

Immediate Effect of Continuous Ultrasound vs Sham Ultrasound for Bilateral Masseter Myalgia: A Double-Blinded Trial

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Aims: To investigate the local and segmental effects of therapeutic ultrasound at a dose of 0.4 w/cm² with 100% duty cycle for 5 minutes compared to the effect of sham ultrasound on painful masticatory muscles. **Methods:** A total of 20 adult female subjects with bilateral masseter myalgia diagnosed according to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) were included. Each subject was randomized to either an active ultrasound group or a sham ultrasound group. The intervention was applied to each masseter muscle for 5 minutes. Measures included pre- and post-self-reported pain intensity recorded on a verbal rating scale (VRS), pressure pain thresholds for the masseter (PPT-M) and temporalis (PPT-T) muscles, and intraoral temperature for the masseter muscle. Preintervention score was subtracted from the postintervention score for all measures to calculate mean change in pain, and nonparametric Mann-Whitney test was used to compare the groups. Statistical significance was set at $P < .05$. **Results:** Changes in VRS did not show a significant difference between groups ($P > .05$). There were significant increases in PPT-M and intraoral temperature in the ultrasound group compared to the sham group ($P < .05$). There was no significant difference in PPT-T ($P > .05$), suggesting no segmental effect. **Conclusion:** Therapeutic ultrasound produced an immediate increase in PPT-M and intraoral temperature compared to sham ultrasound in female subjects with bilateral masseter myalgia. *J Oral Facial Pain Headache 2018;32:304–308. doi: 10.11607/ofph.2000*

Keywords: myalgia, TMD, ultrasound

Temporomandibular disorders (TMD) are defined as “a group of musculoskeletal and neuromuscular conditions that involve the temporomandibular joint (TMJ), the masticatory muscles and all associated tissues.”¹ The current incidence for TMD is 3% to 4% per annum,² and there is an estimated prevalence of 10% for masticatory muscle pain, 11% for disc derangement disorders, and 3% for TMJ pain.³

In terms of etiology, it is well accepted that TMD involves several risk factors⁴ that all work together to cause the disorder. Findings from the Orofacial Pain Prospective Evaluation and Risk Assessment (OPPERA) prospective cohort study support this model. Self-reported somatic symptoms, pain amplification, autonomic function, and comorbid conditions are the strongest phenotypic risk factors for first-onset TMD.⁴

The current Diagnostic Criteria for TMD (DC/TMD)⁵ protocol incorporates the use of history and a standardized examination. Among the pain-related conditions, myalgia shows excellent levels of diagnostic validity.⁵ Myalgia is pain of muscular origin that is modified with jaw function or parafunction.⁵ The present research study focused on myalgia to evaluate the therapeutic effect of ultrasound as a treatment modality.

The management of TMD, specifically myalgia, should aim to reduce pain, manage habits that may aggravate or elicit the symptoms, and restore function to allow for normal daily jaw function.⁶ It is important to note that signs and symptoms of TMD are often self-limiting and may resolve⁶ without any long-term consequences.

Therapeutic ultrasound has been commonly used by physiotherapists⁷ for muscle pain. Ultrasonic energy is mechanical energy in the form of sound waves with a range of 1 to 3 MHz.⁸ The waves are produced by a piezoelectric material⁸ that allows mechanical changes when a voltage

is applied; this phenomenon is known as the reverse piezoelectric effect. Therapeutic ultrasound has been shown to have a thermal mechanism achieved by a continuous frequency (100% duty cycle)⁹ and a non-thermal mechanism achieved by a pulsed frequency (50% duty cycle).¹⁰

There is a limited number of clinical trials in the literature that have evaluated therapeutic ultrasound for the management of TMD. Of the clinical trials reviewed, two found ultrasound superior to muscle relaxants, diathermy,¹¹ and transcutaneous electrical nerve stimulation (TENS).¹² However, the available literature lacks the use of validated criteria and calibrated examiners to diagnose TMD, which limits the characterization of the study population. In addition, there is an absence of a consistent dose, time of application, and application method of therapeutic ultrasound.¹³ These limitations led to the development of a clinical trial to test the dose-response relationship of therapeutic ultrasound for bilateral masseter myalgia.¹⁴ The results from this study showed an increase in pressure pain threshold of the masseter (PPT-M) muscle—indicating a reduction in pain—for subjects receiving ultrasound at 0.4 w/cm² with 100% duty cycle for 5 minutes on each side.¹⁴

Therapeutic ultrasound has also been demonstrated to produce a distant,¹⁵ or segmental, effect. This effect has been seen in the trapezius muscle group¹⁵: A significant increase in PPT in the infraspinatus muscle was seen after ultrasound was applied to the supraspinatus muscle. As both muscles have the same innervation, the authors investigated this effect by comparing the PPT to a control site at the gluteus medius muscle, which has a separate innervation. Based on these results, the clinical trial conducted on the masticatory muscles¹⁴ tested whether applying ultrasound to the masseter muscle would produce a segmental effect on the temporalis muscle and showed a significant increase in PPT of the temporalis (PPT-T)¹⁴ after ultrasound treatment of the masseter.

The aim of the current study was to investigate the local and segmental effects of therapeutic ultrasound at a dose of 0.4 w/cm² with 100% duty cycle for 5 minutes compared to the effect of sham ultrasound on painful masticatory muscles. The measures verbal rating scale (VRS) for pain intensity, PPT-M, PPT-T, and intraoral temperature were used to assess the effects.

Materials and Methods

The randomized clinical trial was conducted in the University at Buffalo School of Dental Medicine. The protocol was approved by the university's Institutional Review Board, and each subject gave informed consent. At the end of their appointment, subjects were

given a \$50 gift card as compensation for their time, travel, and effort. A total of 20 female subjects were recruited from the TMD and Orofacial Pain Clinic. Before the start of the trial, all subjects underwent the DC/TMD standardized examination conducted by a calibrated examiner to provide the diagnosis of myalgia for bilateral masseter muscles.

Inclusion and Exclusion Criteria

According to the DC/TMD, a diagnosis of bilateral myalgia of the masseter muscles was present in all 20 subjects. All subjects needed to have a pain intensity of ≥ 4 out of 10 on the VRS (0 = no pain; 10 = worst pain ever). All reported a pain level of 4 or more when initially recruited by a phone call; however, 4 subjects had pain < 4 during the appointment, and so their data were not included in the analysis.

Subjects with a history of any systemic musculoskeletal or rheumatologic disorders (eg, fibromyalgia) were excluded, as were subjects with any current neoplasms, fractures, neuropathies, or neurologic conditions. Subjects who were at the time undergoing any physical therapy for the masticatory system that targeted the muscles of mastication or the TMJ within the last 60 days were not eligible. If subjects were taking muscle relaxants, over-the-counter analgesics, or any other prescription medications that provided pain relief, they were asked to discontinue use for at least 24 hours prior to the trial or to take their dosage after the study appointment.

Outcome Measures

The VRS was used by each subject to obtain self-reported current pain. For PPT, the pressure at which the subject noted a change from pressure to pain was recorded at one site on the body of each masseter muscle and at one site on each temporalis muscle. An electronic algometer was used for the PPT measurements. Subjects were asked to clench, and the algometer was applied to the greatest bulk of the masseter and 3 to 5 mm above the superior-most portion of the ear for the temporalis muscle. Muscle temperature was measured by using an electronic thermometer placed in the posterior buccal vestibule.

Procedures

The subjects were assigned to either 0.4 w/cm² with 100% duty cycle ultrasound or to sham ultrasound. The clinical trial was double blinded, but the operator was advised on which side to start the treatment by another individual participating in the study as recorder. The selection of intervention and starting side were randomized in blocks of four to ensure an equal distribution among the subjects. The ultrasound machine was placed behind the operator to ensure the blinding process. Once the intervention group

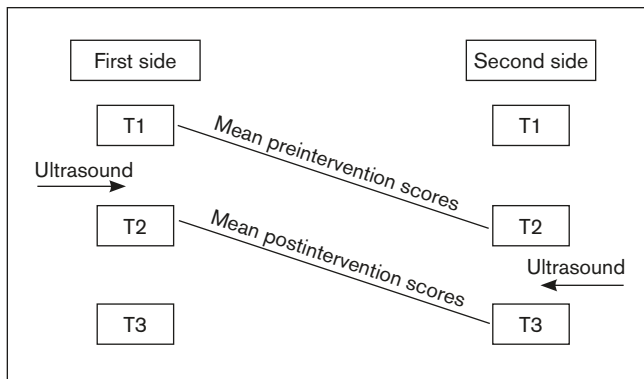


Fig 1 Time distribution of assessment scores and mean scores analyzed. T1 = preintervention assessment scores on both sides; T2 = scores from both sides after first intervention; T3 = scores from both sides after second intervention.

Table 1 Mean Age and Self-Reported Pain Distribution at Baseline Between Groups

Group	Age (y)		Right masseter VRS score		Left masseter VRS score		t test P
	Mean	SD	Mean	SD	Mean	SD	
Ultrasound	35.9	10.3	5.5	1.9	5.0	1.3	> .05
Sham ultrasound	39.4	12.9	4.8	1.1	4.6	0.72	

VRS = verbal rating scale; SD = standard deviation.

Table 2 Changes in Pain Intensity on Verbal Rating Scale (VRS), Intraoral Temperature, and Pressure Pain Threshold of the Masseter (PPT-M) and Temporalis (PPT-T) Muscles Between Groups

	Ultrasound		Sham ultrasound		P
	Mean	SD	Mean	SD	
VRS	-1.6	1.3	-0.8	1.0	.5
Intraoral temperature (°C)	0.2	0.2	-0.1	0.2	.03
PPT-M (KPa)	12.4	22.2	-18.8	38.8	.04
PPT-T (KPa)	18	32.2	-7.3	27.1	.1

SD = standard deviation.

was revealed to the recorder, the machine was set to a dose of 0.4 w/cm² with 100% duty cycle for a period of 5 minutes or to 0 w/cm² for a period of 5 minutes.

A custom template for each subject was made out of a vinyl sheet. Each template was referenced to the ear and the ala of the nose and was taped to the subject to ensure that it remained throughout the procedure. The template defined the anatomical borders of the masseter muscle and focused the treatment area to the masseter.

The data for all of the parameters were recorded on paper forms in the following order:

- Self-reported pain was assessed with the VRS. The subjects were asked to assign a number on the VRS indicating their current pain for each side.

- PPT-M and PPT-T were recorded on the bulkiest part of each muscle. PPT was repeated until two readings less than 20 units apart were obtained.
- Intraoral temperature was measured by placing the metal end of the thermometer in the approximate intraoral location of the masseter against the buccal mucosa.

The duration and duty cycle of the ultrasound treatment was based on Fadol.¹⁴ A single operator performed the intervention to ensure reliability. A gel coupling agent was heated to 27°C by a gel warmer. The intraoral temperature was measured immediately after the treatment to minimize any loss of muscle heating, followed by the VRS and PPT measurements.

Statistical Analyses

The mean change in each measure from preintervention to postintervention was calculated for both sides (right and left) for all subjects (Fig 1). The preintervention score was subtracted from the postintervention score to calculate change. A negative value indicates pain reduction and therefore an improvement in symptoms.

The outcome measures for all 16 subjects were analyzed using SPSS software for Mac, version 22. The nonparametric Mann-Whitney test was used to compare ultrasound and sham ultrasound groups for all parameters.

Results

Subject Characteristics

Twenty female subjects were randomized and completed the study; however, 4 did not have a VRS score of ≥ 4 on one side and so were not included in the analysis. The age of the remaining subjects ranged from 21 to 63 years. Self-reported pain for the right side ranged from 4 to 9, and for the left side from 4 to 8. Mean age and self-reported pain prior to initiating treatment based on VRS scores for both sides are shown in Table 1.

Self-Reported Pain Between Groups

Mean changes for self-reported pain for each group are shown in Table 2. The Mann-Whitney test did not show a significant difference between the groups (P > .05). Five subjects in the ultrasound group and three subjects in the sham ultrasound group reported a ≥ 30% reduction in VRS scores. It has been previously discussed¹⁶ that a 30% reduction in the VRS is deemed clinically relevant.

Change in Intraoral Temperature Between Groups

Results from the nonparametric Mann-Whitney test showed a significant increase in intraoral temperature in the active ultrasound group compared to the sham group ($P < .05$) (Table 2).

Changes in PPT-M Between Groups

Increase in PPT indicates an increase in the amount of pressure it takes for the patient to determine the stimulus is painful. There was an increase in PPT-M in the ultrasound group and a decrease in PPT-M in the sham group. The nonparametric Mann-Whitney test showed a significant difference for PPT-M between the groups ($P < .05$) (Table 2).

The Segmental Effect: PPT-T

There was an increase in PPT-T in the treatment group and a decrease in the sham group (Table 2); however, these differences were not significant when tested with the nonparametric Mann-Whitney test ($P > .05$).

Discussion

The main findings of this study were a significant increase in PPT-M and intraoral temperature for subjects who received the active ultrasound intervention. The increase in temperature provides evidence that the ultrasound did heat the masseter muscle, while the increase in PPT-M provides evidence that the ultrasound had a therapeutic effect.

The increase in PPT-M did not correspond to a significant reduction in self-reported pain. Although the correlation was not an outcome measure in this clinical trial, it was considered an expected outcome. The absence of a correlation may have been due to the subject's awareness of a placebo group, which, although the study was blinded, may have produced a bias by way of behavioral influence¹⁷ affecting the subject's decision in determining their current pain level.

Farrar et al¹⁶ have suggested that a 30% reduction in VRS can be considered clinically relevant. The present results showed that five subjects in the ultrasound group and three subjects in the sham ultrasound group had a reduction of pain of $\geq 30\%$. The inability to show a significant reduction in the VRS of those receiving ultrasound compared to those receiving sham ultrasound may have been due to the expectation of pain relief, especially in those subjects who had previously received ultrasound treatment. Expectation of a desired outcome¹⁸ may have played a role for those who had not received the ultrasound before in a positive sense (feeling relief even with sham ultrasound) or for those who had previously re-

ceived treatment in a negative sense (not feeling as much relief with the ultrasound as they had before). Finally, the subject's ability to recall¹⁸ preintervention self-reported pain may have produced a larger or smaller effect, as they may have believed it was higher or lower than they had expressed.

Whether the ultrasound was able to produce a significant segmental effect was tested with assessments of PPT-T. The treatment group showed an overall increase in PPT-T while the sham ultrasound group showed an overall decrease, but these results were not statistically significant. Although not significant, these results do point in the direction of a potential indirect antinociceptive effect for therapeutic ultrasound.

Effects of the ultrasound may be attributed to its ability to produce central changes. Hsieh et al¹⁰ used an animal model to demonstrate that ultrasound therapy was able to significantly reduce the number of nitric oxide synthase-like neurons (nNOS-L1) in the nucleus proprius (laminae III and IV) and the ventral horn of the spinal cord. The ability of the ultrasound to alter neurons in these areas of the spinal cord¹⁰ suggests a potential central mechanism by which ultrasound may be able to reduce pain, alter temperature, and produce an indirect antinociceptive effect. This proposed central effect might also be reflected in the long-term effect of therapeutic ultrasound; however, the present study did not conduct a follow-up visit to evaluate a potential long-term effect.

Masseter muscle heating was tested by taking the intraoral temperature before and after each intervention. This measure provided an approximation of whether the ultrasound was heating the treated area. The ultrasound group had a significant increase in intraoral temperature compared to the sham ultrasound group, and these findings support the ability for ultrasound to produce muscle heating via a thermal mechanism.¹⁹ Muscle heating may produce a soothing effect, as experienced when placing a warm compress on the area of pain, leading to the perception of pain relief. However, it has been shown previously²⁰ that placement of a heat compress alone did not significantly increase PPT. This suggests that the significant increase in PPT-M observed in the present study was not due to a soothing effect of the ultrasound treatment.

Study Strengths and Limitations

The current study was a double-blinded randomized clinical investigation and was the first to compare ultrasound to sham ultrasound for masseter myalgia diagnosed by use of validated diagnostic criteria (DC/TMD). The present study was also the first to evaluate the immediate effect of ultrasound in TMD patients, as well as the segmental effect and intraoral muscle

temperature of ultrasound treatment compared to sham ultrasound treatment.

The sample size used in the present study was small, and the study was not powered sufficiently to investigate a difference for self-reported pain. The VRS, although efficient, had some disadvantages: There were times when subjects could not recall their baseline scores, so it may have been advantageous to ask the subjects how they felt in comparison to their pain prior to the intervention, and there was also no follow-up visit to evaluate a potential long-term effect. Lastly, the results of this study cannot be generalized to the population due to the limited number of subjects and the exclusion of males from the trial. Although a limitation, the exclusion of males has merit in that there is greater incidence of TMD and odds of chronicity²¹ in females.

Conclusions

Therapeutic ultrasound may be more beneficial than sham ultrasound for the treatment of bilateral masseter myalgia. Ultrasound with a setting of 0.4 w/cm² with 100% continuous duty cycle significantly increased the PPT-M and produced a significant increase in intraoral temperature, indicating heating of the tissues. This study has shown that therapeutic ultrasound may be an effective treatment method for bilateral masseter myalgia.

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