SHORT TERM EFFECT OF THERABITE® ON TEMPOROMANDIBULAR JOINT DYSFUNCTION: RANDOMIZED CONTROLLED TRIAL

EFECTUL PE TERMEN SCURT AL THERABITE® ÎN DISFUNCŢIA ARTICULAŢIEI TEMPOROMANDIBULARE: STUDIU RANDOMIZAT

Richa Singh[1], Keerthi Rao[2], Chandra Iyer[3], Deepak Anap[4], Subhash Khatri[5], Neha Kanjolia[6] , Jalpa Shah[7]

Key words: temporomandibular dysfunction TheraBite®.

Abstract:

Purpose. To determine the effect of TheraBite® on range of motion by TheraBite scale and pain intensity on Visual Analogue scale in Temporomandibular dysfunction.

Method. The study duration was from February 2012- November 2012. Fifty participants both males and females based on inclusion and exclusion criteria were alternately allocated in two groups Group A and Group B. There were 25 participants in each group. There were 2 drop out in group B. Group A received therapeutic ultrasound and exercise with TheraBite, while group B received therapeutic ultrasound, manual stretching and Maitlands mobilization exercises. Both the groups received treatment for 6 days a week for 3 weeks. Assessment was done on day 1 and at the end of 3rd week.

Results. There was no significant difference seen in both the groups in relation to the pain intensity ($p>0.05$) on VAS. While in range of motion for mouth opening, lateral deviation to right and left side of mandible and protrusion there was highly significant difference seen ($p<0.01$) between the groups .

Conclusion. Stretching device i.e TheraBite can

Cuvinte cheie: disfuncţie temporomandibulară, TheraBite®.

Rezumat:

Scop. Determinarea efectului TheraBite® asupra amplitudinii de mişcare, pe scala şi intensitaea durerii pe scala Visuală Analogă, în disfuncţia temporomandibulară.

Metodă. Studiul s-a desfăşurat în perioada februarie 2012 - noiembrie 2012. 50 de participanţi, atât bărbaţi cât şi femei, pe baza criteriilor de incluziune şi excluziune, au fost repartizaţi alternativ în două grupuri: A şi B. În fiecare grup au fost 25 de participanţi. Din grupul B s-au retras două persoane. Grupul A a beneficiat de tratament cu ultrasunet şi exerciţii cu TheraBite, iar grupul B a beneficiat de ultrasunet, stretching manual şi exerciţii de mobilizare Maitland. Ambele grupuri au efectuat tratamentul timp de 6 zile pe săptămână, timp de 3 săptămâni. Evaluarea s-a realizat la începutul şi la sfârşitul tratamentului.

Rezultate. Nu s-au înregistrat diferenţţiee semnificative între cele două grupuri în ceea ce priveşte intensitatea durerii ($p>0.05$), evaluată cu VAS. În ceea ce priveşte amplitudinea de mişcare pentru deschiderea gurii, deviaţia laterală spre stânga şi dreapta a mandibulei şi protruzia, s-au înregistrat diferenţe mari semnificative ($p<0.01$) între cele două grupuri.

Concluzii. Dispozitivul de stretching TheraBite poate fi un instrument folositor în tratarea TMD cu trismus.

[1] Postgraduate Student, College of Physiotherapy,PIMS, Loni
Corresponding author: riichasingh@gmail.com
[2] Associate Professor, College of Physiotherapy,PIMS, Loni
[3] Associate Professor, College of Physiotherapy,PIMS, Loni
[4] Associate Professor, College of Physiotherapy,PIMS, Loni
[5] Principal & HOD, College of Physiotherapy,PIMS, Loni
[6] Postgraduate Student, College of Physiotherapy,PIMS, Loni
[7] Postgraduate Student, College of Physiotherapy,PIMS, Loni

Introduction

Temporomandibular dysfunctions/ disorders (TMDs) comprises of a complex and heterogeneous group of conditions which include Temporomandibular joint (TMJ), soft tissue structures within the joint and the muscles of mastication. [1,2] In 1934, Costen was the first one to describe the signs and symptoms of TMD[3]. TMDs are also referred to as craniomandibular disorders, costen's syndrome, pain dysfunction syndrome and facial arthromyalgia. [3,4] It is seen that about 75% of adult population have at least one symptom associated with TMDs, and 30% have more than one symptom while 3-7% apply for treatment. There is an estimation that 20-25% of the population is affected with TMDs, with female to male ratio being 3:1 to 6:1[5].
The Research Diagnostic Criteria for TMDs (RDC-TMDs) have classified TMDs by a dual- axis system. The RDC-TMD classification was developed for research purpose. This classification does not include less common conditions such as myositis, contracture and myospasm and TMJ conditions such as rheumatic disease, acute trauma, hyperplasia and noeplasia. [6]

The aetiology of TMDs are little understood, but has been associated with many theories and factors. The signs and symptoms related to TMDs include the masticatory muscles or TMJ or both which are jaw pain, orofacial pain, limited mouth opening (trismus) and other ranges, headache, ear pain, clicking or grating of the joint, neck pain, tinnitus and pain in the intra oral structures[8-10]. If this condition is not treated promptly and properly, its hidden disability can seriously affect health and quality of life. [11]

Currently, for TMD various treatments are available from simple self-care practice, reassurance, conservative treatment, injections to surgeries. The physical therapy includes hot and cold packs, electrotherapeutic modalities, manual treatment, acupuncture and mechanical devices. [7,12,13]

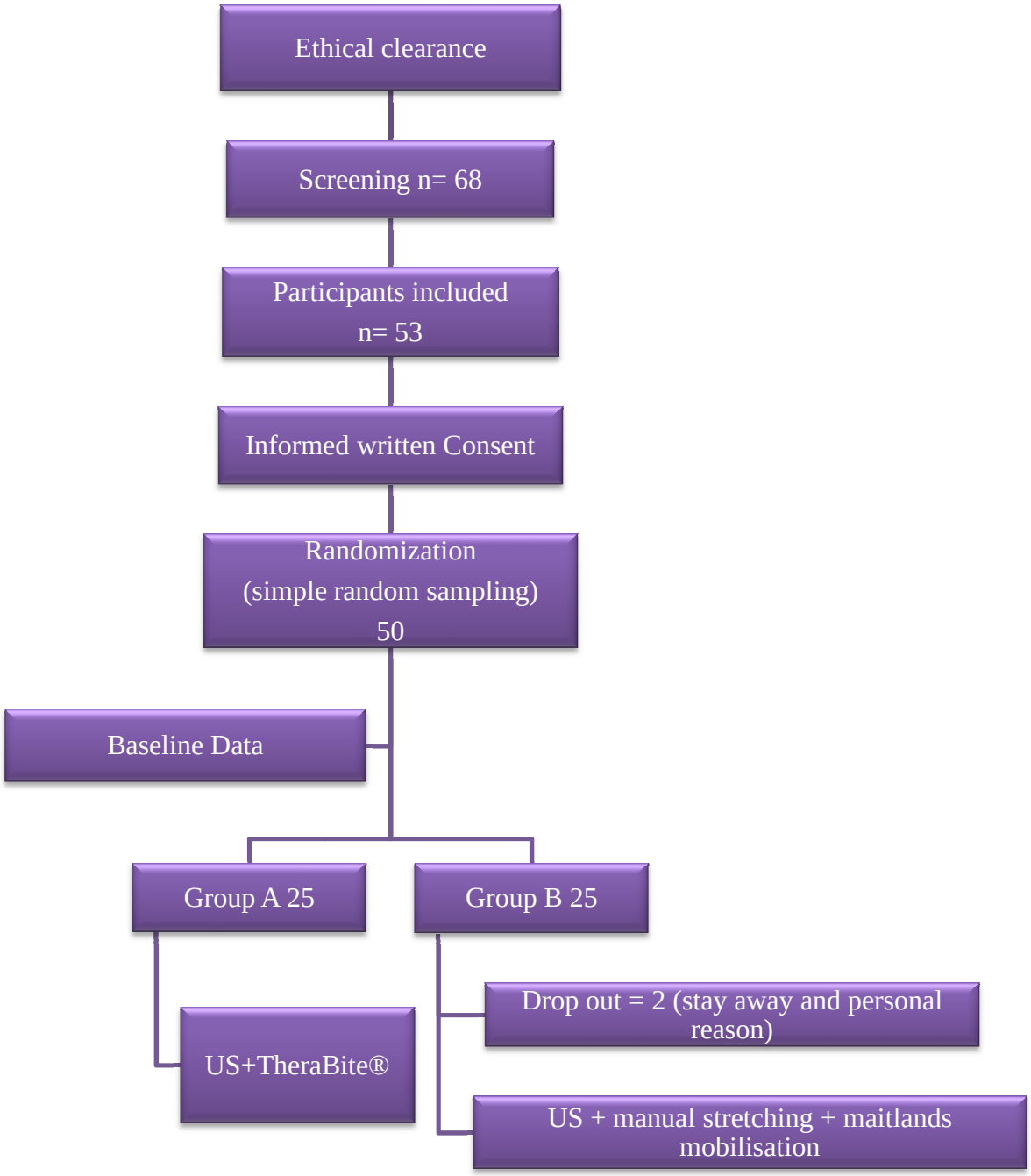
The TheraBite® Jaw Motion Rehabilitation System™ from Atos medical inc.is a portable system which utilizes repetitive passive motion and stretching to restore mobility and flexibility of the jaw musculature, associated joints and connective tissues. The TheraBite is a patient-controlled, mechanical device, with two mouthpieces that are inserted between the teeth of the upper and lower jaw. By squeezing the handles, the mouthpieces open, assisting the mouth opening. It is designed in order to accomplish two objectives, increase the range of motion and pain reduction. [11] Authors have suggested that along with modality, stretching exercise and mobilisation has also helped to increase the range of motion and decrease pain[13,18,17,21], but there is limited evidence as to which is the most appropriate and effective treatment approach. Hence, the present study was aimed to compare the conventional treatment (US, stretching and TMJ mobilisation) and TheraBite® on range of motion and pain for five days/ week for three weeks in patients having TMD.

Methods

Subjects:
50 participants whose age ranges from 20 to 40 years, with TMJ pain, having trismus (≤40mm to ≥8mm), in sub-acute or chronic stage of TMD, with bilateral and unilateral involvement and willing to participate were selected randomly from the Dental department. Participants were excluded if they had any of the following congenital abnormality, concomitant inflammatory or neoplastic conditions any form of treatment within the last month, any surgical intervention for TMJ, Arthritis of TMJ any deviation of mandible and Internal derangement.
Outcome measures:

1. VAS (Visual Analogue Scale): Visual analogue scale was used to measure the intensity of pain before and after the intervention. Highest reported reliability is 0.84. [29]
2. Range of motion of Temporomandibular joint: TheraBite range of motion scale was used to measure TMJ motions before and after the intervention. Highest reported reliability was 0.98[30].All the outcome measures had considerably good reliability and validity.

Procedure



Participants were divided into 2 groups experimental and control group each having 25 participants. Both the groups received therapeutic ultrasound of 1 MHz frequency andcontinuous mode set at 1.25 W/cm, for 3 minutes was applied. [16] (fig 1).

Fig 1: Ultrasound

Experimental group was given therabite jaw motion rehabilitation therabite.us@atosmedical.com was used for increasing the mouth opening which was given for five session per day, five repetition per session with thirty seconds hold (fig 2).

Fig 2: Therabite exercise

For control group Stretching was given to increase the mouth opening for 6 days per week with 4 stretches and 30 seconds hold. [20] (fig 3).

Fig 3: manual stretching

Mobilization – distraction, translation and lateral glide was given for one session with 3 repetitions for 30 seconds. [22] (fig 4,5). Grade 1 and 2 was given to reduce the pain. Once the pain was reduced grade 3 and 4 is given to increase the range of motion. [19].

Fig 4: mobilisation for distraction and translation

Fig 5: mobilisation for lateral glide

Participants received 18 sessions (6 days per week) of 45-60 minutes over the period of 3 weeks. This study was approved by the institutional ethical committee, Pravara institute of medical science ref.no PIMS/CPT/2012/1242/2. All participants were free to withdraw from the study at any time.

Results

Data was analyzed with Graph pad Instat Trial version 13.3. Confidence interval was set at 95%. The data was entered into an excel spread sheet, tabulated and subjected to statistical analysis. Age, BMI, intensity of TMJ pain, active range of motion of TMJ at the baseline for both the groups were analyzed by using student 't' test.

Baseline characteristics across both the groups were similar and are summarized in table no1.

Table1: Demographic data of both the groups

Group	Experimental group (n=25)	Control group (n=23)	P value	Inference
Age (years)	31 ± 5.097	30.86 ± 6.130	0.3099	Not significant
Gender (F/M)	15(60.00%)/ 10(40.00%)	14(60.86%)/ 9(39.13%)		
BMI (Kg/cm^2)	22.89 ± 2.917	22.8 ± 4.377	0.4639	Not significant

50 individuals with TMD had participated in the study and out of them two participants from the control group did not complete the study. No adverse effect was noted during the study period.

Significant difference on intra group comparison (p<0.01)for intensity of pain in both the groups while in inter group comparison there wasn't any significant difference seen. Therapeutic ultrasound was equally effective for both the groups (table 2).

Significant difference was also seen on the active range of motion of TMJ on intra group comparison in both the groups and there was highly significant difference seen in inter group comparison for TMJ mobility (p<0.01). TheraBite was more effective treatment given to increase the TMJ mobility (table 3,4,5,6).

Table2: Pain relief in intra and intergroup comparison

VAS	mean±SD		'p' value
	Pre	post	
Control group	6.870±0.9679	1.087±0.5964	p<0.01
Experimental group	6.320±1.069	0.7600±0.7234	p<0.01
Control vs experimental	Control	experimental	
	5.78±1.043	5.56±0.9165	p>0.05

Table3: Mouth opening in intra and inter group comparison

Mouth opening (mm)	mean±SD	
	Pre	Post
Control group	25.043±5.819	36.435±4.561
Experimental group	21.000±5.958	39.920±2.812
Control vs experimental group	Control	Experimental
	11.739±3.957	19.32±5.809

Table 4: Lateral deviation to right in intra and inter group comparison

Lateral deviation to right	mean±SD	
	pre	Post
Control group	3.609±0.7223	7.348±0.9346
Experimental group	2.960±1.098	8.280±1.242
Control vs experimental group	control	Experimental
	3.739±1.054	5.32±0.9452

Table 5: Lateral deviations to left in intra and inter group comparison

Lateral deviation to left	mean±SD	
	pre	Post
Control group	3.522±0.7903	7.348±0.6473
Experimental group	2.760±1.012	8.160±1.106
Control vs experimental group	control	experimental
	3.826±1.072	5.4±1.000

Table 6: Protrusion of mandible in intra and inter group comparison

Protrusion	mean±SD	
	pre	post
Control group	1.130±0.7570	4.609±0.8973
Experimental group	1.200±0.9574	7.280±1.021
Control Vs experimental group	control	Experimental
	3.478±0.8980	6.08±0.7594

Discussion

The present study shows that the intervention given to both the groups was effective in terms of reduction of pain intensity and in increase TMJ range of motion, irrespective of the treatment received which was conventional or TheraBite. However, it was observed that the overall improvement was significant in the TheraBite group as compared to the control group. Significant reduction in intragroup and intergroup comparison could probably be because of the use of therapeutic ultrasound which is in accordance with the work of previous investigators as the therapeutic ultrasound was common for both the groups. [7,16]

Therapeutic ultrasound is reported to reduce oedema, relieve pain and accelerate tissue repair. Studies have shown that there is significant improvement in pain by the application of therapeutic ultrasound rather than placebo ultrasound in knee osteoarthritis. [23,28]

In the present study US was applied at Continuous modedeliveredat1MHz frequency to the TMJ at 1.0-1.25 W/cm^2 intensity for 3 minutes, which was well tolerated by the patients and it helped in reduction of pain. [16] Continuous US applied at 1.5W/cm^2 for 3-5 minutes over a period of 3 weeks followed by exercise is proven to be more beneficial rather than exercise alone in patients with shoulder pain. [24] Ultrasound given at low intensities and high frequency are given to areas where there is less soft tissues coverage and where bone is closer to the skin. [25] At the intensity of 1.25w/cm^2, the sound waves which causes tissue vibration, creates heat in the treatment field. As there is heat generated, there is also an increase in the blood flow to the tissues, which delivers important nutrients and removes waste. There is decrease in pain due to resolution of inflammation, removal of waste products or there is altered permeability of cell membrane to sodium, which may alter electrical activity or pain threshold. [26]

Experimental group received stretching by TheraBite device while control group received manual stretching. Both the stretching technique which was intermittent in nature works on the principle of cyclic stretching. In cyclic muscle stretching, the amount of deformation that occurs is determined by the number of cycles, the rate of deformation, and the amount and duration of force per cycle. This is in contrast to low load prolonged stretching where soft tissues are stretched; the elongation is in proportion to the magnitude of the locally applied load. Reduced time interval helps to regain a functional range of motion which will be desirable economically and psychologically to the patients. The length of time that the muscle is stretched during the treatment is of considerable importance. [27]

Currently various treatment are available to increase the mouth opening like unassisted mouth opening, finger assisted stretching exercises, spatulas, screws, wooden tongue depressor etc. The devices used are wedged between the upper and the lower jaw, the front teeth, this placement can loosen teeth or can dislodge crowns. They are difficult to use and cause only simple static stretching. But TheraBite is simple and easy to use. Squeezing the handle helps to separate the upper and lower jaw. The horse-shoe shaped surface which comes in contact with the teeth helps to spread the load across 10 anterior teeth at upper and lower jaw. This generates less force on the incisors. As there is squeezing and releasing of the handles it helps to stretch the tissues intermittently. [14,15] Hence, there is more significant improvement seen in experimental group

Maitland mobilization was also given to control group and it was observed that there was extremely significant difference seen in the range of motion of TMJ ($P<0.01$) which could be justified by the mechanical force applied may include breaking of adhesions, realigning collagen or increasing fiber glide, when stress is placed on specific part of the capsule by specific movement. Mobilisation is supposed to increase or to maintain the joint mobility by promoting biological changes in the synovial fluid, enhancing exchange. It consists of rhythmic oscillatory movement which stimulates type II dynamic mechanoreceptor and in turn inhibits the type IV nociceptive receptors. Its rhythmic oscillation also affects the circulatory perfusion. [6] As seen in the present study there was increase in the ranges of TMJ in the control group. Stretching and mobilisation would have contributed to the change in the range. But, there was greater

improvement seen in the TheraBite group. The limitation of this study was small sample size and no follow up of the participants were done.

Conclusion. Stretching device i.e TheraBite can be a useful tool in treating TMD with trismus.

Acknowledgement. Special thanks to Principal, COPT and our participants.

References

[1] AmitaAditya, ShaileshLele, PriyamAditya (2012) Prevalence of symptoms associated with Temporomandibular disorders in patients with psychosocial disorders. *Journal of International Dental and Medical Research;*5(1): 26-29.
[2] Silverman, Eversole, Truelove*Essentials of oral medicine* ©2002 BC decker Inc. chap 30:239-250.
[3] J. Durham (2008)*Temporomandibular disorders (TMD): an overview*. Oral Surgery;1:60–68.
[4] Margaret L McNeely, Susan Armijo Olivo, David J Magee (2006), *A* Systematic Review of the Effectiveness of Physical Therapy Interventions forTemporomandibularDisorders, *Physical Therapy*; 86 (5) 710-725 .
[5] Kurtulufl Kaya, SibelÜnsalDelialiolu, Muzaffer Babada et al. (2010), Combined Physiotherapy in Patients with Arthrogenous Pain of Temporomandibular Joint, *JPMR Sci;*13:6-14.
[6] Greenberg, Glick, Ship Burket's*oral medicine* 11th edition © 2008 BC Decker Inc. Hamilton. Chap 9:238.
[7] Edward F. Wright, Sarah L. North (2009) Management and Treatment of Temporomandibular Disorders: A Clinical Perspective, *J Man ManipTher*; 17(4): 247–254.
[8] Ali Jakubowski (2010) *The effects of manual therapy and exercise for adults with Temporomandibular joint disorders compared to electrical modalities and exercise. Pacific University School of Physical Therapy.* PT Critically Appraised Topics. *http://commons.pacificu.edu/ptcats/13.* Accessed on 5/01/2012.
[9] Eric S. Furto, Joshua A. Cleland et al (2006) Manual Physical Therapy Interventions and Exercise for Patients with Temporomandibular Disorders. *The Journal Of Craniomandibular Practice*; 24(4): 1-9.
[10] Azam S. Madani and AmirtaherMirmortazavi (2011) Comparison of three treatment options for painfulTemporomandibular joint clicking, *Journal of Oral Science*; 53 (3), 349-354.
[11] Stratmedtherabite system brochure Atos medical.*www.therabite.com*accessed on 1/01/2012.
[12] WaseemJerjes**,** TahwinderUpile**,** SyeddaAbbasetal (2008) Muscle disorders and dentition-related aspects in Temporomandibular disorders: controversies in the most commonly used treatment modalities. *International Archives of Medicine*;1:1-23.
[13] Ana Paula Dall´Anese, Karin Schultz, Karina Braga Ribeiro (2010), Early and Long-Term Effects of Physiotherapy for Trismus in Patients Treated for Oral and Oropharyngeal Cancer. *Applied Cancer Research;*; 30(4):335-9
[14] A.J. Gibbsons, S. Abulhol (2006) Use of a TheraBite appliance in the management of bilateral mandibular coronoid hyperplasia British, *Journal of oral and maxillofacial surgery*;(5): 505-506.
[15] George E. Maloney, Noshir Mehta, Albert G. Forgione et al (2002) Effect of a Passive Jaw Motion Device on Pain and Range of Motion in TMD Patients Not Responding to Flat Plane Intraoral Appliances.*The Journal OfCraniomandibularPratice*; 20(1):55-66.
[16] Forrest 1. Waid, James Montana, Daniel M. Badeet al (1992) Tolerance of Ultrasound over the Temporomandibular Joint, *JOSPT*; 13(*5)*: 206-208.
[17] Vaishali M R, RoopashriG, Maria Priscilla et al (2010) Trismus, *IJDA*;2(3): 303-308.
[18] Aveed Samiee, Daniel Sabzerou, Faraz Edalatpajouh (2011) Temporomandibular joint injection with corticosteroidand local anesthetic for limited mouth opening. *Journal of Oral Science*; 53(3): 321-325.
[19] Carolyn Kisner and Lynn Allen Colby (2007), *Therapeutic exercise foundation and techniques*. ©.5thedition.jaypee.chap 5. 114-119.
[20] B Dadebo, J White, K P George (2004) A survey of flexibility training protocols and hamstring strains in professional football clubs in England, *Br J Sports Med;* 38:388–394.
[21] Sevinc Kulekcioglu et al (2003) Effectiveness of low-level laser therapy in temporomandibular disorder, *Scand J Rheumatol*; 32:114–8.
[22] Mark Gugliotti (2011) The Use of Mobilization, Muscle Energy Technique, and Soft Tissue

Mobilization Following a Modified Radical Neck Dissection of a Patient withHead and Neck Cancer, *Rehabilitation Oncology*; 29(1): 3-8.

[23] F Tascioglu, S Kuzgun, O Armagan et al (2010) Short term effectiveness of ultrasound thereapy in knee osteoarthritis.*The journal of international medical research*; 38(4): 1233-1242.

[24] Michelle H. Cameron. *Physical agents in rehabilitation from research to practice*. 2nd edition. ©2003 Saunders. Chap 7. 195-197.

[25] David 0. Draper, Chris Castel, Dawn Castel (1995) Rate of Temperature Increase in Human MuscleDuring 1 MHz and 3 MHz ContinuousUltrasound, *JOSPT*; 22 (4): 142-150.

[26] Koneru J, Alaparthi R, Yalamanchali S et al (2012) Therapeutic ultrasound- the healing sound an its application, in oral disease: The review of literature, *Jorofac Science*; 4: 3-6.

[27] Deborah Turner Starring, Marilyn R Gossman, Garvice G Nicholson (1988) Comparison of Cyclic and Sustained Passive Stretching Using a Mechanical Device to Increase Resting Length of Hamstring Muscles, *PHYS THER.*; 68:314-320.

[28] Subhash Khatri, *Basics of Electrotherapy*, 2stedition, ©2012 Jaypee publishers, New Delhi Therapeutic ultrasound, pages 103-104.

[29] Boonstra, Anne M., SchiphorstPreuper, Henrica R., Reneman, Michiel F et al (2008) Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain; *International Journal of Rehabilitation Research*; 31(2): 165-169.

[30] Merete Bakke, RagnheiðurHansdottir, Akureyri (2008) Mandibular function in patients with Temporomandibularjointpain: A 3-year follow-up; *oral Surg Oral Med Oral Pathol Oral Radiol Endod*; 2008; 1-8.