

# EFFICACY OF ULTRASOUND MASSAGE THERAPY IN MYOFASCIAL PAIN –A RANDOMIZED SINGLE-BLIND CLINICAL STUDY

Running title:Ultrasound Massage Therapy in Myofascial Pain

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**Abstract:** *Aim:To compare the efficacy of conventional therapy over combination of Therapeutic Ultrasound & Conventional therapy in management of Myofascial pain patients.*

**Keywords:** *Myofascial Pain Dysfunction Syndrome (MPDS), Therapeutic Ultrasound, Temporomandibular disorders, Orofacial Pain, Combination Therapy*

## **Materials and Methods:**

*The present randomized comparative study was conducted on 20 patients who came to the Out Patient Department of our institute with a complaint of Myofascial pain.All the patients were evaluated for pain over TMJ area and muscles of mastication on a visual analog scale (VAS), maximum inter incisal distance was measured by Vernier caliper. Patients were randomly assigned into two groups each comprising of 10 patients. Group I*

*patients received conventional therapy while Group II patients received combination of Conventional therapy and Therapeutic Ultrasound. Descriptive Analysis of the dataset was carried out to obtain data estimates and all the variables i.e. Mouth opening (MO), Pain recorded as per visual analogue scale on TMJ, Masseter (M) and lateral pterygoid (LP) muscles in nature except the gender of the patient for which frequencies were observed. The means of the differences between the values of the two groups were compared using Wilcoxon Rank Sum Test/ Mann Whitney U-test.*

*Results – A significant pain reduction was found in the patients who were given Ultrasound massage therapy ( $p = 0.003$ ). There was a decrease in pain over TMJ area, tenderness over Masseter and lateral pterygoid and mouth opening was improved which was statistically significant. This therapy appears to be effective in pain reduction in Myofascial Pain Dysfunction Syndrome.*

*Conclusion–US massage therapy appears to be useful in relieving pain and improves subsequent mouth opening, and hence can be considered as a valuable aid in managing Myofascial pain. Thus, US massage therapy serves as a potent and independent therapeutic modality in Myofascial Pain Dysfunction Syndrome.*

## 1. INTRODUCTION

Myofascial Pain Dysfunction Syndrome (MPDS) is a heterogeneous group of disorders that affect the jaw joint and/or the chewing musculature. Myofascial Pain is defined as pain that originates from myofascial trigger points in the skeletal muscle. It is prevalent in regional musculoskeletal pain syndromes, either alone or in combination with other pain generators like Temporomandibular disorders (TMD).<sup>[1]</sup> Myofascial Pain Dysfunction Syndrome (MPDS) is a chronic pain disorder or a regional pain disorder and is caused by taut bands of muscle fibers called myofascial trigger points. In this condition, pressure on sensitive points in your muscles (trigger points) causes pain in the muscle and sometimes in seemingly unrelated parts of your body which is called referred pain.

MPDS is assumed to be caused by a number of unclear factors which include occlusal disturbances, intracapsular disorders and emotional turmoil.<sup>[2]</sup>

MPDS is managed by exercises, medications, physical therapy and ultrasound therapy. Therapeutic Ultrasound therapy is one such effective procedure for the management.

Nowadays ultrasound is not only used for diagnostic imaging but also widely used and accepted as an adjuvant treatment modality. US therapy shows vasodilatory effect due to deep heating as well as by accelerating the metabolism, enhancing viscoelasticity and decreasing pain and muscle spasm<sup>[3]</sup>. Most of the studies showed that moderate-dose US ( $0.8-1.5 \text{ W/cm}^2$ ) was effective in the management of myofascial pain. Additionally, an increase in the pressure pain threshold after several minutes of application was observed with low-dose US ( $520 \text{ W/cm}^2$ ) on trigger points in MPDS patients<sup>[4]</sup>

The aim of this study was to evaluate the role of ultrasound massage therapy in managing sign and symptoms of a patient with myofascial pain. This study was planned to evaluate the efficacy of Ultrasound massage therapy and conventional therapy in patients with Myofascial pain compared to those receiving only conventional therapy.

## 2. MATERIAL AND METHODS

### *Study Design:*

This randomized single blind study was carried out in the Department of Oral Medicine and Radiology of our institute. A total of 20 patients were included for the study within the age group of 18–60 years of either gender. This study was approved by Institutional Ethical Committee(Registration number ECR/328/Inst/MH/2016).

### *Sampling criteria:*

Patients were clinically evaluated for sign and symptoms of myofascial pain namely tenderness over TMJ area and tenderness over muscles of mastication with limited mouth opening. All those who fulfilled the above-mentioned criteria were included in the study. Patients with osteoarthritis, rheumatoid arthritis, any other TMJ disorder, patients with cardiac pacemakers and cardiac arrhythmias, pregnant ladies, any history of patients suffering from seizures, vascular disorders and neurological pain, mentally disabled patients, and patients with undiagnosed dental pain or who have skin lesions or facial abrasion at the site of acoustic gel placement were excluded from the study.

### *Study Method and observational parameters:*

Twenty patients were selected with clinical features of myofascial pain and were explained about the proposed research project. The study group consisted of 10 males and 10 female patients. The patients were distributed among the two groups as follows: odd numbered patients (Eg: 1, 3 and so on) were enrolled in group A and even numbered patients (Eg: 2, 4 and so on) were enrolled in group B. After obtaining the informed consent, data was recorded in the predesigned case proforma. In both the groups, Pain was evaluated using visual analog scale (VAS). These patients were subjected to radiographic examination to rule out any bony changes in the condylar region and odontogenic infection. These patients were evaluated for pain intensity on TMJ area, mouth opening, and masticatory muscle tenderness such as masseter, medial pterygoid, lateral pterygoid, temporalis, and other accessory muscles, separately on VAS scale. Patients were randomly divided into study and control group with equal number of males and females. In both the groups, conventional therapy was given to all patients i.e. Tab Ibuprofen, Clorzoxazone, Paracetamol( twice a day after food for 5 days), Relaxyl gel (to be applied 2- 3 times on affected area for 5 days) and hot fermentation over the affected area ( for 5-10 minutes after application of gel for 5 days) .

In the study group, in addition to the conventional therapy, therapeutic ultrasound therapy was also given to patients. Ultrasound therapy at the site of pain over the TMJ area using the head of an ultrasound probe that was placed in direct contact with the skin via a transmission coupling gel. The US model used was of P-7 (SOLIDSTATE ULTRASOUND), the therapy provided was with a frequency of 1 MHz and continuous setting at 1:1 for 6 min each session.

The treatment protocol followed was as follows: Once all the parameters were recorded, the patient were subjected to conventional therapy in both the groups. The study group were also subjected to 1<sup>st</sup> session of Therapeutic Ultrasound therapy. All the patients in both the groups were recalled on the 6<sup>th</sup> day, evaluated for the signs and symptoms and the study parameters were recorded and the study group patients were subjected to second session of the Therapeutic Ultrasound Therapy and both the groups were instructed to continue the conventional therapy for another 5 days. The study group were subjected to the 3<sup>rd</sup> and 4<sup>th</sup>

Session Of Ultrasound Therapy on the 11<sup>th</sup> and 16<sup>th</sup> day after the study parameters were recorded. After which the data acquired were tabulated and subjected to statistical analysis.

*Statistical Analysis:*

The analysis of the primary data was carried out using SPSS version 24. The following tests were undertaken:

1. To obtain data estimates, Descriptive Analysis of the dataset was carried out. Mean, Standard Deviation, and Range was observed for the data as all the variables i.e. Mouth opening (MO), Pain recorded as per visual analogue scale on TMJ, Masseter (M) and lateral pterygoid (LP) collected in the primary data were quantitative in nature except the gender of the patient for which frequencies were observed.
2. The means of the differences between the values of the two groups were compared using Wilcoxon Rank Sum Test/ Mann Whitney U-test.

### 3. RESULTS

The mean age of the patients in the study was between 18-60 years of age. Mouth opening, tenderness over Masseter, lateral pterygoid muscles and over TMJ area was compared in both the groups :- Control Group [ Group A] & Study Group [Group B]

Table 1 - Comparison between the tenderness of the muscle of mastication in the Study Group and Control Group

1a) Comparison between the tenderness over the Masseter muscle in the Study Group and Control Group (Table 1a and Figure 3)

At the start of the study, the tenderness over Masseter muscle in both the groups was almost similar (Study group – 8.4 mm and control group -8.2 mm). The therapy was started for both the groups and on first follow up , on day 6 the tenderness over Masseter muscle had reduced 6.1 mm in study group and 6.2 in control group . The reduction of tenderness over masseter muscle between the two groups was found to be statistically insignificant. At the end of second follow up which was on 11<sup>th</sup> day, the tenderness of muscle was further reduced to 4.1 mm in control group and 3.9 mm in study group, which was found to be statistically significant. On the final follow up, On day16th the tenderness over masseter muscle was reduced drastically in study group from 3.9 to 0.9 mm while in control group 4.1 to 3.9 mm. This reduction of tenderness over masseter muscle was found to be clinically as well as statistically significant.

1b) Comparison between the tenderness in the Lateral Pterygoid muscle in the Study Group and Control Group (Table 1b and Figure 4)

At the start of the study, the tenderness over lateral pterygoid muscle in both the groups was almost similar (Study group – 8.2 mm and control group -8.1 mm). The therapy was started for both the groups and on first follow up , on day 6 the tenderness over lateral pterygoid muscle had reduced 6.3 mm in study group and 6.5 in control group . The reduction of tenderness over lateral pterygoid muscle between the two groups was found to be statistically insignificant. At the end of second follow up which was on 11<sup>th</sup> day, the tenderness of muscle was further reduced to 4.5 mm in control group and 3.6 mm in study group, which was found to be statistically significant. On the final follow up, On day16th the tenderness over lateral pterygoid muscle was reduced drastically in study group from 3.6 to 1.8 mm while in control group 4.5 to 3.5 mm. This reduction of tenderness over lateral pterygoid muscle was found to be clinically as well as statistically significant.

Table 2 - Comparison between the tenderness over TMJ area in the Study Group and Control Group (Table 2 and Figure 5)

At the start of the study, the tenderness over TMJ area in both the groups was almost similar (Study group – 8.4 mm and control group -8.0 mm). On day 6, there was reduction in pain over TMJ area in both the groups. But, the reduction was more in study group than control group, it was not found to be statistically significant. On second follow up which was on 11<sup>th</sup> day, again showed reduction in pain which was further reduced to 4.8 mm in control group and 3.8 mm in study group, which was found to be statistically significant. On the final follow up, On day 16<sup>th</sup> the tenderness was reduced drastically in study group from 3.8 to 1.2 mm while in control group 4.8 to 3.3 mm. This reduction of tenderness over TMJ area was found to be clinically as well as statistically significant.

Table 3 - Comparison between the amount of Mouth Opening in the Study Group and Control Group (Table 3 and Figure 6)

At the start of the study, the amount of the mouth opening in control group was slightly more than control group (Study group – 35.1 mm and control group - 33.9 mm). The therapy was started for both the groups and on first follows up, on day 6 the significant improvement in the amount of mouth opening. At the end of second follow up which was on 11<sup>th</sup> day, the amount of mouth opening was further increased to 36.2 mm in control group and 36.9 mm in study group, which was found to be statistically significant. On the final follow up, On day 16<sup>th</sup> the amount of mouth opening was drastically increased in study group from 36.9 to 37.9 mm while in control group 36.2 to 36.7 mm. The improvement in amount of mouth opening was found to be clinically as well as statistically significant.

The two groups were compared using Wilcoxon Rank Sum Test/ Mann Whitney U- test.

A. When Mann-Whitney U test was carried out for the Pain measured at TMJ, the p-value obtained was 0.003. Since  $p < 0.05$ , we can reject the null hypothesis that there is no difference between the improvements observed in both groups. And as observed in table 4, group B shows better improvement in pain.

B. When Mann-Whitney U test was carried out for the Pain measured at Masseter, the p-value obtained was 0.003. Since  $p < 0.05$ , we can reject the null hypothesis that there is no difference between the improvements observed in both groups. And as observed in table 4, group B shows better improvement in pain.

C. When Mann-Whitney U test was carried out for the Pain measured at LP, the p-value obtained was 0.019. Since  $p < 0.05$ , we can reject the null hypothesis that there is no difference between the improvements observed in both groups. And as observed in table 4, group B shows better improvement in pain.

D. When Mann-Whitney U test was carried out for the mouth opening, we observed that  $p < 0.001$ , hence we can reject the null hypothesis that there is no difference between the improvements observed in both groups. And as observed in table 4, group B shows better improvement in mouth opening.

Study Group was showing a significant improvement in both pain reduction as well as mouth opening. So, we can say Ultrasound therapy plays a significant role in improvement of both. But as we observe this improvement because of Ultrasound was seen significant on Day 11 and Day 16, so it suggests that Ultrasound therapy should be given for at least 15 days to get better results.

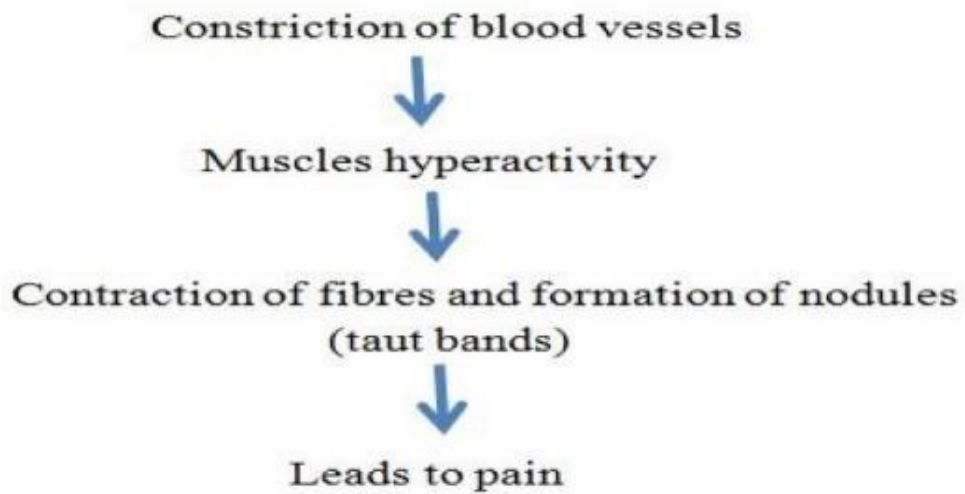


Fig 1: Mechanism to show how pain occurs<sup>2</sup>

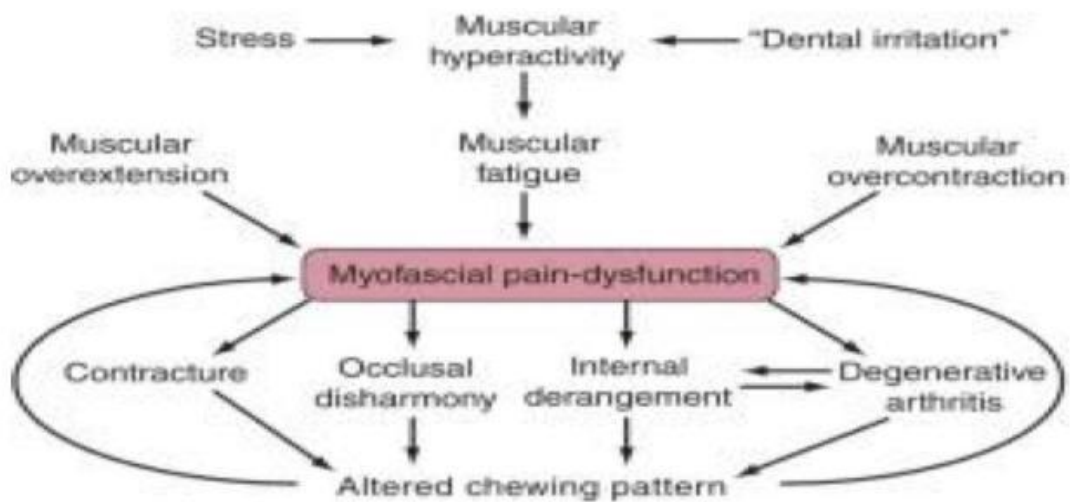


Fig 2: The flowchart show some of the factors and how it leads to the myofascial pain dysfunction.<sup>2</sup>

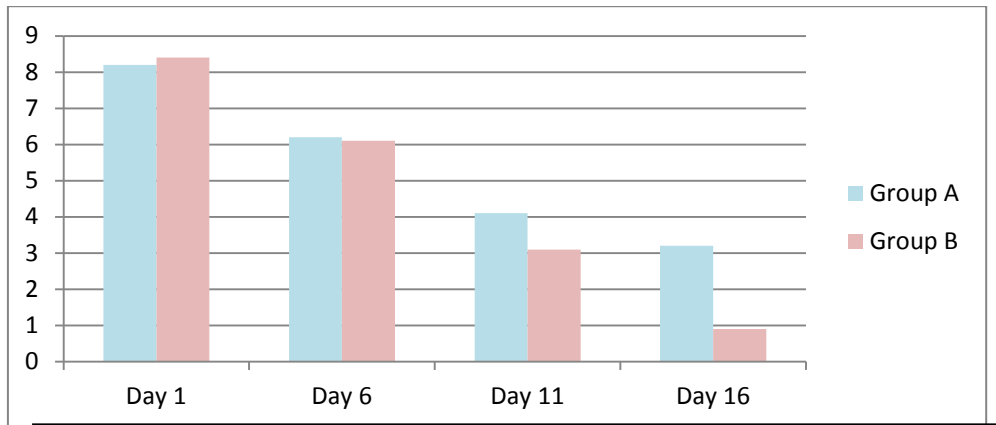


Figure 3 Graph depicting Pain at Masseter on Day 1, 6, 11 and 16 for Groups A and B

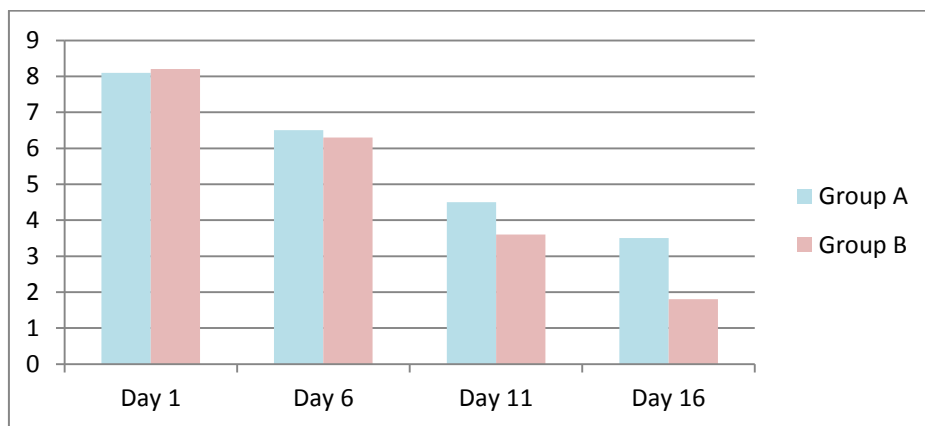


Figure 4 Graph depicting Pain at Lateral Pterygoid on Day 1, 6, 11 and 16 for Groups A and B

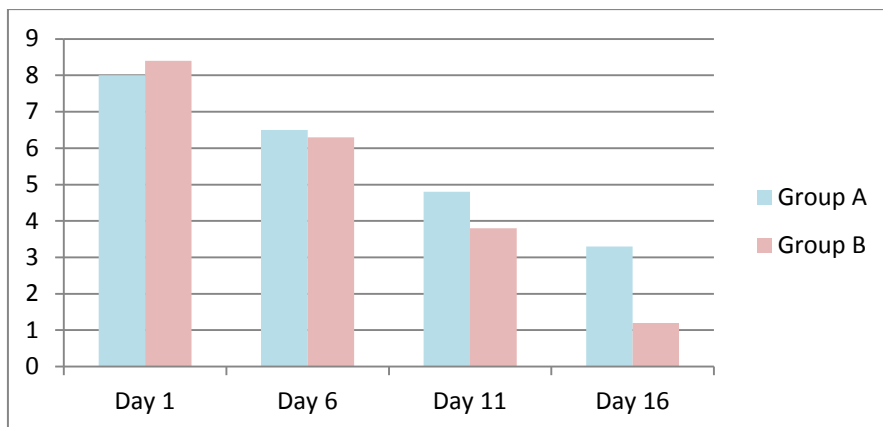


Figure 5 Graph depicting Pain at TMJ on Day 1, 6, 11 and 16 for Groups A and B

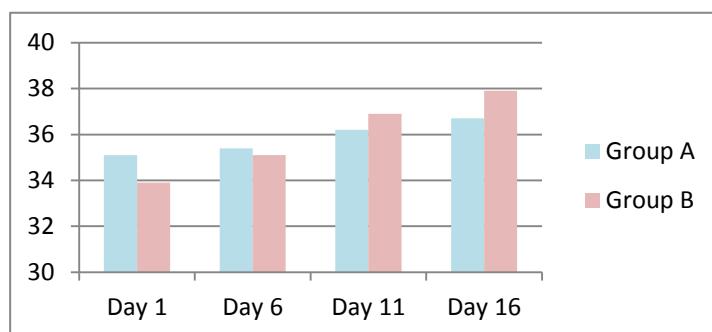


Figure 6 Graph depicting mouth opening on Day 1, 6, 11 and 16 for Groups A and B

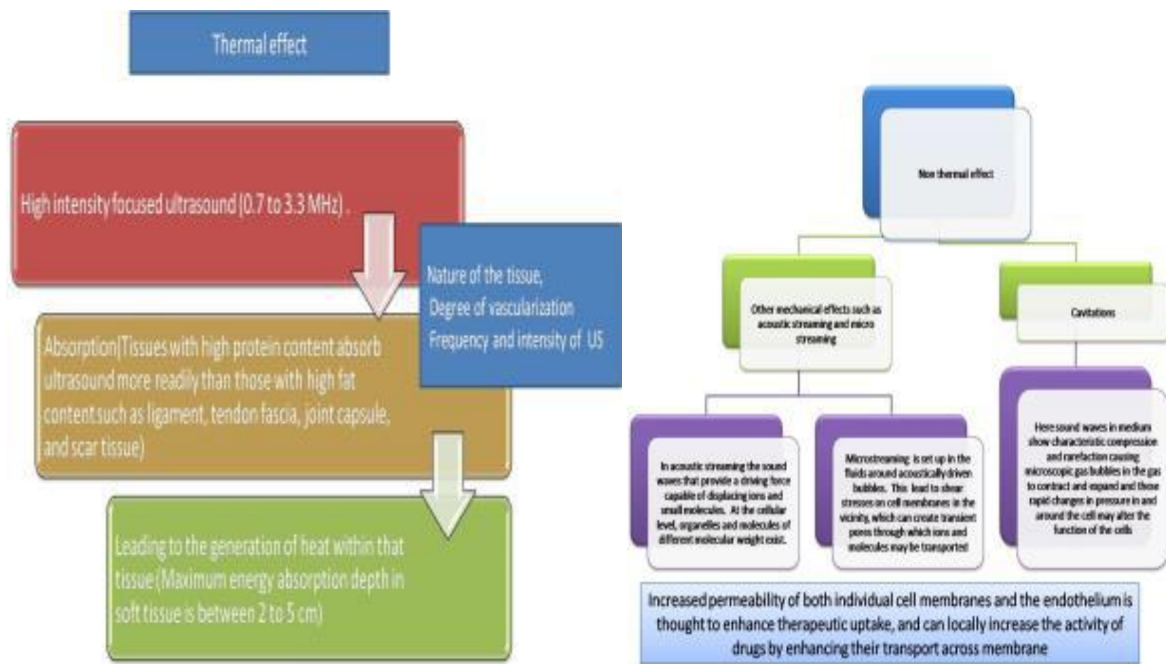


Figure 7,8: Thermal effect of Ultrasound, Non thermal effect of Ultrasound

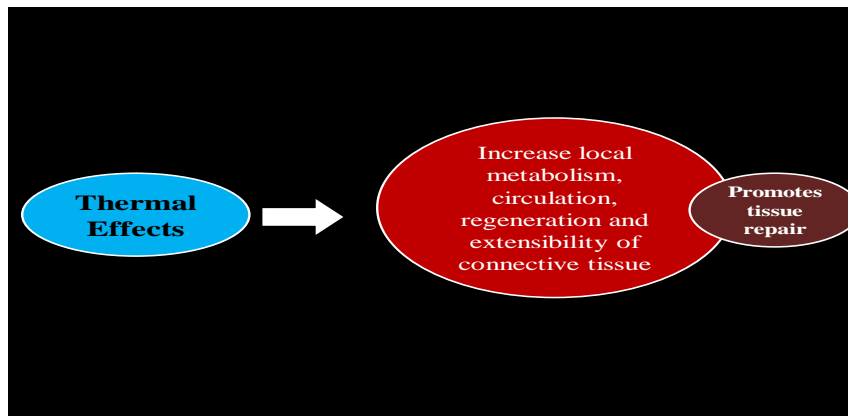


Figure 9- Mechanism of action of Therapeutic Ultrasound

Table 1a- Showing Comparison between the tenderness over the Masseter muscle in the Study Group and Control Group

VAS in mm	At start of the study	Day 6	Day 11	Day 16
Control Group	8.2	6.2	4.1	3.2
Study Group	8.4	6.1	3.9	0.9



Table 1b – Showing Comparison between the tenderness over the lateral pterygoid muscle in the Study Group and Control Group

VAS in mm	At start of the study	Day 6	Day 11	Day 16
Control Group	8.1	6.5	4.5	3.5
Study Group	8.2	6.3	3.6	1.8

Table 2 – Showing Comparison between the tenderness over TMJ area in the Study Group and Control Group

VAS in mm	At start of the study	Day 6	Day 11	Day 16
Control Group	8.0	6.5	4.8	3.3
Study Group	8.4	6.3	3.8	1.2

Table 3 – Showing Comparison between the amount of Mouth Opening in the Study Group and Control Group

In mm	At start of the study	Day 6	Day 11	Day 16
Control Group	35.1	35.4	36.2	36.7
Study Group	33.9	35.1	36.9	37.9

#### 4. DISCUSSION

Temporomandibular disorders (TMDs) are a collection of medical and dental conditions that affect the muscles of mastication along with transmittable tissue components. Physical modality is considered to be an important treatment to relieve musculoskeletal pain to reduce inflammation and to restore oral motor function. The utility of ultrasound (US) for therapeutic purposes in dental is still in its infancy. Ultrasound therapy is a treatment modality commonly used in physical therapy.

Different studies were carried out by different authors to evaluate the efficacy of ultrasound therapy in patients with TMDs. Handa R et al in 2018 and Rai et al in 2016 concluded that US massage therapy in TMJ pain is effective and showed significant improvement in pain as well as in mouth opening.<sup>[5,6]</sup> Ilter L et al. in 2015 carried out a study it concluded that Continuous ultrasound therapy is more efficient in reducing pain at rest for myofascial pain syndrome patients than pulsed ultrasound therapy.<sup>[7]</sup> AtefAbdEl et al in 2014 carried out a similar study , they concluded that US therapy can be used as an adjunctive therapy in myofascial pain .Ultrasound therapy is promising with little or no complications. Also, since it is a noninvasive therapy it can use with or without other treatment modalities for compromised patients<sup>[8]</sup>.Ucar M et al in 2014,it concluded that addingUS to an HE program may better improve the symptoms of patients with TMD<sup>[9]</sup>. UnalanHetal in2011,they found that the relief obtained by both the therapies was similar and therefore concluded that HPPTUS technique can be used as an effective alternative to TrP injection in the treatment of myofascial pain syndrome<sup>[10]</sup>.

A study by Grieder *et al* in 1971 concluded that the ultrasound therapy is more effective when used as an adjunct to the accepted modalities of therapy compared to when it is used alone<sup>11</sup>. Esposito *et al* in 1984 and Trakrooetal in 2014 concluded that ultrasound is more effective in

reducing muscle symptoms as compared to reducing symptoms associated with the disk<sup>12, 13</sup>. Esenyelet *al* in 2000 compared the effectiveness of ultrasound therapy and trigger point injections therapy and found that the results were comparable. The advantage of US therapy being non-invasive was pointed out by them<sup>14</sup>.

US were first used in therapeutic modality in 1950s, late 1960s and 1970s. Reports on non-thermal therapeutic effects primarily in the area of enhanced tissue healing, further bolstered its popularity. Ultrasound therapies are divided into “high” power (include high intensity focused ultrasound (HIFU) and lithotripsy) and “low” power therapies (include sonophoresis, sonoporation, gene therapy, and bone healing).<sup>15</sup> Therapeutic ultrasound (Th US) is a noninvasive therapeutic method which includes vibrations above 16,000 vibrations/s or 16 Hz (range audible to the human ear). The frequency used is between 1.0 and 3.0 MHz<sup>16,17</sup>. It is known to accelerate healing, decrease joint stiffness, alleviate pain, increase the extendibility of collagen fibers, and reduce muscle spasm<sup>11,12</sup>. The Arndt-Schulz law states that weak stimuli increase physiologic activity and very strong stimuli inhibit or abolish activity. In treating the head and neck, one should always use weak intensity for ultrasonic therapy. The weak intensity used for therapy is 0.1-0.6 W/cm and in no case should the treatment exceed 0.6 W/cm or a total output of 3 W<sup>11</sup>

Therapeutic US can have either a thermal effect from absorption (Figure 7) or a non-thermal effect from scattering (Figure 8). The most common uses for US were to decrease soft tissue inflammation, increase tissue extensibility, enhance scar tissue remodeling, increase soft tissue healing, decrease pain and decrease soft tissue swelling. Other uses were to deliver medication for soft tissue inflammation, pain management and soft tissue swelling.<sup>18,19</sup>

Ultrasound therapy has its thermal and mechanical effects on the tissues which include increase in local metabolism, increase in blood flow and also removes inflammatory mediators and prevent accumulation of inflammatory mediators at site of pain. So, overall it promotes tissue repair and hence, reduction in pain and muscle spasm bounds to improves mouth opening. (Figure 9)

## 5. CONCLUSION

With changing trends in dentistry, the old gold standards are getting replaced with newer modalities. US massage therapy in myofascial pain disorders are effective and show significant improvement in pain as well as in mouth opening. Also, being non-invasive, Ultrasound therapy can be considered as potent and therapeutic modality in relieving Myofascial pain.

## 6. LIMITATION

Only the small sample size of the study .

Source of funding: Nil

Conflict of interest: None

Ethical policy and Institutional Review board statement: BharatiVidyapeeth(Deemed to be University) Dental College & Hospital, Pune Institutional Ethics Committee Registration no- ECR/328/Inst/MH/2016Date – 14-09-2018

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*Legends of Tables:*

Table 1a- Showing Comparison between the tenderness over the Masseter muscle in the Study Group and Control Group

VAS in mm	At start of the study	Day 6	Day 11	Day 16
Control Group	8.2	6.2	4.1	3.2
Study Group	8.4	6.1	3.9	0.9

Table 1b – Showing Comparison between the tenderness over the lateral pterygoid muscle in the Study Group and Control Group

VAS in mm	At start of the study	Day 6	Day 11	Day 16
Control Group	8.1	6.5	4.5	3.5
Study Group	8.2	6.3	3.6	1.8

Table 2 – Showing Comparison between the tenderness over TMJ area in the Study Group and Control Group

VAS in mm	At start of the study	Day 6	Day 11	Day 16
Control Group	8.0	6.5	4.8	3.3
Study Group	8.4	6.3	3.8	1.2

Table 3 – Showing Comparison between the amount of Mouth Opening in the Study Group and Control Group

In mm	At start of the study	Day 6	Day 11	Day 16
Control Group	35.1	35.4	36.2	36.7
Study Group	33.9	35.1	36.9	37.9

Table 4-Improvement in Mouth opening, Pain at TMJ, Masseter and LP

Group		Mean	Std. Deviation
DiffTMJ	Group A	4.70	1.059
	Group B	7.20	1.549
Diff_M	Group A	5.00	0.943
	Group B	7.50	1.650
Diff_LP	Group A	4.60	0.843
	Group B	6.40	1.578
Diff_MO	Group A	1.60	0.843
	Group B	4.00	0.943

Results of the Mann- Whitney U test

**Hypothesis Test Summary**

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of DiffTMJ is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.003 <sup>1</sup>	Reject the null hypothesis.
2	The distribution of Diff_M is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.003 <sup>1</sup>	Reject the null hypothesis.
3	The distribution of Diff_LP is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.019 <sup>1</sup>	Reject the null hypothesis.
4	The distribution of Diff_MD is the same across categories of Group.	Independent-Samples Mann-Whitney U Test	.000 <sup>1</sup>	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

<sup>1</sup>Exact significance is displayed for this test.