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5ABAb8. Wearable long duration ultrasound therapy pilot study in rotator cuff tendinopathy

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Approximately one-third of the westernized adult population will experience some type of shoulder pain. The purpose of this pilot study was to evaluate a novel self-applied wearable therapeutic ultrasound device in the management of shoulder pain from rotator cuff tendinopathy. The Institutional Review Board of Cayuga Medical Center (CMC) approved this study and informed consent for the study was obtained from all subjects. The wearable ultrasound device provides 90 mW/cm², 2.95 MHz, continuous-wave ultrasound for 5.5 hours on a single charge. Four subjects meeting the studies inclusion criteria, presenting with rotator cuff tendinopathy, and demonstrating cognitive and functional ability to apply the pager-size device were enrolled at the outpatient physical therapy center of CMC. Subjects were instructed to wear the device for 3-4 hours per day for 12 consecutive treatment sessions, and record their daily pain score on the visual analog scale (1 to 10) and global rate of health improvement scale (-7 to 7). Across the 12 treatments, subjects reported a 30% reduction in pain and 52% improvement in health compared to baseline scores ($p < 0.05$). The results of the pilot study indicate the device may be applied successfully and provides supportive evidence for a placebo controlled study.

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INTRODUCTION

Shoulder pain affects over 30% of the global adult population, and costs Americans 7 billion dollars each year.¹ Pathology that causes shoulder pain includes degenerative causes such as rotator cuff tendinopathy, osteoarthritis, adhesive capsulitis, and more acute causes including tendon tears and proximal humerus fractures. These directly lead to impairments in shoulder motion, daily activities, and decreased function which lead to disability. Conservative treatments are the mainstay of initial care and include over-the-counter and prescription pharmaceuticals.²⁻⁴ However, there are a myriad of public and individual health problems associated with analgesic use especially in older adults, including adverse effects, cost, non-compliance, and physical dependence with opioid analgesics.

A second common conservative treatment is physical therapy which incorporates physical modalities including ultrasound therapy. Ultrasound is widely used to treat soft tissue shoulder pathology including subacromial impingement syndrome, tendinitis, tendinosis, bursitis, calcific deposits, and myofascial tears.⁵⁻⁷ A recent multi-database review of RTCs in using therapeutic ultrasound to treat shoulder pathology examined the treatment parameters of frequency, duration, pulse/continuous wave mode and total amount of acoustic energy delivered to subjects.⁸ Alexander and colleagues⁸ found that the success of therapeutic ultrasound on the treatment of a range of soft tissue shoulder injuries was highly dependent on duration of ultrasound exposure per treatment, the total amount of acoustic energy delivered to the shoulder and the prevalence of treatment application. Specifically, the authors found that RTCs of ultrasound treatments which provided over 4,228 Joules of acoustic energy per treatment session over multiple sessions were beneficial to patients suffering from calcific tendinitis, supraspinatus tendinitis, adhesive capsulitis and subacromial bursitis. Ultrasound treatments for short durations with 2,019 Joules or less energy provided no significant benefit. The authors concluded that ultrasound application for the treatment of shoulder pathology holds promise but must focus on selecting optimal ultrasound treatment parameters that deliver ultrasound energy of 4,228 Joules per session or greater, and treatment schedules that expose tissues to ultrasound for sufficient amounts of time (i.e. greater than 5 hours). This scenario and treatment régime is particularly well suited for wearable long duration low-intensity therapeutic ultrasound (LITUS) that the team has developed and preliminarily evaluated in this Institutional Review Board (IRB) approved pilot study.

METHODS

Wearable Low Intensity Therapeutic Ultrasound Device

Most ultrasound devices with LITUS capability require wall-power, are bulky, and the battery-powered units are shoebox-sized and only deliver short 20-30 minute continuous treatments. All of the devices currently on the market cost more than \$1200.00. The LITUS device developed by the investigative team is based on ultralow impedance design that allows for streamlined circuit architecture, optimized electro-acoustic signal conduction, and construction of low-profile wearable systems.⁹⁻¹³ The wearable LITUS device is a diverging-wave system that operates at 2.95 MHz with 0.03-2 W/cm² ultrasound intensity capability for 0.3-18 hrs of treatment depending on the output setting. This corresponds to 10,800 Joules of total acoustic energy delivered to the patient per treatment session.

The electronics of the LITUS device are constructed on a printed circuit board and housed in a PVC plastic enclosure with lithium-ion battery pack. 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

polystyrene. The active transducer element is a lead-zirconate-titanate (PZT-8), silver-plated piezocrystal that is air backed. The housing and lens in the LITUS device protects the electronics and piezocrystal from deterioration.

In comparison to the Rich-Mar clinical therapeutic ultrasound system shown in Figure 1, the LITUS 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. However, in this study the device was calibrated at 0.65 Watts and a nominal 90 mW/cm² to deliver ultrasound for 5.5 hrs continuously per charge.

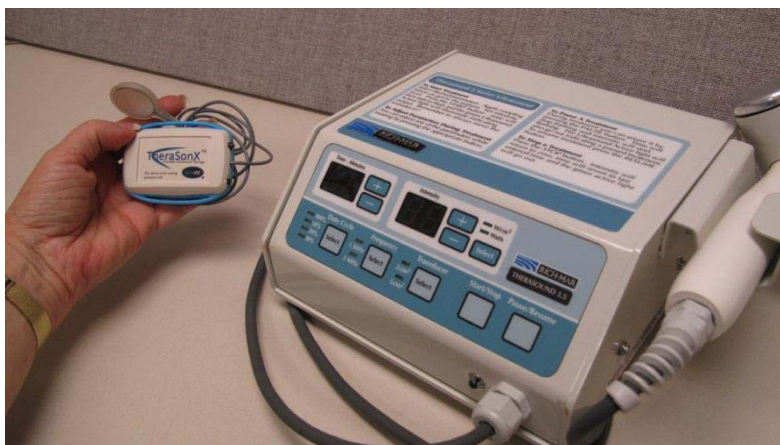


Figure 1. Wearable ultrasound device compared with commercially available therapeutic ultrasound system.

For the purpose of the study, each wearable LITUS device was packaged individually in small boxes with ultrasound gel, TegadermTM bandages, system charger, belt holder and instructions for use. All systems were acoustically calibrated and measured pre and post field deployment with an ultrasonic power meter and beam scanning system from Onda Inc. and Velmex Inc, respectively.

Clinical Pilot Study

The Institutional Review Board of Cayuga Medical Center (CMC), Ithaca, NY approved this study and informed consent was obtained from all subjects. Five subjects were instructed to wear the LITUS device alternating between anterior and posterior placement for 3-4 hours per day for 12 consecutive treatment sessions, and record their daily pain score on the visual analog scale (1 to 10) and global rate of health improvement scale (-7 to 7). Figure 2 demonstrates the device being applied to the shoulder with TegadermTM bandage and ultrasound gel. Inclusion criteria for the study consisted of subjects who: (1) were seeing their physician for shoulder pain due to rotator cuff impingement, tear, tendinosis or tendinitis, adhesive capsulitis, biceps tenosynovitis, proximal humerus fracture, (2) were 40 years or older in age, (3) reported taking pain medication for their shoulder pain during the week preceding enrollment, (4) reported functional limitations due to their shoulder pain, and (5) were deemed appropriate by their physician to participate. Exclusion criteria consisted of subjects who: (1) had known metastatic disease or infectious etiology about the shoulder (2) had a cervical radiculopathy (3) could not successfully demonstrate the ability to put on and take off the device, or (4) were cognitively impaired.



Figure 2. The wearable low-intensity therapeutic ultrasound (LITUS) device (worn by a modeled) shown as used as in this shoulder pain study. Patients wore the device for approximately 3.5 hrs on a daily basis.

RESULTS

The data for mean VAS pain scores over the 12 consecutive treatment sessions is shown in Figure 3 with standard error. Across the total number of treatments the average reduction in pain from treatment start to treatment conclusion was found to be 30%. Figure 3 also shows the results of the mean percent improvement of GROC score as it relates to patients starting pain on the VAS. Across the total number of treatments the average GROC score was +3.22 with normalized improvement to starting VAS of 52%. When compared to starting VAS and GROC, the changes were significant $p < 0.05$ for both measures.

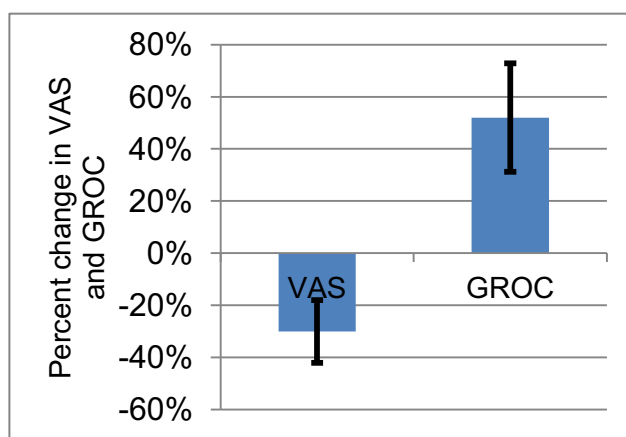


Figure 3. Wearable low-intensity therapeutic ultrasound reduces average pain on VAS by 30% and increases average global health score on GROC by 52% ($p < 0.05$) over baseline starting measures.

For all subjects involved in this pilot, the wearable LITUS device provided some type of pain reduction and no pain increases. All participants were able to self-apply the ultrasound system in the convenience of their own homes after a short training session by a physical therapist.

CONCLUSION

In this clinical pilot study, a miniature long duration low-intensity therapeutic ultrasound system was preliminarily evaluated on rotator cuff tendinopathy. Though the pilot study was not placebo controlled, the results indicate the device may be applied successfully in the outpatient setting and also provide supportive evidence for a more formal larger placebo controlled study. Furthermore, the results of this study agreed with Alexander and colleagues clinical practice suggestion that daily therapeutic ultrasound providing over 4,228 Joules of acoustic energy per treatment session was beneficial to subjects with shoulder tendinopathy.

The wearable ultrasound system shows promise as an innovative therapeutic ultrasound platform for self-applied effective therapy, and as a possible replacement or adjuvant to pharmacotherapies for shoulder pain.

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