The temperature of the water was $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ at the beginning of the treatment, but may have decreased throughout the treatment.
- The homemade template was used to ensure the recommended 1cm distance was kept between the skin and the transducer head. While clinicians try to keep a 1cm distance between the transducer head and the skin, they do not have a template.
- The bubbles were unable to be wiped away from the skin and transducer as recommended to help decrease impedance due to lack of space between the template and the transducer. The treatment would have been interrupted if the bubbles were wiped away.

Delimitations

- The subjects had neither vascular nor neurological conditions.
- The subjects did not have lower extremity surgery or injury within the last 6 months.
- The adipose tissue of the triceps surae was measured using the diagnostic US and subjects did not have more than 1.0 cm in adipose tissue.
- The subjects were both male and female with the age range of 18-30 years old.
- A 10-minute treatment time was used with the following parameters: 3 MHz frequency; 1.0 W/cm² intensity; continuous mode; the treatment area was 2-3 times the ERA; a depth of 1.5 cm; a tub of warm water as the coupling medium.
- A 10-minute treatment time was used with the following parameters: 3 MHz frequency; 2.0 W/cm² intensity; continuous mode; the treatment area was 2-3 times the ERA; a depth of 1.5 cm; a tub of warm water as the coupling medium.
- The temperature of the tub of water ranged from 37°C ±2°C.

CHAPTER 2. REVIEW OF LITERATURE

The purpose of this study was to examine the thermal effects of both 1.0 W/cm² and 1.5 W/cm² at a frequency of 3 MHz with continuous US while the triceps surae is immersed in 37°C water. Any intramuscular tissue temperature increases observed through the thermocouples at 1.5 W/cm² was compared to the control group of 1.0 W/cm². The study is needed to determine which intensity was most efficient at increasing intramuscular tissue temperature in the triceps surae at a depth of 1.5 cm.

Researching the intramuscular tissue temperature at the intensities of, 1.0 W/cm² and 1.5 W/cm² provides clinicians with a more comprehensive understanding of parameters when performing water immersion therapeutic US. The organization of this literature review is as follows: introduction to US, thermal effects, mechanical effects, indications and contraindications, parameters, machine variability, coupling medium, direct method, indirect method, and summary.

Introduction to Ultrasound

Since 1955, US has been frequently used to reduce pain, aid joint dysfunction, treat soft tissue injuries, accelerate wound healing and reduce edema.^{2, 16} Therapeutic US can penetrate through layers of skin and adipose tissue, and effectively treat the underlying muscle.¹⁰ A 2-3 centimeter ceramic crystal, made of lead zirconate or titanate, is used within the transducer of US machines.¹ The crystal is piezoelectric, so when introduced to an alternating current, it expands and contracts.^{1, 10} Expanding and contracting at the rate of the alternating current causes the crystal to produce acoustic energy.¹ The acoustic energy, or US waves, are then transmitted through the body.¹⁰ Tissues high in water content have a lower attenuation rate, and conversely, tissues that are protein-dense have a higher attenuation rate. Attenuation rate is the decrease in

energy caused by the US waves moving through various tissues.^{11, 1} Ultrasound effectively treats tissues deeper within the body, such as muscle, because the overlying structures are high in water content and absorb minimal US waves.¹

Thermal Effects

When used in the continuous mode, US produces a warming effect within the tissue below the transducer. Therapeutic US is capable of penetrating tissues up to 5 cm in depth.¹¹ Thermal effects are affected by tissue temperature increases, which in turn, are dependent on treatment goals. For example, a 1°C temperature increase mildly heats the tissue and increases metabolic rates, as well as reduces mild inflammation.¹⁰ In addition to the effects of mild heating, moderate heating increases of 2-3°C results in reduced pain, reduced chronic inflammation, reduced muscle spasms, as well as increased blood flow in the immediate area.^{2, 10, 17} An increase in blood flow is associated with a minimal increase in tissue temperature of 2°C or higher. Blood flow can be observed through the thermal effects of therapeutic US at a frequency of 1 MHz, but had insignificant raises with 3 MHz.⁷ According to Fabrizio et al.,⁷ an increase of blood flow could only occur with 1MHz. Fabrizio et al.⁷ used an Excell Ultra US machine with the parameter 1 MHz at an intensity of either 1.0 W/cm² or 1.5 W/cm² for 5, 10, or 15 minutes, trying to provide evidence that those parameters can produce significant increases in blood flow velocity due to the depth of penetration. However, Fabrizio et al.⁷ using bidirectional US Doppler to determine blood flow reported no significant increases with 3 MHz at the popliteal artery. This was theorized to be due to the lack of depth of penetration.⁷ Thus, the lack of penetration caused little to no thermal or non-thermal effects. Conversely, a study using a Doppler on a diagnostic US machine showed blood flow significantly increased within the brachial artery with the parameters of continuous US, 3 MHz at 1.0 W/cm² for 5 minutes.¹⁸

Vigorous heating of at least 4°C has the added benefits of increased range of motion through altered viscoelastic collagen, and inhibited sympathetic activity.^{2, 10, 17} Properly selecting parameters is important to achieving treatment outcomes. The viscoelastic properties of collagen when vigorously heated to a tissue temperature increase of 4°C or higher begin to modify the tissue into a more elastic state by inhibiting the natural sympathetic activity.¹⁷ Early research suggested that rather than a 4°C temperature increase from the individual's baseline, an overall absolute temperature of 45°C, for 5 minutes was the optimal temperature and time required to increase viscoelasticity. However, additional research supports that increasing tissue temperature above 45°C can damage the tissue.² The research is inconclusive in determining if a 4°C temperature increase from baseline, or an overall absolute temperature of 45°C is the threshold for tissue extensibility. Athletic Training textbooks advise to increase the temperature 4°C above the patient's baseline tissue temperature.^{9, 10} Indications of US as it relates to thermal tissue temperature increases are for the treatment of pain, reduction of sub-acute and chronic inflammation and muscle spasms, blood flow increases, metabolic increases along with the stretching of collagenous tissue within joints.^{2, 19, 7} When the thermal tissue temperature increases, metabolic rate increases by thirteen percent with each degree of a tissue temperature increase.^{20, 6}

Mechanical Effects

The mechanical effects of therapeutic US occur during both thermal and non-thermal treatments and include regenerate tissue, increase in capillary density, and promote bone healing.^{10, 1} Soft tissue is repaired with US through the stimulation of fibroblasts, which in turn expands protein synthesis.¹ These physiological effects are caused by cavitation. Cavitation is the formation of tiny gas-filled bubbles that expand and compress due to pressure changes caused by

the US treatment.¹¹ Cavitation initiated by US increases the movement of fluid in the area directly below the transducer, creating space as the gas-filled bubbles expand and contract.^{10, 1} The mechanical effect of cavitation can promote fluid movement throughout the area when the gas bubble expands and contracts, however if the intensity or frequency of the treatment is too high, unstable cavitation can occur.^{11, 10, 1} Unstable cavitation can result in the gas bubbles exploding which results in tissue damage.²¹ Adverse reactions from US treatments caused by unstable cavitation are localized cell damage and, in severe cases, blister formation over the anterior aspect of the tibia.²¹

An additional mechanical effect of therapeutic US is Microstreaming. Microstreaming originates from pressure formed by the US sound waves, and is the unidirectional movement of fluids flowing across boundaries of the cell membrane. This results in the displacement of ions and small molecules.¹⁰ Microstreaming caused by the increased viscous stresses alters the membrane of a cell, enhancing the permeability of a cell through its sodium and calcium ion channels.^{11, 1} The pressure of the sound waves displaces the ions and small molecules causing the unidirectional flow along the cell membrane.²² The increased permeability of the cell membrane promotes and accelerates the tissue healing process.¹¹ The velocity gradients within the initial oscillatory sound field is rectification, generating a mean flow.²³ A large velocity gradient is necessary for microstreaming because the bubbles in microstreaming are not large.²³ The mechanical pressure attributed by the US produces stresses, altering the cell's membrane and function. As long as the cell membrane is not damaged, the US will aid in accelerating the healing process.^{10, 22}

Indications and Contraindications

Preceding the use of therapeutic US, it is imperative to understand both the indications and the contraindications for using US. An indication is a situation which it is appropriate to perform a treatment or prescribe medication.²⁴ A contraindication is a known condition that prohibits a treatment or medicine from being administered because of a possible negative outcome.²⁴ The first theorized benefits for therapeutic US included increased range of motion,^{25,26} decreased pain,^{27,28,29} decreased edema, reduced muscle spasms, wound healing, assistance in stretching^{4,30} and increased blood flow.⁷ As the use of US grew, more research was conducted discovering additional benefits of therapeutic US. Benefits include treatment of trigger points, decreased joint stiffness, subacute and chronic inflammation reduced, and increased extensibility of collagen.²⁹

Before administering US, it is of the utmost importance to understand the contraindications for the modality. Ultrasound should not be used as a treatment to promote healing if there is a fracture.¹⁰ However, some textbooks recommend that if a fracture is suspected, US may serve as a diagnostic tool.¹⁰ Traditionally, tuning forks, which have also been used to diagnose fractures, vibrate at a speed of 16,000 times per second, while US has the capability to vibrate at 1,000,000 times per second. Some textbooks suggest US vibrations cause pain when used over a stress fracture almost immediately.¹⁰ Therefore, if a patient has a fracture, this would be a good indication to use US.¹⁰

High intensity continuous US is contraindicated in acute conditions, as the thermal effects will interfere with the vasoconstriction of the area, and could produce excess edema.^{10,9} Ultrasound should not be executed on individuals with vascular issues, such as thrombophlebitis, as the thermal effects could dislodge existing blood clots.¹⁰ Other contraindications include not

administering US over the eyes or reproductive organs. Females who are pregnant should not receive US over the abdominal region or low back.^{10,9} Ultrasound over the abdominal region and chest should be completed with 3MHz and caution should be used watching for any adverse reactions.⁹ Furthermore, US should not be performed over the spine, tumors, or growth plates.^{10,9}

Parameters

Each US machine varies in the depth of penetration and tissue temperature heating capabilities.³¹ When beginning an US treatment, selecting the appropriate parameters for the tissue and expected treatment outcomes are important. The US parameters are: frequency, intensity, duty cycle, effective radiating area, and duration of treatment.

Frequency

Frequency is the number of oscillations per second that a molecule experiences to create a sound wave based on how many times the crystal in the transducer expands and contracts.²⁴ Frequency is measured in hertz (Hz); 1MHz is equal to 1 million cycles per second. Determining the appropriate frequency is contingent on the location of the treatment area, the amount of muscle, and the surrounding structures. The half-value layer is defined as the depth that 50% of the US beam will be absorbed into the tissue. For instance, if the parameters for an US treatment were continuous US, 1MHz at $1.0\text{W}/\text{cm}^2$ at a depth of 2.3cm it loses half of the energy, resulting in the intensity of $0.5\text{W}/\text{cm}^2$.² If the depth is doubled to 4.6 cm, the resulting intensity would be $0.25\text{W}/\text{cm}^2$.

Common frequencies preset on most US machines are 1MHz and 3MHz. Deep tissue penetration is best achieved with 1MHz due to a low frequency and high wavelength. Conversely, a more superficial tissue penetration is achieved with 3MHz, which has a high-frequency and low wavelength.¹¹ According to Draper and Knight¹⁰, a 3MHz frequency is

mostly superficially absorbed and does not penetrate the tissue as deeply as the 1MHz because the wavelengths are not as large. Furthermore, a 3 MHz frequency penetrates up to 2.5cm in depth, treating injuries such as plantar fasciitis, Achilles tendinitis, and epicondylitis.¹⁰ Thus, treating a target tissue that is deeper than 2.5 cm requires a frequency of 1MHz. Draper²⁹ reports 3MHz is appropriate for lateral epicondylitis, patellar tendinitis, and other ligamentous injuries, because they reside more superficially within the body. Draper et al.³² examined trigger points found on the upper trapezius and used the Omnisound US machine with the parameters of 3MHz of continuous US for 5 minutes with an intensity of 1.4 W/cm². In addition, Draper et al.³² discovered trigger point stiffness relief could be accomplished with the aid of the US treatment. In this study, there were statistically significant increases in mobility post treatment when compared to pre-treatment.³²

Prior to 1995, there was little research on the depth of penetration of either 1MHz or 3MHz of continuous US. In 1995, Draper et al.² examined both 1MHz, as well as 3MHz with the Omnisound US Machine. Draper et al.² discovered that with an Omnisound US machine during a 10-minute continuous US treatment, at 3 MHz, 0.8cm and 1.6 cm depth, an intensity of 2.0 W/cm², that the intramuscular temperature increased rapidly causing the discontinuation of treatments around 3-6 minutes. Conversely, when the same parameters were used with the variation of 1 MHz, the depths of 2.5 cm and 5 cm reached an intramuscular temperature of 4°C after a 10-minute treatment. This study provides supporting evidence that a higher intensity with 3 MHz heats at a faster rate than 1MHz at the same intensity. Choosing the proper intensity and frequency are important. In addition, Draper²⁹ reported in 1996 the 10 most common mistakes made by clinicians with US. Determining the correct frequency ranked number 7 on Draper's list.²⁹ Draper²⁹ discussed the importance of selecting the frequency based upon the surrounding

structures. In 2004, Hayes et.al.¹⁷ studied both 1MHz and 3MHz with a Theratouch US machine. Hayes et al.¹⁷ using the parameters, continuous US at a depth of 2.5cm with an intensity of 1.5W/cm² wanted to determine the time required to reach vigorous heating (4°C) and an absolute temperature of 40°C during a 10 minute treatment. Inconsistent with the original theorization that 3MHz maximal depth of penetration was around 1.6cm, Hayes et.al.⁴ discovered that 3MHz penetrated to 2.5 cm, reaching a 4°C temperature increase around 3.4 minutes, and obtaining an overall temperature of 40°C at approximately 4 minutes. Conversely, 1MHz never reached vigorous heating or an overall temperature of 40°C during the 10 minute treatment. The frequency of 3MHz penetrated to a depth of 2.5 cm more effectively than 1MHz.¹⁷

Intensity

Intensity is the rate energy is transported to the tissue.¹⁰ Intensity is also expressed as spatial average intensity (SAI), and is measured in watts per centimeter squared (W/cm²).¹⁰ Spatial average intensity is the intensity that occurs over the central two thirds of the effective radiating area (ERA) of the transducer. Dependent upon the desired effect, intensity can be set to elicit thermal or non-thermal effects. Draper²⁹ suggests that when determining the proper intensity, clinicians should set the parameters with the desired tissue temperature increase in mind and adjust the intensity based upon the patient's tolerance to heat. Prior to an US treatment, the decision of a proper intensity setting should be chosen based upon the following factors: the overall tissue temperature increase, depth of the target tissue, nature of the injury, type of injured tissue, and the desired treatment size area.²

Duty Cycle

The duty cycle is the percentage of time US energy is delivered from the transducer.⁹ Calculating the duty cycle is accomplished by examining the ratio between the pulse duration

over the pulse period.¹⁰ The pulse duration is the time that the transducer is delivering the US waves.¹⁰ The pulse period is the combined time that the transducer is delivering US waves (on time), and not delivering US waves (off time).¹⁰ Duty cycle is categorized into 2 categories, continuous and pulsed.¹⁰ A continuous (100%) duty cycle, or continuous US, is used in the later stages of healing when thermal effects are desired.^{10,9} Continuous US can heat up to depths of 5 cm, dependent upon the frequency.⁹ Conversely, a pulsed duty cycle, or pulsed US, is indicated during the acute phase of healing when heat is contraindicated.⁹ Pulsed US does not create heat; because US is not continuously being emitted from the sound head. Pulsed US allows the heat to dissipate, and thus, does not produce a warming effect within the muscle.^{1,9} However, heat can be produced in the tissue using pulsed US, it is dependent on the duty cycle.⁹ Thus, if the duty cycle is closer to 100% there is a better chance there will be warming effects observed.⁹ Thermal effects produced by pulsed US also depend on the intensity, the higher the intensity the more thermal effects that will be produced.⁹ The lower the duty cycle percentage, such as 25%, the less thermal effects the patient receives, whereas a duty cycle of 80% will provide more thermal effects.⁹ Pulsed US is primarily used for its mechanical effects.⁹

Effective Radiating Area

The effective radiating area is the area within the transducer that produces the US energy from the crystal.¹ The ERA is smaller than the actual size of the transducer.^{10,1} When calculating the ERA, the crystal is scanned 5mm away from the radiating surface.¹⁰ Then all of the areas that produce greater than 5% of the maximal power output are recorded, determining the ERA.¹⁰ The highest amount of recorded energy comes from the center of the crystal and it dissipates as it reaches the periphery.⁹ The outermost area around the transducer plate does not produce any US energy.⁹ Miller et al.²⁷ noted statistical differences when the ERA was measured intramuscularly

while using the Omnisound machine. In this study, thermocouples were placed at the mid-point and periphery of the treatment area for 2 treatments.²⁷ The parameters for the first treatment were 10 of minutes continuous US with a frequency of 1MHz and an intensity of 1.5 W/cm².²⁷ The parameters for the second treatment were 10 of minutes continuous US with a frequency of 3MHz and an intensity of 1.0 W/ cm².²⁷ There was a minimum of 48 hours between the first and second treatments.²⁷ The results of the research showed significant temperature differences from the midpoints to the periphery of the treatment area.²⁷ The research is clinically relevant because, when applying US, the target tissue should be placed in the center of the treatment area for the maximal effect. Because of this dispersion of energy, educators recommend that the treatment area should be 2 to 3 times the size of the ERA.^{10, 1, 9}

Johns et al.³³ reported that a larger soundhead does not mean a larger ERA, nor are larger sound heads always beneficial. Johns et al.³³ compared the following US machines ERA: Chattanooga, Dynatron, Mettler, Omnisound, Rich-Mar, and XLTEK and recommended that clinicians remain consistent with the ERA and treatment size. Therefore, clinicians should consider the treatment values of each individual transducer regardless of the manufacturer. Ultrasound is an effective deep heating modality for smaller treatment areas, however it is not practical for larger areas because the ERA does not allow for the treatment of large areas all at the same time.⁹ Smaller soundheads create divergent US beams, which can cover a similar surface area as the larger soundheads.²⁷ Conversely, larger soundheads create collimated, or focused, beams that appear as columns and can produce hot spots that may injure the patient.⁹ Therefore an incorrect ERA can produce unwanted contraindications, which is a possibility for all, including new, machines. Furthermore, temperature goals will not be reached if too large of a treatment area is used, thus decreasing the effectiveness of the treatment.³³

Manufacturers report the ERA of the US machines. However, there has been evidence to contradict the reported ERAs. Johns et al.³³ researched new transducers and compared the factory reported ERA's to the actual recorded ERAs. Johns et al.'s³³ research suggested that the factory reported ERAs differ from actual ERAs recorded for the US machines.³³ Three companies out of 6 reported lower ERAs than what were actually measured, while 2 out of 6 companies reported higher ERAs than were actually measured.³³ The 6 companies that were researched were Chattanooga, Dynatron, Mettler, Omnisound, Rich-Mar, XL TEX.³³ Only the Omnisound company reported an accurate ERA of the transducer.³³ This is significance because if the ERA is not accurate, then the treatment that the patient receives is not beneficial. Indeed, under reporting an ERA can lead to tissue damage.³³ Also, if an ERA is higher than what is reported, a clinician could administer a treatment with the reported ERA and cause damage to the patient. An ERA higher than what is reported can cause damage because the clinician performing a treatment with a higher intensity, and a higher ERA could create hot spots. Conversely, over reporting an ERA can cause decreased therapeutic effects.³³

Duration of Treatment

The duration of treatment is an important factor in accomplishing treatment goals. The duration of treatment, or treatment time, is influenced by several factors: desired thermal effect, frequency, size of the area being treated, and intensity.^{10, 1, 2} When determining treatment time based upon frequency, the ratio is the greater the frequency, the shorter the time.^{10, 2} As comparable to frequency, when choosing an intensity, the ratio is the greater the intensity, the shorter the time.^{10, 2, 1}

The treatment size also determines a successful treatment time. The treatment size should be no greater than 2-3 times the ERA.^{10, 2, 1, 9, 29} If the treatment area is larger than the ERA, then

the treatment time should be increased accordingly.^{10,2} Lastly, the desired thermal effect should be factored in when selecting an appropriate treatment length.^{2,29} Heating the tissue too rapidly with a high intensity and frequency can be harmful to the patient.¹¹ If the patient notes an uncomfortable rise in intramuscular temperature during treatment, then the intensity should be reduced.¹ Along with the reduction of intensity, the time should be adjusted to a longer treatment time.¹ The rapid heating of the tissue could cause discomfort. However, by decreasing the intensity and increasing the time, the gradual warming could produce the same thermal effects without discomfort.¹ Chan et al.³⁴ examined the rate of temperature increase in the patellar tendon in response to therapeutic US with the Omnisound US machine and the parameters 3MHz of continuous US and an intensity of 1 W/cm² and reported tendon tissue temperature increased 3.45 times faster than muscle. Draper et al.², used the Omnisound US machine as well, examining temperature increases in muscle also using the same parameters of 3MHz of continuous US and an intensity of 1W/cm², providing supporting evidence that there was a difference in heating rates between muscle and tendons.² Understanding the rate of temperature increases in different tissue is important in providing quality care as a clinician.

In 1996, Draper²⁹ stated textbooks were unclear on the duration of a treatment, leading to treatments that were too short. Draper²⁹ reported that most clinicians suggest 5 to 10 minutes as an acceptable treatment time length. However Draper²⁹ noted that most clinicians do not inquire about the aforementioned factors that need to be assessed when determining the length of treatment. Thus, the determination of the duration of treatment requires that treatment goals and treatment parameters must be considered.²

Rates per minute of muscle heating using US outlined in the athletic training textbook by Draper and Knight¹⁰ (Appendix A) are used to determine the treatment time. Draper and

Knight's¹⁰ rates of muscle heating are based upon research by Draper et al.⁴ An intensity of 0.5 W/cm² and a frequency of 1 MHz will heat at a rate of 0.04°C per minute, while a frequency of 3 MHz will heat at a rate of 0.3°C per minute.¹⁰ An intensity of 1.0 W/cm² and a frequency of 1 MHz will heat at a rate of 0.2°C per minute, while a frequency of 3 MHz will heat at a rate of 0.6°C per minute.¹⁰ An intensity of 1.5 W/cm² and a frequency of 1 MHz will heat at a rate of 0.3°C per minute, while a frequency of 3 MHz will heat at a rate of 0.9°C per minute.¹⁰ Finally, an intensity of 2.0 W/cm² and a frequency of 1 MHz will heat at a rate of 0.4°C per minute, while a frequency of 3 MHz will heat at a rate of 1.4°C per minute.¹⁰ Thus, when selecting the duration of treatment, the rate of muscle heating per minute and the desired thermal effects are important to consider.

Machine Variability

While various US manufacturers claim that their machines will provide the identical treatment, the fact that they are different machines from different manufacturers can cause variability in the actual treatment. Artho et al.³⁵ examined the intensity outputs of 83 therapeutic US machines from 11 different manufacturers: Amrex, Bosch, Chattanooga, Dynatronics, Enraf-Nonius, Excel, Linquist, Mettler, Mid-Canada Medical, PTI, and Rich-Mar.³⁵ Thirty-two machines out of 83 reported numbers outside of the standard calibration requirements.³⁵ Standard calibration requirements set forth by the United States Department of Health, Education, and Welfare state that the intensity of a therapeutic US machine must be within $\pm 20\%$ of the desired outcome and the timer must be within $\pm 10\%$.³⁹ Fifteen out of 83 machines, or 18%, reported higher than the $\pm 20\%$ standard.³⁵ This variation from the standard outcome is significant due to the implications of everyday clinical use of therapeutic US. Machines recording variations greater than the $\pm 20\%$ standard could produce unsafe conditions for the patient.³⁵ Conversely, 14

out of 83 machines, or 17%, reported lower than the $\pm 20\%$ standard. The lower reported standard calls into question some machines' effectiveness.³⁵ Calibration of therapeutic US machines should be performed to ensure intensity outcomes are the same or within the $\pm 20\%$ standard, to certify proper treatment.³⁵ If a clinician sets the intensity to $1.0\text{W}/\text{cm}^2$ and the machine is out of the standard calibration, it can have 2 negative effects based upon whether it is above or below the standard. If the calibration is $+20\%$ of the calibration it could lead to tissue damage because the intensity would be too high. If the calibration is -20% of the calibration, the treatment could be ineffective, not producing the desired effect because of the lack of US intensity. Even within the $\pm 20\%$ standard there is a large margin for variability, causing a wide range of effects, dependent upon how close the variability is to the $\pm 20\%$ standard. In any case, proper calibration of a therapeutic US machine is important.

It also follows that variations between different therapeutic US machines should be considered during clinical use. There is a vast amount of research performed on the Omnisound manufacturer.^{2, 27, 28, 4, 30, 33, 35, 36, 34, 12, 37, 38, 39, 40} Other research performed on US manufactures is not as extensive compared to the Omnisound. Research performed on other US manufactures include: Dynatron,^{7, 31, 35, 39, 40,} Chattanooga,^{21, 33, 35, 13} Excel Ultra,^{7, 39} Sonicator,^{5, 35, 41} Mettler,^{33, 35} Rich-mar,^{33, 35} Theratouch,¹⁷ Pulson,¹⁹ Forte,³⁶ and XLTEK UL-5³³. Machine variability provides evidence that research presented on 1 machine may not directly compare to another machine. In fact, Omnisound 3000, Dynatron 950, and Excel Ultra III therapeutic US machines were compared with varying results.³⁹ An US treatment with the parameters 3MHz, $1.5\text{ W}/\text{cm}^2$, 10 minutes, continuous US was performed on 6 subjects with each of the machines.³⁹ The intramuscular temperature was taken with a thermocouple at a 1.6 cm depth.³⁹ The results exposed variations of intramuscular temperature between the 3 machines. The Omnisound 3000

treatment on average was discontinued around 6 minutes due to uncomfortable temperature increases with an average intramuscular temperature of 41°C.³⁹ In the 10 minute treatment, the Dynatron 950 and Excel Ultra III never reached an intramuscular temperature of 40°C.³⁹ This is significant because the amount of research that is based upon the Omnisound 3000 may not translate to the various other US machines. It is important to note that clinical parameters in the athletic training textbooks are based upon research performed on the Omnisound.^{1, 9, 10}

Furthermore, Gange et al.³¹ examined the thermal effects of the Dynatron Solaris machine at 3 MHz, 1.2 W/cm², continuous for 20 minutes, checking intramuscular tissue temperature with thermocouples at depths of 1.0 cm, 1.75 cm, and 2.5 cm.³¹ A 4°C tissue temperature increase was reached at the depths of 1.0 cm and 1.75 cm at 6 minutes and 10 minutes respectively. Data collection suggests that the Dynatron Solaris on average does not increase tissue temperature to 4°C at a depth of 2.5 cm within a 20 minute treatment.³¹ The significance of this research is that the current parameters for therapeutic US are not universal. The research also indicates possible improper use of US during clinical treatments. If a treatment is 5-7 minutes, with the goal of 4°C vigorous heating, the patient may not be receiving the desired effect.

Additionally, a study comparing the Omnisound 3000 and the Forte 400 was conducted to determine the variability in temperature increases.³⁶ The parameters for both machines were set to 3 MHz, 1.0 W/cm², continuous US.³⁶ The researchers looked at intramuscular tissue temperature at a depth of 1.2 cm.³⁶ The treatment was 10 minutes or until a temperature increase of 6°C was noted.³⁶ The Omnisound 3000 increased intramuscular tissue temperatures to 5.81 ±0.41°C, while the Forte 400 only increased 3.85 ±0.75°C.³⁶ Thus, therapeutic US machines have varying temperature increases. In addition, Gange et al.⁴² used similar parameters of 3

MHz, 1.0 W/cm^2 , continuous US at intramuscular tissue temperature depths of 1.0 cm, 1.75 cm, and 2.5 cm. They reported at the depth of 1.0 cm a temperature increase of $4.18 \pm 1.29^\circ\text{C}$ in 6 minutes with a rate of 0.70°C/min .⁴² At the depth of 1.75 cm the temperature increase was $4.18 \pm 2.01^\circ\text{C}$ in 11 minutes with a rate of 0.38°C/min .⁴² Conversely, at the depth of 2.5 cm the temperature had not increased to 4°C after 20 minutes. Consequently, machine variability is supported by comparing the Gange et al.⁴² and Holcomb et al.³⁶ studies.

Coupling Medium

The coupling medium enables the energy from the therapeutic US to be transmitted to the target tissue because therapeutic US is unable to be transmitted through air.^{10, 11} The energy from the US is attenuated and reflected away from the skin when there is no coupling medium.¹¹ The coupling medium serves as a lubricant for the transducer by decreasing air between the transducer and the skin, permitting the desired intensity to reach the target tissue.¹² The coupling medium is applied to the transducer surface, or the transducer is placed into the coupling medium prior to activating the power of the US machine.¹ If the transducer becomes in contact with air during treatment, or prior to treatment when the US beam is emitted, the piezoelectric crystal in the transducer can be damaged.¹ Damage to the piezoelectric crystal can cause over heating of the tissue, and injury to the patient.¹ The gold standard for coupling mediums in therapeutic US is US gel.¹ One of the only reported draw-backs to US gel is that if left on the transducer, the salt in the gel can damage the transducer over time.¹

While the gold standard is US gel, the literature supports several effective coupling mediums which include: US gel, degassed water, and gel pads.¹⁰ Further research suggests mineral oil, distilled water, water, and glycerine as well as other efficient possibilities.²⁹ Analgesic gels with a mixing ratio of 50/50 has been suggested to have additive advantages.¹⁰

Conversely, Draper²⁹ reports that the analgesic mixtures are only effective if the analgesic is a water based substance; otherwise they impede the US beam from transmitting properly through the tissue, decreasing the delivered intensity.

Similarly, water is also an effective coupling medium. However, it can create small bubbles on the transducer head, which must be quickly removed by the clinician as they occur.¹¹ In contrast, ultrasound gel and Aquaflex gel pads produce little to no air bubbles.¹ Klucinec et al.¹³ examined the effectiveness of 8 different coupling mediums on pig skin. Klucinec et al.¹³ used a Chattanooga US machine with the frequency of 3.3MHz for all trials, and examined the coupling medium for the following 5 intensities: 0.2, 0.5, 1.0, 1.5, and 2.0 W/cm². The coupling mediums used were: US gel, gel pad, US gel filled latex glove, tap water filled latex glove, degassed filled latex glove, tap water immersion bath, degassed water immersion bath, and US gel filled condom.¹³ Klucinec et al.¹³ reported the US gel and gel pad had statistically significant temperature increases throughout the various intensities. The water bath and degassed water showed tissue increases that were statistically indistinguishable, which is significant because it was reported in the athletic training textbooks that degassed water was the preferred form of water for the immersion technique.¹³ Additionally, this is significant because the tissue temperature increases were statistically equal between tap water and degassed water as a coupling medium, because tap water is more readily available and more cost efficient.

Direct Method

The application of therapeutic US is categorized into 2 categories: the direct method and the indirect method. The direct method, the most common and effective form of US application, is when a thin layer of US gel is acting as the coupling medium between the transducer and the skin.^{1, 10, 11} The direct method of US is appropriate when the treatment area allows for the entire

transducer to lie flat on the skin with an area of 2-3 times the ERA surrounding it.¹¹ This method is suitable for areas 2-3 times the ERA, because the transducer can move without losing full contact with the skin.¹¹ This is important because it limits the amount of air between the skin and the transducer.¹¹ Ultrasound gel is the most common coupling medium for this method and produces the most desirable thermal effects clinically.¹³ In addition, US gel produces the greatest intramuscular tissue temperature increases when the gel is at room temperature.²³ The direct method is generally used clinically, however it is not applicable in every situation.

Indirect Method

The indirect method is when there is a space between the transducer and the skin.¹⁰ The indication for the indirect method over the direct method is based upon the size and structures of the treatment area. If the treatment area is smaller than 2-3 times the size of the ERA, such as a hand, wrist, ankle, or foot, the indirect method is preferred.^{1, 11} In addition, the indirect method is appropriate if the treatment area has bony prominences, or does not allow for the transducer to remain flat over the treatment area.^{1, 11} The 2 main varieties of the indirect method are the gel pad technique and the immersion technique.¹⁰

The gel pad technique is the use of a gel filled item about the size of a hockey puck.¹² Research attests to the efficacy of the gel pads' thermal heating effects^{12, 13, 37} More specifically, Draper et al.¹² examined US gel as compared to a 2cm full-thickness and a 1cm half-thickness gel pad. They used the Omnisound with the parameters of 3MHz continuous US, an intensity of 1.0 W/cm² for 10 minutes.¹² The half-thickness gel pad increased tissue temperature 9.3°C, while the full-thickness increased tissue temperature 6.5°C.¹² While not as effective as the gold standard of US gel which increased the tissue temperature to 13.3°C, the gel pad was still effective.¹² Draper et al.¹² concluded that the half-thickness gel pad transmitted the US

effectively and could be beneficial in superficial areas such as the hand or ankle. This is because the gel pad acts as a large, flat platform for the transducer to sit on over a bony prominence or small area where the transducer would not normally be able to work efficiently.¹² A draw back to the gel pad is availability and cost effectiveness in the clinical setting. Although the gel pad may be used multiple times on the same patient, the gel pad manufacturers recommend that, in order to reduce cross-contamination, a gel pad should be used on only 1 person.⁴³ These manufacturers sell one gel pad for \$43.75, which works out to be 6 boxes with 6 per box at \$321.75.⁴³ Often extraneous expenses such as gel pads are not the economical option, even with the research supporting their efficacy.

Immersion US technique uses various aqueous solutions as the coupling medium. The following solutions may be used: tap water, degassed water, distilled water, mineral oil, and glycerine.²⁹ Mineral oil and glycerine are not common options as coupling mediums due to the fact that they produce surface heating.¹ The aforementioned research by Klucinec et al.¹³ noted that tap water was just as effective as degassed or distilled water.¹³ Originally it was theorized that degassed water should be used in order to reduce the number of air bubbles that accumulate on the transducer when submerged during the immersion technique.¹³ However, tap water was found to be just as effective, as long as the clinician quickly and effectively wiped away air bubbles as they were produced on the transducer.^{10,1,13} For this reason, tap water is the suggested coupling medium for using the immersion technique.¹⁰ When executing the immersion technique, the tap water should be placed in a plastic, ceramic, or rubber container.¹ A metal bin is contraindicated with immersion US, because the metal can reflect the US beams, causing an increased intensity that could be harmful to the patient.¹

In addition, the tap water should be at room temperature.¹¹ The previously mentioned study by Klucinec et al.¹³ determined the effectiveness of 8 different coupling mediums, including a basin of tap water at room temperature.¹³ Conversely, 2 current athletic training textbooks reported that the tap water should be warmed to 37°C (98.6°F); however, neither of the textbooks provided accompanying research to support the claim.^{1, 10} Furthermore, room temperature water is cooler than normal body temperature. When the body part is placed in the room temperature water, the body will naturally cool and the US will have to heat more since the tissue will be cooled.^{10, 14} Unfortunately, there is no research supporting or refuting either the room temperature or body temperature water. In vitro research performed on pig skin assessed a temperature increase of $2.82 \pm 0.02^\circ\text{C}$, however the tap water was at room temperature.¹³ Body temperature water does not cool the tissue as room temperature water. One of the problems with tap water at room temperature is that during the summer room temperature maybe much warmer than in the winter; it is much more difficult to control consistently for room temperature, unlike tap water which can be controlled with a water heater.

A distance of 1 cm between the skin and transducer is recommended for the immersion technique.¹⁴ The athletic training textbook by Draper and Prentice¹ suggests that the distance between the transducer and skin should be 1cm, referencing the athletic training textbook by McDiarmid et al.¹¹ McDiarmid et al.¹¹ which states “the transducer should be held 0.5 to 3.0cm from the body.” These 2 athletic training textbooks contradict one another without any research supporting either of the claims. The Draper and Knight¹⁰ textbook suggests the transducer should be 0.5 to 1.0cm away, again with no supporting evidence.

One centimeter of distance between the transducer and the skin can cause impedance in the water, reducing the intensity the patient receives.¹⁴ An original unpublished pilot study,

conducted by Draper, noted that the further the transducer was from the skin, the less the intramuscular temperature raised.¹⁴ This study had only 3 participants and was intended to create a baseline for the 1.0 cm distance for a future study that was never published. Draper and Prentice¹ reference the unpublished pilot study mentioned in the Draper¹⁴ research, stating; “In order to ensure adequate heating, the intensity should be increased, possibly as much as 50 percent.”¹ Upon further investigation of the research, no follow up research has been conducted confirming the efficacy of the 50% intensity increase. Unfortunately, this 22-year old unpublished pilot study has been the only source for the 50% intensity increase. Draper referenced this pilot study in his comparative study between gel and underwater US article.¹⁴ The article was then referenced by the Draper et al.¹ athletic training textbook. This unpublished pilot study reference in Draper et al.¹ is the source for the information cited by the academic literature for the subsequent 22 years.

Summary

Therapeutic US is a widely used modality for soft tissue injuries to elicit both thermal and non-thermal effects.³² Thermal effects of US include facilitating metabolic increases, decreasing inflammation, pain and muscle spasms, increasing blood flow, range of motion, and tissue extensibility.¹¹ Mechanical effects of therapeutic US include cavitation, microstreaming, promoting bone healing, and tissue regeneration^{10,1} Non-Thermal effects of therapeutic US occur with both high and low frequencies and intensities of US.¹¹ Thermal effects of US are more consistently shown with continuous US and higher frequencies and intensities within the pulsed US.¹⁰

Selecting the appropriate US parameters is important when providing proper clinical treatments.²⁹ Frequency is determined by the target depth of penetration; if the target treatment

area is at a depth of 2.5cm to 5cm, a frequency of 1 MHz is appropriate.⁹ Similarly if the treatment areas depth is 0.8 to 2.5 cm, then 3 MHz is the suitable frequency.⁹ When assessing the best fitting duration of treatment for a therapeutic US, frequency, intensity, size of treatment area, and desired thermal effect should be taken into consideration.² Appropriate duty cycles are dependent upon preferred thermal or non-thermal effects.¹⁰ A continuous duty cycle is indicated for thermal effects, while pulsed US is indicated for non-thermal effects.¹⁰ In addition, the size of the treatment area should be no larger than 2 to 3 times the ERA.¹ To determine intensity, desired thermal or non-thermal effect, frequency, and desired power output should all be taken into account.¹

Selecting the best suited coupling medium for the immersion US technique can enhance the energy delivered to the tissue.¹ For example, water is an efficient coupling medium when applying the immersion technique for the indirect method.⁹ The immersion technique requires body temperature water in a plastic bin with the transducer 1 cm away from the skin, and that any bubbles be wiped away.¹⁰ The frequency of immersion US is typically 3 MHz because the treatment areas are smaller and do not require penetration deeper than 2.5 cm.⁹ However, the lack of literature supporting the intensity of the immersion technique does not provided definite parameters surrounding intensity. In the athletic training textbook by Draper and Prentice,¹ the statement “the intensity should be increased, possibly as much as 50 percent,” is the only reference to increased intensity when using the immersion US technique. The parameter setting for intensity increase with immersion US was suggested by a single unpublished pilot study cited in a 1993 article.¹⁴ This article stated that the thermal effects of US vary with the space between the transducer and the skin; therefore the intensity should be increased.¹⁴ A close inspection of the literature reveals that, no further research has been reported supporting or refuting the 1993

claim. This method is currently being taught for clinical application. Presently, standard parameters for water immersion therapeutic US do not exist. Therefore, establishing a more conclusive intensity setting with the immersion technique will enable clinicians to provide better care for patients.

CHAPTER 3. METHODOLOGY

The purpose of this study was to examine the thermal effects of both 1.0 W/cm^2 and 1.5 W/cm^2 at a frequency of 3 MHz with continuous US while the triceps surae is immersed in 37°C water. Any intramuscular tissue temperature increases observed through the thermocouples at 1.5 W/cm^2 was compared to the control group of 1.0 W/cm^2 . The study is needed to determine which intensity will be most efficient at increasing intramuscular tissue temperature in the triceps surae at a depth of 1.5 cm. The following research questions guided this study: What is the overall tissue temperature increase with the parameters of 3MHz, continuous US, 1.5 cm depth, treatment time of 10 minutes, 37°C water, at the intensity of 1.0 W/cm^2 , using the Dynatron Solaris Therapeutic Ultrasound Machine? What is the overall tissue temperature increase with the parameters of 3MHz, continuous US, 1.5 cm depth, treatment time of 10 minutes, 37°C water, at the intensity of 1.5 W/cm^2 using the Dynatron Solaris Therapeutic Ultrasound Machine? Is there a statistical difference in the overall tissue temperature increase with the parameters of 3MHz, continuous US, 1.5 cm depth, a treatment time of 10 minutes, with 37°C water, with the intensities of 1.0 W/cm^2 and 1.5 W/cm^2 , using the Dynatron Solaris Therapeutic Ultrasound Machine? This chapter describes the experimental design, population of the study, data collection instrumentation, procedures, and data analysis.

Experimental Design

This study was a repeated measures design. Each subject received both interventions. The independent variable was intensity (1.0 W/cm^2 and 1.5 W/cm^2), and the dependent variable was gastrocnemius intramuscular temperature.

Population of the Study

A sample was obtained from the North Dakota State University student population. Twenty total subjects, 10 males and 10 females, were recruited between the ages of 18-30 years old. The subjects were recruited via the North Dakota State University email list serve. Subjects were excluded from the research if they have had any injuries to the left lower leg in the previous 6 months, or more than 1.0 cm of adipose tissue over the gastrocnemius muscle. Participants were also excluded if the diagnostic US showed any abnormalities to the left gastrocnemius, if there were any rashes or wounds over the treatment area, or if the subject was allergic to betadine or isopropyl alcohol. Lastly, participants were omitted if they had any of the following contraindications to therapeutic US in their left calf: decreased blood flow, decreased sensation, blood clots or tumors, infections, or fractures to bones in the lower left leg.

Instrumentation for Data Collection

To determine abnormalities and measure adipose thickness, the Terason t3200™ Diagnostic Ultrasound (MedCorp, LLC., Tampa, FL) was used. The 15L4 Linear transducer (4.0-15.0 MHz)(MedCorp LLC., Tampa, FL) was used to perform the diagnostic US, with the coupling medium of Aquasonic® 100 ultrasound gel (Parker Laboratories, Inc., Fairfield, NJ). The immersion therapeutic US treatment was administered with the Dynatron Solaris® 700 Series (ERA: 5cm², BNR 6:1; Dynatronics Corp., Salt Lake City, UT). Warm tap water from the faucet with the temperature of 37°C ±2°C was placed in the plastic bin (31.1 cm width x 47 cm depth x 48.9 cm height) (Wal-Mart Inc.). A handmade US template was used (Appendix B); this ensured proper ERA measurements was followed. The template was made of Styrofoam, and wrapped in Scotch electrical tape. The template had a cut out 2 times the ERA and was 1 cm thick to ensure the transducer remained 1cm away from the skin. The inside edge of the template

allowed for the transducer to rest inside of the space and not obstruct any of the US waves. The outer edge of the transducer rested on the inner edge of the template allowing for a distance of 1 cm between the skin and transducer (Appendix B). MetriCide® 28-Day High Level Disinfectant / Sterile solution (Cardinal Health) was used to sterilize the IT-21 one foot thermocouples (Physitemp Instruments, Clifton, NJ) at least 12 hours prior to treatment. The thermocouples were inserted to a depth of 1.5 cm using a 20 gauge x 1.16-inch needle catheter (Cardinal Health), which was inserted into the gastrocnemius muscle belly. The thermocouple was then attached to the Iso-Thermex electronic thermometer (Columbus Instruments, Columbus, OH 43204 U.S.A.), which recorded intramuscular tissue temperature every 5 seconds.

Procedures

Twelve hours before the start of the study, the thermocouples were sterilized in MetriCide® 28-Day High Level Disinfectant / Sterile Solution. The participants were asked to wear clothing that allowed for the left lower leg to be exposed and they were also be asked to not engage in any prolonged athletic activity 2 hours prior to the study. The participants reported to the Bentson Bunker Field House, Room 14 on the North Dakota State University (NDSU) campus at their assigned time. The subject completed an informed consent form to participate in the IRB approved study. The participants were asked to report for 2 sessions. The second session was within 10 calendar days of the first and at least 48-hours after the first session.

The participants laid prone on the treatment table with the left gastrocnemius muscle (calf) exposed. The US treatment area mark was in the middle of the left medial gastrocnemius muscle. The thermocouple insertion site was determined by using a carpenter square with a level fixed on the horizontal axis. The vertical axis of the carpenter square was placed evenly against the medial gastrocnemius muscle of the left leg, at the site with the widest circumference. The

carpenter square was tilted until the level attached to the horizontal axis provides a level reading. On the horizontal axis of the carpenter square, a small mark with a black Sharpie marker was made upon the middle of the medial gastrocnemius while participants plantar-flexed the foot to indicate the treatment area. The treatment area mark was in the center of the ERA. The transducer moved proximal and distal from the mark in a distance equal to the 2 times the ERA. A second mark was made parallel to the vertical axis at 1.5 cm, indicating the thermocouple insertion area. A mark was then made on a piece of white tape attached to the horizontal axis of the carpenter square lined up with the treatment area and another mark was made lined up with the thermocouple insertion. The distance between the two marks on the horizontal arm was the distance the thermocouple was inserted into the tissue. Thus, placing the thermocouple underneath the treatment area.

Next, the Tearson t3200TM Diagnostic Ultrasound was used to measure adipose thickness over the participant's treatment area, and the tissue was scanned for any abnormalities. The diagnostic US transducer was positioned over the treatment mark, the screen was frozen, and the caliper tool measured the adipose tissue thickness. Once the adipose thickness was measured, the tissue was scanned for any abnormalities considered contraindications, such as muscle deformities, fluids, or masses. If necessary, due to body hair, the treatment and thermocouple insertion sites were shaved, then cleaned with Betadine and 70% isopropyl alcohol.

A bucket held body temperature water ($37^{\circ}\text{C} \pm 2^{\circ}\text{C}$) from the faucet. The tap water was run until the desired temperature was reached. The bucket was then filled and the temperature of the water was monitored using a thermocouple, which was placed in the water and recorded every 5 seconds as the intramuscular tissue temperature was recorded.

The implantable thermocouple was dried using paper towels after it was removed from the MetriCide® 28-Day High Level Disinfectant / Sterile solution. Two black Sharpie marks were made on the thermocouples. The first mark was placed at 5cm as a guide for inserting the thermocouple, and the second mark was the insertion depth determined by the previously made marks on the carpenter square. The marks allowed the thermocouple to align directly below the treatment area at a depth of 1.5cm. The portion of the thermocouple to be inserted was wiped with 70% isopropyl alcohol and wrapped in sterile gauze.

The participant was asked to take 2 deep breaths. On the 2nd exhale the 20 gauge 1.16-inch needle catheter was inserted in the gastrocnemius muscle. The carpenter square was used to help guide the needle into the tissue, parallel to the treatment area. Upon insertion, the needle was retracted using its spring-loaded mechanism, leaving the catheter in the insertion site. The thermocouple was then inserted through the catheter to the appropriate depth. Then, the thermocouple was stabilized while the catheter was removed.

Transparent surgical tape was used to secure the thermocouple to the leg to ensure the thermocouple remained stabilized during treatment. The thermocouple was then attached to the Iso Thermex electronic thermometer (Columbus Instruments, Columbus OH). The machine recorded the participant's intramuscular temperatures at the tip of the thermocouple. A pre-made treatment area template 2 times the reported ERA was then attached to the subject with the treatment area mark over the gastrocnemius muscle visible in the center of the template. The template was then attached using Powerflex self-adhering tape. Once the intramuscular temperature had been consistent for 1 minute, the patient was moved to a chair and the left gastrocnemius muscle placed in the prepared water bucket.

The US treatment began with the following parameters: frequency, 3MHz; time, 10 minutes; intensity, 1.0 W/cm²; duty cycle, continuous US; and water temperature, 37°C ±2°C. During the second session, the intensity was increased to 1.5 W/cm². If the thermocouple reached an overall tissue temperature of 45°C, the treatment was discontinued due to concern that tissue damage can occur at temperatures above 45°C. The treatment was also discontinued if the patient reported any discomfort, such as excessive localized warming or pain. Bubbles were not wiped away as they formed on the transducer during the treatment. There was not enough space between the skin and the transducer to wipe away bubbles without interrupting the US treatment.

At the completion of the US treatment, the participant was instructed to remove the left leg from the water and return to the prone position on the table. The leg was then dried and the template removed. The Thermocouple was removed and wiped with 70% isopropyl alcohol before returning it to a separate MetriCide® 28-Day High Level Disinfectant / Sterile solution in a container marked "Used." The participant's leg was cleaned with an alcohol pad and the thermocouple insertion site was covered with a Band-Aid. A Crown Poly Inc. ice bag with ice was made and wrapped on the participant's leg over the thermocouple insertion site using flexi-wrap. The participant was then instructed on the appropriate icing regimen: ice for 20 minutes. The participant was advised of probable soreness for the next 24-48 hours, equivalent to prolonged athletic activity. The participant was advised that if any other symptoms precipitate, to contact the principle investigator or go to the health center on the North Dakota State University campus.

Analysis Procedures

A 2 x 3 Univariate Mixed Model Repeated Measures ANOVA was run to determine any differences in intramuscular tissue temperature at the time points 0 minutes, 5 minutes, and 10 minutes, between the intensities 1.0 W/cm² and 1.5 W/cm². The level of significance was set at $p \leq 0.05$.

CHAPTER 4. MANUSCRIPT

Abstract

The purpose of this study was to examine thermal effects of immersion US on the triceps-surae with $1.0\text{W}/\text{cm}^2$ and $1.5\text{W}/\text{cm}^2$, 3MHz intensities, 37°C water, and continuous US. Twenty college-students, 10 males and 10 females ($M= 23.45 \pm 1.986$ years), participated in 2 sessions, separated by a minimum of 48 hours. A thermocouple was inserted into the gastrocnemius muscle, measuring intramuscular temperature during an immersion US treatment. There was not a significant difference in intramuscular temperature increases between both intensities at 0 minutes ($M=0.1320$, $SE=0.5617$), 5 minutes ($M=-0.3570$, $SE=0.5617$), and 10 minutes ($M= -0.6885$, $SE=0.569$). This study indicated no significant difference between intensities $1.0\text{W}/\text{cm}^2$ and $1.5\text{W}/\text{cm}^2$ throughout a 10 minute treatment. This is clinically relevant because as clinicians, the appropriate parameters should be chosen to best treat patients and this study provides evidence that increasing intensity does not always increase tissue temperature.

Introduction

Therapeutic ultrasound (US) can effectively treat the underlying muscle by penetrating through layers of skin and adipose tissue.¹⁰ Therapeutic US is frequently used to reduce pain, treat soft tissue injuries, reduce edema, accelerate wound healing, and aid joint dysfunction.^{2, 16} Ultrasound waves are produced when the piezoelectric crystal in the transducer is introduced to an alternating current.^{1, 10} The acoustic energy, or US, is transmitted through the various underlying tissues.¹

When used in a continuous mode, ultrasound can produce a warming effect capable of penetrating tissues up to 5 cm in depth.¹¹ Thermal effects produced by US are dependent upon the overall tissue temperature increase. Effects of mildly heating the tissue (1°C), include

increased metabolic rates and reduction of mild inflammation.¹⁰ Along with mild heating effects, moderate heating (2-3 °C) results in increased blood flow and reduction of chronic inflammation, pain, and muscle spasms.^{2, 10, 17} In addition to the aforementioned thermal effects, vigorous heating (4 °C) has the added benefit of increased range of motion through altered viscoelastic collagen, and inhibited sympathetic activity.^{2, 10, 17} Furthermore, mechanical effects of US occur during both thermal and non-thermal treatments and include regenerate tissue, promote bone healing, and increase capillary density. Superficial tissue penetration is achieved with 3MHz while deep tissue penetration is achieved with 1MHz.^{11, 17, 30}

Heating tissue too rapidly or above 45°C can cause tissue damage, therefore, it is important to understand the rate of heating (Appendix A) for different tissues.^{2, 11, 29} Tendons heat 3.45 times faster than muscle.³⁴ Conversely, the rate of tissue temperature increase can vary among different US manufacturers.^{35, 39} Merrick et al.³⁹ compared Omnisound 3000, Dynatron 950, and Excel Ultra III US machines. The subjects discontinued treatment at 6 minutes from uncomfortable temperature increases at 41°C with the Omnisound 3000 and the other 2 machines never reached a 40°C temperature after 10 minutes. Machine variability should be taken into account when selecting proper parameters for treatment.^{35, 36, 39, 42}

Additionally, selecting the proper coupling medium can prevent damage to the piezoelectric crystal in the transducer.¹ When performing the direct method, US gel provides constant contact between the skin and transducer in larger areas. However, the indirect method is used when treating small body parts where the transducer cannot remain in constant contact with the skin, such as the wrist, hand, ankle, and foot. Examples of indirect methods include gel pads, degassed water, tap water, mineral oil and glycerine.^{10, 29} Tap water is a cost effective coupling medium with no significant differences compared to degassed water, as long as clinicians

remove air bubbles that form on the transducer.¹³ When executing the immersion technique, tap water should be placed in a plastic, ceramic, or rubber container and warmed to body temperature (37°C).^{1, 10} The transducer should be held 1cm away from the skin.^{10, 11} Conversely, the 1cm distance causes impedance in the water, reducing the intensity delivered to the tissue.¹⁴ An original unpublished pilot study¹⁴, conducted with 3 subjects by Draper, noted the further the transducer was from the skin, the less the intramuscular temperature raised.¹⁴ Draper and Prentice¹ reference the unpublished pilot study stating; “In order to ensure adequate heating, the intensity should be increased, possibly as much as 50 percent.”¹ Upon further investigation of the research, no follow up research has been conducted confirming the efficacy of the 50% intensity increase. Unfortunately, this 22-year old unpublished pilot study has been the only source for the 50% intensity increase. Draper referenced this pilot study in his comparative study between gel and underwater US article¹⁴ and athletic training textbook.^{1, 10} This unpublished pilot study reference in Draper et al.¹ is the source for the information cited by the academic literature for the subsequent 22 years.

Due to the lack of research over the past 22 years regarding a 50% intensity increase when performing water immersion therapeutic US, the purpose of this study was to examine the thermal effects of both 1.0 W/cm² and 1.5 W/cm² at a frequency of 3 megahertz (MHz) with continuous US while the triceps surae was immersed in 37°C water.

Methods

Participants

A sample of the student population was obtained from a Division 1 institution in the upper Mid-West. Twenty total subjects, 10 males and 10 females, were recruited between the ages of 18-30 years old. Participants were excluded from the research if they had any injuries to

the left lower leg in the previous 6 months, or more than 1.0 cm of adipose tissue over the middle medial portion of the gastrocnemius. Participants were also excluded if the diagnostic US showed any abnormalities to the left gastrocnemius, if there were any rashes or wounds over the treatment area, or if the subject was allergic to betadine or isopropyl alcohol. Lastly, participants were omitted if they had any of the following contraindications to therapeutic US in their left calf: decreased blood flow, decreased sensation, blood clots or tumors, infections, or fractures to the bones in the lower leg.

Instrumentation

To determine abnormalities in the gastrocnemius muscle and measure adipose thickness over the treatment area, the Terason t3200TM Diagnostic Ultrasound (MedCorp, LLC., Tampa, FL) was used along with the 15L4 Linear Transducer. Therapeutic US was administered using the Dynatron Solaris® 700 Series (ERA: 5cm², BNR 6:1; Dynatronics Corp., Salt Lake City, UT). A 20-gauge x 1.16-inch needle catheter (Cardinal Health), was inserted into the gastrocnemius muscle belly. A handmade template made of Styrofoam, and wrapped in Scotch electrical tape was used (Appendix B1); ensuring proper ERA measurements. Water was held in a plastic bin (31.1 cm width x 47 cm depth x 48.9 cm height) (Wal-Mart Inc.)

Tasks

All of the subjects received the 1.0 W/cm² and 1.5 W/cm² intensity conditions. The thermocouple recorded intramuscular tissue temperature every 5 seconds determining a baseline temperature. Following a baseline recording, the subjects were repositioned placing their left leg in a bucket of water 37°C ±2°C. Ultrasound was administered with the parameters: 3 MHz frequency, 10 minutes, continuous duty cycle, 1.5 cm depth, and with a 1.0 W/cm² intensity always preceding the 1.5 W/cm² intensity by 48 hours but no greater than 10 days.

Procedures

Twelve hours prior to the start of the study, the thermocouples were sterilized in Metricide® 28-Day High Level Disinfectant / Sterile Solution. The participants were asked to report for 2 sessions. The second session was within 10 days of the first and at least 48-hours after the first session. Ten minutes prior to the participant's arrival, a bucket with hot tap water at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (98.6°C) was filled and monitored using a thermocouple.

The participant laid prone on the treatment table and the thermocouple insertion site was determined using a carpenter's square with a level fixed on the horizontal axis. The vertical axis of the carpenter square was placed evenly against the medial gastrocnemius muscle of the left leg, at the site with the widest circumference. The carpenter square was tilted until the level attached to the horizontal axis provided a level reading. On the horizontal axis of the carpenter square, a small mark with a black Sharpie marker was made upon the middle of the medial gastrocnemius while participants plantar-flexed their foot to indicate the treatment area. A mark was made along the horizontal axis of the carpenter's square in line with the treatment mark. A second mark was made on the medial gastrocnemius muscle parallel to the vertical axis of the carpenter's square at 1.5cm, indicating the thermocouple insertion area. Two marks were then made on the tape affixed to the horizontal axis of the carpenter's square aligning with the treatment and insertion marks on the participant. The distance between the 2 marks on the tape was measured and marked on the implantable thermocouple as a guide ensuring the thermocouple was inserted underneath the treatment area. Next, the Diagnostic US was used to measure adipose thickness and check for any abnormalities. If participants had excessive body hair, they were shaved and then the treatment area was cleaned with betadine and 70% isopropyl

alcohol. The implantable thermocouple was then marked with the insertion depth measurement and a mark at 5cm as a guide for insertion.

The 20 gauge 1.16-inch needle/catheter was then inserted into the gastrocnemius at the 1.5cm depth mark and then the needle was retracted (Appendix B2). The thermocouple was inserted through the catheter, then the catheter was removed. The thermocouple was secured to the leg and then plugged in to the Iso Thermex. The template with the treatment mark in the center was attached to the medial gastrocnemius muscle using Powerflex over the treatment area. The participant was then moved to a seated position with their left leg submerged in the prepared water bucket (Appendix B3). The US treatment then began with the following parameters: 3 MHz frequency, 10 minute treatment time; 1.0 W/cm² intensity, and continuous duty cycle. During the second session, the intensity was increased to 1.5 W/cm². If bubbles accumulated on the transducer throughout treatment, they were unable to be wiped away due to the position of the template in relation to the transducer. In order for the bubbles to have been removed the transducer would have been pulled away from the skin disrupting the US treatment. Treatment was discontinued if the overall tissue temperature reached 45°C or the participant reported discomfort. At the completion of the US treatment the participant returned to the prone position on the table. The thermocouple was removed and placed in a separate MetriCide container marked “used.” The participant’s leg was cleaned with an alcohol pad and a Band-Aid covered the insertion site.

Statistical Analysis

A 2 x 3 Univariate Mixed Model Repeated Measures ANOVA was run to determine the differences in intramuscular tissue temperatures at 0-minutes, 5-minutes, and 10-minutes, between the 2 intensities. The level of significance was set at $p \leq 0.05$

Results

Among the 20 participants, the mean age was 23.45 ± 1.99 years. The mean measured adipose thickness was 0.48 ± 0.20 cm. There was a significant main effect on time $F(2,113) = 72.31, p < 0.001$. With a 1.0 W/cm^2 intensity, the baseline temperature was $34.55 \pm 0.3972^\circ\text{C}$ and for the 1.5 W/cm^2 intensity, the baseline temperature was $34.42 \pm 0.3972^\circ\text{C}$. After 5 minutes, the overall tissue temperature for a 1.0 W/cm^2 intensity was $37.08 \pm 0.3972^\circ\text{C}$ with a temperature increase of $2.78 \pm 0.3972^\circ\text{C}$ from baseline. Following a 5 minute US treatment, the overall tissue temperature for a 1.5 W/cm^2 intensity was $37.44 \pm 0.3972^\circ\text{C}$. Following a 10 minute treatment, the overall tissue temperature for a 1.0 W/cm^2 intensity was $39.42 \pm 0.3972^\circ\text{C}$ and for a 1.5 W/cm^2 intensity a $39.61 \pm 0.4075^\circ\text{C}$ (Table 1). There is a temperature increase of approximately 2.53°C from baseline to 5 minutes using a 1.0 W/cm^2 intensity and 3.02°C with a 1.5 W/cm^2 (Table 2). The temperature increased 4.37°C from baseline to 5 minutes using a 1.0 W/cm^2 intensity and 5.19°C with a 1.5 W/cm^2 (Table 2). Lastly, there was a temperature increase of 1.84°C from 5 minutes to 10 minutes using a 1.0 W/cm^2 intensity and 2.17°C with a 1.5 W/cm^2 (Table 2). However, while there were significant temperature increases from baseline, there were not significant increases between intensities. Conversely, there was no significant main effect on intensity $F(1,113) = 0.87, p = 0.352$. Similar, to the intensity, there was no significant interaction between time and intensity $F(2,113), p = 0.588$. Due to the lack of interaction between time and intensity, increasing the intensity by 50% may not be indicated while using the Dynatron US Machine.

Table 1. Estimated Mean Intramuscular Temperature Increase from 0, 5, and 10 Minutes for both 1.0 W/cm² and 1.5 w/cm² Intensities

Time (Minutes)	Intensity (W/cm ²)	Mean Tissue Temperature (°C)	Standard Error
0	1.0	34.55	0.3972
0	1.5	34.42	0.3972
5	1.0	37.08	0.3972
5	1.5	37.44	0.3972
10	1.0	39.42	0.3972
10	1.5	39.61	0.4075

Table 2. Estimated Mean Overall Intramuscular Temperature Change from 0, 5, and 10 Minutes for both 1.0 W/cm² and 1.5 W/cm² Intensities

Intensity (W/cm ²)	Starting Time (Minutes)	Ending Time (Minutes)	Starting Temperature (°C)	Ending Temperature (°C)	Temperature Change (°C)
1.0	0	10	34.55	38.92	4.37
1.5	0	10	34.42	39.61	5.19
1.0	0	5	34.55	37.08	2.53
1.5	0	5	34.42	37.44	3.02
1.0	5	10	37.08	38.92	1.84
1.5	5	10	37.44	39.61	2.17

Discussion

The results of this study indicated that a 50% intensity increase did not increase tissue temperature during an immersion US treatment greater than a 1.0 W/cm² intensity during an indirect method US treatment.^{4, 10} These results are contradictory to athletic training textbooks^{1, 9, 10} and Draper's unpublished pilot study mentioned in the Draper et al.¹⁴ research. When examining the parameters of immersion US, there is a lack of research. The direct method of US is the preferred method of US and is studied at great length. However, the direct method is not

always the appropriate choice depending on the location of treatment. Understanding the proper parameters of immersion US allows for clinicians to better treat patients.

This research provided evidence that there was no significant temperature difference between intensities at the time points 0, 5, or 10 minutes (Table 1). This may be a result of the Dynatron US machine and that the 1.5 W/cm^2 intensity setting does not heat as suggested. Perhaps 1.0 W/cm^2 is the preferred intensity with immersion US despite the previous suggestion in the Draper and Prentice¹ textbook. Draper and Prentice¹ supported the 50% intensity increase with an unpublished pilot study examining varying transducer and skin distances and not varying intensities. It is important to understand all aspects of information when practicing evidence-based medicine.

The indirect US method is not commonly used in the clinical setting unless smaller or a bony area needs to be treated. Immersion US using tap water is a cost effective indirect method. Due to how infrequently the indirect method is used, filling a plastic bucket with tap water rather than budgeting other indirect method items such as gel pads is more cost effective. However, compared to the immersion technique results of this study, gel pads are more effective at increasing tissue temperature. Draper et al.¹² compared the efficacy of US gel, a 2 cm gel pad and a 1 cm gel pad. They used the parameters: 3 MHz, 1.0 W/cm^2 , continuous US, 10 minutes, inserting the thermocouple into the Achilles tendon. Draper et al.¹² reported that the direct method using US gel increased tissue temperatures 13.3°C while the indirect method of a 2 cm gel pad increased tissue temperatures 6.5°C , and a 1 cm gel pad increased tissue temperatures 9.3°C . While the US gel heated tissue more effectively than the US gel pads, both of the US gel pads were more effective than the immersion US technique used in this study.

Similarly, Bishop et al.³⁷ observed temperature increases using 3 different approaches; US gel, an Aquaflex gel pad with US gel on the top, and an Aquaflex gel pad with US above and below the pad. They inserted the thermocouple 1 cm into the lateral aspect of the of the left ankle between the lateral malleolus and the Achilles tendon.³⁷ They used the parameters of 1.0 W/cm², 3 MHz, continuous US, and 10 minutes.³⁷ Bishop et al.³⁷ noted that the US gel direct method increased temperature 7.72°C ± 0.52°C which was more than the other 2 indirect methods. The gel pad with US on the top increased tissue temperature 4.98°C ± 0.52°C while the gel pad with US gel on both sides increased tissue temperature 6.68°C ± 0.52.³⁷ Compared to the current research, the gel pad with US gel on the top increased tissue temperature similarly over a 10 minute US treatment however, the direct method was still more effective. As previously mentioned, tap water is more cost effective and is a viable indirect US method option for clinicians with smaller budgets. One explanation that the US gel pads are more effective is because US gel pads have little to no impedance comparably. In the present research, the tiny bubbles that form on the transducer were unable to be removed. The template created allowed for a 1 cm distance from the skin and was made to fit the transducer snugly. In order for the bubbles to have been wiped away the transducer would have to be dragged away from the skin further than 1 cm, disrupting the US treatment. While the tiny bubbles do not explain why the 2 intensities produced similar temperature increases, impedance could have contributed to lower overall temperature increases.

In Addition, Klucinec et al.¹³ performed an in vitro study on pig tissue comparing various indirect methods to the gold standard US gel direct method. They used the following parameters: 3.3 MHz, continuous US, with the intensities 0.2, 0.5, 1.0, 1.5, and 2.0 W/cm².¹³ The various US methods compared were US gel, gel pad, gel filled latex glove, gel filled non-lubricated condom,

tap water filled glove, degassed water filled glove, tap water bath, and degassed water filled bath.¹³ The tap water was room temperature and the transducer was placed 1 cm away from the pig skin.¹³ Klucinec et al.¹³ noted that only 1 small air bubble was observed and left on the outer edge of the transducer during the tap water treatment. The in vitro study was not accomplished on live tissue however, the 1 air bubble does suggest a lower rate of impedance than originally suggested in textbooks.^{1, 10, 11} An overall temperature increase of $6.38 \pm 0.16^\circ\text{C}$ and $7.67 \pm 0.14^\circ\text{C}$ with 1.0 W/cm^2 and 1.5 W/cm^2 intensities respectively, was recorded using the US gel direct method.¹³ Interestingly, the indirect method gel pad increased the temperature greater than the US gel. The temperature increase was $7.07 \pm 0.21^\circ\text{C}$ and $8.31 \pm 0.09^\circ\text{C}$ at 1.0 W/cm^2 and 1.5 W/cm^2 intensities respectively.¹³ Klucinec et al.¹³ noted with the intensities 1.0 W/cm^2 and 1.5 W/cm^2 , a temperature increase of $1.89 \pm 0.02^\circ\text{C}$ and $2.40 \pm 0.06^\circ\text{C}$ with room temperature tap water. The temperature increases may have been more significant if the tap water was body temperature. The US treatment must heat the tissue through the cooling effects of the water when it is performed with room temperature water. When compared, the current immersion US research increased tissue temperature greater than the tap water by Klucinec et al.¹³ They not only used room temperature water but also pig skin which had no blood supply. The temperatures should have been greater because the lack of blood supply did not simulate the heat-dissipating potentials of live tissue.

When administering the indirect US method, the frequency of 3 MHz is often used because it does not penetrate the underlying tissue as deep as 1 MHz. A 3 MHz is appropriate since the indirect method is used on smaller or bony areas. Interestingly, Draper et al.¹⁴ compared the tissue temperature increases between US gel and water immersion US with a 1 MHz frequency. They inserted the thermocouple into the gastrocnemius and used the following

parameters: 1.5 W/cm², continuous US, 10 minutes, 1.0 MHz, 3.0 cm depth.¹⁴ After 8 minutes of treatment, the US gel reached a tissue temperature increase of 4.8°C, while the immersion US only increased the tissue temperature 2.1°C.¹⁴ Draper et al.¹⁴ performed immersion US with 1 MHz and checked tissue temperature at a 3 cm depth. These parameters are not often associated with an indirect method and may not be directly equivalent. However, in the current study, the gastrocnemius muscle was used to assess temperature increases, there is little research on assessing temperature in smaller or bony areas due to patient discomfort with inserting thermocouples in these areas.

Halfway through the US treatment at 5 minutes, the tissue temperature only increased 2.533 ± 0.3972°C with a 1.0 W/cm² and 3.022 ± 0.3972°C with a 1.5 W/cm². According to athletic training textbook¹ information, the tissue temperature should have increased 3°C with a 1.0 W/cm² intensity and 4.5°C with a 1.5 W/cm² intensity with the direct method. At 5 minutes with a 1.0 W/cm² intensity in the current study, the tissue temperature increased just below the textbooks¹ recommendation. However, comparing the textbook¹⁰ for direct method to the current studies results for 1.5 W/cm², they are not similar. The direct method parameters in the textbook¹⁰ cited Draper et al.² when discussing heating rates. The study only used an Omnisound US machine and there is evidence that US machines heat at varying rates. Artho et al.³⁵ examined 83 US machines and found that 18% of the US machines reported higher outcomes and 17% reported lower outcomes than the accepted ±20% standard.

Machine variability can provide challenges for clinicians. When comparing literature on US machines, using the direct method, there is a variation of temperature outputs. The Omnisound US machine is a highly researched machine when compared to the Dynatron US machine. Holcomb³⁶ compared the Omnisound and Forte US machines with the following

parameters: 3 MHz, 1.0 W/cm², 1.2 cm depth, continuous US, 10 minutes. The Omnisound significantly increased tissue temperature $5.81 \pm 0.41^{\circ}\text{C}$ in the calf when compared to the Forte which increased tissue temperature only $3.85 \pm 0.75^{\circ}\text{C}$.³⁶ Moreover, Gange et al.⁴² produced similar temperature increases 3.94°C with the Dynatron US machine as the Forte. Athletic Training textbooks^{1, 10} base their parameters for temperature increases on Draper et al.² which solely examined the Omnisound US machine. Draper et al.² examined heating rates between 1 MHz and 3 MHz with varying intensities and depths. The following parameters were used to determine US heating rates: 1 MHz with 2.5 and 5.0 cm depth, 3 MHz with 0.8 and 1.6cm depth, 0.5, 1.0, 1.5, and 2.0 W/cm² intensities, continuous US, 10 minutes.² They found no significant difference between depths within the same frequency, however 3MHz did heat at a faster rate compared to 1 MHz.² Draper et al.² noted the following heating rates: 0.04°C at 0.5 W/cm², 0.16°C at 1.0 W/cm², 0.33°C at 1.5 W/cm², 0.38°C at 2.0 W/cm² with 1 MHz, and 0.3°C at 0.5 W/cm², 0.58°C at 1.0 W/cm², 0.89°C at 1.5 W/cm², 1.4°C at 2.0 W/cm² with 3 MHz. Conversely, Gange et al.⁴² using the Dynatron US machine with 3 MHz found heating rates of 0.7°C at 1.0 W/cm² at a 1.0 cm depth, and 0.4°C at 1.0 W/cm² at a 1.75 cm depth. In addition, Gange et al.³¹ also using the Dynatron US machine with 3 MHz found heating rates of 0.5°C at 1.0 W/cm² at a 1.0 cm depth, and 0.3°C at 1.0 W/cm² at a 1.75 cm depth. Ultrasound machines from different manufactures do not heat at the same rate.

However, US research implementing the direct method using the Dynatron US machine produced similar temperature increases when compared to the current immersion US research. Using the Dynatron US machine, Gange et al.⁴² provided evidence of a heating rate of $0.7^{\circ}\text{C}/\text{minute}$ when the following parameters were applied: 3 MHz, 1.0 W/cm², 1.0 cm depth, with a goal of a 4°C tissue temperature increase. Gange et al.⁴² also used the same parameters

with an increased depth of 1.75 cm, resulting in a heating rate of 0.4°C/minute. Over a 5 minute US treatment using the heating rate from Gange et al.⁴², the temperature should increase 3.5°C at a 1.0 cm depth and 2°C at a 1.75 cm depth. When compared to the current research, the 1.5 cm depth is between the 2 depths examined above. Comparably, the tissue temperature increase of $2.533 \pm 0.3972^\circ\text{C}$ with a 1.0 W/cm^2 and $3.022 \pm 0.3972^\circ\text{C}$ with a 1.5 W/cm^2 in the present research falls within the heating rate guidelines of the 2 depths examined by Gange et al.⁴² using the Dynatron US machine. At the completion of the 10 minute US treatment, the tissue temperature increased $4.3735 \pm 0.3972^\circ\text{C}$ with a 1.0 W/cm^2 intensity and $5.194 \pm 0.4235^\circ\text{C}$ with a 1.5 W/cm^2 intensity. Conversely, in accordance with athletic training textbook recommendations^{1, 9, 10}, tissue temperatures should have increased 6°C with 1.0 W/cm^2 intensity and 9°C with 1.5 W/cm^2 intensity after a 10 minute US treatment using the direct method. The current study temperature increases were not close to these temperatures, especially with the 1.5 W/cm^2 intensity. Moreover, Gange et al.⁴² reported a tissue temperature increase of 3.94°C at the 1.75 cm depth after a 10 minute treatment. A 1.75 cm depth is 0.25 cm deeper than the 1.5 cm depth used in the current research which could explain the slight temperature difference. Interestingly, Gange et al.³¹ performed another study using the Dynatron US machine and increased the intensity to 1.2 W/cm^2 . The heating rate at a 1.0 cm depth decreased from 0.7°C/minute to 0.5°C/minute and at a 1.75 cm depth decreased from 0.4°C/minute to 0.3°C/minute.³¹ With the increase in intensity, the heating rate should increase, not decrease as shown above. This may be one reason there was no significant differences between intensities over time using the Dynatron US Machine.

Furthermore, the temperature increase may not have been significant because immersion US is indicated over smaller body parts where tendons and ligaments overlay the surrounding

muscles. Tendons are dense causing them to heat at a rate 2 times faster than muscle.³⁴ Further research should be performed to determine if administering the US treatment over a smaller body part, such as the ankle, with a 50% intensity increase would result in a greater tissue temperature increase. In Addition, increasing intensity by 75% or 100% should also be researched to determine if it would increase tissue temperature comparable to the direct method. This research study should also be performed with the same parameters using the Omnisound machine, allowing for a direct comparison of the literature using the same US machine. Lastly, further research should be performed on injured tissue to see if it increases tissue temperature at a different rate than healthy tissue.

There were several limitations that restricted the current research. As previously mentioned there is variation in US machine treatment output. The only machine that was used in this study was the Dynatron 708 Series. The research results could potentially vary based on the selected US machine. Another limitation of the present research is the use of only healthy tissue. Clinically US is used to treat injured tissue not healthy tissue, the study could be more clinically relevant if examined on injured tissue. Additionally, another limitation was the homemade template which ensured that a 1 cm distance was maintained throughout the US treatment (Appendix B). The template did not allow for air bubbles to be removed quickly without the disruption of the US treatment. If air bubbles were removed quickly as they formed, the level of impedance would be reduced possibly increasing tissue temperature more. Lastly, immersion US is frequently executed on smaller or bony areas such as the ankle. In the current research the tissue temperature was collected from the gastrocnemius, a larger area of the body. Inserting a needle catheter in an area such as the ankle would be more painful for the participant with a

higher associated risk. There would be a stronger level of evidence if the research was performed on a smaller or bony area of the body.

Conclusion

The results of this investigation suggest that a 50% intensity increase with immersion US does not significantly increase tissue temperature with the Dynatron Solaris US machine. Since an intensity increase is suggested to increase tissue temperature, these results may be relevant to Athletic Trainers, Physical Therapists and other health professionals who use therapeutic ultrasound. Based upon the findings of this research when administering US with the Dynatron US Machine 1.0 W/cm² is suggested. The Dynatron US machine has a high BNR, using the lower intensity would reduce the risk of creating hot spots with the same benefits of the higher intensity as suggested by the findings of the research. Increased tissue temperature can provide greater tissue extensibility and various other added benefits. Ensuring the correct treatment is delivered via parameter selection is important in providing better care for patients.

CHAPTER 5. CONCLUSIONS AND RECOMMENDATIONS

The purpose of this study was to examine the thermal effects of both 1.0 W/cm² and 1.5 W/cm² at a frequency of 3 MHz with continuous US while the triceps surae is immersed in 37°C water. The research questions that guided this study were: What is the overall tissue temperature increase with the parameters of 3 MHz, continuous US, 1.5 cm depth, treatment time of 10 minutes, 37°C water, at the intensity of 1.0 W/cm², using the Dynatron Solaris Therapeutic Ultrasound Machine? What is the overall tissue temperature increase with the parameters of 3 MHz, continuous US, 1.5 cm depth, treatment time of 10 minutes, 37°C water, at the intensity of 1.5 W/cm² using the Dynatron Solaris Therapeutic Ultrasound Machine? Is there a statistical difference in the overall tissue temperature increase with the parameters of 3 MHz, continuous US, 1.5 cm depth, a treatment time of 10 minutes, with 37°C water, with the intensities of 1.0 W/cm² and 1.5 W/cm², using the Dynatron Solaris Therapeutic Ultrasound Machine?

Therapeutic US is widely used for the treatment of soft tissue injuries to elicit both thermal and non-thermal effects. Non-thermal or mechanical effects include cavitation, microstreaming, bone healing, and tissue regeneration.³⁴ Thermal effects of therapeutic ultrasound comprise of decrease in inflammation, pain, muscle spasms, and increase in metabolic rates, blood flow, and tissue range of motion.³⁴ Properly selecting parameters is important in the providing appropriate care to patients. Frequency is selected based upon the desired depth of US penetration. If the target tissue is 0.8-2.5 cm a 3 MHz frequency is optimal.¹⁷ A target tissue of 2.5-5cm in depth is better suited with a 1 MHz frequency.¹⁷ The duration of treatment is dependant upon the frequency, intensity, duty cycle, and size of the treatment area.²⁹ A continuous duty cycle produces thermal and non-thermal effects, while a pulsed duty cycle produces non-thermal effects.¹ The treatment area should be 2 – 3 time the effective radiating

area.²⁹ When performing water immersion US body temperature water should be used with the transducer 1 cm away from the skin.¹⁰ Draper and Prentice¹ suggest that during a water immersion US treatment intensity should be increased as much as 50% compared to the direct method based upon an unpublished pilot study by Draper et al.¹⁴ However, no subsequent research has been done since the unpublished pilot study in 1993. There are currently no standard parameters for immersion US.

A sample of 10 male and 10 female healthy college age (23.45 ± 1.99 years) students with no lower left leg injuries in the past 6 months participated in this study. Participants received 2 US treatments separated by at least 48 hours but no more than 10 days. Once the participants treatment area and thermocouple site were marked, the area was scanned using a diagnostic US machine. The participants were scanned for any tissue abnormalities and adipose thickness (0.48 ± 0.20 cm thick). The area and thermocouple was then prepped for insertion. Next, the thermocouple was inserted and the template was attached to the calf. The participant was repositioned with their left leg submerged in the $37 \pm 2^\circ\text{C}$ water bucket. During the first session US with the 1.0 W/cm^2 was administered followed by 1.5 W/cm^2 in the second session. Following the US treatment the participant's leg was pulled out from the water and the thermocouple was removed. Throughout both US treatments tissue temperature was significantly increased. However, there was no significant difference in tissue temperature increase between intensities.

Discussion

Selecting appropriate parameters when performing US is important in providing quality care to patients. Immersion US is commonly performed over superficial areas, so 3 MHz was selected due to the depth of penetration for 3 MHz. A frequency of 3MHz is suggested for

superficial penetration of tissue.¹⁷ An intensity of 1.0 W/cm² was selected because it is a commonly researched intensity used with 3MHz and is suggested to reach 4°C in 6.67 minutes.¹ The second intensity of 1.5 W/cm² is the 50% increase of the aforementioned intensity. Next, 10 minutes was selected to allow for at least a 4°C increase. The textbook¹⁰ suggests that a 1.0 W/cm² intensity with 3MHz will take 6.67 minutes to reach a 4°C temperature increase. Conversely, Gange et al.⁴² suggests that with the same parameters using the Dynatron Solaris, it will take 10 minutes to reach a 3.94°C temperature increase. The depth of 1.5 cm was chosen because it is the theoretical range 3 MHz US frequency would be sufficient to be therapeutically effective² and immersion US is generally performed on smaller areas of the body. Continuous US is suggested when thermal effects are indicated rather than Pulsed US.¹⁰ The gastrocnemius was chosen because, there is extensive US research performed over the area, even though commonly immersion US is used over smaller or bony areas of the body.^{1, 10, 11} Inserting a thermocouple in a smaller or bony area would cause more discomfort to the participant than in the gastrocnemius. In addition, Draper et al.¹⁴ the cited article in Draper and Prentice¹ textbook which suggested a 50% intensity increase, examined temperature increases in the gastrocnemius. In order to remain consistent, the gastrocnemius muscle was selected for the current research. Lastly, the tap water for the immersion US was heated to 37 ± 2°C or average body temperature. Average body temperature water is indicated so the US does not have to heat through the cooling effects of room temperature water as suggested in current Athletic Training textbooks.^{1, 10}

The indirect method is utilized for bony prominences and small body areas such as the wrist, hand, ankle, or foot.^{1, 11} Coupling mediums are used to ensure the transducer remains in constant contact with the skin in both direct and indirect methods.^{10, 29} Tap water is a cost effective coupling medium used in the indirect method.¹³ When performing immersion US with

tap water, it is recommended that the transducer is held 1 cm away from the skin.¹⁴ However, the distance causes impedance, reducing the intensity delivered to the tissue.^{10, 11, 14} Based upon a 22 year old unpublished pilot study conducted by Draper,¹⁴ intensity should be increased by 50%. The unpublished pilot study examined varying distances between the skin and transducer and did not observe any intensity changes.¹⁴ Furthermore, Draper and Prentice¹ referenced the unpublished pilot study in their Athletic Training textbook stating; “In order to ensure adequate heating, the intensity should be increased, possibly as much as 50 percent.” Upon further investigation of the literature, there has been no subsequent research in 22 years. Due to a lack of research on a 50% intensity increase, this research study looked at intramuscular temperature increases using 1.0 W/cm² and a 50% intensity increase of 1.5 W/cm² at three time points: 0 minutes, 5 minutes, and 10 minutes.

Administering the indirect method with common direct method parameters in the current study, there was a significant difference between the baseline and ending temperature for 1.0 W/cm² over a 10-minute treatment. From this finding, an intensity of 1.0 W/cm² over 10-minutes does significantly increase intramuscular tissue temperature from the baseline temperature. Based on the Omnisound US machine literature and the Athletic Training textbook¹⁰, the rate of intramuscular temperature increases per minute for a direct method therapeutic US treatment using the parameters 3 MHz, 1.0 W/cm² is 0.60°C per minute (Appendix A).^{4, 10} According to the textbook¹⁰ the parameters 3 MHz, 1.0 W/cm² following a 10-minute treatment should increase tissue temperature 6°C (Appendix A).^{4, 10} However, the current study results indicated an increase of 4.78°C over a 10-minute immersion US treatment. The lack of temperature increase could have been due to impedance. Impedance occurs with water immersion US because the transducer must remain 1cm away from the skin to allow the water to be the medium

for the US.¹⁴ The distance between the skin and the transducer causes impedance reducing the intensity of US treatment delivered to the underlying muscles.

There was not a significant interaction between time and the intensities of 1.0 W/cm² and 1.5 W/cm² in overall intramuscular temperature increases with immersion US. Meaning over a 10 minute US treatment, there was no significant variation of temperature increases between the intensities at each time point. In contrast, Klucinec et al.¹³ looked at 16 different variations of intensity and frequency looking at the energy output in volts produced by the US treatment in pig tissue, with 8 different coupling mediums. They reported that using a Chattanooga US machine with immersion US with tap water at 3.3 MHz produced $1.89 \pm 0.02V$ at 1.0 W/cm² and $2.40 \pm 0.06V$ at 1.5 W/cm².¹³ With US gel they found $6.38 \pm 0.16V$ at 1.0 W/cm² and $7.67 \pm 0.14V$ at 1.5 W/cm².¹³ Even though Klucinec et al.¹³ used pig tissue, it still provided evidence that there is a greater energy output with 1.5 W/cm² than 1.0 W/cm² with both immersion US and the direct method. Conversely, the current research study showed that there was no significant difference between the intensities. According to Klucinec et al.,¹³ there should have been a mild difference. One limitation to the Klucinec et al.¹³ study is they used pig tissue without normal blood flow. Blood flow is important in regulating tissue temperature and removing excess heat.

Similarly, Draper et al.¹⁴ observed a 2.1°C intramuscular temperature increase over a 10-minute immersion US treatment with 1MHz and 1.5 W/cm² using the Sonicator 706. The gastrocnemius was the target tissue with a 3 cm depth, 0.5 cm deeper than the suggested depth of immersion US treatments.¹⁷ However, Draper et al.¹⁴ did not use proper immersion US parameters, rather larger area parameters. Draper et al.¹⁴ compared immersion US and US gel as coupling mediums. According to the textbook parameters when using 1 MHz with 1.5 W/cm², the rate of heating per minute is 0.3°C.^{4, 10} Draper et. al.¹⁴ reported an overall temperature

increase of 4.8°C with US gel and an overall temperature increase of 2.1°C with an immersion treatment after 10 minutes. Interestingly, Draper et al.¹⁴ contradicts the temperature increase per minute as laid out in the textbook by Draper and Knight¹⁰ for the direct method using US gel. As advised by Draper and Knight¹⁰ the temperature should have increased 3°C, instead it increased 1.8°C greater than anticipated. This study by Draper et al.¹⁴ references an unpublished pilot study conducted with 3 subjects comparing varying transducer distances from the skin. The pilot study does not compare various intensities however, and claims that there should be a 50% intensity increase with immersion US.¹⁴ The current research increased temperature $4.78 \pm 0.40^\circ\text{C}$, similar to the 4.8°C temperature increase reported by Draper et al.¹⁴. Conversely, the recent study used a 3 MHz frequency, and a 1.5 cm depth.

The indirect method uses various coupling mediums as a way to provide a smooth surface for the transducer to glide over. Bishop et al.³⁷ examined both direct and indirect methods using US gel, Aquaflex gel pad with US gel on top, and Aquaflex gel pad with US gel on both sides. They used an Omnisound 3000 and the following parameters: continuous US, 3 MHz, 1.0 W/cm², for 10 minutes. The US gel increased tissue temperature $7.72^\circ\text{C} \pm 0.52^\circ\text{C}$, while the US gel on top and bottom of the gel pad increased the tissue temperature $6.68^\circ\text{C} \pm 0.52^\circ\text{C}$, and the US gel on top of the gel pad increased tissue temperature $4.98^\circ\text{C} \pm 0.52^\circ\text{C}$.³⁷ Bishop et al.³⁷ increased tissue temperature nearly 2°C greater than the suggested textbook parameters when using US gel.¹⁰ Ultrasound gel is considered the gold standard of coupling mediums producing desired thermal effects with little to no impedance as compared to the indirect method.¹³ Equivalently, Draper et al.¹² studied the tissue temperature increases over the Achilles tendon at a depth of 1 cm, using the Omnisound US machine with the following parameters; 3 MHz, 1.0 W/cm², continuous US, 10 minutes. They examined temperature differences between US gel, a 2

cm thick US gel pad, and a 1 cm thick US gel pad.¹² They reported temperature increases of 13.3°C with US gel, 6.5°C with a 2 cm thick US gel pad, and 9.3°C with a 1 cm thick US gel pad.¹² Similar to the current research US gel pads reached over a 4°C temperature increase over 10 minutes however, Draper et al.¹² noted temperature increases far exceeding 4°C. Comparably to the aforementioned Bishop et al.³⁷ research, Myrer et al.⁴⁴ reported nearly identical data for US gel. They used continuous US, 3 MHz, 10-minutes, at 1.0 W/cm², comparing US Gel with 2 mixtures of topical analgesics and US gel.⁴⁴ There was no significant difference between the 3 groups and Myrer et al.⁴⁴ reported US gel increased intramuscular temperature 7.47°C ± 1.80°C, only 0.25°C less than Bishop et al.³⁷ While US gel is the preferred method administering the desired thermal effects it is not always applicable when treating the smaller and bony body parts.

Heating rates vary dependent upon the target tissue. This is clinically significant when treating smaller areas, such as the foot, ankle, wrist, or hand; where there are many tendons and muscles throughout the area. Chan et al.³⁴ observed tissue change in the patellar tendon using the Omnisound 3000 with the following parameters: continuous US, 3 MHz, 1.0 W/cm², for 4-minutes. Chan et al.³⁴ stated after a 4-minute treatment, there was an 8.3°C ± 1.70°C temperature increase providing evidence that the rate of heating is greater in tendons than muscles. The tendon rate of heating is 2.10°C ± 0.40°C compared to a muscle 0.6°C with 3 MHz, 1.0 W/cm², and continuous US.^{4, 10, 34} Increasing overall tissue temperature more than 45°C using US can cause tissue damage.³⁴ When administering immersion US over a small area, clinicians should be aware of the underlying anatomy, and that tendons heat over 2 times faster than muscle. Tendons are denser than muscle causing them to heat faster. Due to a lack of vascularization compared to muscles, tendons also retain the temperature increases longer.⁴ From the existing experiment, the treatment was completed over the triceps surae, a large muscle with good

vascularization. The current research was performed over a large muscle while immersion US is typically performed over smaller muscles with overlaying tendons and ligaments. The larger muscle was preferred due to the ease of needle insertion and comparable literature. Needle insertion in small areas has a higher level of discomfort for the participant. Inserting the needle in smaller areas requires exacting precision of placement. Comparable literature of inserting the needle in the larger muscle far exceeds the 2 studies which insert in smaller areas. The tissue temperature increase may have been more equivalent if performed over a smaller area of the body because of the increased tendon temperature.

In comparison to the current research study, Draper and Ricard⁴ performed a direct method US treatment with the same parameters with the exception of depth, and the US machine: Omnisound 3000, continuous US, 1.2 cm depth, 3 MHz, and 1.5 W/cm². They used the triceps surae muscle and determined it took an average of 6 minutes to reach a 5.3°C overall temperature increase.⁴ Conversely, the current research study after 10-minutes increased 4.78°C and after 5-minutes, the overall temperature increase was only 2.78°C. Unlike Draper and Ricard,⁴ a 5.3°C temperature increase was not reached during the 10-minute treatment immersion US in this study. Draper and Ricard⁴ also examined the rate of temperature decay after an US treatment. Following an US treatment, there is a short stretching window in which the extensibility of connective tissue can be increased.²⁵ According to Draper and Ricard⁴ with a temperature increase of 4°C the stretching window is approximately 2-minutes. Clinicians, based upon the present research, would need to administer immersion US for 10-minutes in order for a 2 minute stretching window. Clinicians in the clinical setting who often perform US for 5-7 minutes, which would not reach a 4°C temperature increase. In other research comparing various frequencies and intensities, researchers examined various heating rates.² Draper et al.² noted a

difference in heating rate using the direct method, with an Omnisound 3000, continuous US, 3 MHz, 1.0 W/cm² and 1.5 W/cm². They reported the 1.0 W/cm² heating rate was 0.58°C per minute while 1.5 W/cm² heating rate was 0.89°C per minute, however, the treatment had to be discontinued due to participant discomfort after 6 minutes of treatment.² Likewise, only one participant discontinued treatment in the 8th minute due to discomfort and had an overall temperature change of 5.34°C.

Comparing the current study indirect methods to Gange et al.⁴² direct method research, it provides evidence that the 1.0 W/cm² intensities increased tissue temperatures at similar rates. Both studies used the Dynatron Solaris machine, with similar parameters and methods. Gange et al.⁴² compared the three depths 1.0, 1.75, and 2.5 cm with the following parameters; 1.0 W/cm², 3 MHz, continuous US, 20-minutes, using the Dynatron Solaris US machine. After 6 minutes, the 1.0 cm depth reached an overall temperature increase of 4.18 ± 1.29 °C and after 11-minutes the 1.75 cm depth reached an overall temperature increase of 4.18 ± 2.01°C. The 1.75 cm depth results are comparable to the present study with a 1.5 cm depth which took 10-minutes to reach a 4.78 ± 0.40°C overall temperature increase. Using the same US machine for both studies, with comparable temperature increases provides evidence that the current study using immersion US the intensity does not need to be increased to 1.5 W/cm² in order for the appropriate temperature increase to occur. In addition, Gange et al.³¹ examined the same parameters, except with an intensity of 1.2 W/cm². Fascinatingly, Gange et al.³¹ reported the higher intensity took longer for the tissue temperature to increase. At a 1.0 cm depth, it took 8 minutes for a 4.16°C tissue temperature increase and 15 minutes for a 4.36°C temperature increased.³¹ With a 1 cm depth, the reported rate of tissue temperature increase per minute dropped from 0.7°C/minute to 0.5°C/minute with the increase of intensity. Similarly, a 1.75 cm depth the reported rate of tissue

temperature increase per minute dropped from 0.4°C/minute to 0.3°C/minute with the increase of intensity. The lack of increases in tissue temperature with a higher intensity could be in response to the quality of the Dynatron Solaris US machine. The Dynatron has a higher BNR which can cause hot spots and tissue damage during US treatment. With the aforementioned temperature increases by Gange et al.³¹ and no significant temperature increase between the intensities in the current study, when using the Dynatron US Machine selecting the 1.0 W/cm² intensity is more effective than a higher intensity.

A 50% intensity increase suggested in the Athletic Training textbooks^{1, 10} is to combat impedance occurring during immersion US. Similar to the 1.0 W/cm² results, there was a significant difference between the baseline and ending temperature for the 1.5 W/cm² intensity over a 10-minute treatment. Based on this finding, an intensity of 1.5 W/cm² over 10-minutes is effective at increasing intramuscular temperature from baseline. The rate of intramuscular temperature increases based on the textbook¹⁰ parameters for a direct method therapeutic US treatment using the parameters 3 MHz, 1.5 W/cm² is 0.90°C per minute (Appendix A).^{4, 10} Throughout a 10 minute treatment in accordance to the textbook parameters, there should be a 9°C overall temperature increase (Appendix A).^{4, 10} However, this research study showed only a 4.78°C overall temperature increase and a 0.478°C/minute temperature increase. The rate of heating in the current study is 0.422°C/minute less than the suggested direct method rate in the textbook.¹⁰ This could be due to an increased impedance with the immersion US.

Recommendations Regarding Utilizations of Findings

When administering immersion US, selecting the appropriate parameters is important to providing quality care to patients. From this experiment using the Dynatron Solaris US machine, and intensity of 1.0 and 1.5 W/cm² increase tissue temperature at the same rate over a 10-minute

treatment. Heating at the same rate is clinically significant because as clinicians select parameters, certain treatment outcomes are expected with the various parameter options. If US machines do not heat at the rate as expected, then the patient will not receive the desired effects. Commonly, Athletic Trainers have a short window of time for the treatment of athletes, performing US treatments for 5-7 minutes' total. In the research study, 5-minutes of treatment only increased the tissue 2.78°C. If the goal of the treatment was vigorous heating (4°C), then it would not be met. Only after a 10-minute immersion US treatment would vigorous heating be achieved. Clinically either 1.0 W/cm² or 1.5 W/cm² can be used to vigorously heat tissue temperature. Based upon the findings of this research when administering US with the Dynatron US Machine 1.0 W/cm² is suggested. The Dynatron US machine has a high BNR, using the lower intensity would reduce the risk of creating hot spots with the same benefits of the higher intensity as suggested by the findings of the research.

Recommendations for Future Research

Future research is needed in this area for several reasons. The level of impedance with a 1 cm distance between the skin and transducer is unknown with no significant difference among intensities. Should the intensity be increased by 75% or 100% rather than 50%? With the degree of machine variability, there should be separate heating rate charts for each US machine. Other US machines have been suggested to significantly raise tissue temperature more efficiently than the Dynatron Solaris® 700 Series Ultrasound machine. These parameters should be examined further on various other US machines to determine if a 50% intensity increase would produce significant intramuscular temperature increases. Future studies may also wish to study the effect of such a treatment on damaged or injured tissue for which therapeutic ultrasound is most commonly used.

Limitations

There were several limitations that restricted the current research. As previously mentioned there is variation in US machine treatment output. The only machine that was used in this study was the Dynatron 708 Series. The research results could potentially vary based on the selected US machine. Another limitation of the present research is the use of only healthy tissue. Clinically US is used to treat injured tissue not healthy tissue, the study could be more clinically relevant if examined on injured tissue. Additionally, another limitation was the homemade template which ensured that a 1 cm distance was maintained throughout the US treatment (Appendix B). However, the template did not allow for air bubbles to be removed quickly without the disruption of the US treatment. If air bubbles were removed quickly as they formed, the level of impedance would be reduced, possibly increasing tissue temperature more. Lastly, immersion US is frequently executed on smaller or bony areas such as the ankle. In the current research the tissue temperature was collected from the gastrocnemius, a larger area of the body. Inserting a needle catheter in an area such as the ankle would be more painful for the participant with a higher associated risk. There would be a stronger level of evidence if the research was performed on a smaller or bony area of the body.

Conclusion

The primary conclusion was that there was not a significant interaction between time and the intensities of 1.0 W/cm^2 and 1.5 W/cm^2 in overall intramuscular temperature increases with immersion US over a 10 minute, continuous US, 3 MHz, and a 1.5 cm depth treatment. A 50% intensity increase did not produce greater tissue temperature increases during immersion US than the lesser intensity. This research study is important because it provides the first research in 22 years refuting the claim that intensity should be increased by 50% when performing immersion

US with the Dynatron Solaris machine. While US gel pads are more effective at increasing tissue temperature, immersion US is more cost effective. Future research is necessary to provide more accurate parameters for immersion US indirect method. A lack of suitable parameters for immersion US could lead to a decrease in patient treatment outcomes. As clinicians treat patients with improper parameters, it may inhibit the treatment. More comparable and evidence-based research will provide better patient care by clinicians.

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APPENDIX A. RATE OF MUSCLE HEATING

Table A1. Rate of Muscle Heating*

Intensity (W/cm²)	Frequency; 1 MHz	Frequency; 3 MHz
0.5	0.07°F (0.04°C)	0.54°F (0.3°C)
1.0	0.36°F (0.2°C)	1.08°F (0.6°C)
1.5	0.54°F (0.3°C)	1.62°F (0.9°C)
2.0	0.72°F (0.4°C)	2.52°F (1.4°C)

*Draper and Prentice¹ and Draper and Knight¹⁰

Table Note: The table is from Athletic Training textbooks^{1, 10} displaying the intramuscular tissue temperature rate of heating per minute during a direct method ultrasound treatment.

APPENDIX B. FIGURES



Figure B1. Ultrasound Template.

Figure Note: The template is made of Styrofoam, and wrapped in Scotch electrical tape. The template has a cut-out 2 times the ERA, and is 1 cm thick to ensure the transducer remains 1cm away from the skin. The inside edge of the template will allow for the transducer to rest inside of the hole, not impeding any of the US waves, while allowing the outer edge of the transducer to rest on the template, allowing for a distance of 1 cm between the skin and the transducer.



Figure B2. Needle Catheter Insertion

Figure Note: The insertion of the 20 gauge 1.16 needle catheter is performed with the carpenter square resting level on the left gastrocnemius. The two Sharpie marks on the white tape affixed to the carpenter square align with the treatment area mark and the insertion mark. The distance between the 2 marks on the tape is measured and marked on the thermocouple. The thermocouple was inserted to the measured distance ensuring the thermocouple was 1.5 cm underneath the treatment area.



Figure B3. Ultrasound Treatment

Figure Note: The figure shows the participants leg submerged into the water bucket, while therapeutic ultrasound is performed within the template under water.