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Will Ultrasound Performed with the Rich-Mar AutoSound™ Be as Effective at Increasing Tissue Temperature as Ultrasound Performed with a Traditional Machine?

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A thesis submitted to the faculty of
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ABSTRACT

Will Ultrasound Performed with the Rich-Mar AutoSound™ Be as Effective at Increasing Tissue Temperature as Ultrasound Performed with a Traditional Machine?

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STUDY DESIGN: Randomized crossover experiment. OBJECTIVE: To determine whether the Rich-Mar AutoSound™ would be as effective as traditional ultrasound at increasing the temperature of the triceps surae muscle during a 10-min, 1 MHz, 1.0 W/cm^2 ultrasound treatment. BACKGROUND: The AutoSound™ is a hands-free ultrasound device that is strapped on the body and left for the duration of the ultrasound treatment. It requires no clinician during the actual ultrasound treatment, thus freeing the clinician to perform other tasks and reducing clinician error during treatments. METHODS: 16 healthy subjects (6 males, 10 females, age = 22 ± 1.6 yrs, height = 173.2 ± 8.4 cm, weight = 72.5 ± 11.3 kg, triceps surae subcutaneous fat thickness = 0.85 ± 0.37 cm) received a 10-min, 1 MHz, 1.0 W/cm^2 ultrasound treatment over their left triceps surae muscle with both the AutoSound™ and traditional ultrasound (via the TheraHammer™) with 24 hours between treatments. Temperatures were measured every 30 seconds during the ultrasound treatments by way of a thermistor, approximately 2.25 cm deep in the triceps surae. RESULTS: The AutoSound™ was not effective at increasing the temperature of the triceps surae muscle, as temperature decreased 0.16°C during treatment ($p = 0.334$). On average, the AutoSound™ caused intramuscular temperature to decrease at a rate of 0.016 ± 0.001°C per min. Traditional ultrasound performed using the TheraHammer™ had a total temperature increase of 0.41°C. Rate of temperature increase during traditional ultrasound was 0.025 ± 0.003°C per min ($p < 0.0001$). CONCLUSION: The AutoSound™ is not as effective at increasing muscle temperature as traditional ultrasound during a 10-min, 1 MHz, 1.0 W/cm^2 treatment. However, neither the AutoSound™ nor traditional ultrasound was very effective at increasing the temperature of the triceps surae muscle during the treatment time.

Keywords: AutoSound™, ultrasound, intramuscular temperature changes

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INTRODUCTION

Therapeutic ultrasound is one of the most common deep heating modalities used by physical therapists, athletic trainers, and occupational therapists.[1] The thermal effects of ultrasound are: treating soft tissue injuries[2] and muscle spasm,[3] restoring range of motion,[4] increasing collagen extensibility,[5] aiding in collagen alignment[6,7] and increasing wound strength.[7] The nonthermal effects of ultrasound include: increasing histamine release,[1] increasing phagocytosis,[1,8] increasing protein synthesis,[9] enhancing tissue regeneration[8,10] and wound healing,[11] and increasing fibroblasts and vascular regeneration.[10-12] Therapeutic ultrasound uses high frequency, inaudible, acoustic vibrations to produce these thermal and nonthermal physiological effects. Unfortunately, despite its common use, therapeutic ultrasound is often misunderstood and misused.[13, 10, 12] However, when used properly, it is an effective treatment method that can be applied to both normal and damaged tissue.[4,14-17]

Traditional ultrasound treatments are prone to clinician error (treating too large a surface area,[13] moving the soundhead faster than the recommended speed,[18] etc.), labor intensive and time consuming, requiring a clinician to manually move the ultrasound transducer over the target tissue, leaving the clinician occupied and unable to complete other tasks. Rich-Mar (Chattanooga, TN) addressed these problems by developing the AutoSound™, a hands-free ultrasound alternative. The AutoSound™ works by activating and deactivating four rectangular transducer crystals that lie side-by-side.[19] The first crystal turns on and then quickly turns off when the second crystal turns on. This process repeats down to crystal four, and then starts at crystal one again. The activation and deactivation of the crystals is equivalent to a clinician manually moving the ultrasound transducer at a speed of 4 cm/sec,[20] the recommended speed of traditional soundhead movement.[21-23] The firing pattern of the crystals is equivalent to manually moving the ultrasound transducer from one part of the treatment area to the other, picking the transducer up, and placing it back at the starting point.[24] These crystals are housed in one unit that can be strapped on the body and left for the duration of the treatment.

The AutoSound™ could be a tremendous clinical asset, significantly adding to the time efficiency of the clinician if the machine works. Multiple studies,[24-26] have compared the AutoSound™ against traditional ultrasound in its ability to heat human muscles, and all have found that traditional ultrasound produced significantly greater temperature increases than the AutoSound™. Upon further examination of these comparison studies,[24-26] we discovered that each of the three used the 3 MHz frequency. Ultrasound delivered at a 3 MHz frequency is absorbed superficially in the tissues 1–2 cm deep, but may reach all the way to 3 cm deep,[27,28] whereas ultrasound delivered at 1 MHz is absorbed in deeper tissues 2–5 cm deep.[27]

The intensity used in these studies is important as well. Intensity is the rate at which ultrasound waves are being delivered to target tissues per unit area of the transducer surface (expressed as W/cm^2).[29] The lower the intensity, the longer the treatment duration needs to be in order to achieve the desired results.[27] Two of the previous studies[25,26] on the AutoSound™ used an intensity of 1.5 W/cm^2 for 10 min. The other[24] used 1.0 W/cm^2 for 8 min, even though treatments at a lower intensity should be longer duration to produce the desired results. The purpose of this study was to compare intramuscular temperature changes produced by a 10-min ultrasound treatment via the AutoSound™ and a traditional ultrasound treatment at a frequency of 1 MHz and an intensity of 1.0 W/cm^2.

METHODS

Participants

We recruited 16 healthy subjects for this study (age = 22 ± 1.6 y, triceps surae subcutaneous fat thickness = 0.85 ± 0.37 cm, 6 males, 10 females; weight = 72.5 ± 11.3 kg; height = 173.2 ± 8.4 cm). Subjects were screened for exclusion criteria during their signing of the consent form. Exclusion criteria were: a lower extremity injury within the last two months, a lower leg infection, open wound, rash, swelling, ecchymosis, decreased circulation, decreased sensation in the area being treated or thrombophlebitis. Participants refrained from exercise 2 h prior to each lab visit. All subjects provided written consent before their participation in the study. The study was approved by the University's Institutional Review Board before subject recruitment began.

Instrumentation

Traditional ultrasound was produced via the TheraSound Evo™ (Rich-Mar, Chattanooga, TN) delivered at a frequency of 1MHz. All Rich-Mar ultrasound machines use a beam nonuniformity ratio of 5.5:1 or less, and have an effective radiating area as close to the size of the soundhead as possible.[19] The traditional ultrasound was performed using the TheraHammer™ (Rich-Mar, Chattanooga, TN) which houses a lead zirconate titanate crystal that is 2 cm^2. Hands-free ultrasound was performed using the TheraSound Evo™ with the AutoSound™ attachment. The four crystals of the AutoSound™ are 1.5 cm by 2.5 cm each with 2 mm of dead space between each crystal. The treatment area of the AutoSound™ is approximately 14 cm^2.

Temperature was measured using the ISO-Thermex (Columbus Instruments International, Inc., Columbus, OH) program. Temperature readings were received from an IT-21 thermistor (Physitemp Instruments Inc., Clifton, NJ). The thermistor was inserted via a 20-gauge catheter

(BD Medical, Franklin Lakes, NJ). The depth of the inserted thermistor as well as adipose thickness (adipose levels were taken from 3 locations on each subject: one directly above the thermistor, one on the far left of the frozen image and one on the far right. All measurements were marked from the bottom of the skin to the top of the fascia surrounding the triceps surae muscle, with all measurements averaged together) was measured using Doppler ultrasound imaging (model: LogiQ 55e, General Electric Company, Fairfield, CT). Imaging ultrasound was produced using the 12 L soundhead and a 12 MHz frequency.

Procedures

A randomized cross-over experiment was performed. Participants reported to the lab twice, with at least 24 h between visits. All participants were screened for contraindications via consent form, and those who were still eligible after the screening process reviewed and signed an Institutional Review Board approved consent form. Once subjects were officially enrolled in the study, they were randomly assigned by drawing a piece of paper out of an opaque cup to receive ultrasound treatment first via the AutoSound™ or by using traditional ultrasound.

Catheter and Thermistor Insertion

A single thermistor was inserted via catheter into the medial side of the subject's left lower leg, an average depth of 2.25 ± 0.52 cm in the tissue (see FIGURE 1). Patients laid prone on the treatment table during catheter insertion (and for the remaining time of the treatment) with their left lower leg exposed. The area of greatest girth on the patient's triceps surae was visualized. A T-square was used to measure 2.25 cm anterior on the medial triceps surae and a green dot was marked on the skin where the catheter would be inserted. The insertion site was cleaned with an iodine swab and allowed to air dry before the catheter was inserted. The catheter was horizontally inserted into the medial triceps surae muscle over the previously marked green spot. A thermistor was fed through the catheter, and the catheter was removed, leaving the thermistor in place. Following the methods of another study[24] we used only one depth for the thermistors at 2.25 cm deep. Ultrasound treatment at 1 MHz ideally targets tissues 2–5 cm deep.[27] Thermistor insertion depth was verified using Doppler ultrasound imaging (see FIGURE 2).

Ultrasound Treatment Area

Ultrasound treatment area was centered over the end of the thermistor for each subject. The treatment area of traditional ultrasound was marked using a template two times the size of the ultrasound head (approximately 4 cm^2). Treatments performed via the AutoSound™ covered approximately 14 cm^2.

Manual Ultrasound Treatment

The ultrasound treatment using the manual technique was administered within the previously marked spot on the back of the triceps surae for 10 min. Treatments were performed with a 2 cm^2 transducer at a frequency of 1 MHz and an intensity of 1.0 W/cm^2. Tissue temperature readings were recorded for each patient at baseline (once temperature had stabilized to the point that there was no more than 0.2°C change every 30 sec) and every 30 sec for the duration of the treatment. Ultrasound gel was used as the coupling medium in all traditional treatments.

AutoSound™ Ultrasound Treatment

Treatments performed with the AutoSound™ (see FIGURE 3) were performed on the same leg as the manual ultrasound treatment, once again over the area of greatest girth on the medial triceps surae. Settings of 1 MHz and 1.0 W/cm^2 for 10 min were used. The AutoSound™ was secured in place with 1-inch Powerflex tape. Ultrasound treatments were started after tissue temperature had stabilized to the point that there was no more than 0.1°C change every 30 sec. Intramuscular temperatures were recorded every 30 sec throughout the treatment session using the ISO-Thermex. A 1 cm thick gel pad (designed specifically for the AutoSound™) was used as the coupling medium during all AutoSound™ treatments.

Thermistor Removal

At the conclusion of each treatment, the thermistor was removed from the subject's triceps surae and a bandage was placed over the area for protection. The thermistors and catheters were sterilized using an Anprolene Gas Sterilizer (Model: AN74i, Andersen Products, Inc., Haw River, NC).

Statistical Analysis

A 2x2 repeated measures ANOVA was used to determine interactions among the beginning and ending temperatures of each ultrasound unit. A hierarchal linear model was used to determine the rate of temperature change caused by each machine. In this model a regression line was fit to the slope of temperature change for each individual. Individual slopes were then averaged together for an overall slope of the population. SAS 9.3 (2010) was used for all statistical analysis, and alpha was set at $p < 0.05$.

RESULTS

The 2x2 repeated measures ANOVA on temperature showed a statistically significant interaction between instruments and time ($F = 23.72$ ($p = .0002$)). On average, traditional ultrasound temperatures ranged from a starting temperature of 35.67°C ± standard error of 0.24°C to an ending temperature of 36.08°C ± 0.24°C. Mean tissue temperature before ultrasound performed with the AutoSound™ was 35.88°C ± 0.24°C and ending temperature was 35.73°C ± 0.24°C. Traditional ultrasound mean changes between beginning and ending temperatures were statistically significant, with traditional ultrasound increasing tissue temperature 0.41°C ± 0.09 ($p = .0016$). There was no statistically significant change from beginning to ending temperature (tissue temp went down 0.16°C) with ultrasound performed with the AutoSound™ ($p = 0.33$).

The hierarchal linear model revealed a statistically significant difference in the slopes between traditional ultrasound and the AutoSound™ $F = 124.17$ ($p<.0001$) with regard to the rate of heating. On average, traditional ultrasound increased tissue temperature 0.025°C/min ± 0.003°C ($p < .0001$). The AutoSound™ actually lowered tissue temperature 0.016°C ± 0.001°C/min ($p = 0.95$; see TABLE 1).

DISCUSSION

We compared the heating of the AutoSound™ with traditional ultrasound delivered by the TheraSound Evo™ using the TheraHammer™. We discovered that the AutoSound™ at 1 MHz did not raise the tissue temperature during the 10-min treatment. These findings support previous research[24-26] that the AutoSound™ does not heat as well as traditional ultrasound. Three studies have compared the heating of the AutoSound™ with traditional ultrasound at a frequency of 3 MHz,[24-26] though ours is the first to test the AutoSound™ at 1 MHz. McCutchan et al.[24] used the following parameters for their study: 3 MHz, 1.0 W/cm^2, 8 min, assessing the tissue temperature at a depth of 1 cm. They found a 1.8°C increase in tissue temperature when the AutoSound™ was used and a 3.2°C increase when the Omnisound™ (Accelerated Care Plus, Reno, NV) was used. Like McCutchan et al.,[24] we used an intensity of 1.0 W/cm^2, but a longer treatment time of 10 min. In both cases traditional ultrasound produced a significantly higher increase in tissue temperature when compared with the AutoSound™.

The following parameters were used in the Gulick[25] study: 3 MHz, 1.5 W/cm^2, 10 min, tissue temperature probes 1 and 2 cm deep. The AutoSound™ increased the tissue temperature 5.1°C at 1 cm deep, and 1.5°C at 2 cm deep. The Omnisound™ increased the tissue temperature 6.7°C at 1 cm and 4.0°C at 2 cm. Traditional ultrasound once again produced a significantly greater increase in tissue temperature when compared with the AutoSound™. Though our settings varied from Gulick in every other way, we also used a 10-min treatment time.

Fincher et al.[26] performed ultrasound using the AutoSound™ at 3 MHz and 1.5 W/cm^2 for 10 min and traditional ultrasound via the 5 cm^2 TheraHammer™ transducer on the AutoSound™ 7.6 Combo unit at a depth of 2.5 cm. The AutoSound™ increased temperature 2.05°C, while traditional ultrasound increased tissue temperature 4.53°C. Again traditional ultrasound produced significantly higher temperature increases than the AutoSound™. We, like Fincher at al.,[26] used the same ultrasound machine with different attachments for all ultrasound treatments, but used the 2 cm^2 transducer for the traditional treatment instead of the 5 cm^2 transducer that was used in this study. The 2 cm^2 transducer or the difference in frequency may explain why Fincher et al.[26] received a 4.53°C change and a 2.05°C change with traditional ultrasound and the AutoSound™, respectively, and we saw very little change in temperature.

The AutoSound™ did not increase tissue temperature to the same degree as traditional ultrasound in any of these cases.[24-26] Research has found that heating varies from manufacturer to manufacturer.[30-32] The Omnisound™ was used in two of these studies[24,25] and may heat at a different rate than the TheraSound Evo™ as it seems to increase tissue temperature more than any other ultrasound machine with which it has been compared.[33, 34] To eliminate variability between manufacturers, we, like Fincher et al.,[26] compared 2 devices manufactured by the same company (Rich-Mar).

This is the first study performed on the AutoSound™ at a 1 MHz frequency. Even though there is variability between manufacturers, studies with similar parameters can help give an estimate of temperature changes that would be expected. Demchak et al.[30] found at a depth of 3 cm, a 1 MHz, 1.2 W/cm^2, 10-min treatment from the OmniSound 3000C increased tissue temperature 0.3°C per minute. The same parameters at 1.5 W/cm^2 increased muscle temperature at a rate of 0.4°C per minute.[35] At 2.5 cm, a 1 MHz, 1.5 W/cm^2 treatment increased temperature 0.26°C per minute.[36] The same parameters at 1.0 W/cm^2 increased temperature 0.16 ± 0.072°C per minute.[27] Thus, if our study followed the heating rate found in other studies with similar parameters, intramuscular temperature should have increased anywhere from 0.16–0.40°C. Instead our heating rate with traditional ultrasound was 0.025 ± 0.003°C per minute and -0.016 ± 0.001°C with the AutoSound™.

In our opinion the following are reasons why the AutoSound™ did not raise the tissue temperature: First, there is a slight time lag between the firing of each successive crystal. This means that there is not always a crystal on, which could lead to a decrease in heating. There is also a slight amount of space (2 mm) between each of the four crystals in the AutoSound™. This slight space between each crystal means that there is "dead space" where no heating occurs in the ultrasound unit. This may effect target tissue temperature change. The time delay from one crystal to the next and the fact that there is no heating under the dead space between adjacent crystals[1] could be a reason the AutoSound™ does not appear to heat the tissue to the same degree as traditional ultrasound.

Second, the gel pad used during AutoSound™ application may be too thick. Ultrasound gel has been the coupling medium used during all traditional ultrasound treatments in the studies where traditional ultrasound was compared to the AutoSound™.[24-26] Studies have shown that ultrasound gel (such as used during traditional ultrasound) is the most effective form of coupling medium at increasing tissue temperature when compared to 1 cm or 2 cm gel pads.[37,38] The AutoSound™, however, uses a gel pad that is 1 cm thick. This may impair the ultrasound unit's ability to effectively deliver sound waves into the target tissue. Recent research[39] has shown that the Gel Shot™ (a 2–3 mm thick gel pad) is more effective than ultrasound gel when used at 1 MHz. Therefore it is possible that a thinner gel pad could have been more effective and aid in increasing tissue temperature, but the gel pad currently used with the AutoSound™ may be too thick to see any positive effects.

The third reason the AutoSound™ may not be effective in tissue heating has to do with the activation sequence and arrangement of the 4 crystals. A traditional ultrasound transducer uses one crystal. Ultrasound only produces significant heating when an area 2 times the size of the soundhead is used.[1,18,33,40] Chudleigh et al.[41] found that at 3 cm, a 10-min, 1 MHz, 1.5 W/cm^2 ultrasound treatment resulted in a 3.5°C increase in temperature when an area 2 times the size of the soundhead was treated. However, an area 6 times the size of the soundhead increased the temperature only 0.57°C. Thus a larger treatment area leads to a decrease in the amount of heating that takes place. During traditional ultrasound an area the size of 2 crystals is heated. Although the AutoSound™ uses 4 crystals that lie side by side, this only mimics one crystal moving as only one crystal is activated at a time. This means that the AutoSound™ is technically covering an area 4 times the size of a soundhead (treating only 25% of the surface area at a time), instead of 2 times the size of the soundhead (treating 50% of the surface area). Additionally, by activating the first crystal every time after crystal 4 has turned on and off, the AutoSound™ is mimicking picking the soundhead up and placing it back at the starting position. Though contact with the skin is maintained during AutoSound™ treatments, mimicking this pattern with traditional ultrasound would lead to loss of contact with the skin which would lead to a decrease in heating because the sound waves cannot be transduced into the tissue at this point. We suggest that the manufacturers of the AutoSound™ consider placing 2 large crystals (possibly 10 cm^2) side by side in a new version of the AutoSound™. Most likely, this would produce higher temperatures.

A temperature increase of 1°C is considered mild heating and is used for increasing metabolism and reducing mild inflammation. A 2–3°C increase is considered moderate heating and is indicated for increasing blood flow and reducing pain and muscle spasm. A 4°C increase is considered to be vigorous heating and is used to increase the extensibility of collagen fibers.[1] According to this, Gulick[25] received vigorous heating (5°C increase at 1 cm) and mild heating (1.5°C increase at 2 cm) when the AutoSound™ was used at a frequency of 3 MHz. McCutchan et al.[24] and Fincher et al.[26] produced moderate heating (1.8°C at 1 cm and 2.05°C at 2.5 cm, respectively) when the AutoSound™ was used, again, at 3 MHz. Heating may have occurred in these studies[24-26] and not in ours due to the use of 1 MHz. 1 MHz ultrasound heats at 1/3 the peak temperature as 3 MHz.[27] This is due to the crystal deforming at 1/3 the rate as a crystal at 3 MHz. Another reason might be that the beam diverges (spreads out) the 1 MHz frequency, whereas the beam is collimated at the 3 MHz frequency.[42] This might focus more energy on the temperature probe when 3 MHz is used and not increase tissue temperature at 1 MHz.

At a 3 MHz frequency[24-26] the AutoSound™ may be clinically beneficial as it produces moderate[1] heating. Most clinical practices target superficial tissues, so the AutoSound™ will produce moderate heating in the desired area, as well as free the clinician to perform other tasks. However, at 1 MHz and 1.0 W/cm^2, the AutoSound™ is not beneficial for clinicians or their patients in heating their tissue. At 1 MHz the AutoSound™ did not produce moderate or even mild heating. A 20-min hot-pack treatment can raise tissue temperature 3.6°C at 1 cm and 0.8°C at 3 cm.[43] Thus the AutoSound™ at 1 MHz is no better than a hot-pack treatment at increasing muscle temperature. However, a hot-pack heats a much larger area than the AutoSound™ making the hot-pack the treatment of choice when targeting deeper tissues.

Limitations and Future Research

Our study had limitations. We used healthy subjects from 18–25 years of age to examine tissue temperatures in nondamaged tissue. We assume that tissue temperature changes would be similar in an injured population over damaged tissue. Our results are also limited to the use of a 2 cm^2 soundhead, a frequency of 1 MHz, and an intensity of 1.0 W/cm^2.

We suggest future research should be conducted on the AutoSound™ at 1 MHz and at a higher intensity than 1.0 W/cm^2.

CONCLUSION

We successfully measured intramuscular temperature changes during ultrasound treatment with a traditional and a hands-free device. At a depth of 2.25 cm, a 10-min, 1 MHz, 1.0 W/cm^2 ultrasound treatment did not produce desired heating with either machine. At 1 MHz, the AutoSound™ failed to increase the temperature of the triceps surae muscle, and the TheraHammer™ only minimally increased temperature. We suggest an alteration to the AutoSound™ to where only two larger crystals are used so an area twice the size of the soundhead is treated. We also suggest employing the use of a thinner gel pad during AutoSound™ treatment.

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TABLE 1 Summary of baseline, final, and total temperature change, as well as rate of temperature change (mean ± standard error)

Mode of Change Treatment	Baseline Temperature (°C)	Final Temperature (°C)	Total Change (°C)	Rate of Temperature Change (°C/min)
Traditional	35.67 ± 0.24	36.08 ± 0.24	0.41	0.025 ± 0.003
AutoSound™	35.88 ± 0.24	35.73 ± 0.24	-0.16	-0.016 ± 0.001

FIGURE 1 Temperature probe insertion on the medial side of the left triceps surae

FIGURE 2 Verification of probe depth insertion via Doppler ultrasound imaging

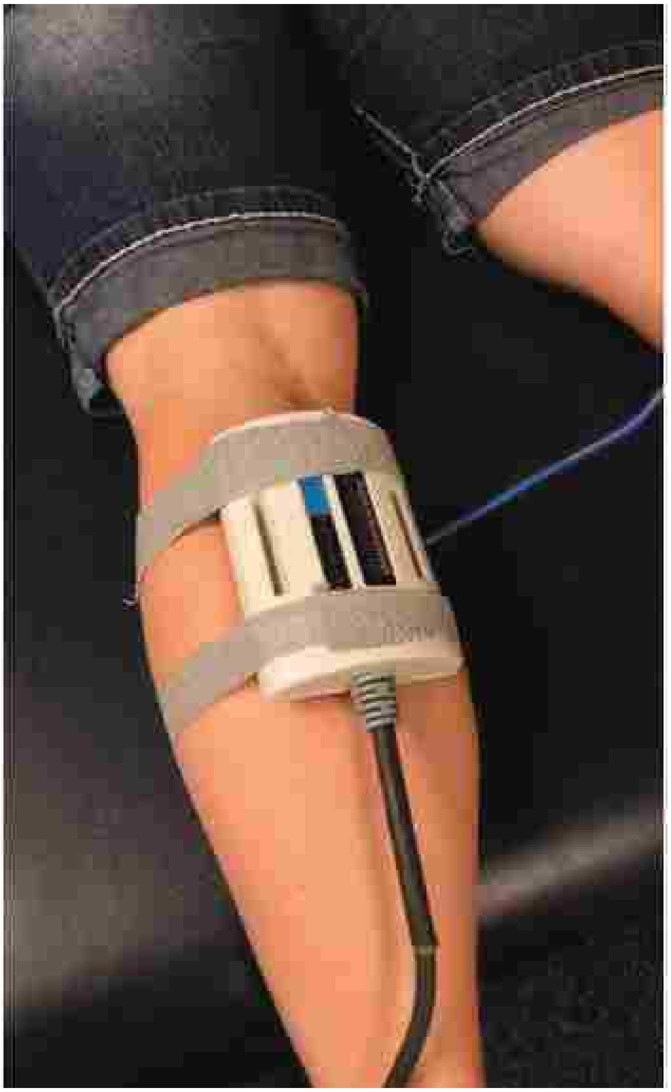

FIGURE 3 Ultrasound performed with the AutoSound™ machine