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Original Article

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Effects of Low-Intensity Wearable Ultrasound Technology on Pain, Muscle Tone, and Body Temperature in Women: Randomized Control Trials

SungYeon Oh, Jaeho Yu

Department of Physical Therapy, Sunmoon University, Asan, Republic of Korea

Purpose: This study investigated the effect of low-intensity wearable ultrasound technology on pain, muscle tension, and body temperature compared to normal medical ultrasounds.

Methods: A total of 36 women volunteered to be in this study. Participants were randomly distributed into a wearable ultrasound group (WUG) (n = 10) and a medical ultrasound group (MUG) (n = 10). The intervention was conducted on a one-off basis. We measured pain using KSF-MPQ, VAS, and an algometer; muscle tension was measured using a Myoton PRO; body temperature was analyzed using an IRIS-XP. All measurements were evaluated using a paired t-test and an independent t-test.

Results: In this study, low-intensity wearable ultrasound positively affected pain, muscle tone, and body temperature. In the independent t-test, there was a significant difference in muscle tension in both groups ($p < 0.05$); in the case of stiffness, there was a significant difference in the WUG ($p < 0.05$). For elasticity, there was no significant difference in the MUG ($p > 0.05$), although there was a significant difference in the WUG ($p < 0.05$). In the stress recovery time, elasticity, relaxation, and creep there were no significant differences in the MUG ($p > 0.05$). For body temperature, and in the KSF-MPQ, VAS, and algometer assessments, there were significant differences noted in both groups ($p < 0.01$).

Conclusion: First, wearable therapeutic devices using low-intensity ultrasound significantly affected pain, tenderness, muscle tension, and body temperature. Second, wearable therapeutic devices using low-intensity ultrasound can be as effective as traditional medical ultrasound devices.

Keywords: Physiotherapy modality, Musculoskeletal diseases, Ultrasonic therapy

INTRODUCTION

Chronic neck pain is a common musculoskeletal disorder observed in many individuals.[1] While various people experience symptoms that vary in severity, there is a tendency to avoid medical consultations due to the perception that the pain does not significantly impact daily life, leading to neglect until the pain becomes chronic and intensifies. Previous studies have reported that the lifetime prevalence of neck pain ranges between 43% and 66.7%[2,3], and the annual incidence rate is between 10.4% and 21.3%, with particularly high rates reported among office and computer workers.[4] Moreover, even when initially resolved, chronic neck pain often shows signs of exacerbation or recurrence, highlighting the need to manage these symptoms before they worsen.[5]

In office settings, visual display terminal (VDT) syndrome is commonly characterized by discomfort symptoms, arising from prolonged sitting in front of a computer. It involves a fixed range of motion in office activities, focusing on monitors, and sustaining incorrect postures, leading to complaints of neck and shoulder pain, among other symptoms. This issue has been continuously highlighted as a modern societal problem since the popularization of personal electronic devices.[6,7] Chronic shoulder and neck pain associated with VDT syndrome is particularly prevalent among women[8], attributed to differences in muscle strength and mass between genders, indicating a continuous need for the management of muscle pain in women.

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Corresponding author Jaeho Yu
E-mail naresa@sunmoon.ac.kr

Ultrasound therapy was previously used as a therapeutic modality before its application in imaging technology. In 1927, it was proven that ultrasound could induce sustained changes in biological systems[9], leading to the development of today's commonly used ultrasound therapy for musculoskeletal disorders, thanks to advancements in safety studies and technology. Ultrasound therapy, utilizing piezoelectric crystals, stimulates human tissues through thermal effects, resulting in increased elasticity of collagen structures, decreased joint stiffness, pain relief, changes in blood flow, and reduced muscle spasms.[10]

The practical benefits of ultrasound therapy at trigger points are its availability and non-invasiveness. The clinical effectiveness of ultrasound therapy in reducing pain and treating muscle fibers is still being studied. Previous research assumed that the effects of ultrasound therapy stemmed from its thermal effects.[11] However, recent studies report a second mechanism due to ultrasound–tissue interactions beyond thermal effects.[12] By actively leveraging non-thermal benefits, reducing the intensity of ultrasound to limit thermal effects, and extending treatment duration to emphasize mechanical effects, beneficial therapeutic outcomes can be achieved.

Wearable low-intensity ultrasound technology has gained attention in recent years due to its potential for various medical applications. Initial studies have primarily focused on the management of chronic pain and musculoskeletal disorders, with most research conducted in clinical settings.[13,14] While previous studies have concentrated on specific disease management, the clinical, safety, and engineering perspectives of wearable ultrasound devices highlight their potential to extend beyond traditional clinical methods to applications in daily life.

Unlike previous studies that primarily focused on clinical environments, this research emphasizes the applicability of wearable devices in everyday life, aiming to evaluate their effectiveness in real-world settings. Traditional ultrasound devices required continuous movement of the treatment head and were limited by the spatial constraints of wired equipment.[15] However, advancements in technology have led to the development of small, portable ultrasound devices based on low-impedance design principles, enabling their use as wearable therapeutic devices without time and space limitations. In this context, this study distinguishes itself by investigating the effects of wearable low-intensity ultrasound on chronic neck pain, muscle tension, and body temperature in women. This is expected to enhance the practicality of wearable technology and improve user convenience.

Table 1. Detailed data values for calculating the number of samples

Test family	T test
Type of power analysis	A priori: compute required sample size - given α, power, and effect size
Effect size d	0.50
α err prob	0.05
Power (1-B err prob)	0.90
Allocation ratio N2/N1	1
Total sample size	36

METHODS

1. Subjects

This study used 36 adult women residing in City A, South Korea. The sample size was calculated using the "G*Power, version 3.1.9.7" program, and the details are presented in Table 1.

The participants were selected based on the following criteria: 1) individuals with chronic, non-specific neck/shoulder pain, 2) individuals with non-traumatic neck/shoulder pain, 3) individuals with no history of cervical disc disease, 4) individuals who had not suffered related injuries in the past three months, 5) individuals without thoracic outlet syndrome, 6) individuals without neurological abnormalities, 7) individuals without adhesive capsulitis, and 8) individuals for whom contraindications to conservative physical therapy did not apply. Participants were recruited through public notices and screened via one-on-one interviews. Furthermore, participants who exhibited pain during the experiment were either allowed to take appropriate breaks before returning or were excluded. All subjects were thoroughly informed about the purpose and methods of the experimental study, and the researchers offered assurances that any physical or personal information acquired during the study would not be disclosed outside of the experiment. Subsequently, participants voluntarily signed written consent forms before participating in the study. Before the experiment started, all participants had their height measured using an autonomic BMI measuring instrument (BSM 370, InBody, Korea) and their weight measured using a Body Composition Analyzer (INBODY 570, Biospace, Korea). The physical characteristics of the participants are

Table 2. General characteristics of participants (n=36)

	WUG (n=18)	MUG (n=18)
Age (year)	23.3±3.3	23.1±2.7
Height (cm)	163.8±4.8	160.7±5.8
Weight (kg)	58.4±7.4	56.3±6.9

Values indicate mean±standard deviation. WUG: Wearable Ultrasound Group, MUG: Medical Ultrasound Group.

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presented in Table 2.

This study was conducted as a single-blind experiment, where participants were unaware of their group assignments or the activities of the other group. Before the experiment, participants were randomly divided into two groups using Excel functions. This study received approval from the Sunmoon University Institutional Review Board (SM-202206-029-3).

2. Experimental procedures

Participants had their height and weight measured once before the experiment, and assessments of muscle strength, pain, muscle tension, and body temperature were conducted once before and after the intervention, totaling two measurements each. Participants were randomly assigned to either the Wearable Ultrasound Group (WUG) or the Medical Ultrasound Group (MUG), and the intervention program was conducted for 10 minutes per session, three times a week for three weeks.

3. Measurement tools and methods

All participants had their height and weight measured once before the intervention, and assessments of pain, muscle tension, and body temperature were conducted once before and after the intervention, totaling two measurements. The same researcher performed all measurements and evaluations to minimize errors, and the evaluation location and methods were standardized.

Pain assessment was measured using the Korean version of the Short Form of the McGill Pain Questionnaire (KSF-MPQ) and the visual analog scale score (VAS score), which are widely used to evaluate the quality and intensity of pain. Muscle tension was measured using the MyotonPro (Myotone Pro, Myotone AS, Estonia), which has excellent reliability. The device measured Tone, Stiffness, Elasticity, Relaxation Time, Creep (Figure 1A). Tone refers to the natural oscillation frequency of the muscle, indicating its state of tension. Stiffness refers to the muscle's resistance to an external force, critical for movement support and injury prevention. Elasticity refers to the muscle's ability to return to its original shape after being stretched. Mechanical Stress Relaxation Time refers to the time taken for a muscle to return to its relaxed state after a contraction. Creep refers to the ratio of relaxation to deformation time, indicating how much a muscle can stretch under a constant load. Tenderness assessment was conducted using an algometer from J-tech. The measurement site was the same as the

Figure 1. Measuring tool. (A) Myotone-pro (B) Algometer (C) IRIS-XP Infrared Imaging - Medicore.

Figure 2. Intervention program. (A) Low-Intensity Wearable Ultrasound (B) Chattanooga group - Intellect Transport Ultrasound.

ultrasound application point (Figure 1B). Body temperature was measured using the IRIS-XP Infrared Imaging device from Medicore, which was applied at the ultrasound attachment site (Figure 1C).

4. Intervention method

The ultrasound devices used in the WUG were employed via a low-intensity ultrasound-based wearable therapeutic device created through 3D modeling. The device incorporates an ultrasound generation module operating at 3MHz, enabling the production of therapeutic ultrasound waves through button operations (Figure 2A). A solid gel pad from Bluemtech was utilized to reduce any resistance encountered during medical ultrasound therapy.

The medical ultrasound used in the MUG was employed from the Intelect Transport Ultrasound device from the Chattanooga Group, which applies a frequency of 3MHz, similar to that of the wearable ultrasound device (Figure 2B).

Ultrasound application targeted the trigger point areas known to be the primary causes of upper trapezius myofascial pain syndrome (Figure 2).

5. Data analysis

In this study, descriptive statistics were utilized to calculate general characteristics, and the mean and standard deviation of each variable were derived. All statistical analyses were conducted using IBM SPSS 26.0 Statistical software (IBM corp, chicago, IL, USA). Within each group, the paired t-test was used to observe effects before and after the intervention, and the independent t-test was employed to compare the two groups. The statistical significance level was set at $\alpha = 0.05$.

RESULTS

Pre- and post-intervention comparisons between the two groups showed no significant differences ($p > 0.05$). However, post-intervention measurements for each factor revealed significant differences in both groups for the KSF-MPQ ($p < 0.05$) and VAS scores ($p < 0.05$). In terms of recovery time from stress, both groups exhibited significant differences ($p < 0.01$), as well as for tone ($p < 0.01$). For stiffness, a significant difference was observed in WUG ($p < 0.05$), but not in MUG ($p > 0.05$). No significant differences were found in elasticity, relaxation, and creep ($p > 0.01$). In contrast, significant differences were noted in both groups for the algometer and temperature ($p < 0.01$)(Table 3).

Table 3. Comparison between & within groups

		WUG	MUG	t (p)
KSF-MPQ	Pre	10.44±3.89	10.94±3.97	-0.593 (0.563)
	Post	7.77±2.55	7.88±3.84	
	t (p)	2.522* (0.034)	5.218*** (<0.001)	
VAS score	Pre	2.66±1.71	2.55±1.61	0.442 (0.661)
	Post	1.27±1.48	1.22±1.43	
	t (p)	2.858* (0.021)	2.309* (0.043)	
Tone (Hz)	Pre	18.81±2.18	17.91±1.98	0.638 (0.529)
	Post	15.89±1.95	15.80±3.32	
	t (p)	3.636** (0.002)	2.140* (0.048)	
Stiffness (N/m)	Pre	360.77±69.70	345.33±70.12	1.226 (0.229)
	Post	299.33±43.14	319.33±54.66	
	t (p)	2.893* (0.012)	1.325 (0.197)	
Elasticity	Pre	1.01±0.19	0.95±0.10	-0.310 (0.758)
	Post	0.97±0.15	0.88±0.26	
	t (p)	0.823 (0.417)	1.160 (0.257)	
Relaxation (ms)	Pre	14.69±2.37	14.45 ±4.11	-0.582 (0.564)
	Post	15.84±2.52	14.70±2.64	
	t (p)	-1.257 (0.218)	-0.200 (0.843)	
Creep	Pre	0.91±0.13	0.92±0.14	-2.338 (0.077)
	Post	0.96±0.14	0.80±0.15	
	t (p)	-1.023 (0.312)	2.261 (0.136)	
Algometer	Pre	5.60±2.02	4.57±1.67	-0.141 (0.889)
	Post	7.28±1.66	6.14±1.65	
	t (p)	-2.961** (0.005)	2.902* (0.037)	
Temperature (℃)	Pre	28.28±0.67	28.54±0.85	-0.358 (0.723)
	Post	30.43±3.57	30.28±2.98	
	t (p)	-2.464* (0.024)	-2.345* (0.041)	

Values indicate mean±standard deviation. WUG: Wearable Ultrasound Group, MUG: Medical Ultrasound Group, KSF-MPQ: Korean version of the Short Form of the McGill Pain Questionnaire, VAS: Visual Analog Scale. *p<0.05, **p<0.01, ***p<0.001.

DISCUSSION

Ultrasound therapy is primarily utilized to treat soft tissue injuries, enhance wound healing, resolve edema, and soften skin tissues; meanwhile, it can also be applied to healing bone fractures and circulatory disorders. Initially developed to generate mild heat through thermal effects comparable to hot packs, microwaves, and high-frequency therapies[16], continuous research has subsequently acknowledged its non-thermal effects. Based on these physiological effects, ultrasound therapy is applied in clinical settings for conditions such as rotator cuff injuries, biceps tendinitis, and bursitis and is also extensively used for treating muscle stiffness caused by back and neck pain.[17]

This study demonstrates that using low-intensity ultrasound devices to treat muscle pain can achieve therapeutic effects comparable to conven-

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tional medical ultrasound in adult women regarding muscle strength, pain, muscle tension, and body temperature. Unlike traditional medical ultrasound, the wearable ultrasound device used in this research is designed to be worn without moving the device's intervention area, fixing it directly over the ultrasound projection area. This is because low-intensity ultrasound produces less surface heat, allowing for prolonged wear. Moreover, because the wearing area is fixed, it overcomes the disadvantage of traditional ultrasound, which restricts movement and activity during treatment.

Due to the large variance in symptoms and signs of pain among patients and their dependency on time/space and emotional contexts, various questionnaires have been developed to differentiate and evaluate pain. The McGill Pain Questionnaire (KSF-MPQ) used in this study effectively assesses the quantity and quality of pain by describing its characteristics in various terms, and its reliability has been proven on pains in multiple areas, including joint pain.[18] The assessment comprises 11 sensory and four affective categories, designed to verify the intensity of each and measure the overall degree of pain. It also contains many terms expressing the characteristics of neuropathic pain, aiding in the distinction between neuropathic and nociceptive pain.[19]

The visual analog scale (VAS) is a validated, subjective pain scale frequently used in both clinical and research settings, dividing the intensity of pain from 0 (no pain) to 10 (very severe pain), assessing both acute and chronic pain. It is utilized to track the progression of pain or compare pain among patients under similar conditions. In addition to pain, it is also used to evaluate mood, appetite, asthma, dyspepsia, and walking and is widely adapted or modified in various fields, including sports, physiotherapy, and medicine.[20,21]

Wearable ultrasound therapy has shown sufficient effectiveness in reducing chronic muscle pain. A comparison before and after using in the WUG showed a significant reduction in pain measured by two scales, which does not differ significantly from the pain reduction in the MUG group. Drapper et al. reported that low-intensity ultrasound therapy worked effectively for patients with chronic pain in their comparative experiments.[22] Lin et al.[23] demonstrated the impact of low-intensity ultrasound therapy on chronic prostatitis, proving its effectiveness in chronic pain. Therefore, this research aligns with previous studies showing significant results from using ultrasound therapy on chronic pain.

The upper trapezius is the most sensitive muscle in the myofascial pain syndrome. One characteristic of the syndrome is the trigger point, which is presumed to be created by the influx of calcium into damaged muscle fibers or by the secretion of acetylcholine at the motor endplate.[24] Based on these characteristics, an algometer is commonly used to measure the severity of myofascial pain syndrome. It quantitatively expresses the degree of pressure applied to the pain area, measuring the pain threshold according to the pressure, and is widely used as a method of pain measurement for various pains.[25]

Wearable ultrasound therapy has also shown sufficient effectiveness in reducing trigger point pain in myofascial syndrome. A comparative look at the pre- and post-application of the wearable ultrasound technology in the WUG showed that the decrease in tenderness measured via an algometer presented statistically significant results, which did not differ from the reduction in tenderness in the MUG group. Kavadar et al.[26] reported that applying conventional ultrasound therapy to patients with myofascial syndrome effectively acts on trigger point pain. Ansari et al.[27] reported that low-intensity ultrasound therapy applied to temporomandibular joint pain produced a greater effect than percutaneous nerve stimulation treatment regarding tenderness. Furthermore, Ay et al.[28] reported that ultrasound therapy creates a significant difference in the pressure pain threshold in patients with myofascial pain syndrome. This study aligns with previous research results in that ultrasound therapy significantly impacts the tenderness of trigger points.

Another benefit arising from the physiological response to ultrasound is the relaxation of muscle tension—defined as the mechanical elastic properties related to the muscle's passive stretch or the resistance that appears due to reflexive stimulation of the muscle.[29] In cases of neurological disorders, such as stroke and traumatic spinal cord injury, damage to the nerves connected to the muscles can lead to flaccid paralysis, where muscle tension is lost, or an abnormally high muscle tension.[30] Abnormal muscle tension can also be commonly observed even in the absence of neurological disorders, with the incorrect posture of modern people being a prime example. An instance of this incorrect posture would be the forward head posture, which induces changes in the muscle and tendon length in the front and back areas of the neck–shoulder due to the limited range of motion or posture maintenance during seated work.[31]

In this study, the Myoton Pro device was used to investigate five variables related to muscle tone. Firstly, muscle tone, which indicates the tension state of muscles, showed significant results in both the WUG and MUG groups. However, no significant differences were found between the WUG and MUG groups for the other variables: Elasticity, Relaxation Time, and Creep. Numerous other studies have also examined the impact of ultrasound therapy on muscle tone. Sahin et al.[32] demonstrated that ultrasound therapy effectively alleviates muscle tone in patients with toe flexor spasticity. Draper et al.[33] reported significant effects on muscle tone when ultrasound therapy was applied to the trigger points of the upper trapezius. The findings of this study are consistent with previous research indicating that ultrasound therapy has a significant impact on muscle tone.

Muscle stiffness refers to the muscle's resistance to external forces. Therefore, a decrease in muscle stiffness allows for more flexible body movements. The study results showed no significant changes in stiffness in the MUG group, whereas the WUG group exhibited significant results in stiffness. This suggests that wearable ultrasound therapy devices may have a greater effect on muscle flexibility compared to conventional therapy devices. Arifin et al.[34] investigated the effects of ultrasound therapy and stretching on improving the function of patients with shoulder stiffness. By analyzing 68 studies from various databases, they confirmed that ultrasound therapy yielded positive results in reducing pain and increasing range of motion (ROM). This aligns with the results of this study, which showed a decrease in muscle stiffness. However, no significant differences were found in the pre-post comparisons between the WUG and MUG groups, indicating that further research is necessary to confirm the definitive effects.

Infrared thermography is presented as a non-invasive, pain-free method that does not require contact with the area of evaluation to understand the metabolic impact in treating trigger points.[35] It serves as a useful method for objectively visualizing the condition of the muscle in musculoskeletal disorders such as myofascial pain syndrome and quantitatively assessing the physiological state of pain.[36] Trigger points can be active or latent and are closely related to changes in metabolic activity, thereby providing the basis for using infrared thermography to evaluate trigger points, as it is regulated by the sympathetic nervous activity.[37] Kanai et al.[38] conducted a clinical trial to evaluate the effectiveness of a treatment device for neck and shoulder stiffness and pain, reporting an increase in skin temperature after infrared thermography treatment.

Wearable ultrasound has also shown a significant effect in raising the body temperature. A comparison of pre- and post-application in the WUG using an infrared thermography device showed that the increase in body temperature presented statistically significant results, which did not differ from the increase in body temperature in the MUG group. Several studies, including those by Chan et al.[39] and Drapper et al.[40] have repeatedly verified the effect of low-intensity ultrasound therapy on raising body temperature. The results of this study are also consistent with those of previous research.

This study has several limitations. Firstly, since the experiment was conducted over 3 weeks, predicting the effects when applied over a longer duration is difficult. Secondly, since only women in their 20s were investigated, it is challenging to represent a patient group that includes a variety of genders and ages. However, based on the results of previous studies, it is reported to be effective across various diseases, symptoms, genders, and age groups.

This study aims to evaluate the effects of wearable ultrasound devices using low-intensity ultrasound on pain, tenderness, muscle tension, and body temperature and to determine whether they can be as effective as traditional medical ultrasound devices. The results are as follows. First, wearable therapeutic devices using low-intensity ultrasound significantly affected pain, tenderness, muscle tension, and body temperature. Second, wearable therapeutic devices using low-intensity ultrasound can be as effective as traditional medical ultrasound devices. From these results, it can be inferred that wearable therapeutic devices using low-intensity ultrasound are as effective as conventional therapeutic devices and can be utilized in various aspects by leveraging the advantage of allowing activity during treatment.

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