A Comparison of Intramuscular Temperatures During 10-Minute 1.0-MHz Ultrasound Treatments at Different Intensities

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Context: Research on therapeutic ultrasound has not focused on the duration needed to cause thermal change with various ultrasound intensities. Objective: To analyze triceps surae intramuscular temperature using 4 intensity levels after a 10-min 1-MHz continuous ultrasound treatment at a depth of 4 cm. Design: 1 × 4 repeated measures. Independent variable: intensity of 4 levels—0.5, 1.0, 1.5, and 2.0 W/cm². Dependent variable: peak intramuscular temperature. Setting: Research laboratory. Participants: 19 volunteers with no lower leg pathologies. Intervention: Treatment order was balanced via Latin square and performed 24 hr apart. Main Outcome Measures: Peak intramuscular temperatures. Results: The only significant difference detected was that the mean temperature after the 1.0-W/cm² treatment (37.3 °C) was greater than that at 2.0-W/cm² intensity (36.1 °C). No treatment reached the desired 4° increase needed for therapeutic efficacy. Conclusions: Treatments at 1.0 W/cm² increased tissue temperatures more than those at 2.0 W/cm². Key Words: thermocouple, therapeutic temperature level, acoustic energy


Therapeutic ultrasound is commonly used to treat athletic injuries to stimulate tissue repair,1-4 increase blood flow,5,6 and increase tissue extensibility.7-9 Specific temperature increases are required to produce beneficial physiologic effects in tissue. It has been generally accepted that tissue temperatures must be elevated at least 3–4 °C from baseline values to achieve thermal benefits.10-12 Although the literature in this area is growing, research has not yet clearly determined the combination of ultrasound-treatment duration and intensity necessary to elevate intramuscular tissue temperature 3–4 °C.
One study\textsuperscript{13} looked at rate of temperature increase with 1- and 3-MHz continuous ultrasound treatments using an Omnisound\textsuperscript{®} 3000 ultrasound unit. That study has come the closest to defining the combination of intensity and duration for thermal ultrasound. Although this study allows for some prediction of thermal effects with ultrasound treatments, its findings need to be corroborated in additional studies and with other brands of ultrasound devices. Two studies\textsuperscript{14,15} recently indicated that all ultrasound machines do not produce similar heating effects. Because manufacturers do not publish heating guidelines for their ultrasound units, clinicians are left to generalize parameters used in other studies with different units to their ultrasound devices. With increasing evidence that ultrasound units do not produce similar heating effects, it is necessary for researchers to produce empirically based parameter guidelines for individual ultrasound devices for clinicians attempting to induce therapeutic temperature changes in muscle. Therefore, the purpose of this study was to examine the effects of several commonly used intensity levels on peak intramuscular tissue temperature during a 10-minute treatment with 1.0-MHz ultrasound using the Rich-Mar Theratouch 7.7.

**Methods**

A $1 \times 4$ repeated-measures factorial design was used in this study. The independent variable was 1-MHz ultrasound intensity with 4 levels: 0.5, 1.0, 1.5, and 2.0 W/cm\textsuperscript{2}. The dependent variable was peak intramuscular temperature.

**Subjects**

Nineteen student volunteers (age 24.4 $\pm$ 2.2 years, height 171.9 $\pm$ 9.5 cm, weight 71.4 $\pm$ 15.7 kg) participated in this study. To rule out potential health risks, subjects were required to fill out a confidential questionnaire designed to evaluate their health status. The criteria that subjects needed to meet were no trauma to the dermis, intramuscular tissues, or connective tissues in either of their legs presently or for the preceding 6 months. Each subject gave written informed consent after all questions and concerns were addressed to their satisfaction. Institutional-review-board approval was granted for the study protocol.

**Instrumentation**

Intratissue temperature data were collected using implantable type T (copper-constantan) thermocouples (Physitemp Instruments IT-23, Clifton, NJ), and ambient temperature was measured using an ungrounded junction type T thermocouple (Columbus Instruments TX-31, Columbus, Ohio). All thermocouples were connected to an Iso-Thermex 16-channel thermocouple...
thermometer (Columbus Instruments). This device has been reported by the manufacturer to be accurate within 1% for the temperature range studied.

The ultrasound treatments were administered using a newly purchased Rich-Mar Theratouch 7.7 ultrasound device (Rich-Mar Corp, Inola, Okla) with a 5-cm² transducer head. The transducer head houses a lead zirconate tatanate crystal. The manufacturer reports an average beam-nonuniformity ratio of 5.5:1 or less and an effective radiating area of 4.5 cm². Because the ultrasound unit was brand new out of the box and this was the first study in which it was used, its factory calibration was not independently confirmed in our laboratory. It had been factory calibrated to within the FDA’s standards immediately before shipping. The FDA standard is output ± 20% of the SA intensity reading displayed by the device. A premeasured amount of 4 g of Aquasonic 100 transmission gel (Parker Laboratory, Orange, NJ) at room temperature was used as the coupling agent for all treatments.

Interventions

An initial orientation session was set up with the prospective subjects in order to explain the study and answer the subjects’ questions. The subjects gave written informed consent and completed the medical questionnaire. Four treatment sessions were scheduled for each subject, allowing 24 hours between sessions. Ambient temperature was recorded and monitored during each treatment session to ensure its stability. Each subject took part in each of the 4 ultrasound treatment groups (intensity levels of 0.5, 1.0, 1.5, and 2.0 W/cm²), which were balanced using a Latin square.

Each subject was positioned prone on a padded treatment table with a pillow placed under the right foot for support. The area of thermocouple insertion was shaved and cleansed using an alcohol prep pad on the area of the triceps surae having the greatest girth. Once the area was marked, the intramuscular depth for insertion was measured using a carpenter’s square, from the posterior calf through the sagittal plane to the insertion site on the medial calf.

The thermocouples were inserted into the medial aspect of the calf, thus allowing the ultrasound treatment to be administered without interfering with the thermocouple wires. In order to implant the thermocouple medially, so that it rested 4 cm below the ultrasound treatment surface, the carpenter’s square was placed flush against the medial calf with its horizontal arm resting on the surface to be treated with ultrasound. A mark was made on the skin indicating a distance 4 cm down the vertical arm of the carpenter’s square. Inserting the thermocouple at this point ensures that it is 4 cm below the ultrasound treatment surface. After insertion of the thermocouple with a 21-gauge hypodermic needle, the needle was removed while the thermocouple remained in the muscle. Next, the thermo-
couple lead wire was backed out of the tissue slightly so that the temperature sensor was directly below and in line with the ultrasound transducer during the treatment. The position of the temperature-sensing end of the thermocouple was controlled by means of a mark made 10 cm from the tip of the lead. By measuring the distance between this mark and the skin, it was possible to determine the distance into the tissue at which the tip of the lead was resting. The lead wires were secured to the skin with tape in order to prevent their disruption from the muscle. The thermocouples were then attached to the Iso-Thermex 16-channel thermometer that was interfaced with a computer. Instantaneous temperature measurements were automatically recorded every 10 seconds for the duration of the treatment.

After insertion of the thermocouple, the subjects rested for 1 minute, allowing baseline temperatures to be established. The intramuscular temperature was taken at the end of the 1-minute rest and was recognized as the baseline temperature.

A template with an area approximately twice the size of the ultrasound head’s effective radiating area was used to outline the ultrasound treatment site on the posterior triceps surae. A standardized amount of room-temperature ultrasound gel (approximately 4 g) was used as the coupling medium over the area in the template. A metronome was used to ensure that the transducer was moved at a set rate of 4 cm/s within the template. The ultrasound treatment was administered at a frequency of 1 MHz, using a continuous-duty cycle. Intensity varied between treatment sessions as determined using a Latin square. Intensities of 0.5, 1.0, 1.5, and 2.0 W/cm² were used. The ultrasound treatments were performed for 10 minutes, but treatments were discontinued if subjects had any complaints of discomfort during the treatment session. Four subjects’ treatments were discontinued from the 2.0-W/cm²-intensity group and 1 from the 1.5-W/cm² group because of reports of discomfort during the treatment session.

**Thermocouple Removal and Wound Care**

At the conclusion of each treatment, the thermocouples were removed and disinfected using CidexPlus 3.4% glutaraldehyde solution (Johnson & Johnson Medical, Arlington, Tex). A Betadine® topical antiseptic solution was used to clean the insertion sites before bandaging them with a sterile bandage. Subjects received instructions on the proper care of their wounds and were instructed to follow up with the student health center if any problems occurred with respect to the thermocouple insertion. Subjects were monitored for 15 minutes after the closure of the experiment for signs of allergic reactions. During this time, they scheduled their next treatment session, leaving at least 1 full day between sessions to allow for adequate tissue cooling and healing of the insertion sites. No subjects reported complications or infections after the study.
Statistical Analysis

A repeated-measures analysis of variance (ANOVA) was used to determine whether there were differences in intratissue temperature between 10-minute ultrasound treatments at different intensities. Sidak-adjusted pairwise comparisons were used for the post hoc analysis. The significance level was set a priori at $P < .05$.

Results

The mean baseline temperature before each treatment was $35.4 \pm 0.7 \, ^\circ C$. A statistically significant difference was observed among the 4 levels of intensity at the depth of 4 cm ($F_{3,36} = 3.94, P = .014, 1-\beta = .795$; Figure 1). Specifically, the 1.0-W/cm$^2$ ($37.3 \, ^\circ C$) and 2.0-W/cm$^2$ ($36.1 \, ^\circ C$) intensity levels were different (Sidak; $P = .035$). No other significant differences were found among the other intensity levels at $P < .05$.

Comments

Researchers examining 1-MHz ultrasound have not definitively described different ultrasound intensities and their ability to raise intramuscular tissue

![Figure 1](image-url)  Rate of temperature increase during a 10-minute 1-MHz ultrasound treatment.
temperatures to therapeutic thermal levels. The clinical application of ultrasound requires more distinct guidelines for intensity levels when thermal effects are desired. Therefore, we hypothesized that treatments with higher spatial averaged intensities (W/cm²) would result in a higher peak temperature after 10 minutes of ultrasound treatment. After analyzing intramuscular temperatures after 10 minutes of ultrasound, we observed a statistical temperature difference between ultrasound intensities of 1.0 and 2.0 W/cm² (see Figure 1). Surprisingly, the 2.0-W/cm² treatments produced lower temperatures than the treatment at 1.0 W/cm². No statistical differences were observed among the other intensity levels.

The intramuscular temperatures we observed were much lower than expected and do not coincide with temperatures reported by other researchers. Researchers have observed that the rate of heating with a 1-MHz treatment differed for each intensity at 0.5, 1.0, 1.5, and 2.0 W/cm². Differences between our findings and those reported by others could be attributed to a variety of factors. One possible, although unlikely, explanation is the use of different temperature-measuring instruments. Thermistors have been used frequently in ultrasound studies in classic literature, as well as recent work. Thermocouples have been used by researchers more recently. Thermocouples were chosen in this study because they allow for increased comfort during use.

A more serious consideration when noting differences in studies’ temperatures should be the different types of ultrasound units being used. We used a Rich-mar Theratouch 7.7 device, which has a maximum beam-nonuniformity ratio (BNR) of 5.5:1, although the specific BNR of the device tested was not reported. By comparison, the device used in the previously published study examining rate of temperature increase was an Omnisound 3000TM (Physio Technology Inc, Topeka, Kans) with a BNR of 1.8:1. Because of the difference in the BNR, it is possible that the ultrasound units might not be raising tissue temperatures to the same levels as expected. Recent research, however, has shown that higher intramuscular tissue temperatures have been seen after using a unit with a 3.7:1 BNR than with a unit with a 2.3:1 BNR. This suggests that BNR might not be the factor explaining heating differences in ultrasound units. That being said, differences in ultrasound units in general have been discovered. One study conducted in phantom tissue demonstrated differences between 2 ultrasound devices and also saw lower tissue temperatures than expected. Two other studies were recently performed in humans to see if there are differences in the various ultrasound units’ ability to heat intramuscular tissue. One study compared the Chattanooga Forte 400 Combo with the Omnisound 3000 and found that the mean temperature elevation was significantly higher with the Omnisound 3000. Another study compared 3 units: Omnisound 3000C, Dynatron 950, and Excel Ultra III. The authors concluded that temperatures from the Omnisound 3000C, measured at 2 different times (6 minutes and ending treatment temperature), were
significantly higher than with either the Dynatron 950 or the Excel Ultra III. The Dynatron and Excel treatments did not differ from one another.\textsuperscript{15}

As seen with these studies, it is becoming evident that ultrasound units have significant differences in their ability to heat intramuscular tissue. Therefore, it is very likely that our Rich-Mar Theratouch 7.7 was not able to produce tissue temperatures similar to those in previous research using the Omnisound unit. It is important to note that this research was conducted using a single Rich-Mar Theratouch 7.7 ultrasound unit—not multiple Rich-Mar units. Just as there are differences between units from different manufacturers,\textsuperscript{14,15} it is very likely that there are differences between units from the same manufacturer. Differences in reported BNRs from unit to unit alone would suggest this. Therefore, further research is needed before we generalize these results to all Rich-Mar Theratouch 7.7 units.

The experimental methods used in this study to ensure that the ultrasound beam was directly over the thermocouple were meticulously followed, and we have good confidence that the temperature sensor was indeed at the depth indicated and in the path of the acoustic energy from the ultrasound. Similarly, great attention was given to closely control the size of the treatment area and to standardize the rate at which the ultrasound head was moved. It is unlikely that methodological issues are the source of variation between our findings and those in the literature.

Results observed in this study have identified a potential problem in the specific ultrasound unit used. We do not know how widespread this problem is because only 1 ultrasound unit was used. It is important to note, however, that our unit was a brand-new, out-of-the-box unit that we purchased immediately before this study. The obviously unanticipated temperature responses we have demonstrated suggest that 1 of 2 different problems might be present. First, this study might be a simple documentation of a manufacturing-practices problem in which our device did not meet manufacturer specifications. If this is the case, it is worrisome that such a device was not screened adequately by the manufacturer and was allowed to enter the public marketplace. Even more troubling is that if a clinician rather than a research lab had purchased this device, the problem would have gone unnoticed, and the clinical effectiveness would have likely been compromised.

The second concern is more ominous in that it calls us to question much of what we expect from therapeutic ultrasound. Our results cause us to question the treatment duration necessary for ultrasound to achieve therapeutic temperature levels, as well as the need to further investigate whether or not ultrasound is effectively heating intramuscular tissue at a depth between 3 and 5 cm in all ultrasound units. Our study was performed for a minimum of 10 minutes with ultrasound intensities ranging from 0.5 to 2.0 W/cm\textsuperscript{2}, and still temperatures did not reach the desired 40 °C temperature. Further research must be performed to determine whether tissue temperature can realistically be raised at depths such as 4 cm during a 1-MHz
ultrasound treatment without damaging patients. Most of our subjects reported discomfort levels after 10 minutes of ultrasound treatment, most likely because of our ultrasound’s higher BNR. If patients cannot tolerate ultrasound treatments beyond 10 minutes, it might be doubtful that those temperatures can be reached at all, let alone maintained for the recommended 5 minutes. A concern when using 2.0-W/cm² intensities is the report of pain during the ultrasound treatment. Treatments using an intensity of 2.0 W/cm² had to be terminated in 4 subjects, who reported intolerable discomfort throughout the lower extremity during the ultrasound treatment. Other subjects reported similar sensations, although tolerable, for a 10-minute treatment session. In another study, only 44.6% of 54 ultrasound treatments were able to achieve a 4 °C increase in temperature, with the remaining treatments being discontinued because of subject reports of pain.

Obvious concerns have been raised in this study. We acknowledge that it was performed using a single ultrasound unit. Although we agree that more research needs to be done in this area, we are cautious to generalize our findings to all Rich-Mar 7.7 units. This study has raised an additional concern for researchers and clinicians. It might not be safe to assume that an ultrasound unit is properly calibrated, even when it is a brand new machine from the manufacturer. Therefore, we recommend that all ultrasound units be checked initially for proper calibration. Moreover, the variability between devices from different manufacturers, coupled with the obvious abnormalities we observed here and the widespread temperature variability recorded in the ultrasound literature as a whole, leads us to believe that the current FDA requirements regarding calibration and quality inspection of ultrasound devices are probably inadequate. For example, at the present time manufacturers are required to report the maximum BNR of their devices. The maximum BNR is defined as “the maximum value of the beam nonuniformity ratio characteristic of a model of an ultrasonic therapy product.” With the notable exception of Omnisound, most manufacturers do not report the actual BNR of each individual ultrasound transducer they sell. Instead, they report the maximum average BNR of a sample of their ultrasound transducers. This is not likely to be indicative of any individual unit that a clinician is actually using. It is likely that there is widespread variability in the transducers sold by most manufacturers, and this variability is likely to influence the temperature response in treatments with these transducers.

Unfortunately, there does not appear to be a convenient remedy for this problem. The high cost of the equipment necessary to measure BNR makes it cost prohibitive for most aftermarket calibration technicians to be able to determine BNRs of devices already present in patient-care facilities. It is likely that the best remedy will be a future revision to the FDA requirements for these devices requiring better reporting of actual device information and tighter calibration tolerances than the current ±20% standards.
Making a strong enough case for such revision will require data that are not yet available and an extended period of time to accomplish. In conclusion, we observed in a single ultrasound device that a continuous ultrasound treatment using a 1-MHz frequency and an intensity level of 1.0 W/cm² increased intramuscular tissue to higher temperatures than did a 2.0-W/cm² intensity at a uniform depth of 4 cm. This counterintuitive result is puzzling and certainly needs to be clarified with further research. It is entirely possible, perhaps even probable, that we are producing inconsistent results with clinical ultrasound treatments as a result of variations in or improperly calibrated ultrasound devices.

It is evident that further investigation is required to delineate the heating rate of intramuscular tissue during therapeutic ultrasound with a variety of ultrasound devices and multiple transducers within a single brand of device, particularly those with varying BNRs. Such research would help clarify whether there are heating differences between devices, as has recently been suggested.

References


