Comparison of Tissue Heating between Manual and Hands-free Ultrasound Techniques using a 1-MHz Frequency

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ABSTRACT

Study Design: Single-factor repeated-measures design. Objective: To examine the effectiveness of tissue heating with a hands-free ultrasound (US) technique compared to a hand-held ultrasound transducer at a frequency of 1 MHz using the Rich-Mar AutoSound™ unit. Background: US is a therapeutic modality often used to provide deep tissue heating. Recently, a “hands-free” US unit has been introduced by Rich-Mar Incorporated. This unit allows the clinician to choose the mode of US delivery, using either a hand-held (manual) transducer or a hands-free (HF) device that pulses the US beam through the transducer. However, the Center for Medicare and Medicaid Services has deemed delivery of US via a hands-free unit to be investigational. Methods and Measures: This study was completed in 2 phases using a manual transducer (5 cm² effective radiating area) and a hands-free transducer (14 cm² effective radiating area). In phase 1, muscle temperature was measured with 26-gauge, 4-cm Physiotemp thermistors placed in the triceps surae muscle at 2- and 3-cm deep. In phase 2, thermistors were placed at 4- and 5-cm deep. Tissue temperatures were recorded at baseline and every 30 seconds. Results: At the 2 cm depth, the tissue temperature increased 0.73°C using the manual transducer and 0.75°C with the HF device. At the 3 cm depth, the tissue temperature did not show a change with either device (-0.04°C manual; -0.07°C HF). At the 4 cm depth, the tissue temperature did not change with the manual device and a decrease of 0.31°C was observed with the HF device. Finally, at the 5 cm depth, the manual device yielded a 0.72°C increase and the HF device again resulted in a decrease of 0.19°C. Conclusions: In this study, neither of the devices on the Rich-Mar Ultrasound unit resulted in the production of a therapeutic heating effect at any depth studied. In fact, the HF device actually resulted in a lowering of tissue temperature. Thus, if the goal is to increase tissue temperature to enhance circulation or the viscoelastic properties of the soft tissue, the 1 MHz component of this device is not effective. Clinicians should be careful about drawing conclusions regarding ultrasound as a modality based on the outcome of a particular parameter.

Key Words: tissue heating, therapeutic ultrasound, thermal modality

INTRODUCTION

As a therapeutic modality, ultrasound (US) is known to have thermal and mechanical effects. Clinicians use therapeutic ultrasound to elevate tissue temperatures to decrease joint stiffness, reduce muscle guarding, increase soft tissue extensibility, decrease pain, and increase blood flow. The frequency of therapeutic US is inversely related to the depth of tissue penetration. Thus, 1-MHz US is believed to penetrate 4-5 cm deep, while 3MHz US has been reported to penetrate 2-3 cm depth.

In the past decade there have been a plethora of US studies in the quest to substantiate the efficacy of this modality. The mitigating factor, however, may not be the physiologic US wave itself but rather the devices used to deliver it. In the past few years, Rich-Mar Incorporated introduced an AutoSound™ unit (Rich-Mar, Inc, Chattanooga, TN) which is capable of delivering US in the traditional method of a manual transducer as well as through a “hands-free” transducer. The “hands-free” device functions by securing a 4-chamber, 14 cm² transducer to the skin with Velcro straps. The US wave is sequentially pulsed through the 4-chambers as follows: A, B, C, D, A, B, C, D, etc. Although this could be a tremendous clinical attribute for time efficiency, the effectiveness has only been reported in 3 studies, all using the 3 MHz frequency. In fact, the Center for Medicare and Medicaid Services (CMS) and several other insurance companies have deemed delivery of US via a hands-free device to be investigational or experimental. The purpose of this study was to examine the amount of tissue heating with a hands-free AutoSound™ transducer compared to a traditional hand-held transducer using a 1 MHz frequency.

Methods

Subjects

Participants were recruited via flyers. Each participant read and signed the informed consent document approved by the University Institutional Review Board for the Protection of Human Subjects. Participants were screened for lower extremity injuries and medical conditions for which US is contraindicated. Phase 1 included 20 volunteers (7 males, 13 females; age 24.05 ± 4.54 yrs; height 1.68 ± 0.11 m; body mass 70.15 ± 16.24 kg). Phase 2 included 25 volunteers (10 males, 15 females; age 25.64 ± 3.29 yrs; height 1.71 ± 0.10 m; body mass 75.57 ± 17.49 kg).

Instrumentation

Muscle temperature was measured with a 26gauge, 4cm Thermalert TH-8™ monitoring thermister (Physitemp Instruments Inc., Clifton, NJ). The Physitemp Thermalert TH-8™ was precalibrated by the manufacturer under the guidelines of the National Institute of Standards and Technology and the device self-calibrated each time it was turned on. The device can measure temperature in the range of -10 to 60°C and accurate to ± 0.1°C. The US treatments were provided with a new, factory calibrated Rich-Mar AutoSound™ device. The two US delivery techniques compared were the manual mode with a hammer transducer and the hands-free AutoSound™ transducer. Beam non-uniformity ratio (BNR) is a measure of the variability of the US intensity across the crystal. The BNR for both devices at the 1 MHz frequency was ≤ 5.5:1. The effective radiating area (ERA) is the surface area of the US transducer that is capable of transmitting an US wave. The ERA for the hammer transducer was less than 5cm² and the hands-free AutoSound™ transducer was less than 14cm² (3.5cm²/transducer x 4 chambers = 14cm²). It should be noted,
however, that the Rich-Mar Operation Handbook\textsuperscript{25} states that the actual ERA for the 5cm\textsuperscript{2} and the hands-free AutoSound\textsuperscript{TM} transducers are ± 25% of the reported values. This is within the ERA range reported by Johns, Straub, and Howard\textsuperscript{26} for the Rich-Mar transducer.

**Procedure**

Each participant was comfortably positioned in prone. The skin on the posterior aspect of the lower leg was cleaned with alcohol and allowed to air dry. The order of the treatment techniques of each participant was alternated between the manual technique and the AutoSound\textsuperscript{TM} technique. By performing each technique on the same subject, there were no issues with differences in body composition. The perimeter of the hands-free transducer was outlined on the region of the triceps surae muscle with the greatest muscular girth. This assured that the same treatment area was used for both transducers, allowing a better comparison of the heating effects of the two devices. For phase 1, each technique was performed on a different leg. For phase 2, the two techniques were performed on the same leg. This change in methodology was elected in an attempt to reduce a potential element of error in the placement of the thermistors. By using the same leg for both techniques and allowing the tissue temperature to return to baseline between treatments, a more accurate comparison of the techniques could be assured.

**Thermistor Insertion**

A T-square with a level attached (Figure 1) was used to horizontally insert the thermistors into the medial aspect of the triceps surae muscle. The thermistors were inserted at a vertical depth of 2 and 3 cm for phase 1 and 4 and 5 cm for phase 2. The placement of the thermistors was based on the depth of penetration of the 1 MHz US frequency. The half-value depth is the distance that the US beam will travel through the tissue before the amplitude/energy is dissipated to 50% of the original value.\textsuperscript{18,27,28} The half-value depth for the 1-MHz frequency has been estimated to be 2.3 cm.\textsuperscript{18,27} Any estimated value for living tissue, however, has the uncertainty of varying thicknesses of each type tissue.\textsuperscript{28} The half-value depth for skin (4 cm), fat (5 cm), and muscle (1-2 cm) have been reported to be notably different.\textsuperscript{29,30} Initially, a methodological decision was made to place the thermistors at the depths of 2 and 3 cm (phase 1). However, when data collection revealed that tissue heating was not effective, phase 2 was implemented with thermistors at a depth of 4 and 5 cm.

The temperature of each thermistor was monitored for at least 3 minutes after insertion. Data collection did not commence until a stable baseline was achieved, ie, temperature measurement was the same for 3 consecutive readings. The US treatment using the manual technique was administered at 1.5 W/cm\textsuperscript{2} with a 5 cm\textsuperscript{2} transducer. The speed of movement was maintained at 3 to 4 cm per second in circular movements\textsuperscript{13} using 5 cc of room temperature Aquasonic gel as a coupling medium.\textsuperscript{27,31-34} Tissue temperature readings were recorded from each thermistor at baseline and every 30 seconds for the duration of the 10-minute treatment. Both temperature readings were always taken in immediate succession (shallow thermistor then deep thermistor).

For the AutoSound\textsuperscript{TM} technique, the triceps surae muscle of the opposite lower leg (phase 1) or the same lower leg (phase 2) of the same participant was used. The thermistors were carefully inserted in the previously identified manner for phase 1 or left in place allowing the tissue temperature to return to baseline for phase 2. The “hands-free” transducer was secured with 2 Velcro\textsuperscript{®} straps (Figure 2) over the portion of the calf muscle with the greatest girth. A room temperature Rich-Mar gel pad was used as the coupling medium as recommended by the manufacturer. The treatment used the same parameters (1.5 W/cm\textsuperscript{2} for 10-minutes) as that of the manual technique. The pulsations of the US wave through the transducer chambers were consistent with the 3 to 4 cm per second movement of the manual technique. At the conclusion of each treatment, the coupling medium was removed from the participant’s skin and antibiotic ointment was applied to the thermistor sites. The thermistors were soaked in Cidex\textsuperscript{®} for a minimum of 12 minutes, rinsed, and dried with sterile gauze.

**Data Analysis**

A repeated measures two-way analysis of variance (ANOVA) was performed for treatment (manual and hands-free) and depth of thermistors (2, 3, 4, and 5cm) repeated over time. Tissue temperatures were assessed at baseline and then every 30 seconds for 10-minutes. Post-hoc analyses were performed when main effects were identified. Statistical significance was set at p < 0.05.

**Results**

Table 1 summarizes the baseline, final, and total change in temperature across thermistor depths. Figures 3 through 6 demonstrate the tissue temperatures for both methods of treatment at each thermistor depth over time. At the 2-cm depth there was a significant difference for treatment method [F(3,85) = 4.11: p = 0.04] and time [F(1,58) = 2.57: p < 0.00]. At the 3-cm depth there was no significant difference for treatment method [F(3,85) = 0.04: p = 0.83] or time [F(1,58) = 0.32: p < 0.99]. At the 4-cm depth there was a significant difference for treatment method [F(3,85) = 13.81: p < 0.00] but not for time [F(1,58) = 0.46: p = 0.99]. At the 5cm depth there was a significant difference for treatment method [F(3,85) = 101.46: p < 0.00] and time [F(1,58) = 2.13: p = 0.01]. A post-hoc power analysis of this study was determined to be 96%.

**Discussion**

Although it is not typical to begin the discussion of a research study with limitations, this was an important component of the research methodology. Conducting this study in 2 phases helped to trouble-shoot 2 of the limitations: similar tissue composition and identical thermistor location. Despite an attempt to use both legs of each individual as their own control in phase 1, there was no guarantee that the tissue composition of the right calf was identical to that
of the left. Likewise, one cannot guarantee, that despite using a standardized thermistor insertion technique with a T-square and a level, the thermistors were at exactly the same tissue depth. Thus, the methodological change was implemented for phase 2. This change involved allowing the tissue temperature of the calf to return to baseline and administering both techniques in the same treatment session to the same calf.

Table 1. Summary of Baseline, Final, and Total Change in Temperature (mean ± standard deviation) Across all Thermistor Depths

<table>
<thead>
<tr>
<th>Tissue Depth</th>
<th>Mode of Treatment</th>
<th>Baseline Temperature</th>
<th>Final Temperature</th>
<th>Total Change in Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 cm</td>
<td>AutoSound</td>
<td>34.85 ± 1.03°C</td>
<td>35.60 ± 0.86°C</td>
<td>+ 0.75°C*</td>
</tr>
<tr>
<td></td>
<td>Manual</td>
<td>34.85 ± 1.20°C</td>
<td>35.58 ± 1.13°C</td>
<td>+ 0.73°C*</td>
</tr>
<tr>
<td>3 cm</td>
<td>AutoSound</td>
<td>35.43 ± 0.90°C</td>
<td>35.36 ± 0.85°C</td>
<td>- 0.07°C</td>
</tr>
<tr>
<td></td>
<td>Manual</td>
<td>35.41 ± 1.04°C</td>
<td>35.37 ± 1.05°C</td>
<td>- 0.04°C</td>
</tr>
<tr>
<td>4 cm</td>
<td>AutoSound</td>
<td>35.65 ± 0.70°C</td>
<td>35.34 ± 0.73°C</td>
<td>- 0.31°C</td>
</tr>
<tr>
<td></td>
<td>Manual</td>
<td>35.57 ± 0.73°C</td>
<td>35.56 ± 0.76°C</td>
<td>- 0.01°C</td>
</tr>
<tr>
<td>5 cm</td>
<td>AutoSound</td>
<td>36.65 ± 0.68°C</td>
<td>36.46 ± 0.73°C</td>
<td>- 0.19°C</td>
</tr>
<tr>
<td></td>
<td>Manual</td>
<td>36.55 ± 0.61°C</td>
<td>37.27 ± 0.73°C</td>
<td>+ 0.72°C*</td>
</tr>
</tbody>
</table>

* indicates a significant difference from baseline to final temperature.

Figure 3.

Figure 4.

Figure 5.

Figure 6.

The purpose of this study was to examine 2 different techniques within the Rich-Mar AutoSound™ device. To date, there are no other studies that have looked at the use of the 1-MHz frequency of the AutoSound™ device. Only 3 studies have examined the 3 MHz frequency. McCutchen, Demchak, and Brucker compared the AutoSound™ technique to that of the manual technique using the Omnisound 3000C device. Treatments were performed with a 3 MHz frequency at 1.0W/cm² for 8 minutes. Although the tissue temperature increased by 1.8°C with the AutoSound™ technique, the tissue treated with the Omnisound (manual technique) increased by 3.2°C. McCutchen, Demchak, and Brucker also compared the AutoSound™ device to that of the manual technique using the Omnisound 3000C device. Treatments were performed with a 3 MHz frequency at 1.5W/cm² for 10 minutes. The tissue temperature increase throughout this study, however, never exceeded 1°C at any depth or with either treatment method. There was no difference in the treatment area or ERA of the techniques. Both methods treated an area that was 14 to 15 cm² in size and equivalent to the hands-free technique when compared to the manual technique at 1.5W/cm² for 10 minutes. The tissue temperature increased by 3.2°C. McCutchen, Demchak, and Brucker also studied the 3 MHz frequency administered at 1.5W/cm² for 10 minutes but the therapeutic depth was 2.5cm. Again, the AutoSound™ device produced a significantly lower temperature increase (2.05 ± 0.6°C) than the manual techniques (3.38 ± 1.36°C and 4.53 ± 1.30°C).

Based on the results of previous studies, the expectation was for a 1 MHz treatment at 1.5W/cm² for 10 minutes to yield a 2 to 3°C temperature increase. This would have been classified as moderate therapeutic heating. The tissue temperature increase throughout this study, however, never exceeded 1°C at any depth or with either treatment method. There was no difference in the treatment area or ERA of the techniques. Both methods treated an area that was 14 to 15 cm² in size and equivalent to a 3:1 ERA. Likewise, the depth of the tissues analyzed clearly covered the half-value depth for the 1-MHz frequency. Perhaps a higher treatment intensity (2.0W/cm²) could have been used. With a BNR of 5:1 in the AutoSound™ device, however, spatial peak intensities as high as 11W/cm² is likely to result in patient discomfort.

One factor that may have influenced the tissue heating is the movement of the US transducer. With the AutoSound™ device, there are 4 rectangular transducer chambers arranged consecutively down the length of the transducer. Each of the transducers had an ERA of 3.5cm² and was energized sides the obvious advantage of not having to physically administer the US treatment, the AutoSound™ device can compensate for poor clinician technique.

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achieve therapeutic heating at 1.5W/cm². The Rich-Mar AutoSound™ unit failed to portance of testing clinical modalities. The concept of providing US treatment through a “hands-free” mechanism is clinically attractive. Using the hands-free technique can do exactly that, free your hands to perform manual techniques to impart a soft tissue stretch to maximize the effect of the “stretching window.”13,27,32 The hands-free technique can also compensate for poor clinical application of this modality, ie, too large of a treatment area and too rapid movement of the transducer. If the heating effect never reaches a therapeutic level, however, the ancillary interventions may not be efficacious.

Conclusions
In summary, this study reveals the importance of testing clinical modalities. The Rich-Mar AutoSound™ unit failed to achieve therapeutic heating at 1.5W/cm² over a 10-minute treatment period with a 1 MHz frequency. As clinicians, aside from deciding to use a modality, the choice of which type of US device to use is an important part of an efficacious treatment. Exploring the literature regarding the effectiveness of available units on the market and the appropriate parameters to use are critical aspects of clinical decision-making.

References

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