DESIGN AND EVALUATION OF A WEARABLE SELF-APPLIED THERAPEUTIC ULTRASOUND DEVICE FOR CHRONIC MYOFASCIAL PAIN

GEORGE K. LEWIS JR.,* MATTHEW D. LANGER,* CHARLES R. HENDERSON JR.,y and RALPH ORTIZz

*ZetrOZ, INC, Trumbull, CT, USA; yDepartment of Human Development, Cornell University, Ithaca, NY, USA; zCayuga Medical Center, Ithaca, NY, USA; and xMedical Pain Consultants, Dryden, NY, USA

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Abstract—Ultrasound therapy for pain and healing is a versatile treatment modality for musculoskeletal conditions that is used daily in rehabilitation clinics around the world. Our group designed and constructed a wearable, battery-operated, low-intensity therapeutic ultrasound (LITUS) device that patients could self-apply and operate during daily activity for up to 6 h. Thirty patients with chronic trapezius myofascial pain evaluated the LITUS system in a double-blind, placebo-controlled, 10-d study under institutional review board approval. While continuing their prescribed medication regimen, patients with the active device reported on average 1.94 reduction in pain and 1.58 improvement in health relative to placebo devices after 1 h of treatment. Both of these results were statistically significant (p < 0.05) for the first 2 d of the study. Male patients reported the majority of benefit, and there is a sex-treatment confound in the sample. The study indicates that wearable, long-duration LITUS technology improves mobile access to drug-free pain relief. (E-mail: george@zetroz.com) © 2013 World Federation for Ultrasound in Medicine & Biology.

Key Words: Low-intensity therapeutic ultrasound, Wearable ultrasound device, Pain management, Physiotherapy, Clinical study, Outpatient setting, Myofascial pain, Pain management, Therapeutic ultrasound device.

INTRODUCTION

Persistent pain is the principal reason U.S. citizens access the health care system according to the National Institutes of Health (2010). Acute as well as chronic pain may seriously affect quality of life and is regularly associated with secondary morbidities such as depression, anxiety and sleep disturbance. Despite increased awareness of chronic pain and its complications, surveys by the American Chronic Pain Association indicate that at least 30% of patients with moderate chronic pain and more than 50% of those with severe chronic pain fail to achieve adequate pain relief (“Chronic Pain in America” 1999). One pain-causing condition that frequently poses challenges to treatment is chronic trapezius myalgia, which is associated with repetitive motions of the upper extremities. It is associated with sensitivity and pain in the neck and shoulder areas, and structural changes in the muscle fibers of the trapezius have been observed (Larsson et al. 1990; Lindman et al. 1991). Current pharmacologic therapies are not adequately meeting patient needs, and many chronic pain sufferers have turned to non-drug therapies to replace or supplement their use of pharmacotherapies.

Common alternative therapies used to relieve pain include electrotherapy, traction, braces, the application of heat or cold and therapeutic ultrasound. Electrotherapy functions through forced stimulation of a nerve, which is targeted to induce a change in the distribution of neurotransmitters and make it more difficult for a pain signal to propagate (Wright 2012). Its efficacy has been called into question, but it is still widely used. Traction is the application of mechanical force to relieve pressure on nerves (Mathews et al. 1987). This can relieve pain in the case where a muscle has been overstimulated or is held uncomfortably for long periods. Braces function by providing an alternative means of support for the injured muscle, reducing the burden on the muscle responsible for the pain stimulus. The application of heat or cold is used to stimulate muscle recovery and reduce inflammation, respectively (McCaffery 1990).

Therapeutic ultrasound is often used by clinicians and physical therapists as a method of relieving pain and improving mobility for a variety of musculoskeletal conditions (Belanger 2003; Huang et al. 1999; Loyola-Sánchez et al. 2010, 2012; Pounder and Harrison 2008). Specifically, a number of studies have looked at the effect
of short-duration ultrasound on trigger points in the trapezius of patients who were myalgic and patients with latent trigger points (Aguilera et al. 2009; Draper et al. 2010; Esenyel et al. 2000; Majlesi and Unalan 2004; Sarrafzadeh et al. 2012; Srbely et al. 2008). Trapezius trigger points are found in the muscle fibers bridging the shoulder joint and neck, generally in close proximity to the shoulder-neck angle, which is a point of high strain under repetitive motion and/or uncomfortable positions (Davies et al. 2004). The formation of trigger points in this region is believed to result from damaged muscle fibers and the opening of the muscle fibers’ sarcoplasmic reticulum, causing the release of calcium and adenosine triphosphate (ATP) (Kelencz et al. 2011). This leads to local uncontrolled muscle contraction and eventual pain from the trigger point that may present as chronic myofascial pain if not treated. The practical benefits of therapeutic ultrasound treatment in trigger point therapy are its availability and non-invasiveness. The clinical effectiveness of therapeutic ultrasound in trigger point therapy for pain reduction, muscle fiber healing and prevention is still being investigated. A number of theoretical and experimental explanations exist for the perceived pain-relieving mechanism; however, the importance of each proposed pain-relieving mechanism is still undergoing research. Researchers originally hypothesized that the thermal effects of ultrasound provided the majority of the therapy (Belanger 2003). New research suggests that although the thermal effects are beneficial, there is a second mechanism of action caused by the ultrasonic mechanical-tissue interactions (Johns 2002). Studies indicate that when the intensity of the ultrasound treatment is significantly reduced, thus limiting the thermal effects, and the length of treatment is significantly increased, thus emphasizing the mechanical effects, beneficial therapeutic effects are obtained (Cui et al. 2006; Dijkman et al. 1999; Loyola-Sánchez et al. 2012; Parvizi et al. 1999; Pounder and Harrison 2008; Qin et al. 2006). Additionally, the mechanical and thermal mechanisms of action in ultrasound have been shown to facilitate wound and bone fracture healing, to promote the penetration of topical ointments into the skin and to modify biological processes across a variety of living tissues.

The application of regular extended therapeutic ultrasound treatments in health care has been constrained by technological limits in power transfer, circuit efficiency and patient lifestyle. Technology previously established by the authors has set new thresholds for achievable efficiency with ultrasound and allowed for miniaturization of the ultrasound therapy unit. Our group has developed a low-intensity therapeutic ultrasound device based on ultralow impedance design principles, which allows for the miniaturization and integration of the ultrasound transducer, electronics and power supply into a device that fits easily into the palm of the hand. The 2.95-MHz ultrasound system delivers portable, convenient and consistent long-duration ultrasound therapy. The integrated ultrasound system was evaluated in a randomized, double-blinded, placebo-controlled study on chronic trapezius myalgia in 30 patients. Because of the severity of subject pre-medicated pain levels, enrolled patients were not asked to discontinue their opioid prescription medication regimen to support study compliance. We therefore looked at the add-on effect of low-intensity therapeutic ultrasound (LITUS) in pain management of the patients.

METHODS

Overview of self-applied wearable ultrasound system

The therapeutic ultrasound system is worn on the shoulder, proximal to the spine (Fig. 1).

The therapeutic ultrasound device is a diverging-wave system that operates at 2.5–3 MHz with 0.03–2 W/cm² ultrasound intensity capability for 0.3–18 h of treatment depending on the output setting. The system is based on ultralow electrical impedance and low-voltage design principles and consists of three primary parts: a 3.7-V lithium-polymer 1500-mA-h rechargeable battery, a low-output-impedance push-pull radiofrequency (RF) ultrasound driver with user push-button control logic and an ultralow electrical impedance, 2.95-MHz divergent ultrasound transducer. The RF electronics are constructed on a printed circuit board and housed in a polyvinyl chloride plastic enclosure with the battery pack. The RF ultrasound driver has been

Fig. 1. The wearable low-intensity therapeutic ultrasound device is approximately the size of a digital music player and provides a nominal 0.44 W of 2.95-MHz ultrasound for 5 to 6 h on a single charge. The device is modeled here as it was used in this research study on chronic trapezius myalgia.
previously described (Lewis and Olbricht 2008a, 2008b, 2009). Here we employed a parallel pin-driver configuration of four MOSFETs to obtain a non-reactive output impedance of approximately 0.5 Ohm and a frequency bandwidth from DC to 40 MHz. The wide voltage and frequency operating range of the ultrasound driver made it particularly well suited for portable and low-voltage battery-powered ultrasound applications.

The transducer of the device is housed in a waterproof, biocompatible ring with a polyurethane rubber boot and a 10° ultrasound diverging lens made from cross-linked polystyrene. The active transducer element is a lead-zirconate-titanate (PZT-4), silver-plated piezocrystal that is air backed. The wide-beam 2.95-MHz ultrasound was characterized for its electrical impedance and the ultrasound beam shape (Figs. 2 and 3) using the mason model (Lewis and Olbricht 2009) and electrical impedance spectroscopy (Lewis et al. 2008). The footprint of the completed transducer is 28 mm in diameter and 4.8 mm in height. The cross-linked polystyrene, ridged lens along with the high quality factor, $Q_m$, of 1800 of the piezo-crystal maintains a ultralow transducer electrical impedance of 3.87 Ohms and 0 rads at resonance for low-voltage power generation with no imaginary losses (Fig. 2) and a divergent treatment volume (Fig. 3).

Under various testing scenarios, the LITUS system is 70–74% efficient in battery-to-acoustic energy conversion. The corresponding transducer efficiency was measured to be 96%, and the RF circuit efficiency was found to be 74%. When operated continuously from the
battery at the acoustic 0.44-W nominal output power, which corresponds to a spatial temporal average intensity of 89.6 mW/cm² at the transducer face, the system lasts between 5.5 and 6 h (Fig. 4). For 1- and 6-h treatments at this calibration setting, the ultrasound device provides 1795 and 9596 J of ultrasonic energy, respectively, calculated by the area under the power curve of Figure 4. Compared the average clinical therapeutic ultrasound systems, the wearable ultrasound device is less than 1/20th of the size, does not require wall power and may provide the same treatment as is customary in current physical therapy, that is, short-duration medium-intensity treatments.

The wearable ultrasound device was supplied in a small kit to each subject in this study. The kit included a wearable ultrasound device with belt clip, three 2-oz ultrasound coupling gel packets, twenty 10 × 10.5-cm adhesive bandages, a system wall charger, a user manual and a patient diary for self-reporting.

**Detailed description of self-applied wearable ultrasound system**

The wearable ultrasound system was designed from commercially available materials to reduce costs. The features of the system included power control (on/off), biocompatible housing, recharge capability and 5.5 to 6 h of ultrasound therapy delivery. The complete ultrasound devices were calibrated with an ultrasound power meter (Onda, Sunnyvale, CA, USA) and packaged for the clinical evaluation.

**Electronics.** The ultrasound-generating RF circuit design previously described (Lewis and Olbricht 2008a, 2009) was reduced to a printed circuit board (PCB) (Sunstone Circuits, Mulino, OR, USA) to make the electronics small, low-cost and reproducible. The 18 × 15-mm PCB was tested in the laboratory to ensure proper performance and then replicated for the devices used in this study (Fig. 5). The PCB components consisted of the power on/off tactile system controller (Linear Technologies, Milpitas, CA, USA), the megahertz oscillator (NDK, Tokyo, Japan), and two MOSFET push-pull drivers (Intersil, Milpitas, CA, USA) in parallel. The power controller also regulated charging and discharging of the lithium-polymer battery pack (Battery Space, Richmond, CA, USA). The PCB was designed to be highly efficient, delivering between 90 and 99% of the power supply voltage directly across the ultrasound transducer, with minimal voltage drop within the MOSFETs because of the parallel configuration. Because the ultrasound-generating PCB was 15 × 18 mm, multiple circuits were fabricated on a single wafer.

**Transducer.** The wide-beam low-impedance transducer consisted of four primary parts: (i) piezoelectric, (ii) polystyrene lens, (iii) air-backed housing and (iv) polyurethane rubber boot for patient comfort and wire strain relief (Fig. 6). The construction of the ultrasound transducer is shown in Figure 6. The 25-mm-diameter, 0.7-mm-thick, 3 MHz ± 50 kHz piezoelectric is a modified lead zirconate titanate with electromechanical coupling coefficient $k_p = 0.58$, static capacitance $C_s = 8600 \text{ pF} ± 20\%$ at 1 kHz and mechanical quality factor $Q_m = 1800$ (Stiener and Martins, Miami, FL, USA). The full list of material properties of the crystal is provided in Table 1. The crystal is housed in a 26-mm-diameter polystyrene ring (C-LEC Plastics, Philadelphia, PA, USA), and the front face of the piezo is protected by a 10° polystyrene lens that is secured with cyano-acrylic (Fig. 6c). A low-impedance flexible coax-cable (Cooner Wire, Chatsworth, CA, USA) is connected to the

![Fig. 4. Wearable ultrasound power and system life measurement over complete charge cycle. The system lasts 5.5 to 6 h and has a nominal ultrasound power output of 0.44 W over the entire discharge cycle.](image)

![Fig. 5. Electronic populated printed circuit board of the wearable ultrasound device pictured between the thumb and pointer finger. The radiofrequency driver is 15 × 18 mm and employs a parallel MOSFET circuit architecture to maintain low output impedance for efficient voltage and total energy transfer.](image)
piezoelectric with solder on the inside of the ring housing. The polyurethane rubber boot strain relief was designed for aesthetics and function using the master shape machined on a computer-automated milling machine (Sherline, Vista, CA, USA) (Fig. 6a). RTV (room temperature vulcanizing) Silicone (McMaster-Carr, Robbinsville, NJ, USA) was used to make the mold for the boot casting (Fig. 6a). The rubber boot was made by filling the RTV mold with 2056 polyurethane (McMaster-Carr), positioning the mandrel and pin in place in the mold and allowing the device to cure (3 h at 50°C) (Fig. 6b). The housing, lens and rubber boot are made Food and Drug Administration-approved materials for class 3 medical devices and are not cytotoxic (Fig. 6d).

**Electronic and transducer testing.** The electronics were tested over a wide temperature range from −56°C to 90°C in a dry ice-cooled refrigerator and laboratory oven. The circuit’s DC voltage and current draw from the battery were measured using a digital multimeter (Tektronix, Beaverton, OR, USA). The RF output power from the ultrasound driver to the transducer was measured using a digital oscilloscope (Tektronix), alternating-current (AC) current probe (Tektronix) and voltage probe (Tektronix) attached to the center conductor of the coax-cable of the transducer. The root-mean-square (RMS) of the voltage current product was calculated using the digital oscilloscope real-time and recorded as the electrical RMS RF output power into the transducer. The ultrasound output power was measured with an acoustic power meter with 2-mW resolution (Onda). The power meter was calibrated immediately before testing. All measurements were repeated five times and used to determine efficiencies of power conversion. Total system DC-to-acoustic efficiency was calculated as the ratio of acoustic power out to DC power.

### Table 1. Piezoelectric crystal properties of ultrasound transducer

<table>
<thead>
<tr>
<th>Piezoelectric Material</th>
<th>PZT-4 lead-zirconate-titanate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>25 mm in diameter, 0.7 mm thick</td>
</tr>
<tr>
<td>Electromechanical coupling coefficients</td>
<td>( k_p = 0.58 ), ( k_t = 0.45 ), ( k_{33} = 0.34 )</td>
</tr>
<tr>
<td>Frequency constants (Hz • M)</td>
<td>( N_p = 2200 ), ( N_t = 2070 ), ( N_{33} = 1680 )</td>
</tr>
<tr>
<td>Piezoelectric constants ((\times 10^{-12} \text{ m/V}))</td>
<td>( d_{33} = 320 ), ( d_{31} = -140 )</td>
</tr>
<tr>
<td>Piezoelectric constants ((\times 10^{-3} \text{ V-m/N}))</td>
<td>( g_{33} = 2 ), ( g_{31} = -11 )</td>
</tr>
<tr>
<td>Elastic constants ((\times 10^{10} \text{ N/m}^2))</td>
<td>( y_{33} = 7.3 ), ( y_{31} = 8.6 )</td>
</tr>
<tr>
<td>Mechanical quality factor</td>
<td>( Q_m = 1800 )</td>
</tr>
<tr>
<td>Dielectric constant at 1 kHz</td>
<td>( T_{33000} = 1400 )</td>
</tr>
<tr>
<td>Dissipation factor at 1 kHz</td>
<td>( \tan \delta = 0.4 )</td>
</tr>
<tr>
<td>Curie temperature (°C)</td>
<td>( T_c = 320 )</td>
</tr>
<tr>
<td>Density (g/cm³)</td>
<td>( p = 7.9 )</td>
</tr>
</tbody>
</table>
Table 2. Performance characteristics of wearable ultrasound device

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total acoustic output power</td>
<td>0.44 W ± 10%</td>
</tr>
<tr>
<td>Average spatial intensity</td>
<td>0.087 W/cm² ± 10%</td>
</tr>
<tr>
<td>Maximum temporal intensity</td>
<td>0.180 W/cm² ± 10%</td>
</tr>
<tr>
<td>Frequency</td>
<td>2.95 MHz ± 5%</td>
</tr>
<tr>
<td>Duty cycle</td>
<td>100%, continuous wave</td>
</tr>
<tr>
<td>Beam form</td>
<td>Diverging, 10° angle</td>
</tr>
<tr>
<td>Applicator dimensions</td>
<td>Circular, 2.5-cm diameter</td>
</tr>
<tr>
<td>Beam non-uniformity ratio</td>
<td>&lt;6:1 (max) ± 10%</td>
</tr>
<tr>
<td>Effective radiating area</td>
<td>6 cm²</td>
</tr>
<tr>
<td>Battery life (max)</td>
<td>5.5 ± 0.5 h</td>
</tr>
<tr>
<td>Maximum treatment duration</td>
<td>6 h</td>
</tr>
</tbody>
</table>

The transducer electrical to acoustic efficiency was calculated as the ratio of acoustic power out to RF power in. Circuit efficiency was calculated as the ratio of RF power out to DC power in. Finally, voltage transfer efficiency was calculated as the ratio of voltage across the transducer during the on drive state to the DC supply voltage.

The electrical properties of the ultrasound transducer were mapped using impulse electrical impedance spectroscopy and further refined with 10 specific frequency impedance measurements around the resonant point of the transducer. The electrical impedance magnitude and phase were fit to the standard Mason model of a single resonant piezoelectric transducer to determine the electrical equivalent circuit components and obtain the transducer’s resonant quality factor.

Final wearable ultrasound system assembly and acoustic calibration. The electronics and battery pack were integrated into a commercially available housing (OKW, Bridgeville, PA, USA). The housing was machined appropriately to accommodate the tactile on/off switch, the blue LED on/off indicator light, the micro-barrel recharger port and the coax cable sending RF energy to the ultrasound transducer. Before final system closure, calibration of the acoustic output power was made to be 0.44 ± 0.05 W by adjusting the oscillator frequency and inductive matching of the electronic driver to the transducer resonance region. Acoustic power was measured using a calibrated acoustic power meter with 2-mW ultrasound power resolution. The LITUS transducer was placed in a power meter filled with degassed deionized water and rubber absorbing target, the meter was zeroed and the device was then turned on. The ultrasound energy from the transducer causes a force that was detected on the power meter in acoustic watts. The power meter is connected to a computer via USB to log measurement data from the LITUS device. The spatial average acoustic intensity is calculated by dividing the total acoustic power by the surface area of the transducer. For the wearable ultrasound transducer with 25-mm active piezoelectric diameter, the acoustic intensity from the device at full charge is 89.6 mW/cm². Finally, the 10° diverging lens on the devices increases the treatment area in addition to natural divergence of the acoustic beam according to \( I = \frac{power}{(\pi * (1.25 + \tan(10°)) * x)²} \), where \( I \) = intensity of the acoustic beam in watts per square centimeter.

Peak spatial and temporal ultrasound intensity is measured using a beam scanning system in conjunction with a calibrated hydrophone. The beam scanning system is also used to measure the effective radiating area (ERA) and beam non-uniformity ratio (BNR) and to characterize the width of the ultrasound acoustic field during development of the transducer lens. Performance characteristics of the wearable ultrasound device are summarized in Table 2.

Clinical outcome variables

Outcomes were measured using three clinical readouts: visual analogue scale (VAS) score, global rating of change (GROC) and annotated pain diagrams. VAS is a 0 to 10 scale on which patients rate their overall pain level, with 0 representing no pain and 10 representing agonizing pain. It is strictly a reporting of the patient’s current pain level. The GROC scale asks patients to recall their pain level before treatment, compare it with their pain level after treatment and give that comparison a numeric score between −7 and 7. Negative numbers indicate an increase in pain and worsening of the condition, whereas positive numbers represent a decrease in pain and beneficial improvement. The annotated pain diagram was completed by the patient before and after treatment. It was a diagram of the back, and patients were instructed to draw circles around areas with minor pain and to mark sites of severe pain. This was quantified by comparing the number and severity of the notations made by a patient before and after treatment.

Patients

The research protocol was approved by the institutional review board of Cayuga Medical Center and by Pain Management Consultants, and all participants gave written informed consent to participate in the study in accord with the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Patients. Patients were required (i) to be between 40 and 60 y of age; (ii) to not be pregnant; (iii) to be willing and able to self-administer treatment daily within their place of residence or during normal daily activity, excluding bathing, showering or other...
water activities that could have resulted in submersion of the ultrasound device; and (iv) to undergo an evaluation by a physician to determine if they were functionally and cognitively capable of self-treatment on a daily basis during the course of the study; (v) to record any reduction or increase in prescription drug use in their daily diary; and (vi) to be in pain with acute, moderate to severe muscle spasms in the trapezius muscles, as indicated by a VAS pain severity score between 4.0 and 7.0, inclusive, within 4 d before screening. Potential patients were excluded if they (i) had known neuropathy; (ii) were pregnant; (iii) were prisoners; (iv) had had surgery in the target area within the last 6 mo; (v) were non-ambulatory; (vi) chose to increase use or initiate new use of pharmaceuticals during the course of the study unless medically necessary to ensure patient safety; (vii) used any cream, gel or topical solution during the administration of treatment other than the approved ultrasound gel provided at the initiation of the study; (viii) had a clinically significant or unstable medical or psychological condition that, in the opinion of the physician, would compromise participation in the study; (ix) participated in a clinical trial for an investigational drug and/or agent within 30 d before screening; (x) were involved in any injury-related litigation in the target area; (xii) had back spasm related to major trauma or a work-related injury, or had other severe pain that may have confounded assessment or self-evaluation of the trapezius myalgia.

Thirty patients who met the sampling criteria were recruited for the study. They were randomly assigned to the placebo (10 patients) and active (20 patients) conditions. Patients were recruited sequentially and assigned as recruited on a 2:1 basis to active and placebo. By chance in the sampling, there were 10 males and 10 females in the active group but a disproportionate 1 male and 9 females in the placebo group. Both the clinic staff and the patients were blind to their treatment assignment.

The 30 patients participated in at least ten 1-h ultrasound treatment sessions at the onset of heightened pain caused by trapezius spasm. Each treatment session was self-diagnosed, the ultrasound therapy was self-applied and VAS/GROC metrics were self-reported in a user daily diary. All 30 patients completed at least 10 treatment sessions with 100% compliance and no patient dropout. One study kit was accidently broken by a subject; this device was replaced with an identical device without the patient or clinical investigator knowing whether the device was active or a placebo. Once trained by research assistants, patients were able to self-apply the ultrasound treatment in their own homes and/or work environments in most treatment cases.

Handling of devices and data

All devices and kits were tracked by serial numbers and have an associated log with key to placebo-sham and active device. Each device log tracked any repairs,
defects, issues, returns or other activities associated with the unit. The key was provided to the statistician (C.R.H.) but was kept blinded from the research assistants and the clinical investigator (R.O) enrolling patients and issuing kits. Data from each daily diary were tabulated by the research assistants and provided to C.R.H. for statistical analysis.

Statistical models and methods

The core statistical model includes fixed classification factors for treatment assignment and time of assessment; age as a covariate; and patients as levels of a random classification factor. We initially examined a two-level treatment variable (placebo vs. active); because of the imbalance of sex of subject in the placebo group, it was not possible to include sex, treatment, and their interaction in the model, and in final models we used a three-level variable: placebo, active females and active males. The tests of treatment effects are the tests of the interaction of treatment and time and $2 \times 2$ subsets partitioned from this interaction. Analysis was by general linear mixed models with an assumption of an unstructured error.

Visual analogue scale. There are five pain reports on each of 10 d for each subject. We examined models with two repeated-measures factors, day of assessment (10) and time of assessment in a given day (5), and models with the single repeated measure for day of assessment and various functions of the daily scores as the dependent variable (e.g., the difference score between the fourth and first VAS measurements). For reporting results in this article, the dependent variable in the model with a repeated measure for day is the fourth assessment minus the first assessment (the quantity) divided by the first assessment. This is equivalent to the fourth divided by the first, but is in the more natural form. In this model, we specified a priori a contrast for levels of the treatment factor restricted to the first 2 d. We also examined time as a covariate in a growth curve model.

Global rating of change. The daily scores over the first 10 d were the outcomes in a repeated-measures model of the type described for VAS.

Pain Diagram. If a patient did not indicate which was the focal shoulder and on which shoulder the device was worn, we used the average of the reports for both shoulders. With this outcome, the model is the same as for GROC and VAS.

Results were considered significant with a $p$-value $\leq 0.05$; $p$-values $>0.05$ and $\leq 0.10$ are discussed as trends.

RESULTS

Patients successfully recorded their pain and overall therapeutic benefit scores using the visual analogue and global rate of change scales, respectively. Patients also successfully annotated a pain diagram of the upper back post-LITUS treatment. Figure 7 shows the average pain reduction for these three primary outcomes averaged over the 10 d of treatment.

The VAS results among all patients were positive, with the majority of patients reporting the greatest reduction in pain during the first 3 to 4 d of usage (Fig. 8). On average, placebo users had an 8% pain reduction, female active users had a 12% pain reduction, and male active users had a 19% pain reduction (Fig. 7). The 2 active groups differed significantly from placebo ($p = 0.03$) (Fig. 8). This was due more to active males, who differed significantly from placebo ($p = 0.04$); active females differed from placebo as a trend ($p = 0.10$).
Across the 10 treatments, the average GROC score in the test group reported improvement 60% greater than that reported in the placebo group. Placebo users had a 0.36 GROC improvement, female active users had a 0.41 GROC improvement and male active users had a 0.73 GROC improvement (Fig. 7). Over the first 2 d, the active group differed significantly from placebo ($p = 0.05$), with active males significantly different from placebo ($p = 0.05$) and producing the overall difference (Fig. 9).

The average reported upper back pain after 60 min of LITUS treatment on days 1 through 10 using the annotated patient diagram was recorded by all trial patients (Fig. 10). Female patients receiving ultrasound treatment reported no statistically significant or trending effects versus placebo. On average across the 10 treatment sessions, active female patients reported slightly higher pain than placebo control. Across the entire 10 d, active men reported a 30% reduction in pain over placebo, a significant difference ($p = 0.02$) (also significant for the first 2 d, $p = 0.004$).

Figure 11 illustrates the temporal percentage change in VAS over a 60-min treatment and 60-min post-treatment as recorded in the patient’s diary averaged across the 10 treatment sessions. Active male and female users respond faster than placebo treatment as shown by the greater slope in the percentage pain reduction graphs. The mean time to pain reduction (MTPR) is calculated from Figure 11 using the placebo 60-min time point 8% VAS reduction as the nominal comparative value. To reach this respective pain reduction value, female active users had a MTPR of 29 min, whereas male active users reported a 13-min MTPR. This corresponds to improvements of 52% and 78%, respectively, over placebo.

DISCUSSION

Our group has revealed the feasibility and safety of chronic muscle pain relief with a self-delivered, wearable, therapeutic ultrasound device in an opioid-medicated population of chronic pain sufferers. The device itself is smaller than a typical smart phone and was not reported to interfere with patients’ normal activity patterns during the study. Overall, the wearable LITUS device provided a means for pain reduction and health improvement over placebo in this small clinical trial carried out in a disparate population of rural patients at a regional pain clinic in central New York State. All patients involved in the study were able to self-apply ultrasound therapy successfully in their own homes and during daily activity after a short 20-min training session, and no adverse events were reported during or after the study.

This study is distinct from other studies of therapeutic ultrasound treatment of the trapezius. In other studies, a higher intensity (>1 W/cm²) was employed, and the duration of the treatment was on the order of minutes (Aguilera et al. 2009; Draper et al. 2010; Sarrafzadeh et al. 2012; Srbely et al. 2008). Additionally, the other studies in the field have looked at the pain threshold caused by either compression or stretching. This study allowed testing of the benefit of ultrasound therapy on normal activity and reporting on the ability
of the treatment to reduce pain during lifestyle use, which are of more direct clinical relevance than previous data collected. Finally, the patients who were evaluated in this trial were already on opioids and other pain medications and were not asked to cease or change their medication regimen. So the statistically significant benefits observed with the ultrasound treatment are in a population that is already pain controlled.

In this 30-patient placebo-controlled double-blinded study, active users of the device reported an average pain reduction double that reported with a placebo and an improvement in global health 60% larger than that attained with placebo. In this study, active male patients clearly had larger pain reductions and overall improvements in response to the therapeutic device than did active females. The evaluation of the effect of the device is limited by the lack of males in the placebo group. This confound makes it difficult to determine whether differences between active males and placebo are treatment effects or sex effects. We did, however, observe global health improvements on a day-to-day basis in the treatment group.

CONCLUSIONS

Our group believes that these are both significant and successful early clinical results, particularly because the patients involved in this study maintained their pain management medication regimen during the evaluation of the LITUS system. Furthermore, the results of this study and the means and variances of visual analogue scale, global rating of change and annotated pain scores support a larger clinical study by the investigatory team. The wearable ultrasound system proved useful as an adjuvant therapeutic approach to reducing patients’ chronic trapezius myalgia while producing no reports of negative side effects.

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