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Report on the Effectiveness of Long-Wave Ultrasonic Stimulation for Patients with Temporomandibular Joint Disease and Masticatory Muscle Pain Disorder (Is Dolphin Waves Effective for Temporomandibular Joint Disease?)

Research Article

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Article History

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Abstract

The device has been confirmed to increase cerebral blood flow in humans [1-3], and its safety and effectiveness have been confirmed in clinical trials for cranial nerve diseases [4-6]. Efficacy and safety were confirmed for temporomandibular joint disease and masticatory muscle pain disorders. [Subjects] A clinical trial was conducted on 12 Japanese men and women under the age of 65 with temporomandibular joint disorder and masticatory muscle pain disorder. [Study Design] A randomized, sham-controlled, single-blind comparative study was conducted. [Device use] A Siam device was used for the first evaluation, and then the actual machine was used continuously at home for 14 days. The device was placed at the temporomandibular joint site and operated for 20 minutes, and after a 5 minutes break, it was operated for an additional 20 minutes (twice a day). [Evaluation period] Evaluations were made before use, and after 7 days (1W), 14 days (2W), and 21 days (3W). [Evaluation Items] Pain at the palpable area (10 sites) was evaluated in 5 stages, mouth opening (6 items) was measured, and pain (4 items) was evaluated using VAS. The safety of the device was evaluated. For statistical analysis, Wilcoxon signed rank test and t-test were performed, and a risk rate of less than 5% ($p<0.05$) was determined to be a significant difference. [Results] Compared to before using the device, significant improvements were seen in 4 items after 7 days, 14 items after 14 days, and 15 items at follow-up after 21 days. [Conclusion] Particularly in the subject's own assessment (VAS), significant improvements were seen at all observation points in terms of difficulty in mouth opening, chewing, and daily life. It is presumed that the pain was reduced. No adverse events occurred during the period of use. In parallel, a single use trial was conducted on 12 other subjects. As a result, significant improvements were seen in three items, and it is expected to be effective as an emergency treatment for acute patients. The results of this study showed that the condition of temporomandibular joint disorder was alleviated after continuous use for 7 days, and many symptoms were alleviated after 14 days of use. During subsequent observation for 7 days, the patient's symptoms remained stable even without the use of the device.

Keywords: long-wave ultrasonic; temporomandibular joint pain; masticatory muscle pain disorder; headphone-type ultrasound stimulator

Introduction

We have developed a low-frequency ultrasonic stimulation device that focuses on the frequency band emitted by dolphins in the ocean. This paper summarizes a report of a clinical trial conducted to improve the symptoms of temporomandibular joint disorders.

This headphone-type device uses ultrasound to stimulate the temporomandibular joint area. The ultrasonic frequency is 30KHz (0.03MHz), which is a non-standard ultrasonic frequency for medical equipment. The wavelength inside the body (simulated in water) is approximately 5cm, and it is characterized by a low attenuation rate of propagation within the body and good penetration of acoustic vibrations.

The body is said to be 60% water, and the speed of sound propagating underwater is approximately 1,500meters/second, while in bones it is 5,000meters/second, so acoustic vibrations are transmitted well. Motion stimulation to capillaries and nerve cells in the human body is thought to be obtained with vibration energy of several micro-watts/cm2. The ultrasonic intensity of this device is approximately 1/10,000 or less of the intensity that causes cavitation. In preliminary clinical study, we confirmed that stimulating the capillaries and nerve cells in the brain with weak ultrasound waves for 20minutes increases cerebral blood flow [1,2,3]). Furthermore, clinical trials for cranial nerve diseases confirmed its safety and efficacy [4-6]). Based on the above clinical trial results, we conducted a clinical trial to ensure safety for patients with temporomandibular joint disorders.

Based on the 2016 dental disease survey in Japan, the number of patients with some type of temporomandibular joint symptoms is estimated to be approximately 19 million. The wave massage effect of pulsed stimulation using 30kHz long-wave ultrasound on capillaries and muscle cells is expected to alleviate temporomandibular joint disorders by reducing muscle tension. It is presumed that the acoustic vibration waves of this device spread throughout the muscles surrounding the temporomandibular joint, relieving tension and increasing blood flow.

The device used in this clinical trial was developed by Kamiyama, Ltd., a medical device manufacturing and sales company. The clinical trial was outsourced to the Japan Clinical Trials Association (JACTA). This paper introduced an overview of the report on ``Specific clinical research using this device on 12 patients with temporomandibular joint disorders". [7]).

Subjects and Method

Subjects

Japanese men and women under the age of 65, those who have been diagnosed with temporomandibular joint disease masticatory muscle pain disorder according to the Japanese Temporomandibular Joint Society's diagnostic criteria (2019) "1. Masticatory muscle pain disorder", and those who are sufficiently satisfied to participate in this study. Target patients were those who could obtain written informed consent of their own free will and understanding.

Ethics review committee and subject consent

After receiving approval (specific clinical research) from the Japanese Society of Skin Regenerative Medicine Clinical Research Review Board (JSSRM of CRB, certification number: CRB3190003), and it was carried out after being notified to the Minister of Health, Labor and Welfare.

[Clinical research implementation plan number: jRCTs 032210354, September 30, 2021, study implementation organization: Japan Clinical Trials Association (JACTA) (Tokyo)].

Medical Institution

The clinical study was conducted by Yosuke Naito (dentist at O motesando FM Clinic).

Study Design

Randomized, sham-controlled, single-blind comparative study.

a. Use of clinical device

The Sham device was used for the first evaluation, and then the

actual machine was used continuously at home for 14days. The second evaluation was performed after 7days (1W), and the third evaluation was performed after 14days (2W).

b. How to use

Place a headphone-type device (Figure 1) on your head, set the left and right ultrasonic output parts on the temporomandibular joints, and rest for 20 minutes. After resting for 5 minutes, apply the device for an additional 20minutes. Table 1 shows the specifications of this device, and Figure 1 shows how it is installed.

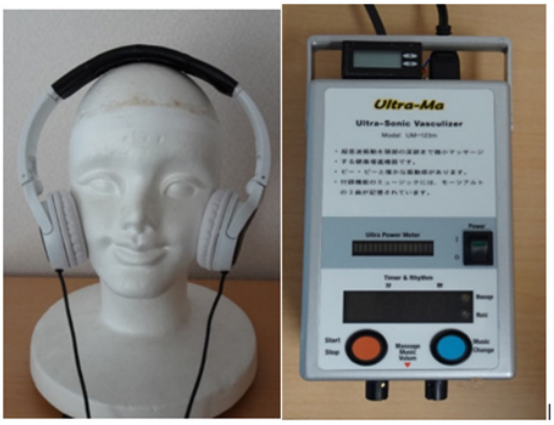


Figure 1: Test device installation status and control unit.

Table 1: Test device specifications.

Items	Specifications
Rated voltage, current	AC 100v, 0.2A
Ultrasonic output	30kHz, 0.01W/sec, Each vibrator
Type of treatment head	Pulse stimulation on left and right alternately, 10% pulse ratio
Timer	20 minutes

Test schedule

The study was conducted from October 2021 to December 2021. Evaluation was performed four times as observation days: before use, 7days (1W), 14days (2W), and 21days (3W). During the study period, local treatments such as anti-inflammatory analgesics, central muscle relaxants, antidepressants, sleep-inducing drugs, intramuscular injections to the masticatory muscles, and occlusal therapy (splint therapy, occlusal adjustment) that affect the test area were prohibited. The patient was instructed not to perform electrical stimulation therapy, heat therapy, massage, or other physical therapy for the masticatory muscles.

Evaluation Items

Palpation

A temporomandibular joint specialist diagnoses 10 areas(Deep masseter muscle, superficial masseter origin, anterior edge of masseter superficial stop, posterior edge of masseter superficial stop, superficial part of masseter medium, anterior part of temporalis muscle, middle part of temporalis muscle, posterior part of temporalis muscle, pain on palpation of the anterior belly of the digastric muscle and the posterior belly of the digastric muscle), which are classified into -, ±, +, ++, and +++. Diagnosis was made on a 5-point scale.

Opening amount

A temporomandibular joint disorder specialist used a gag-cage to measure six items (opening distance, painless maximum mouth opening, voluntary maximum mouth opening, forced maximum mouth opening, forward movement, right lateral movement, and left lateral movement).

VAS

Four pain items (pain during palpation of masticatory muscles, masticatory muscle pain when opening the mouth, masticatory muscle pain during mastication, degree of difficulty in daily life) were evaluated using VAS. For the VAS, subjects were shown a 10-cm-long horizontal line (left end: no pain, right end: the most severe pain they had ever experienced), and the participants themselves wrote on the line how much pain they were currently experiencing.

Safety

The safety of the test product was evaluated based on visual confirmation of the presence or absence of skin abnormalities on the day of observation, a diary survey regarding lifestyle habits and adverse events during the test period, and a doctor's diagnosis on the day of observation.

Statistical Processing

Measured values and scores were expressed as mean value ± standard deviation. Wilcoxon signed-rank test was used for palpation, and paired t-test was used for mouth opening and VAS. In both cases, a significance rate of less than 5% ($p<0.05$) was determined to be a significant difference using a two-tailed test.

Result

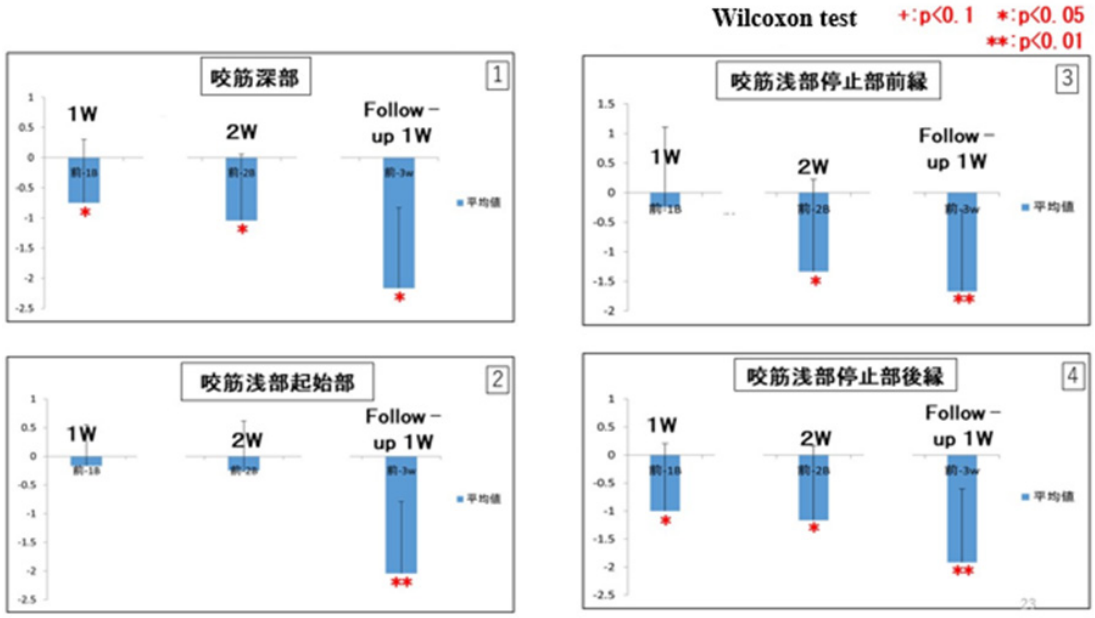
A total of 12 subjects (39-62years, 52.1 ± 7.6 years) completed the study.

Palpation pain

A comparison with before the start is shown in Figures 2.

a. After 14days, there was a significant decrease in 9 out of 10 items. (Deep part of the masseter muscle, origin of the superficial part of the masseter muscle, posterior edge of the superficial part of the masseter muscle, middle part of the superficial part of the masseter muscle, anterior part of the temporalis muscle, middle part of the temporalis muscle, posterior part of the temporalis muscle, anterior belly of the digastric muscle, posterior part of the digastric muscle stomach).

b. Follow-up observation after 21days showed a significant decrease in all 10 items. (Deep part of the masseter muscle, origin of the superficial part of the masseter muscle, anterior edge of the superficial part of the masseter muscle, posterior border of the superficial part of the masseter muscle, middle part of the superficial part of the masseter muscle, anterior part of the temporalis muscle, middle part of the temporalis muscle, posterior part of the temporalis muscle, chin (Anterior belly of abdominal muscles, Posterior belly of digastric muscles).



1. Deep Part of masseter muscle.
2. Superficial part of masseter muscle origin.
3. Anterior border of the superficial part of the masseter muscle insertion.
4. Posterior border of the superficial part of the masseter muscle insertion.

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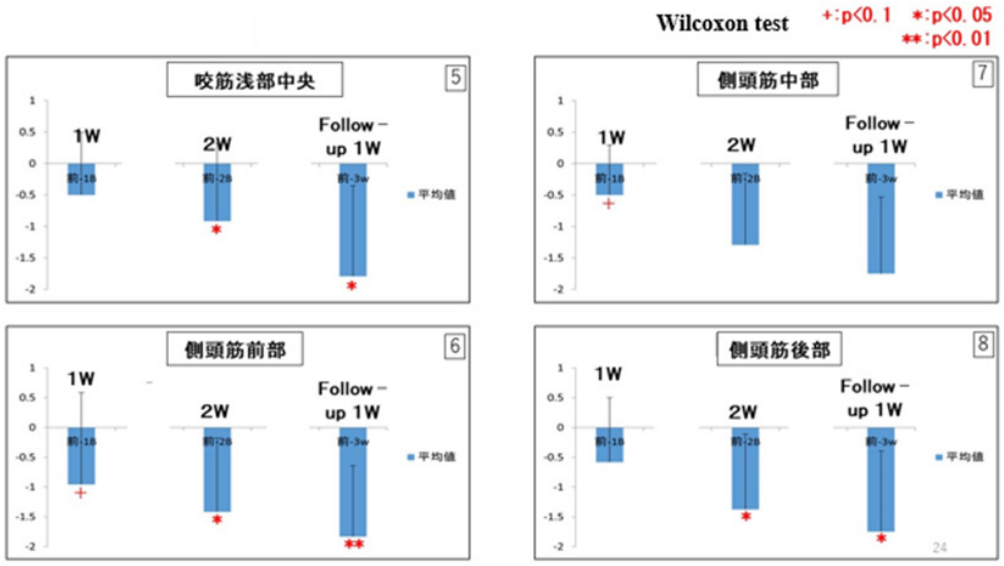
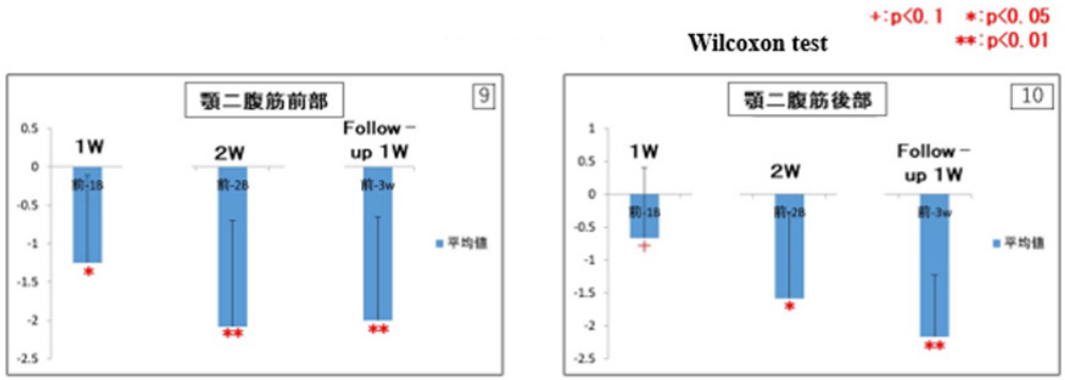


5. Central part of the superficial part of the masseter muscle.
6. Anterior part of the temporalis muscle.
7. Central part of the temporalis muscle.
8. Posterior part of the temporalis muscle.



9. Digastric anterior ventral.
10. Jaw Two Abs Hind Abdomen.

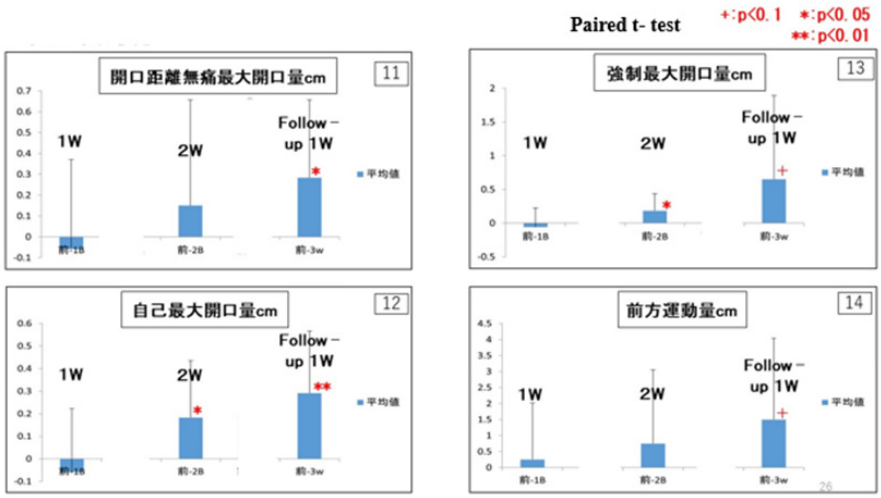
Figure 2: Changes in palpation pain.

Opening amount

Figure 3 shows a comparison with before the start.

i. After 14 days, there was an increasing trend in one item (forward momentum) and a significant increase in two items (voluntary maximum mouth opening amount and forced maximum mouth opening amount).

ii. Follow-up observation after 21days showed an increasing trend in 2 items (forced maximum mouth opening amount, forward movement amount), a decreasing trend in 1 item (left lateral movement amount), and a significant increase in 2 items (painless maximum opening distance, painless maximum opening amount). (self-maximum opening amount).



11. Maximum painless opening distance (cm).
12. Maximum mouth opening distance (cm).
13. Maximum opening distance (cm).
14. Forward momentum (cm).

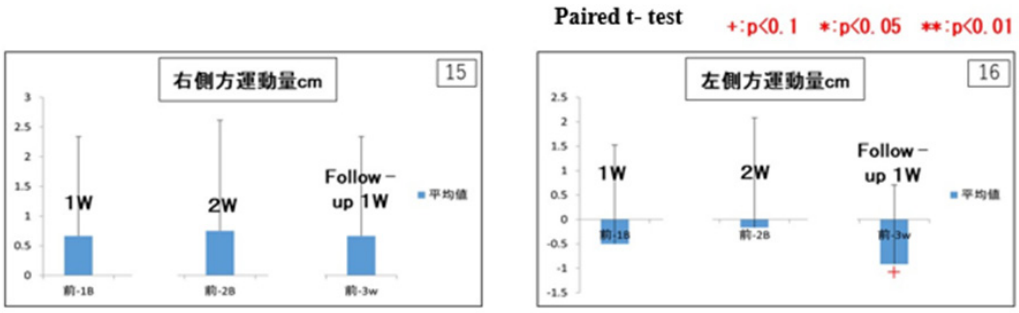
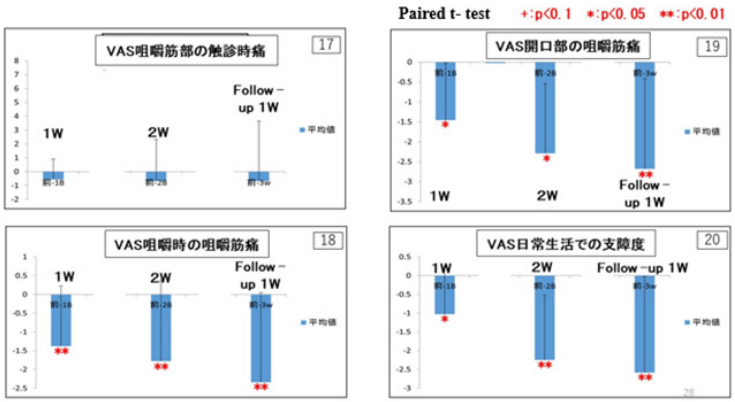


Figure 3: Changes in opening amount.

VAS

Figure 4 shows a comparison with before the start.

Significant decreases (improvements) were observed in 3 items at follow-up after 14 and 21days (masticatory muscle pain when opening the mouth, masticatory muscle pain during mastication, and difficulty in daily life).



17. VAS Pain on palpation of the masseter muscle.
18. VAS Chewing muscle pain.
19. VSA Jaw pain when opening mouth.
20. VAS QOL.

Figure 4: Changes of VAS.

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Adverse events

There were no adverse events or side effects in this study, and there were no reports of device malfunctions, so it was thought that there were no safety issues with the test product.

Summary

Compared to before use, significant improvements were seen in 4 items after 7days, 14 items after 14days, and 15 items at follow-up after 21days. In particular, in the subject's own assessment (VAS), significant improvements were seen at all observation points regarding the degree of difficulty in mouth opening, chewing, and daily life, indicating that the pain that interferes with daily life was reduced. It is assumed that.

Ultrasonic treatment has a thermal effect due to continuous ultrasonic waves and a non-thermal effect (sound pressure effect) due to vibrations of ultrasonic pulses. Thermal effects include improved blood flow due to vasodilation, improved skeletal muscle contractile function, and increased pain threshold. On the other hand, non-thermal effects include micro-massage effects such as improving muscle spasms and promoting healing of inflammation.

The current device uses long-wave ultrasonic waves with a frequency of 30kHz and a maximum ultrasonic strength of 16mW/cm2, with a weak intensity. It is thought that the vibrational energy reaches deep inside the body and exerts a non-thermal effect, which improves the symptoms of temporomandibular joint disorder (symptoms of masticatory muscle pain disorders such as pain and mouth opening). Furthermore, no adverse events occurred during the period of use, indicating that there is no problem with human safety.

At the same time, a single trial was conducted on 12people. As a result, significant improvements were seen in three items (middle temporalis muscle, anterior belly of digastric muscle, and posterior belly of digastric muscle). Therefore, it is expected to be effective as an emergency treatment for acute patients.

The results of this study showed that the condition of temporomandibular joint disorder was alleviated after continuous use for 7days, and many symptoms were alleviated after 14days of use. During subsequent observation for 7days, the patient's symptoms remained stable even without the use of the device.

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