Effect of coupling medium temperature on rate of intramuscular temperature rise using continuous ultrasound

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Abstract:
Objective: We determined the effects of coupling medium temperature on the rate of intramuscular temperature rise (RTR) during continuous ultrasound.

Design and Setting: Ultrasound was applied in a continuous mode at a frequency of 1 MHz and intensity of 1.5 W/cm². Each subject received 3 treatments, using water-based coupling gel at temperatures of 18 deg C, 25 deg C, and 39 deg C. All treatments were performed in an athletic training room under controlled environmental conditions.

Subjects: Eighteen healthy male subjects (mean age = 23.6 +/- 3.5 years; height = 177.8 +/- 6.9 cm; weight = 76.6 +/- 8.2 kg; calf size = 37.6 +/- 2.4 cm) participated in this study.

Measurements: A thermistor was inserted into the left medial triceps surae at a depth of 5 cm, and baseline tissue temperatures were recorded before treatment. Intramuscular temperature was recorded every 30 seconds until the temperature rose 4 deg C above baseline or until discomfort was felt. RTR was calculated by dividing the absolute temperature change by treatment time.

Results: A 1-way, repeated-measures analysis of variance revealed a significant difference in RTR among gel temperatures. RTR was significantly faster using the 25 deg C gel compared with the 18 deg C and 39 deg C gels. There was no difference between the 18 deg C and 39 deg C gel treatments.

Conclusions: These results suggest that the use of a cooled or heated gel may be counterproductive when maximal thermal effects are desired within a given time frame.

Key Words: modalities, thermal, water-based gel

Article:
Therapeutic ultrasound is a commonly used modality in the treatment of physical injuries. Many factors have been found to play a part in the effective transmission of ultrasound to the target tissues. Treatment-area size, treatment duration, frequency and intensity parameters,
soundhead pressure,3 and angle of application4 have all been found to influence treatment efficacy.

A major factor influencing the transmission of sound waves during ultrasound is the coupling medium applied.5,6 Because ultrasound cannot be transmitted through air, a dense coupling medium is needed between the transducer and the skin. Previous studies 6, 9-12 have investigated the effectiveness of coupling mediums by measuring temperature increases intramuscularly3 and the transmission of ultrasonic waves. Their results indicate that a water-based gel provides the highest percentage of acoustic energy transmission compared with other mediums tested.5,13-15 In addition to the coupling medium used, clinicians have sought to enhance the transmission of ultrasound by combining it with other therapeutic agents.16-20 These agents have been thermal in nature and are often administered before treatment to produce superficial tissue temperature and density changes in order to enhance effectiveness. Lehmann et al 18 evaluated the effects of an 8-minute hot-pack application before ultrasound and found that the hot pack produced no adverse effects to the ultrasound treatment. Whether any positive benefits resulted from the addition of the hot pack was not explored. However, Draper et al16 reported an additive effect to overall temperature increase when a hot pack was applied for 15 minutes before an ultrasound treatment.

The effects of cold application before continuous ultrasound have also been explored.17,19 Rimington et al 19 found that an ice bag applied for 15 minutes before ultrasound decreased tissue temperature to the point that even baseline levels were not reached during the treatment. Similarly, Draper et al 17 demonstrated that a 5-minute ice-bag application resulted in only a 1 deg C increase in tissue temperature rise after ultrasound application. Baker and Bell20 evaluated the effect of cold on blood flow rather than rate of temperature rise and found ultrasound, alone and when preceded by an ice massage, was effective in increasing blood flow. Interestingly, they found no significant increase in blood flow with the application of moist hot packs before ultrasound treatment.

Considering the effect of superficial thermal agents on intramuscular temperature rise, little research to date has evaluated the effects of varying the coupling medium temperature. Lehmann et al 21 sought to determine which coupling medium and temperature resulted in the greatest peak tissue temperature with ultrasound administered at 1 MHz and 1 W/cm^2. Using mineral oil and degassed water as the coupling mediums at both 21 deg C and 24 deg C, they reported that the 21 deg C mineral oil produced the highest peak temperatures in the deep tissues near the bone and the 24 deg C oil produced the highest peak temperatures in the superficial tissues. However, from the graphic data presented in the article, peak temperatures in the deep tissue appeared quite similar for both the 21 deg C and 24 deg C oil samples.21 Therefore, it seems that coupling medium temperature may have had little effect on peak deep tissue temperatures. Although this was not reported by Lehmann et al 21 it does appear from their data that the time rate to achieve peak temperature differed, with the 24 deg C oil being faster than the 21 deg C oil in the deep tissues.

Collectively, these researchers have attempted to evaluate the influence of superficial temperature changes on the thermal effects of ultrasound. While some studies indicate superficial heating enhances, or has no adverse effect on, intramuscular temperature during
sonation, others have shown no change or a decrease in intramuscular temperature rise with the application of heat and cold. However, these studies differed considerably in their methods (eg, duration of heat or cold application, type of coupling medium used), which makes comparison across studies difficult. Furthermore, with the exception of Lehmann et al., thermal agents were always applied before, rather than during, the ultrasound treatment. We were unable to find any research that specifically addressed whether varying the temperature of a water-based coupling medium would influence the rate of intramuscular temperature rise (RTR) during sonation. Therefore, our purpose was to compare the effect of cold, room temperature, and heated coupling mediums on the RTR in the human gastrocnemius muscle during continuous ultrasound.

METHODS

Subjects
Eighteen college-aged men (age = 23.6 +/- 3.5 years; height = 177.8 +/- 6.9 cm; weight 76.6 +/- 8.2 kg; calf circumference = 37.6 +/- 2.4 cm) volunteered to participate in this study. All subjects were asymptomatic at the onset of the study and free of injury, infection, and swelling in the left leg for the past 6 months. All subjects read and signed an informed consent that explained all potential risks before participating in the study. The study received approval from the University's Human Investigation Review Board.

Instruments
We used the Omnisound 3000 (Accelerated Care, Inc, Topeka, KS) ultrasound unit, equipped with a lead zirconate titanate crystal and 1-MHz frequency sound head. The transducer size was 5 cm^2, with an effective radiating area of 4.1 cm^2 and a beam nonuniformity ratio of 4:1. The unit was calibrated 1 month before the study and was dedicated to the research project through the duration of the study. For the coupling medium, we used Aquasonic 100 (Parker Laboratories, Inc, Newark, NJ) transmission gel at standardized temperatures of 18 deg, 25 deg, and 39 deg C. We heated the 39 deg C gel using the model TM-1 Gel Warmer (Chattanooga Group, Inc, Hixson, TN).

To record intramuscular temperatures, we used a 23-gauge thermistor needle (Phystek MT-23/5, Physitemp Instruments, Clifton, NJ) attached to a monitor (Bailey Instrument BAT-10, Physitemp Instruments) to provide continuous digital temperature readings in degrees Celsius (C). According to the manufacturer, temperature accuracy is within +/- 0.1 deg C.

Procedure
The subjects remained prone for all ultrasound treatments. All treatments were performed in the University's athletic treatment facility, with the room temperature controlled at 22.77 deg C. We performed all treatments during the same session, and gel samples were counterbalanced to control for order effect.

We controlled and monitored each gel sample temperature individually using a mercury thermometer before and during the treatment sessions. The 18 deg C gel sample was placed in the refrigerator before treatment, and the temperature was maintained during the treatment session using an ice bath. The 25 deg C gel sample was maintained at room temperature, and we maintained the 39 deg C gel temperature with the commercial gel warmer. Although we did not
monitor the temperature of the gel once it was applied to the skin's surface, we maintained the respective gel temperatures throughout the ultrasound treatment by adding a new gel sample approximately every 2 minutes. The primary investigator (C.A.O.) administered all ultrasound treatments perpendicular to the thermistor in a continuous mode at intensity of 1.5 W/cm$^2$. In order to limit and standardize the treatment area, we cut a template to precisely 2 times the size of the effective radiating area of the ultrasound applicator (8.2 cm$^2$). We moved the ultrasound head within the template at a rate of approximately 4 cm*s$^{-1}$.

We applied all ultrasound treatments to a 10-cm diameter area on the left medial triceps surae muscle. We positioned the subject prone and measured the circumference of the lower leg to determine the cross-sectional area with the greatest muscle girth. We shaved and cleansed the area thoroughly with a 10% povidone-iodine scrub, followed by a 70% isopropyl alcohol swab. We used a caliper to determine the site of thermistor insertion (5 cm deep), and a physician injected 1 mL of 1% lidocaine subcutaneously to anesthetize the area before the thermistor was inserted. Once the area was anesthetized, the physician inserted the thermistor into the left medial triceps surae muscle belly at a tissue depth of 5.0 cm, using a level to keep the thermistor parallel to the frontal plane. We then connected the thermistor to the monitor, and tissue temperature was allowed to stabilize for 5 minutes. After this procedure, we recorded the baseline temperature for each subject.

Once the baseline temperature was established, we initiated the ultrasound treatment and recorded intramuscular temperatures at time 0 and every 30 seconds thereafter until intramuscular tissue temperature increased 4 deg C above baseline or the subject began to feel discomfort. At the end of each treatment, the tissue temperature was allowed to return to baseline levels and stabilize for 5 minutes before we initiated the next treatment condition. On completion of the testing, we removed the thermistor, cleansed the area with the povidone-iodine solution, and applied an antibiotic ointment and bandage over the injection site. Before releasing the subject, we placed an ice pack over the area for 10 minutes to help reduce hematoma formation. After each test session, we sterilized the thermistor using ethylene oxide gas in the Central Sterile Supply area at the University's Medical Center.

**Statistical Analysis**

RTR was calculated by dividing the absolute temperature change by the total treatment time for each subject. We analyzed the data using a 1-way, repeated-measures analysis of variance with 1 within variable (rate of temperature rise) measured at 3 temperature levels (18 deg, 25 deg, and 39 deg C). We used the Tukey HSD method to determine which specific gel temperatures differed significantly. The a level for all analyses was set a priori at P < .05.

**RESULTS**

The mean baseline tissue temperature across all subjects was 35.47 deg C +/- 0.74 deg C. Of the total 54 ultrasound treatments performed (3 treatments per subject), 44.6% of the treatments (44.6% cold, 55.8% room, and 33.5% hot) achieved the 4 deg C target increase in temperature, with the remaining treatments being terminated due to subject discomfort. The mean temperature increases obtained in treatments terminated by discomfort were 3.13 deg +/- 0.71 deg C (cold), 3.33 deg +/- 0.64 deg C (room), and 3.10 deg +/- 0.75 deg C (hot).
Means and standard deviations for final temperature, total temperature change, time to reach final temperature, and RTR for each gel condition are listed in the Table. The Figure plots the change in RTR across time for each treatment condition. We found a significant difference in RTR among the 3 gel samples (F (2,34) = 6.487, P = .004). Observed power was 0.879. The Tukey post hoc analysis revealed that the RTR was significantly faster using the 25 deg C gel, compared with both the 18 deg C and 39 deg C gel treatments. There was no significant difference between the 18 deg C and 39 deg C gel treatments.

DISCUSSION
Our primary finding was that the room-temperature coupling medium was more efficient than either the cooled or heated gel in achieving maximal thermal effects at a 5-cm depth intramuscularly. Many clinicians attempt to enhance the efficacy of continuous ultrasound by applying superficial thermal agents, such as moist heat and ice packs, to the skin before sonation.16-19 The superficial temperature change brought about by these agents is thought to influence ultrasonic wave propagation to deeper tissues by altering blood flow20,22 and tissue density8,16,17,19,21 in the superficial tissue layers. While some have tested the theory that the application of cold before ultrasound increases tissue density and, thus, improves wave propagation,17,19 others used moist heat in an attempt to produce an additive heating effect.16 Based on these therapeutic rationales, we sought to investigate whether varying the superficial temperature of the water-based coupling medium could similarly enhance the thermal effects of ultrasound.

Gel Temperature and Density
As previously stated, in order for wave propagation to occur, the ultrasound head must be in contact with a dense coupling medium. Various mediums have been tested, with a waterbased gel producing the highest percentage of acoustic energy transmission. It would, therefore, be plausible that if the density of a water-based gel was altered, ultrasound transmission and, thereby, RTR could be affected. While previous authors have tested the theoretical model of increasing tissue density through cold application,17,19 we are unaware of any studies that have directly evaluated the effects of thermal changes on the water-based gel density and ultrasound transmission. Theoretically, one might expect cooling to increase and heating to decrease the density of the coupling medium, thus affecting ultrasound transmission and RTR. While our findings, in part, indirectly support this theory with a smaller RTR for the heated gel compared with room-temperature gel, we found a smaller RTR rather than a greater RTR with the cooled gel. Lehmann et al21 represent the only other researchers to evaluate the effects of a cooled coupling medium when applied during an ultrasound treatment. They concluded that a mineral oil coupling medium at temperatures of 21 deg C or less was more effective for deeper tissue heating than 24 deg C. However, on careful review of their data, while the 24 deg C oil resulted in slightly lower peak temperatures compared with the 21 deg C oil, it appears to have produced a faster RTR in deeper tissues. They did not evaluated heating effectiveness using a heated mineral oil.

Based on these findings, we believe that the density of the gel as a result of temperature change had negligible effects on tissue temperature or at least cannot alone explain our findings. It is likely that other factors, such as the cooling or heating effect of the gels on superficial tissue temperatures, also influence RTR.
Gel Temperature and Additive Thermal Effects

With regard to superficial heating, our results contrast with those of Draper et al.16 who demonstrated an additive thermal effect when a hot pack was applied to the calf for 15 minutes before ultrasound. In fact, Draper et al.16 found such a profound heating effect that less energy was required by the subsequent ultrasound treatment to produce maximal heating effects. We believe the contrast in these findings can be explained by the difference in heating intensity, method of application, and the depth at which the temperatures were recorded. While we recorded tissue temperature at a depth of 5 cm, Draper et al.16 measured tissue temperature more superficially at 1- and 3-cm depths, which may be more sensitive to the effects of superficial heating. Moreover, with a 15-minute hot-pack application, a larger area was heated and the terry cloth cover limited the subject's skin exposure to ambient air temperatures, resulting in less heat
attenuation and greater penetration. In our study, the temperature of the heated gel was
appreciably lower that of a standard moist pack, covered a smaller surface area, and was applied
for a shorter period of time. However, while these methodologic differences may explain why we
were unable to show an additive effect, they do not explain why the heated gel was less effective
than the room-temperature gel.

Other than the potential thermal effects on gel density previously discussed, the decreased
effectiveness of the heated gel may also be explained by the body's physiologic reactions to
thermal agents. When heat is applied to the skin, feedback from thermoreceptors initiates a
sympathetic reflex circulatory response to increased blood flow to the area in an effort to
regulate and maintain peripheral temperatures. Hence, it is likely that the application of the
39 deg C coupling medium to the skin initiated this vasodilatory response, effectively dissipating
heat in the surrounding tissues and potentially explaining the slower RTR in the deeper tissues.
Therefore, it appears from these contrasting studies that the magnitude of superficial heating may
dictate whether maximal thermal effects are enhanced or diminished. While profound heating
may overwhelm the thermoregulatory response and result in an additive thermal effect, moderate
heating may actually be counterproductive.

With regard to superficial cooling, we found the 18 deg C gel was also counterproductive to
achieving maximal thermal effects. While absolute temperature increases were similar to those
for the 25 deg C and 39 deg C gel treatments, the RTR was significantly reduced compared with
room temperature. Therefore, it appears that using an 18 deg C gel does not produce any additive
physiologic effect sufficient to overcome the gel's cooling effect, thereby enhancing the
transmission of ultrasonic energy to deeper tissue layers. These findings are consistent with
Draper et al and Rimington et al, who found the superficial application of an ice bag (5 and
15 minutes, respectively) before ultrasound reduced heating effectiveness in comparison with
ultrasound alone. While our cooling may have been less intense than the ice-pack applications
used in these studies, even moderate cooling is sufficient to limit the RTR in deeper tissue.

Clinical Implications
The clinical implication of these findings is that there are no apparent additive benefits when
using a cooled or heated gel during a standard ultrasound treatment. The room-temperature (25
deg C) gel produced the fastest RTR, thus providing the most effective and time-efficient
treatment to achieve maximal thermal effects. However, these findings were limited to
temperature changes in muscle tissue at a 5-cm depth. As previous research has indicated,
temperature increase and tolerance may vary considerably depending on the type, depth, and
thickness of the target tissue, as well as its distance from the bone.

Our findings also reinforce the need for clinicians to carefully consider the total treatment time
required to achieve maximal thermal effects. As busy clinicians, treatment time is always a
concern when treating injuries. However, in order for maximal thermal benefits to be achieved
during continuous ultrasound, treatment duration must be sufficient to allow vigorous heating of
the tissues. Based on our RTR data (Table), we determined that the time required to reach
vigorous heating (~4 deg C or maximal temperature tolerated) at a 5-cm depth was 13.0, 10.6,
and 11.1 minutes for the 18 deg C, 25 deg C, and 39 deg C gel treatments, respectively. These
time durations are considerably longer than the traditional 5-minute ultrasound treatment that is
commonly administered to patients. Therefore, clinicians should consider a minimum treatment duration of 10 minutes if maximal thermal effects are warranted. Furthermore, when other thermal agents are used in conjunction with ultrasound, total treatment time may need to be adjusted further. Although the heated gel was found to be less effective in increasing tissue temperature compared with room temperature gel, it still can be used effectively to provide patient comfort if a longer treatment time is incorporated.

REFERENCES