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# A Comparison of Intramuscular Temperatures During Ultrasound Treatments With Coupling Gel or Gel Pads

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**Study Design:** A repeated-measures design was used. The independent variable was ultrasound coupling medium with 2 levels: gel pad and traditional gel. The dependent variable was peak intramuscular (IM) tissue temperature.

**Objective:** To compare changes in IM temperature during similar ultrasound treatments with 2 different coupling media.

**Background:** Gel pads are gaining popularity as an ultrasound coupling medium. Intramuscular temperatures during ultrasound with gel pads and standard gel have not been compared.

**Methods and Measures:** Subjects were 13 student volunteers ( $21.3 \pm 1.4$  years of age) without lower-extremity pathology. Ultrasound treatments were administered in a laboratory on two separate occasions 48 hours apart, each with a different coupling medium (standard ultrasound gel or gel pad). One-MHz continuous ultrasound was administered for 7 minutes at  $1.5 \text{ W/cm}^2$  with the transducer head moving 3 to 4 cm/s over an area approximately twice the size of the transducer head. Tissue temperature was measured every 10 seconds using implantable thermocouples inserted at a 3-cm depth to the surface of the right medial calf. Data were analyzed using an ANCOVA with pretreatment temperature as the covariate.

**Results:** Tissue temperatures increased during both treatments, with the mean and standard deviation peak temperature during the gel pad treatment reaching  $39.4^\circ \pm 1.5^\circ\text{C}$  compared to  $39.2^\circ \pm 2.4^\circ\text{C}$  during the normal gel treatment. Statistical analysis revealed no difference in temperature between ultrasound treatments using gel and those performed using gel pads.

**Conclusions:** Because temperature changes were similar with both treatments, we conclude that these coupling methods are equivalent under the ultrasound application parameters tested.

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**Key Words:** acoustic transmission, coupling medium, thermocouple

**T**hermal ultrasound has been suggested to have numerous therapeutic effects including reduced scar tissue and adhesions,<sup>1,20,22</sup> reduced pain,<sup>1,22</sup> increased metabolism,<sup>9</sup> and increased healing.<sup>1,2,9,22</sup> To achieve these thermal effects, ultrasound is typically delivered transcutaneously in a continuous mode using a coupling medium. The therapeutic benefits of thermal ultrasound are directly dependant on the coupling medium's ability to transmit the sound energy to the treated tissue, leading to changes in tissue temperature.<sup>1,16,22</sup> In many studies, both classic<sup>5,11,16,17</sup> and contemporary,<sup>4,6–10,21</sup> researchers have used deep-tissue temperature as a dependent measure in ultrasound research.

Coupling media commonly used with direct application of ultrasound for noncontoured areas of the body include topical gels, mineral oils, and lotions.<sup>2,3</sup> For contoured areas, indirect application is often performed by immersing the body part and transducer in water.<sup>7,12,15</sup> However, water immersion is not the only means by which ultrasound can be

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This study was approved by the School of Health and Human Performance Human Subjects Committee, Indiana State University.

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transmitted to irregularly shaped body parts. Manufacturers of recently introduced gel pads, which resemble firm, gelatinous hockey pucks, claim that these gel pads are effective in the transmission of ultrasound.<sup>15</sup>

Because the benefits of thermal ultrasound directly depend on the ability of the coupling medium to transmit sound energy, several researchers<sup>2,3</sup> have studied the transmission quality of many coupling agents. Researchers have demonstrated the transmission efficacy of various topical gels, oils, and lotions by recording peak-to-peak voltages and actual temperature increases in human tissue.<sup>4,12</sup> Furthermore, gel pads have been shown to be more effective than standard ultrasound coupling gel in peak-to-peak voltage transmission.<sup>15</sup> However, data comparing tissue temperature changes during ultrasound coupled with gel pads and during ultrasound with other coupling media are lacking. The purpose of this study was to compare intramuscular (IM) temperature during direct ultrasound application using gel pads and using standard ultrasound gel to determine if these media produce different results. We hypothesized that there would be no difference in intramuscular temperature between the treatments.

## METHODS

### Design

A repeated-measures design was used in this study. The sole independent variable was coupling medium with 2 levels: gel pad and standard ultrasound gel. Each subject received both treatments with approximately 48 hours between treatments. The dependent variable was peak IM tissue temperature at a depth of 3 cm to the skin surface.

### Subjects

Thirteen student volunteers (5 men and 8 women,  $21.3 \pm 1.4$  years of age) with no history of lower leg pathology participated in this study. Each subject was given a memorandum concerning this study and provided written, informed consent for participation. To rule out any complicating medical conditions, each subject completed a confidential health status questionnaire prior to participation. This questionnaire screened for factors including blood-borne diseases, clotting disorders, known vascular abnormalities (eg, deep-vein thrombosis), or history of pathology to the extremity used in the study. No subject reported having conditions meriting exclusion. The procedures in this study were approved by the Indiana State University School of Health and Human Performance Human Subjects Committee.

## Instruments

All temperature measurements in this study were made using an Iso-Thermex 16-channel thermocouple thermometer (Columbus Instruments, Columbus, OH). The manufacturer described this equipment as being accurate to within 1% in the temperature range studied.<sup>14</sup> Intramuscular temperatures were measured using type-T, tissue-implantable thermocouples (0.41 mm in diameter) with an ungrounded tip (Model TX-23-21, Columbus Instruments, Columbus, OH). Thermocouples were disinfected by immersion in CidexPlus 3.4% glutaraldehyde solution for a minimum of 20 minutes. Room temperature was also measured with a type-T, ungrounded junction thermocouple (Model TX-31, Columbus Instruments, Columbus, OH).

Ultrasound treatments were administered with a FORTE 200 ultrasound electric stimulation combination unit (Chattanooga Group Inc., Chattanooga, TN). The ultrasound parameters used were 1.0 MHz frequency, 100% duty cycle, 1.5 W/cm<sup>2</sup> intensity, 5 cm<sup>2</sup> transducer size, 4.5 cm<sup>2</sup> effective radiating area (ERA), treatment area twice the transducer head size, duration 7 minutes, and beam nonuniformity ratio (BNR) less than 6:1. A 1-MHz ultrasound frequency was chosen over the more superficial 3-MHz frequency due to a concern that the relative thickness of the pad might interfere with the ability of 3-MHz ultrasound to heat deep tissues.

Two different coupling media were used. The first coupling medium was 5 ml of room-temperature Aquasonic 100 ultrasound transmission gel (Parker Laboratory, Orange, NJ). This is a commonly used gel for ultrasound coupling. The second coupling medium was an Aquaflex ultrasound gel pad (Parker Laboratory, Orange, NJ), also at room temperature. This pad is marketed for use over bony prominences and irregular surfaces. No commercial support was received from any manufacturer for this study, nor do the authors have any commercial interest in these products.

## Procedures

Subjects participated in an initial orientation session where they received an explanation of the study, gave informed consent, and completed a health status questionnaire. Following the orientation session, each subject reported for 2 testing sessions (1 for each coupling medium) with approximately 48 hours between sessions. The order in which subjects received each coupling agent was counterbalanced.

During each testing session, subjects assumed a prone position on a treatment table. Using a template with a hole cut to an area approximately twice the width of the ultrasound transducer head, a treatment area was traced onto the skin on the right posterior calf over the medial head of the

gastrocnemius. The proximal-distal position of this template was over the point where the calf had the greatest girth. The medial side was chosen because it presents a reasonably large window into which a needle may be inserted with less risk of injury to bony structures and nervous structures such as the fibula, superficial peroneal, and lateral sural cutaneous nerves found on the lateral side. The hair was then shaved from this area and the area was cleaned using an alcohol swab.

Using aseptic technique and universal precautions, an implantable thermocouple was inserted into the medial side of the right triceps surae complex using a sterile 21-gauge (3.81-cm long) hypodermic needle. Needles were inserted into the calf from the medial side and carefully oriented parallel to the ultrasound treatment surface at a vertical distance of 3 cm below the ultrasound treatment surface. Vertical depth was determined using a standard carpenter's square. Side insertion allowed temperature measurements to be made without entangling the thermocouple wires with the transducer head. No local anesthetic was used because after the initial needle prick, subjects in our pilot studies did not report feeling any discomfort from the fine-wire thermocouples. In the absence of subject discomfort, we saw no reason to potentially confound the temperature data because of the potential vasoconstrictive effects of common local anesthetics containing epinephrine. There is some evidence that hypoperfused tissues have greater temperature changes with ultrasound than do normal tissues.<sup>24</sup>

Following insertion, the needles (but not the thermocouples) were removed by pulling them back along the thermocouple wire, leaving only the fine-wire thermocouple in place. The insertion depth of the thermocouples was verified by means of marks made on the thermocouple lead at a known distance from the tip of the thermocouples as described in several previous studies.<sup>18,23</sup> By measuring the distance from the marks to the skin, we were able to calculate the depth of insertion to ensure that the thermocouples did not migrate during the needle removal.

Needles were taped to the base of the Iso-Thermex unit to reduce the likelihood of accidental needle-stick injury. The lead wires of the thermocouples were secured with Dermaclear tape (Johnson & Johnson, Skillman, NJ) to prevent them from accidentally being pulled out.

Ambient and IM temperatures were recorded at 10-second intervals for the duration of the experiment. Baseline temperatures were recorded for 2 minutes prior to the beginning of the ultrasound treatment. At the conclusion of the 2-minute baseline measurement period, 1 of the 2 coupling media (gel or gel pad) was applied. Ultrasound (1.0 MHz, 100% duty cycle, 1.5 W/cm<sup>2</sup> intensity, 5 cm<sup>2</sup>

transducer area) was administered for 7 minutes with the sound head moving at a rate of approximately 3 to 4 cm/s.

A metronome was used to pace the movement of the sound head. Because the width of the treatment area was twice the diameter of the sound head, any given point on the sound head only moves 1 diameter in a single pass (twice the head diameter – width of head = 1 × diameter). Because the diameter of the sound head was approximately 3.3 cm, each sound head pass was approximately 3.3 cm in length. To move the head at a rate between 3 and 4 cm/s, each pass would need to be approximately 1 second in duration (a 1-second pass would be 3.3 cm/s). The cadence of the metronome was set to 60 beats/min (ie, 1 beat/s). Therefore, moving the sound head so that its edge reached the margin of the treatment area on each beat ensured that the speed of the sound head movement was within tolerances.

At the conclusion of the 7-minute treatment session, thermocouples were removed and disinfected and a topical antiseptic and a sterile bandage were placed over the needle insertion site. Subjects were given instructions regarding wound care and signs of infection. A second treatment session, administered 48 hours later, followed the same protocol except the other coupling medium was used. During the second treatment, thermocouple reinsertion was located less than 1 mm from the original insertion site. There was no observable difference in baseline temperature between session 1 and session 2 for any subject.

## Statistical Analysis

A repeated-measures analysis of covariance (ANCOVA), using mean baseline temperature as a covariate, was used to identify differences in peak intramuscular temperatures between the 2 treatments. ANCOVA was chosen rather than a dependent *t*-test in an effort to partial out the variance from fluctuations in starting temperature and to maximize statistical power.<sup>13</sup> The alpha level was set a priori at 0.05.

## RESULTS

Room temperature across all treatments was 22.6° ± 0.8°C and was similar and stable during all treatments. Mean IM temperatures during all temperature samples for both baseline and both experimental treatments are depicted in the Figure. Baseline temperature for the gel pad treatment was 36.9° ± 0.7°C, while baseline temperature for the gel treatment was 37.1° ± 0.7°C. Peak temperature during the gel pad treatment was 39.4° ± 1.5°C. Peak temperature during the normal gel treatment was 39.2° ± 2.4°C. Peak temperatures during ultrasound did not statistically differ between treatments with the 2 cou-

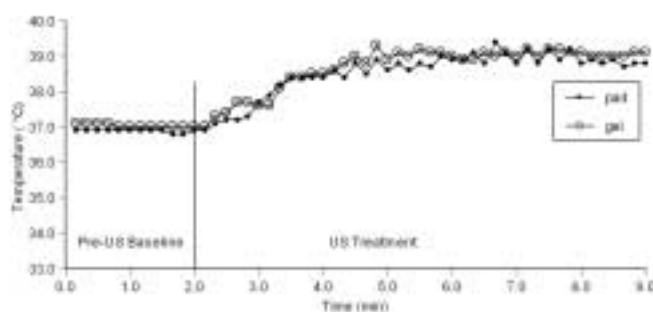


FIGURE. Intramuscular temperatures for 2 minutes prior and during 7 minutes of 1.0-MHz, 1.5 W/cm<sup>2</sup> continuous ultrasound.

pling media ( $F_{1,11} = 1.9$ ,  $P = 0.20$ , 95% confidence interval for the difference in means =  $-0.81^{\circ}\text{C}$ ,  $1.2^{\circ}\text{C}$ ).

## DISCUSSION

We observed that there was no statistical difference in peak IM temperature reached during 7 minutes of 1-MHz ultrasound applied at 100% duty cycle and an intensity of 1.5 W/cm<sup>2</sup> with standard gel versus an Aquaflex gel pad. We believe that either coupling method is equally effective in the transmission of ultrasound to produce thermal effects. Note, however, that we did not examine temperatures during a maximal heating protocol and it is possible that our observations may not be generalizable to ultrasound treatment for other intensities, durations, or frequencies.

We observed that during 7 minutes of continuous ultrasound (1.0 MHz, 1.5 W/cm<sup>2</sup>, 5 cm<sup>2</sup> sound head, BNR < 6:1), temperatures did increase with both of the ultrasound coupling methods examined. While the 2 ultrasound treatments in this study produced temperature increases similar to each other, the increases were not quite as large as the 3° to 4°C increases reported by Draper and colleagues,<sup>6,8,21</sup> who used longer treatment durations and equipment with a considerably smaller BNR. Because our ultrasound parameters differed from those in these previous investigations, we suggest that our findings be limited to the parameters used in our study.

Another related observation is that both of our treatments produced final absolute temperatures above 39°C, but the relative temperature increases from baseline were only approximately 2°C. In the classic early paper describing the necessary IM temperature to increase collagen extensibility, Gersten<sup>11</sup> suggests that temperatures at or above 39°C are required. Using this criterion, it appears that the small temperature increase we produced may have (barely) reached the lower boundary of the therapeutic range. In other papers<sup>5,17,19</sup> investigators have suggested that temperatures of 40° to 45°C are required, while still others<sup>6,8,21</sup> recommend an increase of 3°

to 4°C from baseline instead of a specific absolute temperature. The recommendation of a relative temperature change from baseline instead of an absolute tissue temperature<sup>6,8,21</sup> may be problematic. In some of our pilot work, we've observed subjects with resting triceps surae IM temperatures as low as 34°C. In such subjects, a 4°C increase from baseline (ie, an increase to 38°C) would not have raised the tissue temperature into the range specifically observed to alter collagen extensibility (39–45°C).<sup>5,11,17,19</sup>

During standard ultrasound treatments, gel is applied directly to the skin and the distance between the sound head and the skin is typically a millimeter or less. The gel pad is somewhat thicker (approximately 2 cm) and therefore greatly increases the distance between the skin and the sound head. Our concern was that by measuring temperature at a uniform depth beneath the skin (3 cm), the pad might produce lower temperatures simply by being farther from the temperature sensor (approximately 5 cm for the pad instead of 3 cm for the gel). For this reason, we chose to use the deeper penetrating 1-MHz ultrasound frequency instead of the more superficial 3-MHz frequency. After evaluating our results, we suggest that this difference in distance with the gel pads does not appear to produce a difference in efficacy because both treatments produced similar IM temperatures. Therefore, future studies should evaluate the use of these pads with 3-MHz ultrasound. The higher frequencies of ultrasound would usually be selected when treating superficial tissues around bony prominences where gel pads are most likely to be used.

Both methods appear to be equally effective at raising IM temperatures; in some cases gel pads may be a wiser choice for ultrasound treatment. Gel pads are easy to apply, reusable, and reduce the burden of cleanup after treatment. They also reduce the likelihood of damage to the transducer's crystal from inadequate coupling, particularly when treating irregular surfaces. However, neither the manufacturer nor any independent investigator has yet examined the useable life of these pads and therefore no data are available to describe the number of treatments obtainable with this product. The manufacturer originally marketed the pads for single use, although they report that many clinicians reuse the pads on an individual patient. To prevent cross-contamination, they do not recommend using the same pad on more than one patient.

One potential disadvantage of the gel pads may be their cost. At a retail cost of roughly \$6 (US) per pad, they are considerably more expensive than standard gel, although an analysis of cost per treatment is not yet possible because the usable life of the pads has not yet been described. For comparison, retail cost of Aquasonic 100 gel is roughly \$2.50 (US) for a 250-ml bottle that will yield up to 50 treatments,

translating to roughly \$0.05 per treatment. A study confirming the longevity of gel pads is certainly needed to examine whether they are an economical choice. Nonetheless, because they are equally effective in allowing temperature increases during ultrasound treatment, the ease of application and cleanup make coupling gel pad use a good idea, particularly when treating irregular surfaces.

## CONCLUSIONS

Seven-minute ultrasound treatments (1.0 MHz, 100% duty cycle, 1.5 W/cm<sup>2</sup>) using standard ultrasound gel and a gel pad produced similar IM temperatures. Gel pads are reusable, easy to apply, good for coupling over bony surfaces, do not require significant cleanup, and reduce potential for damage to the sound head from inadequate coupling. We suggest that gel pads be considered as an effective alternative to standard ultrasound coupling gel. However, additional studies should be conducted to confirm these findings for ultrasound application parameters other than those examined here and to examine the cost-effectiveness of these pads.

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