Intramuscular Heating Effect Produced by Long Duration Continuous Low Intensity Therapeutic Ultrasound (LITUS)

Rigby JH*, Draper DO*, Taggart RM†, Stratton KL‡, Lewis Jr. GK†
*Human Performance Research Center, Brigham Young University, Provo, UT
†ZetROZ, Inc., Trumbull, CT

ABSTRACT
Recently, a wearable low intensity therapeutic ultrasound (LITUS) device was developed for sustained therapy for up to 4 h. Prior to this study, it was unknown whether an ultrasound device could maintain therapeutic intramuscular (IM) heating for a long duration without overheating human tissues. PURPOSE: To measure IM temperature during long duration LITUS therapy, and to compare the heating effect from 1 or 2 transducers each emitting continuous 3 MHz, 0.132 W/cm² intensity ultrasound with a BNR of <5:1 and ERA of 6 cm².

METHODS: In an IRB-approved, randomized crossover study, 20 subjects (M = 11 and F = 9, age = 22.6 ± 2.0 yrs, ht = 1.73 ± 0.09 m, mass = 73.5 ± 14.2 kg) received 3 h ultrasound treatments from the LITUS device over the triceps surae muscle. Over the course of the treatment, subjects received 7,020 or 14,040 J of energy from 1 or 2 transducers, respectively. IM temperature was measured by two MT-26/6 needle thermocouples horizontally inserted into the left triceps surae muscle at depths of 1.58 ± 0.15 and 2.91 ± 0.16 cm from the posterior surface of the calf. Thermocouples were positioned under a single transducer or the intersection of two transducers placed side-by-side. Surface skin temperature on the opposite leg was measured by a PT-6 thermometer. Temperatures were recorded at 5 min intervals throughout the treatment and for 30 min post-treatment. The resulting temperature profiles were analyzed in 3 phases: 1) heating, 2) steady-state, and 3) cooling. Repeated measures (condition x time) ANOVA were used to determine the significance between treatment conditions. RESULTS: At 1.5 cm, the LITUS device heated tissues 1.63 ± 1.23 and 1.12 ± 0.95 °C for 1 and 2 transducer(s), respectively. Peak temperatures were maintained for approximately 2 h during the steady-state phase. IM temperature at 3 cm did not increase above initial baseline; however, surface skin temperature decreased by 1.51 ± 1.89 °C. Dual transducers provided an equivalent peak IM temperature increase while also treating a larger area than 1 transducer (p = 0.99). CONCLUSION: The wearable LITUS device provided sustained tissue heating throughout a 3 h treatment without overheating the tissue. Environmental conditions seen by decreased surface skin temperature are hypothesized to have negatively affected IM temperature.

BACKGROUND
- A wearable long duration low intensity therapeutic ultrasound (LITUS) device was developed for treatments lasting 1-4 h (Figure 1).
- Traditional therapeutic ultrasound requires the application be performed by a trained health care practitioner. Treatments usually occur 1-3 times per week for 5-15 min depending on patient access, clinic time and cost of care.
- Therapeutic ultrasound with higher energy delivery per treatment strongly correlates to greater positive clinical outcomes.
- The heating characteristics of tissue from the new LITUS device have not been measured previously. The heating characteristics will help determine the appropriate dosimetry necessary to produce desired physiological response for rehabilitation of musculoskeletal conditions.

EXPERIMENTAL PROCEDURES
- Randomized placebo-controlled crossover study
- Independent variable: Intramuscular (IM) temperature of triceps surae muscle group at 1.5 and 3.0 cm depths.
- Independent variables: Treatment group (active, N = 20 vs. sham, N = 6), number of transducers used for treatment and treatment time. Subjects were blinded to their treatment group.
- Subjects: N = 26 (16 males, 10 females, age = 23.0 ± 2.1 y, ht = 1.74 ± 0.09 m, mass = 7348 ± 14.65 kg)
- We inserted 2 temperature probes (Model: MT 23/5 needle microprobe thermocouples, Physitemp, Inc., Citron, NJ) at depths of 1.5 and 3.0 cm from the posterior surface of the calf. The depth was verified with musculoskeletal imaging ultrasound (Figure 2).
- A therapeutic ultrasound treatment was delivered with either 1 or 2 transducer(s) for 3 h (Figure 3).
- IM temperatures were measured at 1 min intervals throughout the treatment (temperature increase) and for 30 min post-treatment (temperature decay).
- Sham treatments were performed in the same manner except the device remained in the off position.

DATA ANALYSIS
- IM temperatures were normalized from baseline measurements to indicate temperature change.
- Sham subjects had a physiological cooling while lying supine for 3.5 h (Figure 4). Data from active treatments were plotted against sham data to account for cooling which occurs at rest.
- IM heating profiles were determined and analyzed in three phases: heating phase, peak temperature reached and post-treatment cooling phase.

RESULTS
- 3 MHz frequency
- 0.132 W/cm² intensity
- Continuous wave
- Single or dual transducers
- BNR: <5:1
- ERA: 6 cm²
- Delivers 1-4 hours of therapy/Rx
- 4,680 – 18,720 J of energy based on Rx time

Figure 1. Long duration low intensity therapeutic ultrasound (LITUS) device (Model: sam®, ZetROZ, Inc., Trumbull, CT) and the device’s specifications

Figure 2. Insertion of 2 temperature probes at 1.5 and 3.0 cm verified with imaging ultrasound

Figure 3. LITUS treatment with 2 transducers

Figure 4. Physiological cooling of triceps surae muscle associated with sham treatment with subject at rest

RESULTS
- 3.0 cm depth - 2 transducers
- 1.5 cm depth - 2 transducers
- 3.95 ± 1.10°C
- 3.18 ± 0.90°C
- 3.22 ± 0.95°C

When adjusted for physiological cool, which occurs at rest, the wearable LITUS device elicited vigorous heating (> 4°C mean temperature increase) at 1.5 cm deep in IM tissue and moderate heating (2-3°C mean temperature increase) at 3 cm deep after 3 h of continuous treatment.

The LITUS device is a safe alternative to traditional therapeutic ultrasound while delivering greater amounts of ultrasonic energy to the tissues due to its longer treatment time.

CONCLUSIONS

Acknowledgement
ZetROZ, Inc. received a grant from NIH to fund this study. Grant # 1R43MD008597-01