Effectiveness of Clinical Ultrasound Parameters on Changing Intramuscular Temperature

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Context: Researchers have recommended certain ultrasound treatment parameters for deep heating; however, we observed different parameters in the clinical setting. Objective: To compare the treatment effect of using observed clinical parameters (OCP) from 8 clinicians to the treatment effect of using the recommended parameters (RP) sited in research. Design: 2 × 2 repeated measures design. Setting: Sports injury research laboratory. Participants: Ten healthy volunteers. Interventions: Two 1 MHz treatment, 1 RP treatment (1.5 W/cm², 10-min, area-2 to 3 × ERA), and 1 OCP treatment (1.3 W/cm², 8-min, area 3.9 X ERA) Main Outcome Measure: Tricep surae temperature 3 cm below superficial tissue Results: The RP treatment increase temperature from 36.4 ± 1.0 to 40.3 ± 2.0°C, which was a greater change than the OCP (36.5 ± 1.2 to 38.2 ± 1.6°C). Conclusions: The OCP treatment resulted in a lower heating affect than the RP. Small change in treatment area, intensity, and duration can have a large effect on temperature change.

In the use of many therapeutic modalities, clinical practice often precedes scientific research. Researchers1–4 have recommended certain ultrasound treatment parameters to be used based on the treatment goals, which include the frequency, intensity, duration, transducer velocity, and the treatment area. Draper et al1 reported heating rates for the Omnisound 3000 at 0.5, 1.0, 1.5, and 2.0 W/cm² for both 1 MHz and 3.3 MHz. These rates can be used to estimate the duration of the treatment to achieve a certain heating goal (mild, moderate, or vigorous) dependant on the treatment intensity. The suggested physiological effects of different temperature increases have been described in two ways: absolute tissue temperature (37.5 to 42°C) or relative temperature (increase of 1 to 5°C). One goal of many researchers is to achieve vigorous heating to affect the elastic properties of tendon; however, this research was performed using rat tail tendons, which elastic properties are affected between 39 and 42°C.5 The absolute temperature for elastic changes is based on the assumption that resting temperature is 37°C. The amount of temperature increase or the absolute temperature needed to cause changes in human muscle elasticity is unclear; however, resting muscle temperature is 34 to 36°C.4,6–8 For example, to achieve deep vigorous heating (increase of 3 to 5°C):3,8 a frequency of 1 MHz, at
an intensity of 1.5 W/cm² for a duration of 10 min, would be sufficient to increase in temperature 3°C, which would be an absolute temperature of 40°C, assuming a baseline of 37°C. Many researchers have achieved vigorous heating in the calf muscle by using an intensity of 1.5 W/cm² for a 10 min treatment.¹,⁷,⁹–¹³

Recently it has been reported that there is little evidence to support the clinical effectiveness of ultrasound.¹⁴ However, when comparing the treatment parameters used in the clinical studies that showed no effect to the suggested treatment parameters a large discrepancy exists.¹⁵ Some clinicians used treatment areas greater than the recommended 2 to 3 × ERA, while others did not treat long enough to achieve heating goals according to the published heating rates or at the intensity needed to deliver enough ultrasound energy to achieve their treatment goals.¹⁶–¹⁸ Therefore, it appears that clinicians may not be using the recommended parameters and this may affect clinical outcomes. Our research questions were these: What ultrasound parameters are being used clinically to produce vigorous heating and are they effective?

The purpose of this study was to identify the common therapeutic ultrasound treatment parameters used in clinical settings to achieve vigorous heating and compare their treatment effect to the treatment affect of using the recommended treatment parameters to achieve vigorous heating. Our hypothesis was that ultrasound treatment using observed clinical parameters will result in a smaller temperature increase than using the recommended parameters.

Method

Design

Guiding this study were 2 × 2 repeated measures design. Independent variables were treatment condition (recommended parameter, RP, and observed clinical parameters, OCP) and time (pretreatment, PreTX, and posttreatment, PostTx). The dependent variable was left triceps surae intramuscular tissue temperature at a depth of 3 cm below one-half the measured skinfold thickness. This was chosen in order for us to compare our results to other ultrasound studies using similar ultrasound units and parameters.

Subjects

Ten healthy volunteers (M = 5, F = 5, Mean ± SD; Age: 25 ± 4 years, Height: 175.7 ± 13.7 cm, Body Mass: 82.5 ± 19.5 kg) completed this study. Subjects were excluded if they self reported vascular or neurological disorders, blood borne infectious disease, injuries or surgeries in the 6 months before testing, allergies to latex, were pregnant, or have mitral valve prolapse. In addition, subjects were excluded if they self-reported taking prescription and over the counter medicines or supplements that have anticoagulation or antiplatelet effects. The Indiana State University Institutional Review Board approved the study and each subject consented to participate before data collection.
Interventions

Identification of Observed Clinical Parameters. The parameters used in clinical situations vary from clinician to clinician. Currently, there are no standard treatment protocols for therapeutic ultrasound. Therefore, we performed a pilot study to determine what ultrasound treatment parameters are being used clinically. We identified the observed clinical treatment parameters used in this study through a pilot study conducted in the laboratory and local physical therapy clinics. Using a brief survey, 8 clinicians were asked to state what frequency, intensity, and duration they would use to produce deep vigorous heating in the calf. The clinicians were then asked to perform a mock ultrasound treatment using a 5 cm² omnisound transducer, which was photographed to determine the treatment area. Results of the pilot study revealed an average frequency 1.36 ± 0.75 MHz, duration 7.14 ± 1.11 min, intensity 1.33 ± 0.17 W/cm², and treatment area of 33.3 ± 20.2 cm² oval. The following treatment parameters were used as the Observe Clinical Parameter (OCP) condition: frequency of 1 MHz, duration of 8 min, an intensity of 1.3 W/cm², and an oval treatment area of 3.9 × ERA, which was maintained with a template taped to the skin. The duration of 8 min was used because it is currently the minimal treatment time that can be billed for reimbursement.

Temperature Study. Each subject reported to the laboratory dressed in shorts and a t-shirt for a testing session. Upon arrival, the subjects completed the informed consent and were screened. The subjects were assigned to a treatment order, odd numbered subjects received the recommended parameters (RP) treatment first, and the even numbered subjects received the observed clinical parameters (OCP) treatment first. During the entire testing procedure, all subjects remained prone. The thermocouple insertion procedure has been previously described and will be summarized here. A pen mark was made on the posterior aspect of the left medial tricep surae muscle at the greatest girth to identify the center of the treatment area. A mean of 3 consecutive vertical skin fold measurements at this site was calculated and divided by 2 to estimate superficial tissue thickness. The desired depth for thermocouple below the treatment area was 3 cm plus the calculated superficial tissue thickness. The insertion site was located and marked by laying the carpenter’s square flush against the medial triceps surae muscle so that the 90° angle was 48mm (length of the catheter) from the desired thermocouple location and measuring down from the right angle of the carpenter’s square 3 cm plus half the value of the measure superficial tissue thickness. The treatment area, insertion site, and the surrounding areas were shaven (if necessary) and the insertion site was thoroughly cleansed with Povodone and alcohol. An 18 gauge, 1.3 × 48mm catheter (Becton, Dickinson and Company) was fully inserted parallel to the carpenter’s square (Figure 2) and treatment area so that the thermocouple was located in the center of the treatment area. Once the catheter was in place the spring loaded needle was retracted and the thermocouple (Type TX-23 to 18, Columbus Instruments, Columbus, OH) was threaded into the catheter to the appropriate depth as marked on the thermocouple. The thermocouple was stabilized as the catheter was extracted and then secured to the leg with clear adhesive tape to prevent it from moving.
Figure 1 — Determination of thermocouple insertion site. Middle of the treatment area is 4.88 cm horizontal from the insertion site. The insertion site is 3 cm plus the half of the measure skinfold thickness.

Figure 2 — Thermocouple insertion is made parallel to the carpenters square.
The thermocouple was connected to a data acquisition device (Datalogger, MSS-3000, Commtest Instruments, Christchurch, New Zealand), which measured and recorded the temperature at the tip of the thermocouple. The Datalogger is described by the manufacturer to be accurate within 0.1% of a ± 0.5°C temperature change. Each thermocouple was calibrated in a circulating water bath and compared with an NIST thermometer. Calibration curves for each thermocouple were developed and used to correct the temperature data. Intramuscular temperature was recorded every second starting at the time the thermocouple was connected to the data acquisition device and continued until the end of the treatment. The pretreatment intramuscular temperature (PreTx) was recorded after temperature remained unchanged, (± 0.1°C) for 5 min, which took approximately 20 to 30 min post thermocouple insertion. Before each treatment condition, a template cut to the size for the appropriate condition (OCP or RP) was placed on the skin and secured with tape in a manner that the thermocouple was located in center of the treatment area. The room temperature was controlled using a wall mounted thermostat.

Each subject received both treatment conditions (recommended parameters (RP) and the observed clinical parameters (OCP)) on the same day, using the same ultrasound unit (Omnisound 3000C, Accelerated Care Plus, Reno, NV) and transducer (5 cm² area transducer, with an ERA = 4.0 cm², BNR= 3:1). Each treatment was delivered with at a frequency of 1 MHz with a 100% (continuous) duty cycle. The RP condition used an intensity of 1.5 W/cm² for 10 min over a treatment area approximately 2 to 3 times the size of the ERA. The transducer velocity was controlled using a metronome set at 88 beats per min for a transducer velocity of 3 to 4 cm/s. The OCP condition ultrasound was delivered at a frequency of 1 MHz with a 100% (continuous) duty cycle and intensity of 1.3 W/cm² for 8 min over a treatment area that was approximately 3.9 times the ERA. The distance the transducer traveled each beat was dependent on the condition. After the initial treatment, the subsequent treatment did not begin until the intramuscular temperature returned to PreTx temperatures and remained unchanged (± 0.1°C) for 5 min. Aquasonic Clear® ultrasound gel (Parker Laboratories, Inc., Fairfield, NJ), kept at room temperature, was applied to the treatment area to prevent direct contact of the transducer with the skin or air during the treatment. Ultrasound gel was applied as needed throughout each of the conditions.

After the ultrasound treatments, the template and thermocouple were removed, the subject’s leg was cleansed with alcohol and a sterile bandage was applied to the insertion site. The subjects were given instructions on proper wound care and were instructed to go to the emergency room or contact their physicians if any concerns arose. Thermocouples were disinfected by soaking them in CidexPlus® 3.44% glutaraldehyde solution (Johnson & Johnson Company, Irvine, CA) for at least 1 hour before use. The disinfected thermocouples were rinsed with sterile water before the next use.

Data were transferred from the Datalogger into an Excel spreadsheet. We used two thermocouples to collect the temperature data and we know that no two thermocouples are the same, nor will they record the exact same temperature when they are in the same environment (ie, two thermocouples in the same place in room will have different temperature readings). In order for us to compare the temperature data from the different thermocouples we needed to standardize the temperature data. We placed both thermocouples and a National Institute of Standards and
Technology (NIST)-traceable mercury in glass thermometer into a circulating water bath. We collected temperature data from both of the thermocouples and the NIST-thermometer at 6 different temperatures between 30 to 45°C. To standardize the thermocouples to the NIST thermometer reading we developed a standard curve and line of best fit for each thermocouple ($R^2$ T1 = 0.999 and T2 = 0.997). We converted all of the temperature data using the respective line equation for each thermocouple. The converted temperatures were used in the statistical analysis.

**Statistical Analysis**

Descriptive statistics for each condition were calculated. A Repeated Measures $2 \times 2$ ANOVA was used to determine if there were differences between conditions over time and a Tukey Post Hoc test was used to determine where the differences occurred. Significance level was set at $P \leq 0.1$ before testing. All statistical analyses were performed using SPSS statistical software package.

**Results**

Descriptive statistics for each treatment condition pre- and posttreatment temperatures are presented in Table 1. Temperature data are presented graphically in Figure 3 to show the rate of temperature increase during each treatment. The results of the $2 \times 2$ ANOVA indicated a difference in temperature between conditions ($F_{3,36} = 16.126, P = <0.0001$). The Tukey posthoc analysis revealed no temperature differences existed between conditions at PreTx ($P = .999$). The RP ultrasound treatment resulted in a greater increase in temperature ($3.9 \pm 1.6^\circ C$) than the OCP ($2.2 \pm 0.9^\circ C$).

**Comments**

Our data reveal that using the recommended ultrasound treatment parameters for vigorous heating with an Omnisound 3000T increased intramuscular temperature greater than the observed clinical parameter condition. We observed a temperature increase of $3.9 \pm 1.6^\circ C$ ($36.4 \pm 1.0$ to $40.3 \pm 2.0^\circ C$). The observed parameters did not achieve vigorous heating, but did achieve a moderate heating effect ($2.2 \pm 0.9^\circ C$). These data support our hypothesis that the observed clinical parameters are

<table>
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<tr>
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<th>PreTX</th>
<th>Post TX</th>
<th>Temperature Change</th>
<th>Heating Rate ($^\circ C/min$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP</td>
<td>36.5 ± 1.2</td>
<td>38.7 ± 1.6</td>
<td>2.2 ± 0.9</td>
<td>0.2</td>
</tr>
<tr>
<td>RP</td>
<td>36.4 ± 1.0</td>
<td>40.3 ± 2.0</td>
<td>3.9 ± 1.6</td>
<td>0.4</td>
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CP = Calculated Common Parameters; RP= Recommended Parameters; PreTX= Pretreatment; PostTX = Posttreatment.
Effects of Common Ultrasound Procedures

not optimal for reaching vigorous heating. Our study shows that small deviations in the treatment parameters have large affect on temperature changes.

We observed a temperature increase of 3.9±1.6°C (36.4±1.0 to 40.3±2.0°C) for the RP condition, which is considered vigorous heating and was similar to those reported in other studies using the same treatment parameters.1,7,9–13 We achieved the elastic threshold for absolute tissue temperature. The OCP condition increased the intramuscular temperature 2.2±0.9°C (36.5±1.2 to 38.2±1.6), which is considered moderate heating for relative temperature changes and mild heating in absolute temperature terms. Moderate heating is suggested to cause the following physiological effects: acceleration to the metabolic rate in affected tissue, reduction in muscle spasm, pain and chronic inflammation, and an increase in blood flow.8,20 Vigorous heating is suggested to have the following additional physiological effects: tissue elongation, scar tissue reduction, and inhibition of sympathetic activity.8,20 The elastic threshold between 39 to 42°C, however, was determined using rat tail tendon and this study was performed on human muscle. The effect of temperature change on in vivo muscle elasticity has not been determined at this time. We know that as temperature increases, muscle elasticity increases.21

We believe that there are three main reasons why the OCP achieved a lower temperature than the RP condition. The first is that OCP treatment area was approximate 3.9 times the ERA of the transducer, while the RP treatment area is 2.6 times the ERA. The absorption of ultrasound energy by the tissue is directly related to the size of the treatment area5 As the size of the ultrasound treatment area increases, the rate of temperature increase slows.22 Current research shows that increasing the treatment area reduces the temperature change 30% to 60% of that seen in an “optimal” treatment area.23,24 In this the OCP condition temperature increase was 56% of the RP condition (Figure 4). The duration and intensity are directly related and are the second and third possible cause for the decreased tissue temperature seen in the OCP treatment. The OCP

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**Figure 3** — Heating rate graph of temperature (°C) over time (min).
intensity was 1.3 W/cm², which should heat at a rate between 0.2 to 0.3°C/min, which means over an 8 min treatment the temperature should be approximately 1.6 to 2.4°C above pretreatment temperatures. We reported a 2.2 ± 0.9°C increase, which fits in with published estimates; however, applying the same calculation to the OCP condition, the treatment would have to be 13 to 19 min to achieve the same temperature increase seen in the RP condition.

Our results suggest that the calculated observe clinical parameters are able to increase muscle tissue at least 2°C. This increase may not be enough to aid in tissue elongation or scar tissue reduction, which is suggested to be an effect of a temperature increase of 3 to 4°C or an absolute temperature of 39 to 42°C. Recently it was reported that ultrasound was not an effective treatment; however, it was noted that one reason it was not effective was due to improper application for the desired treatment goals. Our study shows that small deviations in the treatment parameters could possibly affect clinical outcomes, therefore it is important to choose the proper parameters to attain the treatment goal.

There are several possible ways to improve the use of ultrasound; one is education of the clinicians through continuing education or in-services; however, this is costly, tedious and may seem remedial. To aid in maintaining the proper treatment area, the ultrasound manufacturers could supply treatment area template for each transducer. This would help the clinicians maintain a treatment area that is the proper size. To help clinician reach their desired temperature increase, one ultrasound manufacturer has developed a delta T mode, which automatically alters the treatment duration based on the intensity being used. The calculations for the duration are based on research using this ultrasound machine. However, the same durations or using the intensity-duration tables may not work for all ultrasound machines.

Figure 4 — Templates used for the Observed Clinical (OCP) and the Recommended (RP) parameter treatments.
Our study is limited to the clinicians we observed and the common parameters that we calculated based on these observations; however, we believe that this study is important because it is the first to address the actual treatment parameters used in a clinical setting and test these parameters. Not all of the clinicians observed usually use the Omnisound; this may have influenced their survey answers; however, recently two studies have reported that the Omnisound has a greater heating effect than other ultrasound units from other manufacturers.\textsuperscript{6,25} Therefore, we would expect a lower temperature to be reached if the OCP were tested using a different US unit.

Our results demonstrate that a small change in treatment area, intensity, and duration can have a large effect on temperature change. It is difficult to control treatment area without a template; therefore it may be beneficial to use a template when performing ultrasound. The observed parameter group did achieve what is considered moderate heating, which is thought to speed up healing through increased blood flow and metabolism as well as decrease pain and chronic inflammation. These are clinically beneficial and may be the goal of many ultrasound treatments.

**Acknowledgments**

This study was partially funded by an Indiana State University Research Grant. We would like to thank Rudolph Medical Equipment & Supply Co., Inc (West Chester, OH) for the use of the Omnisound\textsuperscript{®} 3000T Ultrasound Unit. We would also like to thank Lawrence Reynolds and David Bokulich MS, LAT, ATC for helping with data collection.

**References**