Ultrasound Heating is Curvilinear in Nature and Varies Between Transducers From the Same Manufacturer

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Context: Ultrasound heating rates are known to differ between various manufacturers; it is unknown whether this difference exists within a manufacturer. Objective: Determine if intramuscular heating differences exist between transducers from the same manufacturer. Study Design: 3 × 10 repeated measures. Independent variables were Transducer (A, B, and C) and Time (10-min time points during the treatment). Setting: Controlled laboratory. Participants: Twelve volunteers (M = 4, F = 8; age: 23 ± 4 years; calf-girth: 37.94 ± 4.16 cm; calf-skinfold: 27 ± 17 mm). Intervention: Three 10-min 1MHz continuous ultrasound treatments performed at an intensity of 1.2 W/cm², over an area 2x transducer. Main Outcome Measures: Calf temperature increase. Results: Heating curve generated for each transducer were significantly different (P = .034) but the overall temperature increases following 10 minutes of treatment were within 0.1°C (F = 1.023 P = .573). Conclusion: Heating curves differ between transducers from the same manufacturer but peak heating at 10 minutes was similar. Key Words: Calf heating, piezoelectric modality, therapeutic modality, ERA, SAI

Therapeutic ultrasound is commonly used during physical rehabilitation to decrease pain, increase tissue extensibility, and accelerate healing. Specifically, application of this modality in higher dosages is used to raise tissue temperature to help achieve these goals. In a move toward evidence based medicine, researchers have established tissue heating rate guidelines which can be found in many textbooks; however, these rates are based solely on one transducer from a single manufacturer. Recent side-by-side comparisons of ultrasound transducers from different manufacturers indicate that the tissue heating rate guidelines appear manufacturer specific. Holcomb and Joy compared a Forte 4000 (Chattanooga Corp., Chattanooga TN) to an Omnisound 3000 (Accelerated Care, Inc., Reno, NV) at 3 MHz and reported a 50% higher final heating level for those treated with the Omnisound unit. Most recently, Merrick et al compared an Omnisound 3000C, an Excel Ultra III, and a Dynatron 950 (Dynatronics, Salt Lake City, UT) functioning at 3 MHz.
These researchers reported that the Omnisound treatment resulted in a significantly higher tissue temperature at six minutes (when subjects requested the treatment ended) than did the Excel or Dynatron following a full ten minutes of treatment. Although none of the authors can fully explain why these differences occur, one can argue manufacturer differences in heating rates exist.

There are no data directly examining heating rates between transducers from a single manufacturer. However, there have been enough studies performed using the Omnisound 3000 with similar treatment parameters, that heating rates may be compared. For 1 MHz, 1.5 W/cm$^2$ treatments, Draper et al$^1$ reported a heating rate of 0.34 deg/min, while other researchers had heating rates of 0.28 deg/min,$^7$ 0.42 deg/min,$^8$ and 0.5 deg/min.$^9$ This indirect comparison suggests that there may be heating rate differences between transducers from a single manufacturer.

The purpose of this study was to compare intramuscular tissue temperature heating rates of three transducers from the same manufacturer with similar reported ERA, total power, SAI, and BNR during a standardized ultrasound application. We chose the Omnisound 3000 transducer because there are published heating curves for comparison. We hypothesized that no significant differences in tissue heating rates between the 3 transducers would be found.

**Methods**

A double blinded $3 \times 10$ factorial design with repeated measures was used to guide this study. The independent variables were transducer (A, B, and C) and time (1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 minutes) during the treatment. The dependent variable was the left triceps surae intramuscular temperature rise above baseline at a depth of 3 cm below one-half the measured skin fold thickness. This depth was used in order to compare our results to other ultrasound studies.

**Subjects**

Twelve healthy volunteers ($M = 4$, $F = 8$, Mean ± SD; Age: $23 ± 4$ years; Calf Girth: $37.8 ± 3.9$ cm; Skinfold: $26 ± 14$ mm) completed this study. Subjects were excluded if they self reported vascular or neurological disorders, blood borne infectious disease, injuries, or surgeries in the six months prior to testing, allergies to latex, were pregnant, or have mitral valve prolapse. Also, subjects were excluded if they self reported taking prescription and over the counter medicines or supplements that have anticoagulation or anti-platelet effects. The University Institutional Review Board approved the study and the rights of all participants were protected. Each subject consented to participate prior to data collection.

**Interventions**

Prior to the experimentation period, the three experimental ultrasound transducers were tested for total power (Testco Corp, Windsor Locks CT), and Effective Radiating Area (ERA; Onda, Sunnyvale CA) to determine measured Spatial Average Intensity (SAI). The SAI is equal to the transducer output power (Watts) divided by the Effective Radiating Area (ERA) measured in square cm. Based upon these assessments, it was determined that transducer A was delivering an SAI of 1.2
W/cm², transducer B was delivering 1.3 W/cm², and transducer C was delivering 1.4 W/cm² all when the digital display read 1.2 W/cm². This information was blinded for the primary data collectors and the subjects. The BNR, ERA, and measured SAI for the transducers used in this study are listed in Table 1.

Each subject reported to the laboratory dressed in shorts and a t-shirt. Upon arrival, the subjects completed the informed consent and were screened using a Health History Questionnaire. During the entire testing procedure, all subjects remained prone. Thermocouple insertion procedures used in this study have been previously described and are summarized here. A pen mark was made on the posterior aspect of the left medial triceps surae muscle at the greatest girth to identify the thermocouple location within the treatment area. Superficial tissue thickness was estimated by calculating the mean of three consecutive vertical skin fold measurements and dividing by two. The desired depth for thermocouple below the treatment area was 3 cm plus the value of the estimated 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 48 mm (length of the catheter) from the desired thermocouple location and measuring down from the right angle of the carpenter’s square 3 cm plus the estimated superficial tissue thickness (Figure 1).

Table 1 Characteristics of Transducers A, B, and C

<table>
<thead>
<tr>
<th>Transducer</th>
<th>Serial #</th>
<th>BNR</th>
<th>ERA (cm²)</th>
<th>Measured SAI (W/cm²)</th>
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</thead>
<tbody>
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<td>A</td>
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<td>2.4</td>
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<td>1.2</td>
</tr>
<tr>
<td>B</td>
<td>28436</td>
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</tr>
<tr>
<td>C</td>
<td>028445</td>
<td>2.7</td>
<td>4.4</td>
<td>1.4</td>
</tr>
</tbody>
</table>

BNR = Beam Non-uniformity Ratio; ERA = Effective Radiating Area; Measured SAI = Spatial Average Intensity, which is equal to Power (W)/ERA (cm²) measured at a display of 1.2 W/cm² prior to the start of the study.

Figure 1 — Thermocouple insertions technique.
The treatment area, insertion site, and the surrounding areas were shaved (if necessary) and the insertion site was thoroughly cleansed with Povidone and 70% isopropyl alcohol. An 18 gauge, 1.3 × 48 mm catheter (Becton, Dickinson and Company) was fully inserted parallel to the carpenter’s square (Figure 1) 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-23-18, Columbus Instruments, Columbus, OH) was threaded into the catheter to the appropriate depth as marked on the thermocouple. The thermocouple was stabilized and the catheter was extracted and then secured to the leg with clear adhesive tape to prevent it from moving.

The thermocouple was connected to a data acquisition device (Physitemp, Clifton, NJ), which measured and recorded the temperature at the tip of the thermocouple. This equipment is described by the manufacturer to be accurate within ± 0.1°C temperature change. The thermocouple was calibrated in a circulating water bath and compared to an NIST thermometer. A calibration curve for the thermocouple was developed and used to correct the temperature data. The corrected data was used in the statistical analysis.

Intramuscular temperature was recorded every 30 seconds 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 minutes, which took approximately 20-30 minutes post-thermocouple insertion. A template cut to two widths of the transducer head was secured to the skin to make sure the transducer remained over the treatment area. All data were collected in a temperature (set at 21°C) controlled research laboratory.

Each subject received all three transducers conditions (A, B, and C) in one session. This was done to ensure that the thermocouple was in the same position for all three treatments and is similar to other studies.9,10 Treatment order was guided by a balanced Latin square to control for a possible treatment order effects. For all conditions, the ultrasound (Omnisound 3000C, Accelerated Care Plus, Reno, NV) treatment was delivered with a transducer (face plate = 7.1 cm², crystal = 5.0 cm² and ERA = 4.4 cm²) for 10 minutes at a frequency of 1 MHz with a 100% (continuous) duty cycle and intensity of 1.2 watts/cm² as determined by the digital display. Each ultrasound transducer was calibrated to a specific ultrasound unit and port prior to data collection. During each treatment, the transducer handle was parallel to the tibia and the faceplate was flat on the skin’s surface and moved at a velocity 4-5 cm/s, which was maintained using a metronome (88 bpm). The transducer traveled 2.4 cm each beat. After the initial condition, the subsequent conditions did not start until the intramuscular temperature returned to within 0.1°C of pretreatment temperatures (average wait time 16 ± 6 minutes) and remained unchanged (± 0.1°C) for 5 minutes. Aquasonic Clear® ultrasound gel (Parker Laboratories, Inc., Fairchild, NJ) was applied to the treatment area in order to prevent direct contact of the transducer with the skin or air during the treatment. Additional ultrasound gel was added to the treatment area as needed throughout the treatment.

After the last ultrasound treatment, 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. The thermocouple was disinfected by soaking it in CidexPlus® 3.44% glutaraldhyde solution (Johnson & Johnson Company, Irvine, CA) for at least 1 hour and was rinsed with and stored in sterile water prior to the next use.

**Statistical Analysis**

The dependant variable was the temperature rise above baseline at each time point, analyzed every minute. SPSS 12.0 for Windows (SPSS Inc, Chicago, IL) was used to perform a one-way ANOVA to determine if the absolute start temperatures were significantly different between transducers. Following determination that the start temperatures were similar \( (P = .938) \), a 3 (transducer) × 10 (time points, each minute for ten minutes) repeated measures ANOVA was performed. Maulchley’s test of sphericity was significant for time but not for transducer, so the moderately conservative Huynh-Feldt correction was applied to the statistics. Tukey’s HSD procedure was used for post-hoc comparisons. To further explore the heating rate capabilities of the transducers, each transducer was ranked (1-3) based upon the time that was required to raise each subject’s calf 2.5 deg from baseline (1, the fastest; 3, the slowest). If the subject did not hit a 2.5 degree rise, the transducers were ranked by which transducers achieved the highest heating point during the treatment. Rankings were evaluated using a 3 × 3 Chi square statistic. Statistical significance for all tests was set a priori at \( P < 0.05 \).

**Results**

There was no main effect for transducer \( (P = 0.573) \) and as expected there was a main effect for time \( (P < 0.001) \) with a start temperature of 37.0 ± 0.53 and an ending temperature of 39.6 ±1.12 (Figure 2). Most importantly, there was a transducer by time interaction \( (P = .034; \text{Figure 3}) \). All three transducers produced a significant rise in tissue temp after just 1 minute of treatment \( (P = 0.01) \). Transducer C (measured SAI 1.4 W/cm²) then produced a second significant rise by 3 minutes \( (38.9 \pm 1.11) \) and a third rise by 8 minutes \( (39.6 \pm 0.92; P = 0.05) \). Transducer B (measured SAI 1.3 W/cm²) produced a second significant rise by 4 minutes \( (38.7 \pm 0.86) \), followed by a third significant rise by 7 minutes \( (39.4 \pm 1.16) \). Transducer A (measured SAI 1.2 W/cm²) did not have a second significant rise until minute 7 \( (39.2 \pm 1.04; P = 0.05) \) and had no further significant increases. By the completion of the 10 minute treatment, all three transducers had similar overall temperature changes (A: 2.48 ± .80, B: 2.66 ± 1.1, C: 2.57 ± 1.3). The chi square test of independence for heating rankings was significant \( (P = .021) \), indicating that ranking is associated with transducer. Transducer C earned eight number one rankings and four number 2 rankings.

**Comments**

Our results showed that after 10 minutes of treatment, the three ultrasound transducers from the same manufacturer (Accelerated Care Plus, Reno NV) and with similar reported ERA, power, BNR, and set to the same digitally displayed SAI 1.2 W/cm² produced different heating curves in human tissue. This is in spite of the fact that
these transducers heated to a similar final tissue temperature (39.8 ± 1.1°C). The final tissue temperature was similar to previously reported heating using transducers from the same manufacturer with similar treatment parameters.\textsuperscript{1,7-9,11-13} The tissue temperature rise was also closely predicted by previously reported heating rates for the Omnisound 3000, based upon an extrapolated heating rate of 0.25°C/min\textsuperscript{4} for a predicted rise of 2.5°C. This estimation assumes that the temperature changes are linear in nature. However, as indicated in Figure 2, and our statistically significant interaction, the temperature increases measured here were curvilinear in nature and not consistent between transducers.
In contrast to a linear rise in heating, we saw two to three distinct phases, depending on the transducer. All three transducers had a significant rise in temperature (≈1.2°C) within the first minute. Following this, each transducer followed its own path to maximum temperature with each transducer reaching its highest temperature at a different point in time. Transducer C crossed the predicted 2.5 degree rise threshold by 5½ minutes into the treatment, equating to a rate of temperature increase of 0.48°C/minute during this time frame. This temperature was maintained for the remainder of the treatment; however, transducers A and B did not reach a 2.5 degree rise until 8½ and 9 minutes, respectively, during the treatment, which results in approximate heating rates of 0.30°C/minute and 0.29°C/minute, respectively, during this time frame. Therefore, transducer C reached and maintained a moderate heating range for 4½ minutes, while transducers A and B were in this range for only 1½ and 1 minutes, respectively.

Thermoregulatory changes to local circulation may explain why the heating slopes are curvilinear and why a SAI setting of 1.2 W/cm² appears to have a ceiling heating effect. In the first 60-90 seconds of ultrasound treatment, normal blood flow to the treatment area occurs; however, as temperature reaches a critical point, increased circulation begins to carry a larger percentage of the heat from the treatment area, which results in a slower overall rate of increase. Once a thermal equilibrium is established between the rate at which ultrasound is depositing energy/heat into the tissue and the rate at which blood flow is removing heat from the treatment area, a ceiling temperature is established. It appears that under these conditions (approximately 1.2 W/cm²), an average of just under 40°C is the maximum temperature that this tissue may reach. This type of ceiling effect has been previously reported for lower SAI values; researchers have concluded that at 1 MHz, an intensity of 0.5 W/cm² is insufficient for significant thermal effects.

We surmise that the higher measured SAI for transducers B and C may have been a causative factor in the generation of the individual heating curves. Transducer C was measured to have an SAI of 1.4 W/cm² and heated the fastest and had the greatest number of number 1 rankings. Transducer B was measured at 1.3 W/cm² and lagged Transducer C during the second heating phase. Transducer A was measured right at the digitally displayed value of 1.2 W/cm² and took the longest to reach maximum heating and never reached a third heating rise. Johns, Straub, and Howard have previously suggested that variability within displayed SAI values may alter energy dosage and ultimately tissue temperature. While most clinicians utilize SAI as the guiding clinical metric, the FDA does not regulate the accuracy of measured SAI relative to the digital display. SAI is sensitive to variation in both ERA and total power emitted by the transducer; it has been reported that a possible 150% error in the calculation of SAI may be permissible while the transducer still falls within FDA guidelines. While we saw only a 17% error in SAI values in this small cohort, clinicians should be sensitive to the large variability that may exist between multiple transducers in their clinics.

The variability in SAI does not fully explain our reported heating rates. During the period of greatest tissue temperature rise, transducers A and B had heating rates of 0.32 and 0.31°C/min, respectively. These rates would be expected from an SAI of 1.5 W/cm². During the period of greatest tissue temperature rise, Transducer C had a heating rate of 0.5°C/min, which would be expected from an SAI of 2.0 W/cm². The heating rates reported here may be due to variability
in the ultrasound field that is not fully explained by ERA and/or BNR.\textsuperscript{15,17} If the hottest area of the ultrasound field is continually running over the thermocouple, higher than expected measures may result. Standard recommendations of moving the head within the treatment area in small overlapping cycles may not allow the areas of high intensity to be adequately dispersed. Future research of ultrasound heating may require additional thermocouples in the treatment area in order to fully describe the heating process.

**Conclusion**

Within our cohort of three ultrasound transducers from a single manufacturer, there were differences in the incremental rate of heating and the time to maximal temperature increase in spite of the fact that no significant differences existed in the overall degree of heating after 10 minutes. This overall heating rate was reflective of the estimated tissue heating rates suggested by Draper et al.\textsuperscript{1} Heat build-up in muscle tissue does not appear to be linear and may not be best described by flat heating rates. Variation in reported SAI may affect tissue heating between transducers from the same manufacturer. Future research should focus on controlling SAI values when measuring/reporting heating throughout the treatment field.

**References**


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