

THE EFFECT OF 2 MHZ ULTRASOUND ON INTRAMUSCULAR TEMPERATURE AT
1.5, 2.5, AND 3 CM DEPTHS

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The Effect of 2 MHz Ultrasound on Intramuscular Temperature at 1.5, 2.5,
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ABSTRACT

The research objective was to determine the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depths after a 20 minute treatment at 1.0 W/cm². A two-factor ANOVA experimental design guided this study. Three thermocouples were inserted into the medial gastrocnemius of twenty participants at all 3 depths. The ultrasound parameter settings consisted of: 2 MHz, continuous, 1.0 W/cm². The mean intramuscular temperature increase at 20 minutes was the greatest at the 1.5 cm depth (5.22°C ± 1.25°C), then the 2.5 cm depth (3.59°C ± 1.61°C), then the 3 cm depth (2.75°C ± 1.48°C). Significant differences were found in the increase of intramuscular temperature of 2 MHz therapeutic ultrasound at all 3 depths, particularly at the 1.5 cm depth. Treatment goals and the type of machine need to be taken into account when delivering an ultrasound treatment in order for it to be effective.

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TABLE OF CONTENTS

ABSTRACT.....	iii
ACKNOWLEDGMENTS.....	iv
LIST OF TABLES.....	viii
LIST OF FIGURES.....	ix
CHAPTER 1. INTRODUCTION.....	1
<i>Purpose of the Study</i>	2
<i>Research Question</i>	2
<i>Definition of Terms</i>	3
<i>Importance of Study</i>	4
<i>Limitations</i>	4
<i>Delimitations</i>	4
CHAPTER 2. REVIEW OF LITERATURE.....	5
<i>Ultrasound Definition</i>	5
<i>Thermal and Non-Thermal Effects</i>	6
<i>Indications and Contraindications</i>	7
<i>Parameters</i>	8
Frequency.....	8
Intensity.....	10
Duty Cycle.....	11
Transducer Head and Effective Radiating Area.....	12
Movement Speed of the Transducer.....	14
Treatment Duration.....	14

Coupling Medium.....	15
<i>Ultrasound Equipment</i>	17
<i>Ultrasound Efficacy</i>	20
<i>Summary</i>	23
CHAPTER 3. METHODOLOGY.....	24
<i>Experimental Design</i>	24
<i>Population of the Study</i>	24
<i>Instrumentation for Data Collection</i>	25
<i>Procedures</i>	25
<i>Analysis Procedures</i>	27
CHAPTER 4. MANUSCRIPT.....	28
<i>Abstract</i>	29
<i>Introduction</i>	30
<i>Methods</i>	32
Participants.....	32
Instruments.....	32
Procedures.....	33
<i>Statistical Analysis</i>	35
<i>Results</i>	35
<i>Discussion</i>	36
<i>Conclusion</i>	39
<i>References</i>	46
CHAPTER 5. DISCUSSION.....	47

<i>Conclusion</i>	53
REFERENCES.....	55
APPENDIX A. SAMPLE SIZE CALCULATION.....	59
APPENDIX B. AMOUNT OF TIME TO INCREASE INTRAMUSCULAR TISSUE TO 1°C, 2°C, AND 4°C AT 1.5, 2.5, AND 3 CM DEPTHS WITH THE DYNATRON SOLARIS ULTRASOUND MACHINE.....	60

LIST OF TABLES

<u>Table</u>	<u>Page</u>
1. Mean rate per minute temperature increase at the 1.5 cm depth, the 2.5 cm depth, and 3 cm depth at 1.0 W/cm^2	40
2. Clinical amount of time to increase intramuscular tissue to 1°C , 2°C , and 4°C at 1.5, 2.5, and 3 cm depths based on heating rate with the Dynatron Solaris ultrasound machine.....	41
3. Mean intramuscular temperature increase from baseline to 10 and 20 minutes at 1.5, 2.5, and 3 cm depths.....	42

LIST OF FIGURES

<u>Figures</u>	<u>Page</u>
1. Beginning and ending temperatures at the 10-minute and 20-minute mark for the 1.5 cm depth.....	43
2. Beginning and ending temperatures at the 10-minute and 20-minute mark for the 2.5 cm depth.....	44
3. Beginning and ending temperatures at the 10-minute and 20-minute mark for the 3 cm depth.....	45

CHAPTER 1. INTRODUCTION

Therapeutic ultrasound (US) uses acoustic energy to penetrate tissue and cause healing.¹ One of the main uses for US is for the treatment of orthopedic injuries in the field of sports medicine. Ultrasound can be used to create thermal effects which result in various physiological outcomes including increased tissue temperature, blood flow and metabolic rate, decreased trigger point stiffness, as well as non-thermal effects like edema reduction and collagen synthesis.²⁻⁶ These indications for US are used to treat athletic injuries.

Tissue temperature increase is desired with the use of US because as the tissue temperature increases, different physiological effects occur which provide an ideal environment for healing. An increase in metabolic rate is seen in the tissue with an increase of 1° Celsius (C).⁷ A 2°-3° C tissue temperature increase will increase blood flow⁶, decrease muscle spasms, and decrease pain.^{6,7} An increase of at least 4° C will increase tissue extensibility,^{1,3,8} allowing the tissue to be stretched more easily. These tissues must be stretched immediately after the US treatment to take full advantage of the 'stretching window' and increase range of motion (ROM) of that tissue.⁴ An increase of at least 1°C is needed for a therapeutic effect to take place, but an increase of 8°C or higher can result in damaged tissue.⁷

In order to reach the therapeutic temperature goal, US can be delivered and adjusted by altering parameters for use in a clinical setting. Common parameters include frequency, duty cycle, intensity, and treatment duration. The frequency parameters are either 1, 2, or 3 MHz. Frequency is measured in megahertz (MHz) and can range from .8 up to 3 MHz.⁹ A frequency of 1 MHz can penetrate from 2.5 cm up to 5 cm within the tissue, while 3 MHz reaches up to a 2.5 cm depth.^{6,8,10}

The most commonly used frequencies in a clinical setting are 1 and 3 MHz. While 1 and 3 MHz are the most frequently used, a 2 MHz frequency is a setting available on some therapeutic ultrasound machines. Theoretically, 2 MHz US should fall between 1 and 3 MHz in terms of depth reached, between 2.5 and 5 cm. The US manufacturers state that the 2 MHz frequency is to be used for medium depth tissues¹¹. However, to date there has been no published research performed on 2 MHz US and the depth to which it can penetrate the tissue to support or refute this statement. Information and data regarding the depth to which 2 MHz US penetrates muscle tissue may aid clinicians in choosing an US setting, depending on the depth of tissues they want to treat.

Purpose of the Study

The purpose of this study was to determine the depth of penetration of 2 MHz for medium depth tissues. Researching the specifics of 2 MHz US will allow clinicians to ascertain whether or not 2 MHz therapeutic US can be used as an effective treatment for medium depth tissues.

Research Question

What is the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depths after a 20 minute treatment at 1.0 W/cm²? It was hypothesized that at a 2.5 cm depth, intramuscular temperature would reach a therapeutic increase of 1°C or higher, but the 1.5 and 3 cm depths will not.

Definition of Terms

Beam non-uniformity ratio (BNR) – The ratio between the highest intensity in an ultrasonic beam and the output reported on the meter.⁷

Duty cycle - The ratio between the pulse duration and the pulse interval: $\text{Duty cycle} = \frac{\text{pulse duration}}{\text{Pulse duration} + \text{Pulse interval}} \times 100$.⁷

Frequency - The number of times the crystal in the ultrasound head expands/contracts, affecting the depth of penetration.⁷

Intensity – The amount of power, strength of sound waves, generated by the ultrasound unit at a given location.⁷

Non-Thermal – Using a pulsed output and normal treatment intensities or a continuous output at a low intensity on an ultrasound unit. Non-thermal effects are used when temperature increase is not desired.⁷

Therapeutic - Having healing properties.⁷

Therapeutic Temperature – Begins when tissue temperature raises at least 1°C.⁷

Thermal – Used when a tissue temperature increase is desired.⁷

Ultrasound – A deep penetrating modality capable of producing changes in tissue through both thermal and non-thermal mechanisms.⁷

Importance of Study

There is currently no research on 2 MHz US, yet it is displayed as a parameter setting on many modalities used in the clinical setting. Manufacturers of US machines report 2 MHz should be used for the treatment on medium depth tissues¹¹. Researching the specifics of 2 MHz US will allow clinicians to determine the appropriate frequency for medium depth tissues.

Limitations

1. Only a Dynatron 708 ultrasound machine was used.
2. Only uninjured subjects were used.

Delimitations

1. Subjects did not have any vascular or neurological conditions.
2. Male and female volunteers had an age range of 18-30.
3. All subjects were tested with 2 MHz US treatment for 20 minutes at 1.0 W/cm² with thermocouples inserted at 1.5, 2.5, and 3 cm at one time.
4. A 20-minute treatment was used with the following parameters: 2 MHz frequency; 1.0 W/cm² intensity; continuous mode; 5 cm² transducer head at 2-3 times ERA; at depths of 1.5, 2.5, and 3 cm deep.
5. Subjects did not have a lower extremity surgery or injury within the last 6 months.
6. The triceps surae adipose was measured with diagnostic US and did not have more than 1.0 cm in adipose tissue.

CHAPTER 2. REVIEW OF LITERATURE

The purpose of this study was to determine the depth of penetration of 2 MHz ultrasound (US) for medium depth tissues. The following research question guided this study: What is the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5 and 3 cm depth after a 20 minute treatment at $1.0\text{W}/\text{cm}^2$? Researching the specifics of 2 MHz US will allow clinicians to ascertain whether or not 2 MHz therapeutic US can be used as an effective treatment for medium depth tissues. This literature review was organized into the following areas: ultrasound definition, thermal and non-thermal effects, indications and contraindications, parameters, ultrasound equipment, ultrasound efficacy, and summary.

Ultrasound has been used as a therapeutic modality to treat various soft tissue injuries for over 60 years.¹² To date, there are no standard treatment protocols for ultrasound in a clinical setting.¹³ While frequencies of US range from 0.75-3 MHz,¹ frequencies of 1 and 3 MHz are the only two commonly used by most clinicians.⁷ Currently, there has been no published research investigating 2 MHz US and to which depth in the tissue it can penetrate. Therefore, this is a literature review of 1 and 3 MHz US in order to draw conclusions about 2 MHz US.

Ultrasound Definition

Ultrasound can be defined as a deep penetrating modality capable of producing changes in tissue through both thermal and non thermal (mechanical) mechanisms.⁷ A crystal, located inside the transducer head, receives an alternating current of both positive and negative electrical charges created from the electricity through the wall outlet. This electrical current from the wall outlet causes the crystal to expand and contract. When the crystal contracts, it produces a positive and negative current under the transducer and when it expands, the polarity is reversed.⁷ This, in turn, produces US and is referred to as the piezoelectric effect. The piezoelectric crystal

expands and contracts and the US creates acoustic sound waves in the tissue causing vibration within the tissue.⁷ These sound waves from the piezoelectric crystal and transducer head move energy through the tissue. As this occurs, energy is lost and absorbed in the tissue as it disperses from the transducer head, resulting in heating of that tissue.^{1,14}

Thermal and Non-Thermal Effects

The use of US results in both non-thermal and thermal effects.¹⁴ Non-thermal, or mechanical, effects are generally associated with pulsed US with cavitation and acoustic microstreaming occurring as a result. Cavitation is the effect of gas bubbles moving in a recurring manner. These bubbles expand and contract with sound waves.⁷ Acoustical streaming is also a non-thermal effect of US, which is a unidirectional fluid movement along cell membranes caused by the sound wave.⁷ This streaming effect causes the cell membrane to change its permeability, enabling an enhanced environment to promote increased cell activity, and collagen synthesis.⁷

Using US in a continuous mode usually results in a thermal effect.⁶ The mechanical effects discussed previously occur in both thermal and non-thermal US. The rate of absorption and consequently the increase in tissue temperature is in direct relation to the tissue's density and heat capacity,¹ the type of tissue penetrated, the intensity, and the frequency produced by the US machine.⁶ Tissue temperature increase is a main thermal effect of US.² The degree to which the tissue is heated results in different effects on the tissue itself. Mild heating is considered an increase of 1°C, moderate heating is an increase of 2°C to 3°C, and vigorous heating is an increase of greater than 3°C.³ When a tissue is mildly heated, an increase of metabolic rate by 13% has been found^{2-4,6} as well as a decrease in mild inflammation.³ Common moderate heating results are the decrease of muscle spasms, decrease in pain, and increase in blood flow.^{2,7}

Vigorous heating of the tissue is utilized to gain collagen elasticity as well as scar tissue extensibility.^{1,3,8}

Indications and Contraindications

In addition to thermal and non-thermal effects, there are both indications and contraindications for the use of US. Original indications had been found that US can be used to increase range of motion,^{2,8} decrease pain,^{1,8,14,15} decrease muscle spasm, edema reduction, and wound healing.⁷ Recently, Sahin¹⁶ looked at the treatment of US with a stretching program and the effects of decreasing muscle spasms in post-stroke patients. His findings contradict with Starkey⁷ because Sahin¹⁶ found that there was no significant difference between the group that received US and stretching versus just stretching. The evaluation criteria for spasticity was graded via modified Ashworth scale (MAS), Hmax/Mmax amplitude ratio, Brunnstrom Motor Recovery Stage (BMRS), and the Functional Independence Measurement (FIM). While these tests are reliable for rehabilitation purposes, they may not grade spasticity objectively enough. Ultrasound was applied to the calf muscle in one of the two groups in a continuous mode for 10-minutes, at 1.5 W/cm^2 . The frequency was not stated, which could indicate why decreased spasticity was not found. If 1 MHz was used, it would explain why the tissue was not heated and a decrease in spasticity was not found. According to a study done by Draper and Castel⁶, an US treatment of an intensity of 2.0 W/cm^2 took 10-minutes to heat tissue up to 4° C . This 4° C temperature increase is the minimal increase that has to occur to be considered a therapeutic effect to increase tissue extensibility. In addition, 1 MHz would be an inappropriate frequency setting for the gastrocnemius because it is not considered a deep tissue muscle. Sahin¹⁶ also only looked at patients who have had a stroke, which is a small population in comparison to the many other types of patients that receive rehabilitation.

More indications were discovered throughout the years. Draper¹⁴ has stated that 3 MHz US is indicated for conditions like elbow epicondylitis, patellar tendinitis, plantar fasciitis, and damage to ankle ligaments because of the more superficial location of the structures involved. Draper et al.⁵ discovered that US could be used to decrease trigger point stiffness by 2mm in depth measured by a pressure algometer. There are also contraindications for the use of US. Ultrasound, in a 100% duty cycle, continuous mode, is contraindicated for acute injuries because of the thermal effects that will cause the tissue temperature to increase, causing further damage to the already injured tissue. Ultrasound should not be utilized over sensitive body parts (eyes, genitals, ears, head and face), over the spine, growth plates, tumors, the abdomen of pregnant women, diagnosed stress fractures, and body parts with impaired circulation and/or sensory deficit.⁷

Parameters

Currently, there are no standard treatment protocols when using US as a therapeutic modality treatment. However, there are different parameters to be chosen for an effective US treatment including frequency, intensity, duty cycle, transducer head and effective radiating area, treatment duration, and coupling medium.

Frequency. Frequency, measured in MHz, is the number of ultrasonic waves output in one second.⁷ Frequency choices on therapeutic US machines in rehabilitation of injuries can range from 1 MHz to 3 MHz. The most common frequencies used are 1 MHz and 3 MHz. One MHz US is considered a low-frequency, high wavelength ultrasound and penetrates deeper than 3 MHz, which is considered high-frequency, low wavelength. Different frequencies are chosen to heat different tissue depths based on the half-value depth.⁷ Half value depth is defined by

Draper and Castel⁶ as the depth by which 50% of the US beam is absorbed in the tissue.

Therefore, in order to heat deeper tissues, 1 MHz should be used and vice versa for 3 MHz.

There has been some discrepancy over the years as to the depth these two common frequencies can reach. In 1995, Draper and Castel⁶ found that 1 MHz heats the tissues up to 5 cm. Up until then, no concrete research had been published about the depth of 1 MHz US. This research was contradicted when Leonard¹⁷ found that 1 MHz at 2.0 W/cm² produced lower intramuscular temperatures than 1.0 W/cm². Draper and Castel⁶ used the Omnisound 3000 for their experiment in which the manufacturer guide over reported its output power, 5.0 versus 4.91 Watts, as opposed to the Rich-Mar Theratouch used by Leonard which reported 5.0 versus 4.62 Watts. These differences could possibly be due to the different machines used and/or the use of different intramuscular temperature measuring methods. A study performed by Draper and Castel⁶ showed that US used at 3 MHz frequency heated tissues up to 1.6 cm deep. The authors themselves stated that the depth limit of 3 MHz US had not been researched. Nine years later, Hayes¹⁰ performed a study that further delved into 3 MHz US and contradicted those previous findings, discovering that 3 MHz heated deeper than originally thought and was appropriate for depths up to 2.5 cm. Hayes also stated that selecting the right frequency to treat tissues of medium depth was undefined because the depth to which 3 MHz can penetrate is unknown.¹⁰ Draper lists the use of the wrong frequency as number seven rank of his list of top ten mistakes clinicians make when administering US.¹⁴ Draper¹⁴ stated that 1 MHz US was the most commonly used, which was supported by a survey study (8/8 clinicians) conducted by Demchak¹³ where he found that every clinician chose 1 MHz as their frequency of choice when attempting to achieve deep heating. This may be due to the fact that 3 MHz was developed around 1986,⁶ later than 1 MHz, so clinicians were set in their ways of what they were first

taught. To date, however, popularity and common choices among US frequencies remain 1 and 3 MHz.

Two MHz US was introduced in the mid-1990's¹⁴ and currently, there has been no research published on its effects or penetration depth. One MHz US has reached tissue depths from 2.5-cm to 5-cm deep,⁶ while Hayes¹⁰ supported the notion that 3 MHz US can penetrate tissues from 0 to 2.5-cm deep, further than the 1.6 originally thought.⁶ In theory, 2 MHz ultrasound should be able to penetrate tissues somewhere in between the ranges of 3 and 1 MHz. Unfortunately, researchers make little to no mention of 2 MHz US as a treatment option. Leonard et al.¹⁷ does, however, stated that more research needs to be done on intramuscular tissue that lies between 3 and 5-cm deep to see if US is heating those tissues efficiently. Hayes¹⁰ also supported this belief, stating that the question of which frequency is appropriate to use for medium depth tissues needs to be answered. This lack of information on 2 MHz US shows a need for more research to be conducted in this area.

Intensity. Ultrasound, used at a lower intensity, has been used to promote a normal physiological response to an injury of the human body, particularly, soft tissue injuries.¹ Intensity of an US treatment is defined by Starkey⁷ as “the strength of the sound waves at a given location within the tissue being treated” (p. 161).⁷ It is also called spatial average intensity (SAI). Spatial average intensity is measured in W/cm^2 and is a measure of the power per unit area of the effective radiating area (ERA) of the transducer.⁷ Different intensities will result in different rates of tissue temperature increase as well as different physiological outcomes. Draper and Castel⁶ found that at $2.0 W/cm^2$, a 10-minute treatment at 1 MHz raised the intramuscular temperature $4^{\circ}C$ at both a 2.5 and 5 cm depth. An intensity of $2.0 W/cm^2$ at 3 MHz was also tested, but had to be discontinued at an average of 3 minutes, due to the rapid temperature

increase causing it to be uncomfortable for the subjects. Draper et al.² also looked at an US treatment of 3 MHz with an average of 1.5 W/cm² and found that continuous 3 MHz ultrasound increased tissue temperature, on average, 5.3°C in 6 minutes from a mean baseline temperature of 33.8°C.⁶ These studies helped to support that higher intensities heat tissues at a faster rate as compared to lower intensities. While there is no standard protocol as to what intensity to choose when giving an ultrasound treatment, a number of factors need to be considered. These factors include the type of tissue to be targeted and the depth, the treatment size area, the type of injury, and the temperature increase appropriate for that type of tissue.⁶

Duty Cycle. There are only two possible choices of duty cycle options in US treatments, pulsed or continuous. Duty cycle is based on a ratio between pulse length and pulse interval which equals a certain percent duty cycle.⁷ Pulse length refers to the amount of time for the pulse to start from nonzero charge and return to nonzero charge; a complete cycle. Pulse interval is time between the pulses.⁷ It is considered pulsed US when the duty cycle is less than 100%. Using pulsed US has been generally used to achieve mechanical effects.^{1,18} In theory, this would make pulsed US ideal for use on injuries that are still in the acute stage, because a therapeutic temperature increase in the tissue would not be seen. However, there is evidence that disputes this original information. Researcher ter Haar¹ stated in his article that mechanical effects occur in both thermal and non-thermal effects. Later on, Gallo¹⁹ conducted a study in which the results showed that pulsed US increased intramuscular temperature at a very similar rate as continuous US, with a difference in temperature increase only 0.08°C. Gallo's study compared continuous US with pulsed US, setting the spatial average temporal average (SATA) intensity at 0.5 W/cm². While similar temperature increases were seen, there were no significant statistical differences between the baseline temperature, extent, or rate of tissue temperature increase in the two

groups. Gallo also discussed the SATA intensities, stating that these need to be taken into account when giving an ultrasound treatment because they can affect the temperature to which the tissue is heated. Spatial average temporal average intensity measures the power delivered to the intramuscular tissues over a period of time and is only applicable to pulsed US.⁷ If a pulsed US is set at a 50% duty cycle, then the energy delivered will only be 50% of the energy that would be delivered in a 100% continuous duty cycle mode. Gallo's study provides data that pulsed and continuous US, when equal SATA intensities are given, will increase intramuscular tissue temperatures in a similar fashion. If pulsed US at 50% duty cycle is used to achieve only mechanical effects, the intensity should be at 0.4 W/cm² or lower.²⁰ Given these results, pulsed US seems to deliver unwanted thermal effects when only non-thermal effects are desired. Implications in Gallo's study may be that subject's received both treatments, the second treatment given after tissue temperature had returned to baseline and remained consistent for another 5 minutes. Further research on continuous compared to pulsed US effects is needed.

Transducer Head And Effective Radiating Area. Sound waves created from ceramic or quartz piezoelectric crystals are emitted from a transducer head, usually made of low loss lead zirconate titanate.^{1,21} This transducer head can come in various sizes, which will affect the effective radiating area (ERA) of the treatment space. The US transducer head should be determined by the size of the area being treated. The ERA is actually dependent on the size of the crystal located in the transducer. It is suggested that when using US, treatment size should not go outside 2-3 times the ERA. For example, a 5-cm transducer head has a crystal inside it that is approximately 2/3 the size of the head itself, so the ERA of the treatment area will be in correlation to the crystal size, not the transducer head.^{1,22} This notion has remained consistent in the literature throughout the years, although different ERA's have been tested. A study

performed by Chan⁸ compared a 2-ERA to a 4-ERA in 3 MHz US and found that the 2-ERA was more effective in heating the human patellar tendon tissue than an area 4-ERA. The 2-ERA treatment increased 2.1°C per minute whereas the 4-ERA treatment increased 1.3°C per minute, respectively. Demchak¹³ found that a 1 MHz treatment at 1.3 W/cm² continuous for 8 minutes over an area that was 3.9 ERA over the triceps surae muscle did not heat the tissues efficiently enough to reach vigorous heating (only 2.2°C). The tested parameters were based on a survey conducted of eight clinicians, asking what parameters they would use to vigorously heat the triceps surae muscle. Draper and Castel⁶ found that US at a frequency of 1 MHz heats at 1/3 of the rate of 3 MHz. Reasons for the lower tissue temperature results could be due to the increased ERA, the decreased minute duration of treatment (8-min compared to 10-min), and the lower intensity utilized (1.3 W/cm² compared to 1.5 W/cm²), and the frequency used.

Miller et al.¹⁵ compared temperature increases at the midpoint and periphery of an area 2 times the size of the ERA. They found that for a 1 MHz, 1.5 W/cm² at continuous mode treatment, the midpoint temperature increased 0.26°C per minute (2.62°C average increase) and periphery temperature increased 0.16°C per minute (1.58°C average increase) at a 4 cm depth. The midpoint temperature of a 3 MHz, 1.0 W/cm² continuous mode treatment increased 0.59°C per minute (5.88°C average increase) and periphery temperature increased 0.36°C per minute (3.64°C average increase) also at a 4 cm depth. This data coincides with Draper's⁶ study that found an average temperature increase of 5.3°C in ten minutes. Miller's data of 3 MHz US contrasts with a study performed by Chan⁸, who found that an area 2 times the ERA increased tissue temperature 2.1°C per minute with 3 MHz US. Discrepancies in results may be due to the equipment used, as Chan used thermistors and Miller et al. used thermocouples. Tissue density differences may have been another cause, because tendons heat faster in comparison to muscle.⁷

Chan's results were based on a study conducted on the patellar tendon, whereas Miller et al. conducted the study on the triceps surae muscle. Draper, Chan, and Miller et al. all used the Omnisound 3000 and therefore could not be a likely reason for any discrepancies found between the studies.^{6,8,15}

Movement Speed of the Transducer. Movement speed of the transducer can also affect the rate and intensity of tissue temperature increase. Intensity of US can vary and depends on the beam nonuniformity ratio (BNR). This ratio depicts the peak intensity that is found within the beam compared to the average intensity.⁷ Therefore, the higher the BNR, the higher the peak intensity. An ideal ratio would equal 1:1, meaning that the surface beam would be even and would not have any peak intensities.^{7,14} As BNR increases, the speed of the transducer must also increase in order to prevent creating a hot spot of the tissue. For example, if the intensity is 1.5 W/cm² and the transducer has a BNR of 6:1, the peak intensity would be 9 W/cm². A temperature increase of this amount could result in tissue damage. It has been found that the US treatment is more tolerable when the BNR is low.¹⁴ Prentice²³ states that a BNR ratio of 4:1 and lower is considered low.

Treatment Duration. The duration of treatment is another parameter that needs to be chosen when administering US. A 5-10 minute treatment duration has been anecdotally viewed as a common duration time for US treatments.⁶ Draper and Castel⁶ looked at the different temperature increasing rates of 1 and 3 MHz. This data is still utilized by many clinicians today.¹⁷ Draper and Castel stated that if vigorous heating of the tissue was the goal and the standard 1.5 W/cm² intensity was utilized, the US treatment should take around 10-12 minutes when using 1 MHz and 3-4 minutes when using 3 MHz.⁶ A 2.0 W/cm² intensity is also appropriate for a 10-minute treatment duration for vigorous heating. When moderate heating is

desired: a 4-6 minute treatment duration is required with a 2.0 W/cm^2 intensity at 1 MHz and a 6-8 minute treatment duration is required with a 1.5 W/cm^2 intensity at 1 MHz.⁶ Intensities lower than 1.5 W/cm^2 do not heat the tissue enough in a 10-minute duration.⁶ Moderate heating can also be achieved through 3 MHz US. A 3-4 minute treatment duration is required with a 1.0 W/cm^2 intensity and a 7-10 minute treatment duration is required with a 0.5 W/cm^2 intensity at 3 MHz. Intensities higher than 1.0 W/cm^2 at 3 MHz heated the tissue at a fast rate, causing the subject's to ask the treatment to be discontinued.⁶ The 1 MHz treatment would be used to heat tissues between 2.5 to 5 cm deep and the 3 MHz treatment would be used to heat tissues up to 2.5 cm deep. In addition, if these parameters are performed on an US machine that has a 6:1 beam non-uniformity ratio (BNR), the intensity would need to be decreased and the treatment time increased. Increased intensity also increases the overall Watts going into the tissue. Therefore, a high BNR ratio is considered unsafe. Leonard et al.¹⁷ found that a 10-minute treatment duration of 1 MHz at 0.5, 1.0, 1.5, and 2.0 W/cm^2 did not heat the tissues up to the preferred 40°C . This data contrasts the study performed by Draper and Castel.⁶ Inconsistencies could be due to the equipment used as Draper and Castel used an Omnisound 3000, while Leonard used a Rich-Mar Theratouch 7.7. Draper and Castel used thermistors as compared to Leonard, who used thermocouples. Finally, Draper and Castel measured intramuscular temperature of their 1 MHz treatments at 2.5 cm and 5 cm deep. Leonard inserted the thermocouple up to only 4 cm. Treatment duration is dependent on desired tissue temperature and what type of heating effects one wants to occur as a result of the treatment.

Coupling Medium. A coupling medium is necessary in order to allow the sound waves to pass from the transducer head through the skin.¹ The most common types of coupling agents used are gel, degassed water, white petroleum, and mineral oil.²⁴ Ultrasonic gel seems to be the

gold standard of coupling mediums. Water is commonly used for certain extremities that have an awkward shape.¹ Different types of coupling mediums have been researched and tested. Casarotto et al.²⁴ conducted an experiment comparing the thickness of four types of coupling agents and their temperature heating rates. They found that the mineral oil and white petroleum increased tissue temperature more so than the water and gel agents and that subjects felt increased heat with the white petroleum agent. Merrick et al.²⁵ tested the difference of temperature increase between coupling gel and a gel pad. They found that the gel pad was just as efficient as using a coupling gel when giving a treatment of 1 MHz US for 7 minutes, with a 1.5 W/cm² intensity. The coupling gel, from a baseline temperature of 37°C ± 0.7°C had a peak temperature of 39.2°C ± 2.4°C. The gel pad treatment had a baseline temperature of 36.9°C ± 0.7°C with a peak temperature of 39.4°C ± 1.5°C. Statistical analysis showed there was no significant difference between the gel pad and coupling gel treatment.

However, a study performed by Bishop et al.²⁶ produced different results than Merrick's study. The study tested a combination of using US gel on the skin, followed by an Aquaflex gel pad, and finally more US gel on top compared to a gel/pad and coupling gel only treatment to see if tissue temperature increased. They found that the gel treatment increased tissue temperature the most (7.72°C ± 0.52°C) as compared to the gel/pad treatment (4.98°C ± 0.52°C). They also found that the gel/pad/gel combination increased tissue temperature an average of 6.68°C (± 0.52°C) over a 10-minute treatment duration of 3 MHz US. Differences in results between Merrick and Bishop could be attributed to the difference in frequencies, duration of treatment, level of intensity used, and body area treated.

In 2010, Draper et al.²⁷ supported the notion that ultrasound gel was the most efficient coupling medium to heat intramuscular tissues (overall increase = 13.3°C ± 0.73°C, peak

temperature = 42°C). The US gel raised the temperature of the human Achilles tendon the most in comparison to a 1-cm and 2-cm gel pad ($9.3^{\circ}\text{C} \pm 0.75^{\circ}\text{C}$; $6.5^{\circ}\text{C} \pm 0.72^{\circ}\text{C}$, respectively). While the 1-cm gel pad did not heat at the same rate the ultrasound gel did, it could be useful when treating patients with open wounds, those with sensitive skin, or over areas that are difficult to keep good contact with the body part and transducer head.²⁷ Draper's results contrast Merrick's²⁴ results in that US gel heated the tissue more so than using a gel pad as a coupling agent. Draper's²⁷ results also contrasted with Bishop's results, which may be due to the type of tissue being treated (muscle versus tendon).

Another study performed by Chester²⁸ two years earlier which looked at US and the Achilles tendon, contrasts Draper's²⁷ study. Chester²⁸ looked at the use of US compared to eccentric calf muscle training in the pain management of Achilles tendon pathology over a 12-week period. Subjective data showed a decrease in pain for the US group in the first 6 weeks of the study and an increase in subjects' self assessment of functional ability. However, he found that there were no significant differences between the US and eccentric training groups. Differences between Draper and Chester's results may be attributed to the small sample size, that it was only a single blind study, and that it looked at more subjective data whereas Draper's experiment solely looked at temperature increase in the Achilles tendon. While the two studies looked at two seemingly different outcomes, the results differ in concluding whether or not to use US as a therapeutic treatment for the Achilles tendon.

Ultrasound Equipment

The use of different US equipment has been a topic of debate in administering accurate US treatments. To date, clinicians are only recommended, not required to calibrate their US machines every two years.²⁹ Accredited Commission on Accreditation for Athletic Training

Education (CAATE) Athletic Training programs are required to calibrate their machines every year.³⁰ Artho et al.³¹ performed a study that measured the calibration accuracy of 83 US machines to see if the standard power output and timer accuracy was within the $\pm 20\%$ power output and $\pm 10\%$ timer accuracy standard given by the US Department of Health, Education, and Welfare. A Bio-Tek Digital Ultrasound Wattmeter and a digital stopwatch were used to test the accuracy of the power output and timers. The machines were tested at four different intensity settings (0.5, 1.0, 1.5, and 2.0 W/cm²) and one of five sizes for the transducer head (4, 5, 6, 8.5, or 10 cm²). For the power output category, 32 of the 83 machines tested were outside of the $\pm 20\%$ calibration standard in one or more of the four intensity settings.³¹ Fifteen of the 32 machines were over the $\pm 20\%$ calibration standard and 17 machines were under the $\pm 20\%$. Twenty-six of the 32 machines were outside the $\pm 20\%$ calibration standard of two or more tested settings. The timer accuracy category was further subdivided into mechanical timers and digital timers. All digital timers (58/83) were within the $\pm 10\%$ standard, while 7 (of 25) of the mechanical timers were outside of the $\pm 10\%$ standard.³¹ Further development of accurate power output of US machines is necessary to provide sufficient treatment of injuries.

Furthermore, US machines that have a high BNR might be more inconsistent when it comes to heating the tissues. Leonard et al.¹⁷ reported the Rich-Mar Theratouch had a BNR of 5.5:1 while the Ominsound 3000 had a BNR of 1.8:1. The drastic difference in BNR may have been the cause of the contrasting results Leonard obtained in the experiment when compared to Draper and Castel's⁶ study. Straub²² conducted a study that looked at the accuracy of different parameters such as ERA, power output, and intensity, according to the manufacturers guide. Straub²² found that the values reported on the manufacturer's guide on the different US machines varied greatly, with 23% (out of 15) outside of the manufacturer guidelines and FDA

guidelines. The ERA value category was overestimated. The machines tested were Chattanooga, Dynatronics, Mettler, Omnisound, Rich-Mar, and XLTEK. Of these, all but the Dynatronics and Omnisound machines over estimated their ERA value. Reported values and values experimentally measured were 4.0/3.95 cm², 5.0/5.35 cm², 5.0/4.01 cm², 4.45/5.05 cm², 5.0/3.83 cm², 5.0/4.61 cm², respectively.²¹ Output power was both over and underestimated. The Dynatronics, Omnisound, and Rich-Mar machines all overestimated the Watt output power (5.0/4.48 W, 5.0/4.91 W, and 5.0/4.62 W, respectively). The Chattanooga, Mettler, and XLTEK were all underestimated (5.0/5.37 W, 5.0/5.54 W, 5.0/5.23 W, respectively). These results of power output seem to contrast with a previous study performed by Artho et al.³¹ They found that the Dynatronics brand had a higher percentage of machines that were within the $\pm 20\%$ standard (n=10; =80%) and the Chattanooga, Rich-Mar, and Mettler brands had a lower percentage within the $\pm 20\%$ standard (n=51; <50%). Differences in results could be attributed to the use of different equipment. Artho et al.³¹ used a Bio-Tek Digital Ultrasound Wattmeter that was reported to have an accuracy percentage of $\pm 10\%$. Straub²² also used a wattmeter (UPM-DT-10), but reports were not specific as to the percent accuracy of the wattmeter machine.

In the Straub et al.²² study, differences in reported and actual values were found with intensity as well. Dynatronics and Omnisound both overestimated their intensity values (1.0/0.84 W/cm², 1.0/0.88 W/cm², respectively). Chattanooga, Mettler, Rich-Mar, and XLTEK underestimated their intensity values (1.0/1.10 W/cm², 1.0/1.39 W/cm², 1.0/1.21 W/cm², 1.0/1.15 W/cm², respectively). The tested transducers were all within the required 20% FDA guidelines for output power.²² This means that their actual readings did not deviate more than 20% of what was stated in the manufacturer's guide. All of this variability between ERA and power output affects the SAI and can result in inconsistency of US treatments.

Ultrasound Efficacy

Schabrun²⁹ conducted a systematic review to determine the accuracy of therapeutic US equipment since January 1973, and concluded that inaccurate output may be around two-thirds of US machines and one-third of timing devices on those machines used in a clinical setting. Eighteen studies were analyzed and 907 machines were tested in these experiments for accurate power output production and timing devices. Schabrun²⁹ found that over half of these studies (13/18) concluded that the US machines were inaccurate in the amount power output generated. He further broke the 18 studies down into three categories: single tests, individual tests, and multiple tests performed. Of the single tests, five studies (5/18) were analyzed and found that the average percent of machines inaccurate were 68.24%. Two studies were analyzed for the individual tests reported and found that 64.6% of the US machines were inaccurate. For the multiple tests performed category, 11 studies were assessed and the percentage of inaccuracy for one or more settings discovered was 63.2%.²⁹ The study then looked at the timing device accuracy of the US machines. Eight studies (8/18) were analyzed with 30.1% and 22.6% of the timers were inaccurate at 5 and 10 minutes. Schabrun speculates a number of different factors that may affect these inaccuracy reports. These include the calibration process and frequency of it, machine design, application technique, and type of water used during the treatment.³⁰ The results of Schabrun's study²⁹, while calculated in a different manner, seem to show increased inaccuracy of US machines in comparison to Schraub's study. This may be due to the fact that Schabrun looked at studies that were as old as 1973, when equipment was less developed than today. Furthermore, Schabrun²⁹ stated that the studies analyzed were given a rank of Level 4, low-quality cross-sectional surveys, on the hierarchy of evidence created by Sheffield University. Poor quality or flawed research design is more apt to produce skewed results.

Furthermore, Baker³² conducted a review of therapeutic US to determine its efficacy as a therapeutic modality. He reviewed 35 randomized control trial (RCT) studies that were published between the years 1975 and 1999. These studies were analyzed for their patient outcomes and efficiency of methodology. Ten of the 35 studies were deemed to have sound methodology. Of these 10, two RCT's found a beneficial improvement with the use of US for calcifications in the shoulder and carpal tunnel syndrome. The other 8 studies found no significant difference between the US and placebo treatments conducted. Baker³² concluded that there is little evidence to support that therapeutic ultrasound is effective.

The following year, Draper³³ produced an article contradicting Baker's article. He analyzed the eight studies which Baker stated had no significant difference between US and placebo groups. First, he found that of those 8 studies, only one used the optimal parameters of 2-3 times the ERA as a part of the study. Draper states that because the ERA used was more than the recommended 2-3 times the ERA, adequate temperature increase was not achieved. Next, Draper found that one³⁴ of the eight studies used the wrong frequency to treat a superficial tissue, owing that flaw to the undesired results. Then, Draper analyzed the treatment duration for the 8 studies and found that one study³⁵ only used US for 3 minutes for joint mobility. He cited his previous study⁶, saying that this would only cause a 1.2°C increase of tissue temperature and that this was not enough to increase mobility of a joint. Finally, he found that 7 of the 10 studies Baker did find appropriate used pulsed US at only 25%, with treatment times ranging from 2 to 15 minutes. The two in which Baker³² said US showed to be more beneficial than a placebo group had an increased treatment time of approximately 15 minutes. Draper³³ stated that had the treatment time been increased for the other 5 studies, the outcome could have been quite different.

Studies looking at effectiveness of clinical US parameters have also been performed. Demchak's¹³ study on clinical US effectiveness found that both observed and recommended clinical parameters in an US treatment heated the tissues $2.2^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$ and $3.9^{\circ}\text{C} \pm 1.6^{\circ}\text{C}$, respectively. Demchak states these findings also contradicts Baker's article and that even the slightest difference in parameters could affect whether or not that US treatment is effective. Both Draper and Demchak report that the correct parameters must be used. Demchak goes on to state that further education in the use and application of US is necessary as well.

Effectiveness of US with musculoskeletal injuries has also been researched. Shanks¹² recently conducted a literature review solely looking at the lower extremity and the efficacy of therapeutic US use in musculoskeletal injuries. He analyzed ten studies which discussed injuries that included knee pain, heel pain, Achilles tendon pain and ankle ligaments injuries. Two of the earlier studies performed by Antich in 1986³⁶ and Makuloluwe in 1977³⁷ were the only two studies that concluded US was an effective treatment for knee extensor mechanism disorders and ankle sprains, respectively. The remaining eight studies analyzed concluded that there was no significant difference or no additional benefit of the ultrasound group as compared to the placebo group to treat heel pain, Achilles tendon pain, injuries to the ankle ligaments, and knee injuries.¹¹ However, there were limitations to this literature review. The ten studies were all randomized control trials and were critically appraised for trial quality. Shanks¹² reported that these studies only averaged a 9.5 out of 20 points for overall trial quality. This lends to question the validity and quality of methods in these studies and whether or not they produced accurate results. Further research on the efficacy of therapeutic US is necessary.

Summary

Therapeutic ultrasound is commonly used to treat soft tissue injuries and ranges in frequency from 1 - 3 MHz.^{1,12} The use of ultrasound results in both thermal and non-thermal effects on the tissue. Thermal effects cause an increase in tissue temperature (heating), while non-thermal effects should not. Researchers believe that mechanical effects cannot be isolated from thermal effects,^{12,19} so clinicians need to be careful in what parameters they set for an US treatment. There are no standard protocols on what parameters to use when administering an US treatment. Draper and Castel⁶ came up with the first concrete evidence for the depth of which 1 MHz and 3 MHz US can reach (5 cm and 1.6 cm, respectively) while Draper² and Rose⁴ discovered the amount of time a clinician has to stretch the tissue before collagen elasticity diminishes (approximately 3 minutes for 3 MHz and 5 minutes for 1 MHz). Hayes¹⁰ later found that 3 MHz can reach depths up to 2.5 cm deep, reaching deeper tissue than once thought. These studies have helped clinicians choose parameters based on the type of tissues they are treating. For example, with deep tissues, 1 MHz should be used and for superficial tissues, 3 MHz should be used. On the other hand, Baker¹⁸ disagrees with Draper, Castel, Rose, and Hayes stating that US has low efficacy and is unlikely to be beneficial. Other studies^{12,13,22} state that further research on US is also needed.

Despite the fact that research has been deemed inconclusive in a lot of parameter areas, it still remains one of the most used therapeutic modalities today.¹⁰ There is merit in all of the research that has been completed and that further research needs to be done. There are so many other possibilities in the topic of US to research, particularly 2 MHz ultrasound. By establishing a base of knowledge about 2 MHz ultrasound, further clinician modality choices can be made when treating a condition and therefore enhance all around patient care.

CHAPTER 3. METHODOLOGY AND PROCEDURES

The purpose of this study was to determine the depth of penetration of 2 MHz for medium depth tissues. The following research question guided this study: What is the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depths after a 20 minute treatment at $1.0\text{W}/\text{cm}^2$? Researching the specifics of 2 MHz US will allow clinicians to ascertain whether or not 2 MHz therapeutic US can be used as an effective treatment for medium depth tissues. This chapter focused on the experimental design, population of the study, instrumentation for data collection, procedures, data collection, and analysis procedures conducted to complete the research study.

Experimental Design

A two-factor ANOVA experimental design guided data collection in this study. The independent variables were time (pre- and post treatment) and tissue depth (1.5, 2.5, and 3 cm). The dependent variable was gastrocnemius temperature.

Population of the Study

A sample of 20 healthy, male and female college-aged volunteers were recruited from a Midwestern university for this study. A convenience sample of 20 subjects with no injuries to their gastrocnemius was selected. The sample size was estimated a priori using a specific calculation (Appendix A). While the a priori calculation estimated a sample size of 12 subjects, 20 subjects were used in case of subject attrition. Subjects were excluded from participation if they had any contraindications to US including acute injury to the gastrocnemius, any local infection, a diagnosed stress fracture, or a malignant tumor or cancer. They were also excluded if they had a gastrocnemius adipose tissue measurement greater than 1.0 cm, had a history of

neuromuscular or neurological conditions, blood disorders, or an injury or surgery to the lower extremity within the last 6 months.

Instrumentation for Data Collection

The Terason t3200TM Diagnostic Ultrasound (MedCorp, LLC., Tampa, FL) was used to image and measure adipose thickness and Aquasonic® 100 ultrasound gel (Parker Laboratories, Inc., Fairfield, NJ) was applied to the 15L4 Linear transducer (4.0-15.0 MHz) (MedCorp LLC, Tampa FL) to perform this technique. The therapeutic ultrasound treatment was given via the Dynatron Solaris® 700 Series (ERA: 5cm²; BNR 6:1 as reported by the manufacturers; Dynatronics Corp., Salt Lake City, UT). A 20 gauge x 1.16 inch needle catheter (Cardinal Health) was inserted, leaving the catheter in the medial gastrocnemius muscle belly. A 21-gauge, 1 foot thermocouple (Physitemp Instruments, Clifton, NJ) was then inserted through the catheter into the medial gastrocnemius muscle belly to the depth of the distance from the treatment area and edge of the medial gastrocnemius at the 1.5, 2.5, and 3 cm depths. The thermocouples were sterilized with CidexPlusTM 28-day solution at least 24 hours before the treatment. All data was collected via the Iso-Thermex electronic thermometer (Columbus Instruments, Columbus, OH 43204 U.S.A.).

Procedures

Prior to arrival, participants were asked to refrain from strenuous exercise at least 2 hours before testing and to wear shorts to the session. The university institutional review board approved the study and all participants signed an informed consent. Upon arriving to the lab, each participant was asked to read and sign the informed consent form. The participant laid in a prone position, with his/her legs in a figure-four position on the treatment table provided. The

participant was then asked to point their toe and contract their gastrocnemius muscle. A dot was marked on the middle of their medial gastrocnemius muscle belly for the ultrasound treatment area. The right leg of each participant was used in order for the researcher to be able to insert the needle catheter with the left hand. The participant was then told to relax his/her figure four position. Adipose tissue thickness was then measured with the diagnostic ultrasound. Once again, the participants were asked to put their legs in a figure-four position if it was comfortable. Then, a carpenter's square was placed flush against the medial gastrocnemius muscle belly and the depths were marked with a sharpie from the right angle of the carpenter's square at the 1.5, 2.5, and 3 cm depths. The thermocouple was taken out of the Cidex Plus™ 28-day solution, wiped dry, and marked with a sharpie was marked at the 5 cm mark and then also at the lateral measurement from the treatment area. Universal precautions and OSHA regulations were followed throughout the entire data collection process. The 20 gauge x 1.16 inch needle catheter (Cardinal Health) was removed from its packaging. The area of insertion was shaved and cleaned with the Betadine solution. Following the Betadine solution, the area was swabbed with 70% isopropyl alcohol. The thermocouple section that was to be inserted into the tissue was wiped with an alcohol pad and wrapped in a piece of sterile gauze.

The needle catheter was inserted and the spring loaded needle was retracted, leaving the catheter in place. The thermocouple was threaded into the catheter up to the appropriate depth while the catheter was removed from the insertion point, and then the thermocouple was secured in place with tape to prevent movement. The needle catheter was disposed of in a sharps container and all other remains in an appropriate waste basket. This procedure was repeated for the remaining depths of 2.5 and 3 cm. An 8x8 cm high density foam treatment ERA template

was secured to the participant with tape to ensure consistency when the treatment was given. Finally, the thermocouple was connected to the computer via the Iso-Thermex cord.

The treatment began after the participant's intramuscular temperature remained stable for 1 minute. The average time to stabilize the temperature was 1:57 minutes. Aquasonic® 100 ultrasound gel (Parker Laboratories, Inc., Fairfield, NJ) was placed on the area inside of the treatment ERA template and a 20-minute, continuous ultrasound treatment of 2 MHz at $1.0\text{W}/\text{cm}^2$ was given. The ultrasound treatment was performed for 20 minutes, but the temperature increases at the 10-minute mark were looked at to follow suit with other recent research studies. A study going on at the university showed temperatures continuing to increase after the 10-minute mark using the 3 MHz parameter. Therefore, it was decided to continue the ultrasound treatment for 20 minutes. The Iso-Thermex recorded the temperature readings every 5 seconds for the 20-minute ultrasound treatment duration. If at any point the participant felt any pain or discomfort, or if the intramuscular temperature increased more than 8°C the treatment was discontinued. No treatments were discontinued. Following the treatment, the ultrasound gel was wiped from the skin, the template removed, and then the thermocouples removed from the participant's leg. The insertion points were cleaned with 70% isopropyl alcohol before applying a sterile bandage.

Analysis Procedures

A 2-factor ANOVA was used to determine differences in intramuscular tissue temperature changes between the depths and a Tukey HSD post hoc test was used to determine where any significant difference in the data occurred. The level of significance was set at $p \leq 0.05$. (SPSS Software. 20th edition; Pearson Education Inc., Upper Saddle River, NJ).

CHAPTER 4. MANUSCRIPT

The effect of 2 MHz ultrasound on intramuscular temperature at 1.5, 2.5, and 3 cm depths

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Abstract

Context: There is little research on 2 MHz ultrasound although it is an option on the Dynatron Solaris® 700 Series. We wanted to research the depth of penetration of 2 MHz for medium depth tissues. **Objective:** To determine the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depth after a 20 minute treatment at 1.0 W/cm^2 . **Design:** A two-factor ANOVA experimental design guided this study. Independent variables were time (pre- and post treatment) and tissue depth (1.5, 2.5, and 3cm). The dependent variable was the gastrocnemius muscle temperature change. **Setting:** University Research Laboratory.

Patients/Other Participants: Twenty individuals (11 males and 9 females; 20 ± 2.2 years)

Intervention: We inserted 3 thermocouples into the medial gastrocnemius at the depths of 1.5, 2.5, and 3 cm. Therapeutic ultrasound was delivered for 20 minutes with the following parameter settings: 2 MHz, continuous, 1.0 W/cm^2 . **Main Outcome Measures:** The temperature was recorded every 5 seconds for 20 minutes. **Results:** The mean rate per minute temperature increase for the 20 minute ultrasound treatment was the greatest at the 1.5 cm depth ($0.42^\circ\text{C}/\text{min}$), followed by the 2.5 cm depth ($0.26^\circ\text{C}/\text{min}$), and then the 3 cm depth ($0.17^\circ\text{C}/\text{min}$) at 1.0 W/cm^2 . Mean intramuscular temperature increase at 10 minutes was the greatest at the 1.5 cm depth (increase = $4.18^\circ\text{C} \pm 2.45^\circ\text{C}$), then the 2.5 cm depth (increase = $2.56^\circ\text{C} \pm 1.82^\circ\text{C}$), and finally the 3 cm depth (increase = $1.74^\circ\text{C} \pm 1.52^\circ\text{C}$). **Conclusions:** There was a significant difference in the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at all depths; however, only the 1.5 cm depth reached a 4°C increase. Treatment goals and the type of machine need to be taken into account when delivering an ultrasound treatment. **Key Words:** therapeutic ultrasound, thermal, intramuscular temperature, ultrasound parameter settings.

Introduction

Therapeutic ultrasound (US) uses acoustic energy to penetrate tissue and cause healing.¹ One of the main uses for US is for the treatment of orthopedic injuries in the field of sports medicine. Tissue temperature increase is desired with the use of US because of the different physiological effects that can occur, which provide an ideal environment for healing. An increase of at least 1°C is needed for a therapeutic effect to take place, but an increase of 8°C or higher can result in damaged tissue.²

Therapeutic US treatment duration is a parameter that needs to be taken into consideration when administering US to a patient. A 5-10 minute treatment duration has been clinically viewed as a common duration time for US treatment.³ Draper and Castel³ researched the rates of temperature increase in 1 and 3 MHz and stated that when using 3 MHz, a 3-4 minute treatment is required with a 1.0 W/cm² intensity if moderate heating is desired.³ They also looked at 1 MHz and concluded that intensities lower than 1.5 W/cm² do not heat the tissue enough in a 10-minute duration.³

There are also other facets of therapeutic US parameters to be considered when administering an US treatment including effective radiating area (ERA) and intensity. Effective radiating area is dependent on the size of the crystal in the transducer head, which should be chosen based on the size of the treatment area. It is recommended that the treatment size does not go outside 2-3 times the ERA. For example, a 5-cm transducer head has a crystal inside it that is approximately 2/3 the size of the head itself, so the ERA of the treatment area will be in correlation to the crystal size, not the transducer head.^{1,4}

Intensity is another parameter to be taken into account. Different intensities will result in different rates of tissue temperature increase, as well as different physiological outcomes. Draper and Castel³ found that at 2.0 W/cm², a 10-minute treatment at 1 MHz raised the intramuscular temperature 4°C at both a 2.5 and 5 cm depth. Draper and Castel³ also looked at an US treatment of 3 MHz with an average of 1.5 W/cm² and found that continuous 3 MHz ultrasound increased tissue temperature, on average, 5.3°C in 6 minutes from a mean baseline temperature of 33.8°C.³ There is no set protocol as to what intensity to choose when giving an ultrasound treatment, so these numerous factors need to be considered.

The most commonly used frequencies in a clinical setting are 1 and 3 MHz. One MHz US is considered a low-frequency, high wavelength ultrasound and penetrates deeper than 3 MHz, which is considered high-frequency, low wavelength. A frequency of 1 MHz can penetrate from 2.5 cm up to 5 cm within the tissue, while 3 MHz reaches up to a 2.5 cm depth.^{3,5,6} Different frequencies are chosen to heat different tissue depths based on the half-value depth.² Draper and Castel³ define half-value depth as the depth by which 50% of the US beam is absorbed in the tissue. While 1 and 3 MHz are the most frequently used, a 2 MHz frequency is a setting on the Dynatron model therapeutic ultrasound machine. Theoretically, 2 MHz US should fall between 1 and 3 MHz in terms of depth reached, between 2.5 and 5 cm.

The Dynatron US manufacturers state that the 2 MHz frequency is to be used for medium depth tissues⁷. However, to date there has been no published research performed on 2 MHz US and the depth to which it can penetrate the tissue to support or refute this statement. Information and data regarding the depth to which 2 MHz US penetrates muscle tissue may aid clinicians in choosing an US setting, depending on the depth of tissues they want to treat.

The purpose of this study was to determine the depth of penetration of 2 MHz for medium depth tissues. Researching the specifics of 2 MHz US will allow clinicians to ascertain whether or not 2 MHz therapeutic US can be used as an effective treatment for medium depth tissues. The following research question was proposed: What is the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depths after a 20 minute treatment at 1.0 W/cm²?

Methods

Participants. Twenty individuals (11 males and 9 females; 20 ± 2.2 years) volunteered to participate in this research experiment. Participants did not have any contraindications to US which included acute injury to the gastrocnemius, any local infection, a diagnosed stress fracture, a malignant tumor or cancer, gastrocnemius adipose tissue measurement greater than 1.0 cm, a history of neuromuscular or neurological conditions, blood disorders, or an injury or surgery to the lower extremity within the last 6 months. The average adipose tissue thickness was 0.52 cm ± 0.16 cm. The university institutional review board approved the study, and all participants signed an informed consent.

Instruments. The Terason t3200TM Diagnostic Ultrasound (MedCorp, LLC., Tampa, FL) was used to image and measure adipose thickness and Aquasonic® 100 ultrasound gel (Parker Laboratories, Inc., Fairfield, NJ) was applied to the 15L4 Linear transducer (4.0-15.0 MHz) (MedCorp LLC, Tampa FL) to perform this technique. The therapeutic ultrasound treatment was given via the Dynatron Solaris® 700 Series (ERA: 5cm²; BNR 6:1 as reported by the manufacturers; Dynatronics Corp., Salt Lake City, UT). A 20 gauge x 1.16 inch needle catheter (Cardinal Health) was inserted, leaving the catheter in the medial gastrocnemius muscle belly. A

21-gauge, 1 foot thermocouple (Physitemp Instruments, Clifton, NJ) was then inserted through the catheter into the medial gastrocnemius muscle belly at the depth of the distance from the treatment area to the medial aspect of the medial gastrocnemius. The thermocouples were sterilized with Cidex Plus™ 28-day solution at least 24 hours before the treatment. All data was collected via the Iso-Thermex electronic thermometer (Columbus Instruments, Columbus, OH 43204 U.S.A.).

Procedures. Prior to arrival, we asked participants to refrain from strenuous exercise at least 2 hours before testing and to wear shorts to the session. Upon arriving to the lab, we asked each participant to read and sign the informed consent form. The participant laid in a prone position, with his/her legs in a figure four position, to help rotate the leg into a neutral position, on the treatment table provided. We then asked the participant to point his/her toe and contract their gastrocnemius muscle. We marked a dot on the middle of their medial gastrocnemius muscle belly for the ultrasound treatment area. The right leg of each participant was used so we could insert the needle catheter with the left hand. We then told the participant to relax his/her figure four position. The adipose tissue thickness was then measured with the diagnostic ultrasound. Once again, we asked the participants to put their legs in a figure-four position if it was comfortable. Then we placed a carpenter's square flush against the medial gastrocnemius muscle belly and marked the depth measurement with a sharpie from the right angle of the carpenter's square at the 1.5, 2.5, and 3 cm depths. We measured the distance from the treatment area to the vertical shaft of the carpenter's square. This was the measurement of insertion into the gastrocnemius. The thermocouple was taken out of the Cidex Plus™ 28-day solution, wiped dry, and marked at the 5 cm mark and then also at the lateral measurement from the treatment area. We then wiped it with an alcohol pad and wrapped in a piece of sterile gauze. We used

universal precautions and OSHA regulations throughout the entire data collection process. The 20 gauge x 1.16 inch needle catheter (Cardinal Health) was removed from its packaging. We shaved the area of insertion and cleaned it with the Betadine solution. Following the Betadine solution, we swabbed the area with 70% isopropyl alcohol. We marked the thermocouple section that was to be inserted into the tissue,

We inserted the needle catheter and retracted the spring loaded needle, leaving the catheter in place. We threaded the thermocouple into the catheter up to the appropriate depth, removed the catheter from the insertion point, and then secured the thermocouple in place with tape to prevent movement. We disposed the needle catheter in a sharps container and all other remains in an appropriate waste basket. We secured an 8x8 cm high density foam treatment ERA template to the participant with tape to ensure consistency when the treatment was given. Finally, we connected the thermocouple to the computer via the Iso-Thermex cord. We repeated this procedure for the remaining two depths.

We began treatment after the participant's intramuscular temperature remained stable for 1 minute. The average time to stabilize the temperature was 1:57 minutes. We placed Aquasonic® 100 ultrasound gel (Parker Laboratories, Inc., Fairfield, NJ) on the area inside of the treatment ERA template and gave a 20-minute, continuous ultrasound treatment of 2 MHz at $1.0\text{W}/\text{cm}^2$. We performed the ultrasound treatment for 20 minutes, but looked at the temperature increases at the 10-minute mark to follow suit with other recent research studies. However, a study that was going on at the university while setting up this one showed temperatures continuing to increase after the 10-minute mark using the 3 MHz parameter. Therefore, we decided to continue the ultrasound treatment for 20 minutes. The Iso-Thermex recorded the temperature readings every 5 seconds for the 20-minute ultrasound treatment duration. If at any

point the participant felt any pain or discomfort, or the intramuscular temperature increased more than 8°C, we discontinued the treatment. No treatments were discontinued. Following the treatment, we wiped the ultrasound gel from the skin, removed the template, and then the thermocouples from the participant's leg. We cleaned the insertion points with 70% isopropyl alcohol before applying a sterile bandage.

Statistical Analysis

We used a 2-factor ANOVA to determine differences in intramuscular tissue temperature changes between the depths and a Tukey HSD post hoc test to determine where any significant difference in the data occurred. We performed follow-up paired sample t-tests for each depth to determine any significant difference between baseline and ending temperature. The level of significance was set at $p \leq 0.05$. (SPSS Software).

Results

Mean intramuscular temperature increase at 10 minutes was the greatest at the 1.5 cm depth (increase = $4.18^{\circ}\text{C} \pm 2.45^{\circ}\text{C}$), then at the 2.5 cm depth (increase = $2.56^{\circ}\text{C} \pm 1.82^{\circ}\text{C}$), and finally the 3 cm depth (increase = $1.74^{\circ}\text{C} \pm 1.52^{\circ}\text{C}$). The mean baseline and ending temperatures at 10 minutes for 1.5, 2.5, and 3 cm depths were $34.90^{\circ}\text{C} - 39.08^{\circ}\text{C}$, $35.06^{\circ}\text{C} - 37.62^{\circ}\text{C}$, and $35.04^{\circ}\text{C} - 38.33^{\circ}\text{C}$, respectively (Figures 1-3). The mean rate per minute temperature increase was also the greatest at the 1.5 cm depth ($0.42^{\circ}\text{C}/\text{min}$), followed by the 2.5 cm depth ($0.26^{\circ}\text{C}/\text{min}$), and then the 3 cm depth ($0.17^{\circ}\text{C}/\text{min}$) at $1.0 \text{ W}/\text{cm}^2$ (Table 1). Mean intramuscular temperature increase at 20 minutes was also the greatest at the 1.5 cm depth (increase = $5.22^{\circ}\text{C} \pm 1.25^{\circ}\text{C}$), then the 2.5 cm depth (increase = $3.59^{\circ}\text{C} \pm 1.61^{\circ}\text{C}$), and then the 3 cm depth (increase = $2.75^{\circ}\text{C} \pm 1.48^{\circ}\text{C}$) (Table 3 and Figures 1-3). The mean highest temperatures were 41.13°C

(~15.3 minutes), 39.26°C (~18.3 minutes), and 38.26°C (~19.2 minutes) at the 1.5, 2.5, and 3 cm depths, respectively.

According to results from the two-factor ANOVA, there was a significant difference in temperature increase in the depths from baseline to ending temperature for depth and time, respectively ($F_{2,112} = 5.690$, $p = 0.004$) ($F_{1,112} = 146.529$, $p < 0.001$). The Tukey HSD post hoc test revealed that there was a significant difference between the 1.5 and 3 cm depths ($p = .004$). There was no significant difference between the 1.5 and 2.5 cm depths ($p = .066$), and the 2.5 and 3 cm depths ($p = .539$).

Discussion

To date, there are no standard treatment protocols for ultrasound in a clinical setting.⁸ In addition, there is no current published research investigating 2 MHz US and to which depth in the tissue it can penetrate. We looked at 2 MHz therapeutic ultrasound because there is a 2 MHz setting on the Dynatron Solaris therapeutic ultrasound machine, yet no research has been published on this frequency setting. We found a significant difference between the baseline and ending temperatures at all three depths. Based on the findings, we believe the 2 MHz ultrasound frequency is the most appropriate choice when targeting a tissue around the 1.5 cm depth because the tissue at this depth was heated the most efficiently within the clinically acknowledged 5-10 US treatment time frame.

Two MHz therapeutic ultrasound at 1.0 W/cm^2 at the 1.5 cm depth had a heating rate of $0.42^\circ\text{C/minute}$. This rate is slower than what Draper³ reports. Draper's results showed that 3 MHz, 1.0 W/cm^2 at a 1.6 cm depth had a heating rate of $0.58^\circ\text{C/minute}$. We expected this result because in theory, 3 MHz targets more superficial tissues (0-2.5cm) and 2 MHz should target medium depth tissues (~2.5 cm). On the contrary, this study showed the heating rate at the 2.5

cm depth, for 2 MHz, was 0.26°C/minute, which is almost twice as fast as the 0.16°C/minute heating rate reported by Draper³ for 1 MHz, 1.0 W/cm² at a 2.5 cm depth. Hayes⁹ found a heating rate of 1.19°C/minute for 3 MHz, 1.5 W/cm² at a 2.5 cm depth. This may be attributed to the use of different ultrasound machines, the Omnisound 3000 used by Draper³ compared to the Dynatron Solaris® 700 Series (Dynatronics Corp., Salt Lake City, UT) in this study, the Theratouch 7.7 used by Hayes⁹, or the different frequency parameters, 2 MHz versus 3 MHz, 1.0 W/cm² versus 1.5 W/cm², and 1.6 cm depth versus 2.5 cm depth. When comparing all of these studies, the 2 MHz heating rate does fall in between 1 and 3 MHz (Draper with 1 MHz: 0.16°C/minute, 2 MHz: 0.26°C/minute, 0.58°C/minute, and Hayes with 3 MHz at 1.5 W/cm²: 1.19°C/minute). Hayes⁹ used the Theratouch 7.7 ultrasound machine, which produced a seemingly higher heating rate. The manufacturers of the Dynatron Solaris ultrasound machine state that “2 MHz frequency should be selected for moderate depth lesions; about 2.6 cm half-value distance.”⁷

We chose the depths of 1.5, 2.5, and 3 cm because they are in the theoretical range that a 2 MHz ultrasound frequency would be sufficient to be therapeutically effective. If the target tissue is around 1.5 cm deep and a therapeutic effect is desired, the ultrasound treatment, with the Dynatron Solaris model, would need to take at least 2.4 minutes for a 1°C increase, 4.8 minutes for a 2°C increase, and 9.6 minutes for a 4°C increase. For a medium depth tissue around 2.5 cm deep, a therapeutically effective ultrasound treatment would need to take at least 3.9 minutes for a 1°C increase, 7.7 minutes for a 2°C increase, and 15.4 minutes for a 4°C increase. Finally, if tissues around 3 cm deep need to be heated, in order for the ultrasound treatment to have any therapeutic effect, the ultrasound treatment would need to take at least 5.9 minutes for a 1°C increase, 11.8 minutes for a 2°C increase, and 23.6 minutes for a 4°C increase (Table 2).

Ultrasound machine efficacy remains an issue in the clinical setting. A study conducted by Schabrun¹⁰ looked at the accuracy of therapeutic US equipment and found that over half of the 18 studies analyzed were inaccurate in the amount of power output generated. If a clinician is going to use therapeutic ultrasound on a patient with a treatment goal of increasing tissue elasticity so joint mobilizations can be performed after the treatment, the ultrasound treatment, with the Dynatron Solaris, would need to last 23.6 minutes. If the clinician only performs a 5-10 minute ultrasound treatment, thinks the tissue is adequately heated, and proceeds to perform joint mobilizations on the patient, that could result in tissue damage.

Differences in machine outputs also affect ultrasound machine efficacy. In a study done by Straub et al.¹¹, differences in reported and actual values were found with intensity as well. Dynatronics and Omnisound both overestimated their intensity values (1.0/0.84 W/cm², 1.0/0.88 W/cm², respectively). Chattanooga, Mettler, Rich-Mar, and XLTEK underestimated their intensity values (1.0/1.10 W/cm², 1.0/1.39 W/cm², 1.0/1.21 W/cm², 1.0/1.15 W/cm², respectively). The tested transducers were all within the required 20% FDA guidelines for output power.¹¹ This means that their actual readings did not deviate more than 20% of what was stated in the manufacturer's guide. All of this variability between ERA and power output affects the SAI and can result in inconsistency of US treatments.

Approximately a 5-10 minute ultrasound treatment has been clinically viewed as a common duration time.³ Based on the heating rate per minute calculated for the Dynatron Solaris series, the only depths that would increase in temperature to be therapeutically effective are the 1.5 and 2.5 cm depths. Both of these depths would reach a therapeutic 1°C increase. However, only the 1.5 cm depth would reach a 2°C increase, and neither would reach a 4°C increase within the 5 minute treatment time. If this data was applied to the clinical setting, ultrasound treatments

would take too long to complete, which would result in decreased amount of patients treated.

Tissue temperature, the goal of the ultrasound treatment, and treatment time all need to be taken into consideration when clinically applying these results.

Conclusion

The primary conclusion was that there is a significant difference in the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depths after 20 minutes of treatment at 1.0 W/cm^2 . However, the goal of the individual ultrasound treatment needs be assessed each time. While there was a significant difference in the increase in intramuscular temperature, this does not translate over to be applicable in the clinical setting because ultrasound treatments that last at least 10 minutes is not common.³ The results of this study dispute the manufacturers recommendations of using this therapeutic ultrasound machine on medium depth tissue, specifically with a 1.0 W/cm^2 intensity. Therefore, further research is needed using the Dynatron Solaris ultrasound machine to determine if it is more beneficial to increase the intensity of the ultrasound treatment at 2 MHz or to use the 3 MHz frequency setting. Furthermore, because there is variability of treatment temperatures within machines when using different sized transducer heads,^{11,12} future research studies could investigate the use of multiple Dynatron machines to see if intramuscular temperature increases at the same rates as well as explore other common depths with 1 and 3 MHz in order to establish treatment guidelines specific to the Dynatron Solaris therapeutic ultrasound machine.

Table 1. Mean rate per minute temperature increase at the 1.5 cm depth, the 2.5 cm depth, and 3 cm depth at 1.0 W/cm².

Depth	Rate/min
1.5 cm	0.42
2.5 cm	0.26
3 cm	0.17

Table 2. Clinical amount of time to increase intramuscular tissue to 1°C, 2°C, and 4°C at 1.5, 2.5, and 3 cm depths based on heating rate with the Dynatron Solaris ultrasound machine.

Depth (cm)	Desired Temperature Increase (°C)	Time (minutes)
1.5 cm	1°C	2.4
	2°C	4.8
	4°C	9.6
2.5 cm	1°C	3.9
	2°C	7.7
	4°C	15.4
3 cm	1°C	5.9
	2°C	11.8
	4°C	23.6

Table 3. Mean intramuscular temperature increase from baseline to 10 and 20 minutes at 1.5, 2.5, and 3 cm depths.

Depth	Baseline (°C)	10 minutes (°C)	20 minutes (°C)
1.5 cm	34.90	39.08	40.12*
2.5 cm	35.06	37.62	38.65*
3 cm	35.04	38.33	37.79*

***Significant difference from baseline to ending temperature was reached**

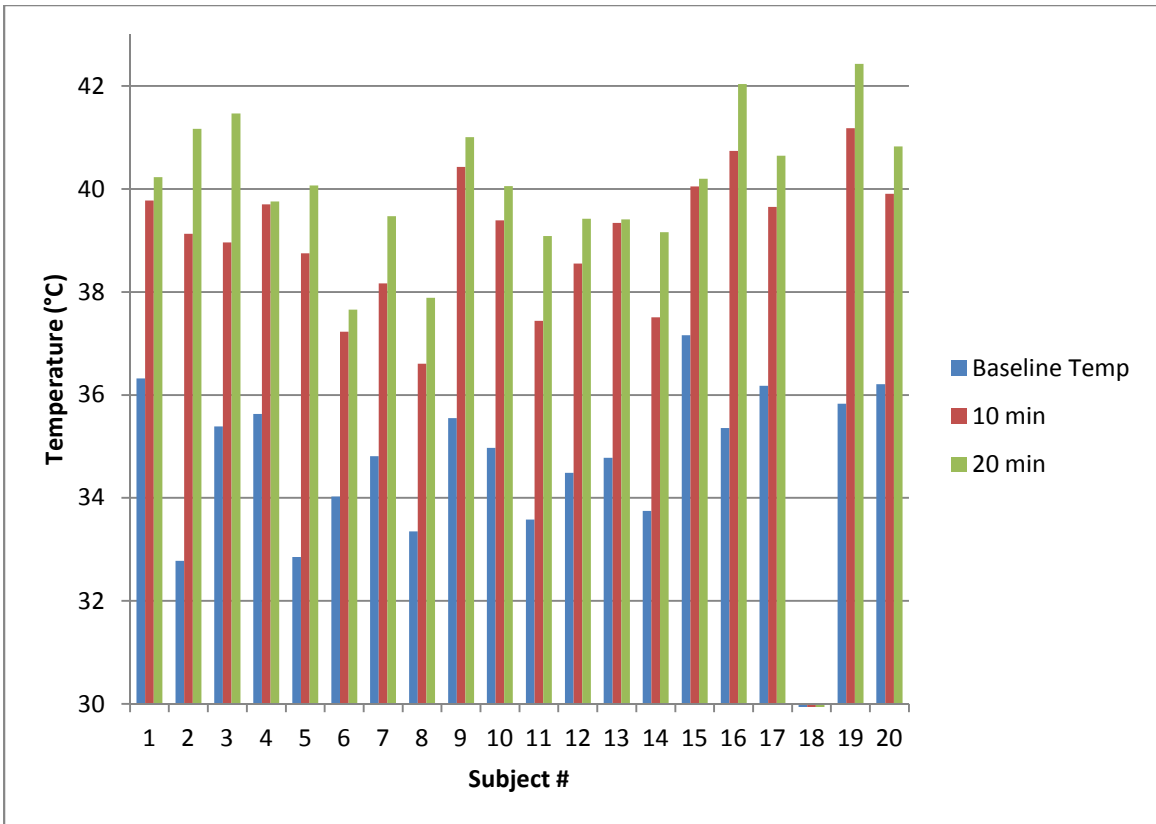


Figure 1. Beginning and ending temperatures at the 10-minute and 20-minute mark for the 1.5 cm depth.

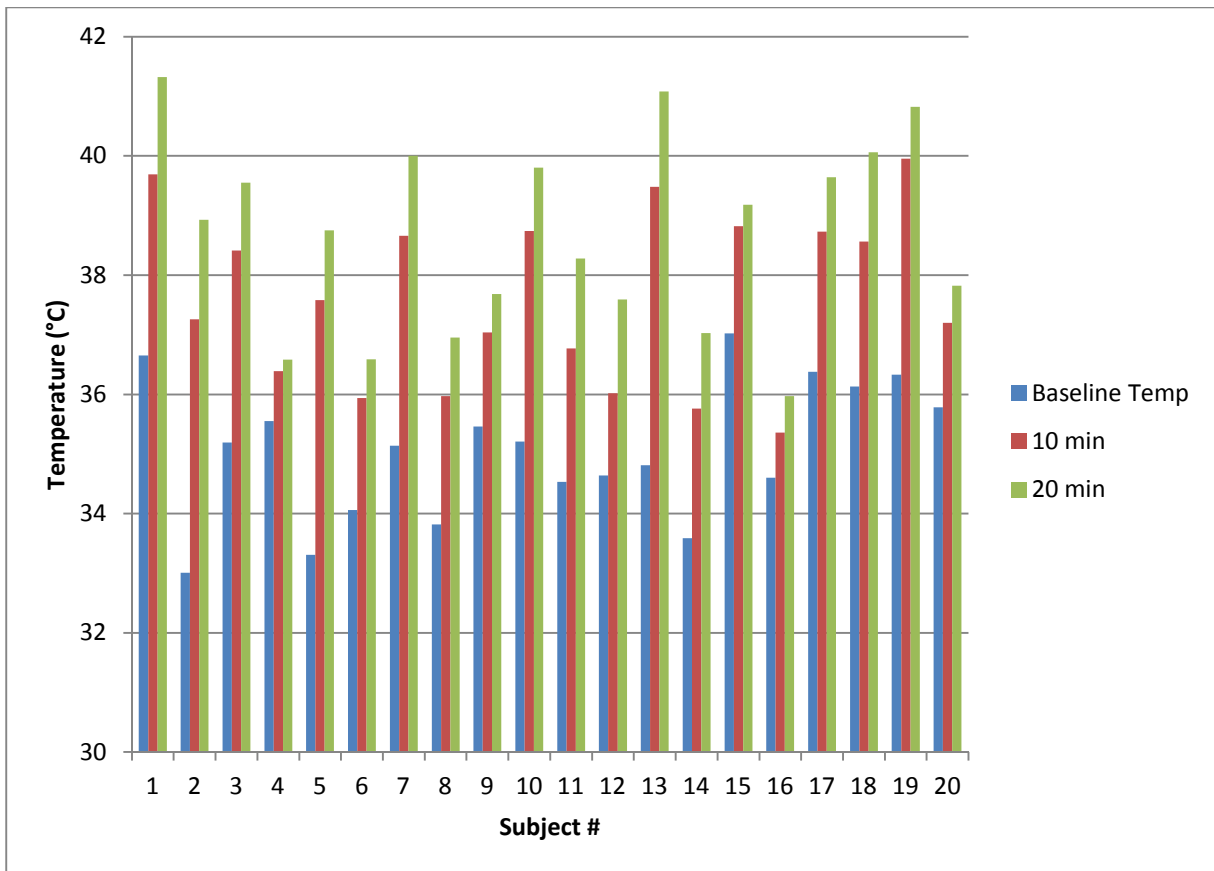


Figure 2. Beginning and ending temperatures at the 10-minute and 20-minute mark for the 2.5 cm depth.

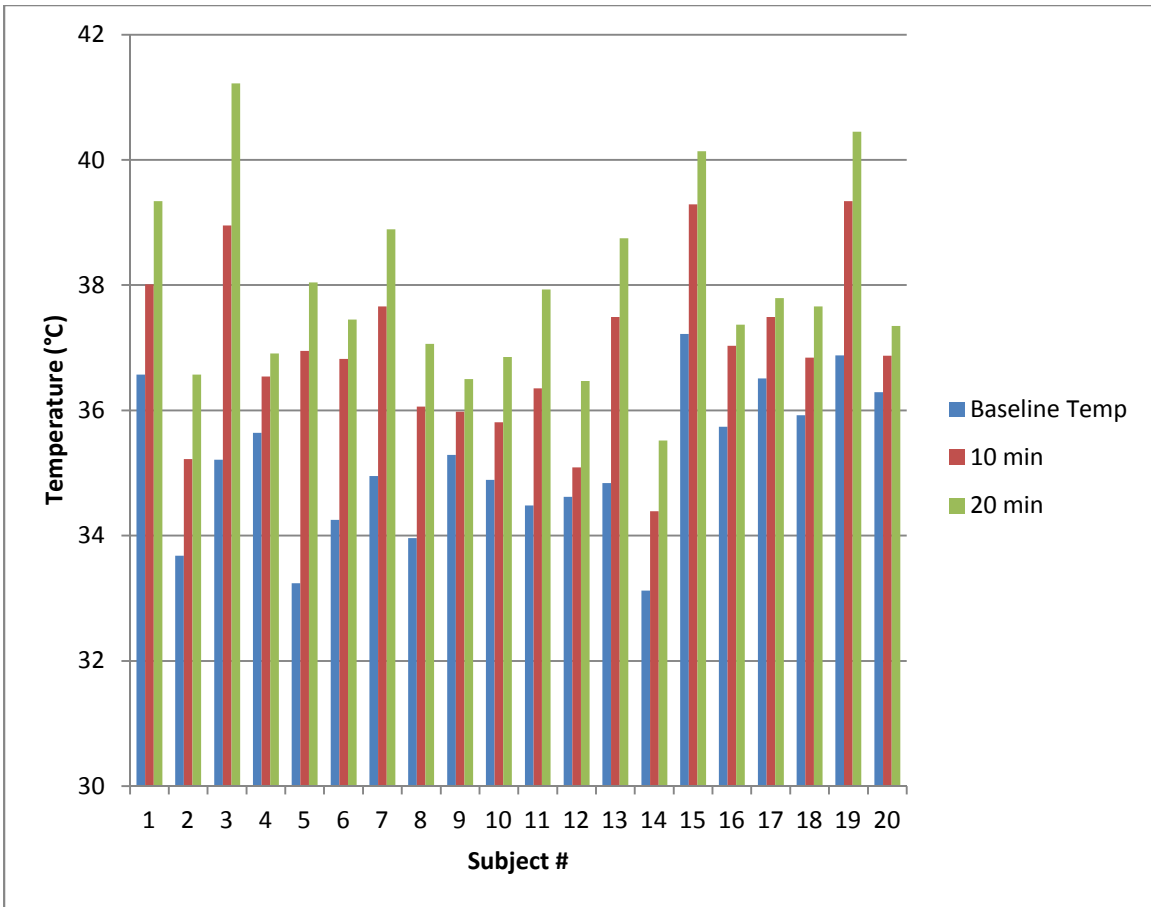


Figure 3. Beginning and ending temperatures at the 10-minute and 20-minute mark for the 3 cm depth.

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CHAPTER 5. DISCUSSION

The purpose of the study was to determine the depth of penetration of 2 MHz for medium depth tissues. The research question of the study was: What is the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depths after a 20 minute treatment at 1.0 W/cm²? There was a significant difference between the baseline and ending temperatures at all three depths. Based on the findings, the 2 MHz ultrasound frequency is the most appropriate choice when targeting a tissue around the 1.5 cm depth at a 1.0 W/cm² intensity.

The literature states that the degree to which the tissue is heated results in different effects on the tissue itself. An increase of 1°C is considered mild heating, moderate heating is an increase of 2°C to 3°C, and an increase of 4°C or higher is considered vigorous heating.³ When a tissue is mildly heated, the metabolic rate increases^{2-4,6} and any mild inflammation is shown to decrease.³ Decrease of muscle spasms, decrease in pain, and increased blood flow result from moderate heating.^{2,7} Vigorous heating of the tissue is utilized to gain collagen elasticity as well as scar tissue extensibility.^{1,3,8} To date, there are no standard treatment protocols for ultrasound in a clinical setting.¹² While frequencies of US range from 0.75-3 MHz,¹ frequencies of 1 and 3 MHz are the only two commonly used by most clinicians.⁷ Currently, there has been no published research investigating 2 MHz US and to which depth in the tissue it can penetrate. Because there is a 2 MHz setting on the Dynatron Solaris therapeutic ultrasound machine, yet no research has been published on this frequency setting, this research study looked at intramuscular temperature increase using 2 MHz.

The manufacturers of the Dynatron Solaris ultrasound machine state that “2 MHz frequency should be selected for moderate depth lesions; about 2.6 cm half-value distance.”¹¹ Two MHz therapeutic ultrasound at 1.0 W/cm^2 at the 1.5 cm depth had a heating rate of $0.42^\circ\text{C/minute}$. This rate is slower than what Draper,⁶ reports. Draper’s results showed that 3 MHz, 1.0 W/cm^2 at a 1.6 cm depth had a heating rate of $0.58^\circ\text{C/minute}$. This result was expected because in theory, 3 MHz targets more superficial tissues (0-2.5cm) and 2 MHz should target medium depth tissues (~2.5 cm). On the contrary, this study showed the heating rate at the 2.5 cm depth, for 2 MHz, was $0.26^\circ\text{C/minute}$, which is almost twice as fast as the $0.16^\circ\text{C/minute}$ heating rate reported by Draper³ for 1 MHz, 1.0 W/cm^2 at a 2.5 cm depth. Hayes¹⁰ found a heating rate of $1.19^\circ\text{C/minute}$ for 3 MHz, 1.5 W/cm^2 at a 2.5 cm depth. Hayes¹⁰ used the Theratouch 7.7 ultrasound machine, which produced a seemingly higher heating rate. This may be attributed to the use of different ultrasound machines, the Omnisound 3000 used by Draper³ compared to the Dynatron Solaris® 700 Series (Dynatronics Corp., Salt Lake City, UT) in this study, the Theratouch 7.7 used by Hayes¹⁰, or the different parameters, frequency of 2 MHz versus 3 MHz, intensity of 1.0 W/cm^2 versus 1.5 W/cm^2 , and depths of 1.6 cm versus 2.5 cm. When comparing all of these studies, the 2 MHz heating rate does fall in between 1 and 3 MHz ($0.16^\circ\text{C/minute}$, $0.26^\circ\text{C/minute}$, $0.58^\circ\text{C/minute}$, and $1.19^\circ\text{C/minute}$).

The depths of 1.5, 2.5, and 3 cm were chosen because these three depths are in the theoretical range that a 2 MHz ultrasound frequency would be sufficient to be therapeutically effective. If the target tissue is around 1.5 cm deep and a therapeutic effect is desired, the ultrasound treatment would need to take at least 2.4 minutes for a 1°C increase, 4.8 minutes for a 2°C increase, and 9.6 minutes for a 4°C increase. For a medium depth tissue around 2.5 cm deep, a therapeutically effective ultrasound treatment would need to take at least 3.9 minutes for a 1°C

increase, 7.7 minutes for a 2°C increase, and 15.4 minutes for a 4°C increase. Finally, if tissues around 3 cm deep need to be heated, in order for the ultrasound treatment to have any therapeutic effect, the ultrasound treatment would need to take at least 5.9 minutes for a 1°C increase, 11.8 minutes for a 2°C increase, and 23.6 minutes for a 4°C increase (Appendix B).

As previously discussed, therapeutic ultrasound treatments in the clinical settings generally do not last more than 10 minutes. If a clinician gives multiple 20-minute ultrasound treatments, they would take up too much of the day to complete, limiting the amount of patients able to be treated daily. In addition, not heating the tissue to a proper temperature before performing manual therapy could injure the tissue further. If the treatment goal is to increase tissue elasticity so joint mobilizations can be performed after the treatment, the ultrasound treatment would need to last 23.6 minutes. However, if the clinician only performs a 5-10 ultrasound treatment and the tissue is not adequately heated, performing joint mobilizations could result in tissue damage. Performing therapeutic ultrasound treatments with machines that are not heating the tissue sufficiently for the treatment goal could further injure the tissue or even prolong healing time of the injury itself. Healthcare providers strive to take the best care of their patients/athletes, with a goal of returning them to sports or activities of daily living as quickly and as safely as possible. Unknowingly inhibiting the healing process and prolonging the patient/athlete recovery does not coincide with a healthcare provider's standard of care. It is therefore very pertinent, that all ultrasound machines that are used clinically establish guidelines for patient/athlete quality care.

Approximately a 5-10 minute ultrasound treatment has been clinically viewed as a common duration time.⁶ Based on the heating rate per minute calculated for the Dynatron Solaris series, the only depths that would increase in temperature to be therapeutically effective are the

1.5 and 2.5 cm depths. Both of these depths would reach a therapeutic 1°C increase. However, only the 1.5 cm depth would reach a 2°C increase, and neither would reach a 4°C increase within the 5 minute treatment time. If this data was applied to the clinical setting, ultrasound treatments would take too long to complete, which would result in decreased amount of patients treated. Further research looking at an increased intensity using 2 MHz ultrasound is needed because increased intensity would result in increased tissue temperature and a more therapeutically beneficial ultrasound treatment.

Adipose tissue thickness can also be discussed as a factor of therapeutic ultrasound tissue heating. The average adipose tissue thickness of the subjects was 0.52 cm \pm 0.16 cm. Some may argue that different adipose tissue thickness causes a difference in tissue heating efficiency and depth to which therapeutic ultrasound can penetrate. However, the literature has shown that adipose tissue has no effect of therapeutic ultrasound because of its low protein content. The higher the protein content in a tissue, the higher the absorption rate.^{38,39} Absorption and penetration of tissue have an inverse relationship when it comes to therapeutic ultrasound, so as absorption increases, penetration of the tissue decreases, and vice versa. Adipose tissue has a low protein content, so lower protein content equals lower absorption rate and a higher penetration rate. This means that the ultrasound waves are not absorbed in the adipose tissue, rather the waves penetrate through to the tissues beneath the adipose layer.

Tissue temperature, the goal of the ultrasound treatment, and treatment time all need to be taken into consideration when clinically applying these results. If the treatment goal for the tissue is simply to increase metabolic rate for tissues (1°C increase) at a 1.5, 2.5 cm, or 3 cm depth, the treatment would need to take 2.4, 3.9, and 5.9 minutes, respectively. If the treatment goal is to increase blood flow (2°C increase) at a 1.5 cm or 2.5 cm depth, the treatment would need to take

4.8 and 7.7 minutes, respectively. These are all acceptable clinical treatment times, so the Dynatron machine would be sufficient to use. Temperature increases greater than 2°C prove to be more difficult. For example, a clinician is going to use therapeutic ultrasound on a baseball player who has a tight posterior capsule on his throwing arm, which results in decreased internal rotation range of motion. A treatment goal of increasing tissue elasticity so joint mobilizations can be performed after the treatment would be desired for this pathology. If using the Dynatron therapeutic ultrasound machine and trying to achieve a temperature increase of 4°C for tissue elasticity, the ultrasound treatment would need to last 23.6 minutes at the 3 cm depth target tissue. If the clinician only performs a 5-10 minute ultrasound treatment, thinks the tissue is adequately heated, and proceeds to perform joint mobilizations on the patient, that could result in tissue damage such as tearing the capsule. Provided the desired tissue temperature increase is only 1-2°C, the Dynatron Solaris therapeutic ultrasound machine would be a sufficient choice to use in the clinical setting at the 1.0 W/cm² intensity. If the desired tissue temperature is greater than 2°C, treatment times become longer than 10 minutes, and clinically unfavorable.

Ultrasound machine efficacy remains an issue in the clinical setting. A study conducted by Schabrun¹⁰ looked at the accuracy of therapeutic US equipment and found that over half of the 18 studies analyzed were inaccurate in the amount of power output generated. Three categories were analyzed: single tests, individual tests, and multiple tests. Of the single tests, it was found that the average percent of machines inaccurate were 68.24%, 64.6%, and 63.2% respectively.²⁸ In a study done by Straub et al.²², differences in reported and actual values were found with intensity as well. Dynatronics and Omnisound both overestimated their intensity values (1.0/0.84 W/cm², 1.0/0.88 W/cm², respectively). Chattanooga, Mettler, Rich-Mar, and XLTEK underestimated their intensity values (1.0/1.10 W/cm², 1.0/1.39 W/cm², 1.0/1.21 W/cm²,

1.0/1.15 W/cm², respectively). The tested transducers were all within the required 20% FDA guidelines for output power.²² This means that their actual readings did not deviate more than 20% of what was stated in the manufacturer's guide. All of this variability between ERA and power output affects the SAI and can result in inconsistency of US treatments. Different factors like the calibration process and frequency of it, machine design, application technique, and type of water used during the treatment may affect the accuracy/inaccuracy reports.

While ultrasound efficacy may play a role in ineffective treatments, using incorrect parameters is also a factor. An article written by Draper¹⁴ discussed the ten most common mistakes made with ultrasound use in a clinical setting. Some of these include treating too large of an area so the ERA is greater than 2-3 times the treatment area, treatment duration, using the wrong frequency and intensity. Using too large of an area would result in the tissue not being heated as quickly as it would with a 2-3 ERA and thus not being heated to the correct temperature within the ultrasound treatment. Using a 3 MHz frequency for a deeper tissue would result in the tissue not being heated enough and using a 1 MHz frequency on a superficial tissue could result in burning the tissue. Furthermore, choosing too low of an intensity could also result in the tissue not being heated enough, while using too high of an intensity could result in burning the tissue. Going back to the baseball player example, each of these mistakes could play a part in the tissue not being heated to the correct temperature increase and therefore result in inefficient ultrasound treatments.

The frequency of which the ultrasound machines are calibrated could also make a difference. Most places with ultrasound equipment have their machines calibrated every 2 years, but machines at universities with a CAATE accredited Athletic Training program are required to

have their ultrasound machines calibrated every year. This could result in variability of how efficient the ultrasound machine is at heating up the intramuscular tissue.

Further research in this area is needed for a few reasons. This study only used one Dynatron Solaris therapeutic ultrasound machine. While this particular machine was calibrated right before the study took place, the literature has shown that there is variability even within the same ultrasound machines. There is even variability of treatment temperatures within machines when using different sized transducer heads.^{21,30} Furthermore, not every clinical setting uses the Dynatron Solaris machine. Future research studies could investigate the use of multiple Dynatron machines to see if intramuscular temperature increases at the same rates, increasing the intensity of the different frequencies offered on the Dynatron Solaris machine, as well as explore other common depths with 1 and 3 MHz in order to establish treatment guidelines specific to the Dynatron Solaris therapeutic ultrasound machine.

Conclusion

The primary conclusion was that there is a significant difference in the increase in intramuscular temperature of 2 MHz therapeutic ultrasound at 1.5, 2.5, and 3 cm depths after a 20 minute treatment at 1.0 W/cm^2 . The goal of each individual ultrasound treatment needs be assessed because while there was a significant difference in the increase in intramuscular temperature, this does not translate over to be applicable in the clinical setting because ultrasound treatments that last at least 10 minutes is not common.⁶ The results of this study dispute the manufacturers recommendations of using this therapeutic ultrasound machine on medium depth tissue, specifically with a 1.0 W/cm^2 intensity. Therefore, further research is needed using the Dynatron Solaris ultrasound machine to determine if it is more beneficial to

increase the intensity of the ultrasound treatment at 2 MHz or to use the 3 MHz frequency setting.

This research study is important because it provides the first documented information about 2 MHz ultrasound and gives way to many more research opportunities in order to begin setting consistent guidelines for parameter settings to use in an ultrasound treatment. In addition, by gathering information about the Dynatron Solaris ultrasound machine, evidence-based parameter guidelines can be provided specific to that machine for those working in the clinical setting. More efficient and beneficial ultrasound treatments will result in better patient care, something athletic trainers strive for on a daily basis. By compiling data about 2 MHz frequency, it can be further investigated whether or not the 2 MHz setting is a beneficial option on an ultrasound machine, not a clinically effective frequency, or not more efficient than a 1 or 3 MHz frequency.

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APPENDIX A. SAMPLE SIZE CALCULATION

$$n = \frac{2*(SD)^2 * (Z_{\alpha} + Z_{\beta})^2}{\Delta^2}$$

SD: 1.2 °C

Z_{α} : 1.96

Z_{β} : 0.84

Δ : 1.4 °C

n= 11.52

**APPENDIX B. AMOUNT OF TIME TO INCREASE INTRAMUSCULAR TISSUE TO
1°C, 2°C, AND 4°C AT 1.5, 2.5, AND 3 CM DEPTHS WITH THE DYNATRON SOLARIS
ULTRASOUND MACHINE**

Depth (cm)	Desired Temperature Increase (°C)	Time (minutes)
1.5 cm	1°C	2.4
	2°C	4.8
	4°C	9.6
2.5 cm	1°C	3.9
	2°C	7.7
	4°C	15.4
3 cm	1°C	5.9
	2°C	11.8
	4°C	23.6