Effect Of Therabite Exercises Versus Ketoprofen Phonophoresis On Tempromandibular Joint Pain And Trismus After Tonsillectomy

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Abstract: Purpose: To assess TheraBite influence versus ketoprofen phonophoresis on tempromandibular joint pain and trismus after tonsillectomy.
Methods: (Vernier caliper gauge to evaluate maximum mouth-opening capability, visual analogue scale for the assessment of pain and Mandibular Function Impairment Questionnaire (MFIQ) to assess tempromandibular joint disorders. Forty patients with ages range from 15 to 22 years complaining from tempromandibular joint pain and trismus following tonsillectomy. Participants were randomly allotted into two groups equivalent in number; every group consisted of twenty patients. The first study group (A) contained 20 patients who undertook the routine medical care in addition to the TheraBite exercises five times per day, each time for 2 minutes. The second group (B) was composed of 20 patients who received the routine medical care in addition to the ketoprofen 2.5% gel phonophoresis on the mastication muscles area for 5 minutes for each side of the face at an intensity of 1.0 w/cm² and frequency of 1.0 MHz with pulsed mode. Measurements will be done before the initial management as a primary score and at the termination of the third week of management as a second last record.
Results: Results revealed that the TheraBite exercises and ketoprofen phonophoresis reduced tempromandibular joint pain and trismus after tonsillectomy but TheraBite exercises showed significant effect.
Conclusion: TheraBite exercises and ketoprofen phonophoresis were advantageous and fruitful in decreasing the tempromandibular joint pain and trismus after tonsillectomy but TheraBite exercises was more successful.

Key words (Thera Bite, ketoprofen phonophoresis, tempromandibular pain, tonsillectomy).

INTRODUCTION
Increased recurrence of tonsillitis requires tonsillectomy which is the major surgical procedure. Numerous clinicians have focused on the need for enhanced pain, swelling, and trismus control in subjects with tonsillectomy. Tonsillectomy is frequently followed by pain, swelling, trismus, and over-all oral dysfunction throughout the healing phase. Cautious surgical procedure and reliable perioperative carefulness could diminish the complications and reduce their severity [1, 2, 3, 4].

Trismus or lockjaw is severely limited mouth opening that may take place as an outcome of intra capsular pathology of the tempromandibular joint (TMJ) or because of extra capsular
pathology. Extra-capsular reasons of trismus are for instance otolaryngology practice, dental infections, trauma to mouth closing muscles. However, it is mostly harmless, but it could give rise to numerous restraints for the patient as social restrictions that could cause anxiety and danger. Consequently, it is vital for clinicians to be conscious of this noteworthy condition, its main causes, and managements [5, 6].

Phonophoresis is chosen as an alternative of ultrasonic (US), particularly in patients who feel pain with eating, speaking and related actions. It was established that phonophoresis of diclofenac sodium or ketoprofen was beneficial in releasing the symptoms of TMJD combined with occlusal splint [7, 8, 9, 10, 11]. Phonophoresis provides a higher initial drug concentration at the delivery sites, avoid gastric irritation and avoid the first-pass metabolism by the liver. Because the US exerts only a few force, it is thought that it increases transdermal drug penetration by elevating the permeability of the stratum corneum through cavitation. [8, 10, 12].

TheraBite was used for jaw mobilization. The effect of treatment with the TheraBite has previously been evaluated in patient with restricted maximum mouth opening resulting from head and neck cancer. A C-Shaped-hand aid assists the patient or the helper to maintain constant opening during the stretching procedure. The stretch program was constructed to include ten consecutive repetitions daily with short interval of rest in between where each repetition should have a duration of 30 seconds. Helpers were instructed to squeeze the handle when the patient is too weak to perform the task [13, 14].

The purpose of this work was to investigate the efficacy of Therabite exercises versus ketoprofen phonophoresis on TMJ pain and trismus (lockjaw) following tonsillectomy. So, this study may assist in planning an optimal and ideal treatment protocol for such cases.

MATERIAL AND METHODS

Subjects
The current study was done on 40 subjects of both sexes with (age 15 to 22 years) complaining of TMJ pain and trismus following tonsillectomy. Patients were randomly allocated into two equal groups. Group (A) was consisted of 20 patients who had the routine medical care in addition to the TheraBite exercises. Group (B) contained 20 patients who received the routine medical care in addition to the ketoprofen 2.5% gel phonophoresis on the mastication [7, 9, 10, 12].

Inclusion criteria
- The patients' ages were ranged from 15 to 22 years.
- All patients were screened by an otolaryngology surgeon before starting of the study.
- All subjects suffering from TMJ pain and trismus (lockjaw) following tonsillectomy.
- They were medically stable
- All subjects were conscious and cooperative

Exclusion criteria
- Uncontrolled hypertension.
- Pregnant.
- Diabetes.
- Severe fungal diseases and acute viral diseases.
Peritonsillar abscess.

Instruments
The measuring tools were the vernier calliper gauge to measure maximum mouth-opening (MMO), visual analogue scale (VAS) for the evaluation of pain and the Mandibular Function Impairment Questionnaire (MFIQ) to evaluate TMJD [3, 4, 13, 15].

Procedures
All records were done before beginning the management as a primary record and at the termination of the third week of management as a last record.

(A) Measurement Procedures
1- Vernier calliper gauge: Incisal edge of the maxillary central incisor and incisal edge of mandibular central incisor at maximal opening were the reference point. The definite initial distance was tested for the zero value (for micrometers of 0-25 mm) by narrowing the micrometer (using the ratchet) till it narrows no more. Then the value or values except zero in the similar manner were recorded but through using a gauge block of proper dimension (e.g. for micrometer 50-75 mm beginning area was tested via a gauge block 50 mm). The alteration was identified in the calibration report. The gauge block (or a mixture of gauge blocks) is located in between both anvils, with the micrometer tighten up in the standard manner by the ratchet so that the block is fixed steadfastly. The block was given a minor twist to check the grip of the anvils, and to eliminate any dust that might be present on the surfaces. The block was similarly cited in a position such that the anvils touch the centre of the gauge measurement sides [4, 13,14, 16].

2- Visual analogue scale (VAS): It is a ten cm line anchored at each end with words of no pain and the worst pain. Patients were inquired to put a mark at the point on the line which better signifies their feeling of pain between "no pain" to "worst pain". The reliability of VAS was the greatest and its validity was the uppermost among other pain scales [3, 4, 14, 15].

3- Mandibular Function Impairment Questionnaire (MFIQ): It used to evaluate TMJD and was suggested by the American Academy of Orofacial Pain, MFIQ and the Research Diagnostic Criteria for TMJD. This questionnaire consisted of 17 items evaluating apparent problems in mandibular tasks throughout social actions, speaking, taking a large bite, chewing hard food, chewing soft food, work and/or daily activities. It consists also of drinking, laughing, chewing hard food, yawning, and kissing. Six factors measure observed troubles in mandibular function when eating hard cookies, meat, raw carrot, French bread, peanuts/almonds, and an apple. Eating consists of taking a bite, chewing, and swallowing. Possible answers were: 0, no difficulty; 1, little difficulty; 2, quite bit of difficulty; 3, much difficulty; and 4, considerable effort or impossible with no assistance. The records are supplemented to provide a total score (range 0-68). A greater record shows additional observed mandibular deficiencies and a MFIQ score of ‘0’ point to no mandibular deficiency [5, 6, 14, 15, 16].

(B) Therapeutic Procedures
Total patients in both groups (A and B) were given the identical traditional physical therapy in form of hot packs for 5 minutes and the similar medical care and medications [7].

1- TheraBite exercises for the study group (A): The device is constructed with a mandibular mouth piece that moves downwards in an anatomically correct track when the handle is
squeezed. Broad mouth pieces with foam cushions spread the force to protect the teeth. A precision-adjustment screw enables slow opening and permits precise setting. The exercise program comprised a three-week constructed exercise program including exercise five times daily, each time for two minutes. The program involved the following phases: 1-warm up activities containing jaw opening 10 times and slight side activities of the jaws 10 times with no use of jaw apparatus, 2-passive stretch with TheraBite 30 seconds, recurring five times, three-five replications of active exercise (bite towards resistance). Subjects were taught to relax within sessions. Moreover, subjects were taught to progressively rise the quantity and power of the exercises to prevent pain or injuries [3, 4, 13, 14].

(B) Ketoprofen 2.5% gel phonophoresis for the study group (B)
By the patient in the relaxed sitting position, the mastication muscles were prepared, and then ketoprofen 2.5% gel phonophoresis was applied on them. Ultrasound was applied over ketoprofen 2.5% gel for 5 minutes for each side at an intensity of 1.0 w/cm² and frequency of 1.0 MHz with pulsed mode [7, 8, 9, 10, 11, 12, 16].

Data analysis
Mean, standard deviation and the standard error of vernier calliper gauge, visual analogue scale and MFIQ were evaluated for every group. They were used as a main basis of relating evidences about every parameter to measure central tendency. Paired t-test was used for comparison within each group and to identify level of significance in every group. Two way MANOVA between subject design to compare the variables amongst groups and to identify significance level was used. The statistical package for social science (SPSS) was utilized for data analysis and the level of significance was set at the 0.05 level [17].

Ethical approval
The research related to human use has complied with all the relevant national regulations and institutional policies. It has followed the tenets of the declaration of Helsinki, and has been approved by the ethical committees of faculty of physical therapy, Cairo University NO.P.T.REC/012/002062.

Informed consent
Informed consent has been obtained from all individuals included in this study.

RESULTS
A total of 40 participants of both sexes with (age 15 to 22 years) complaining of TMJ pain and trismus following tonsillectomy completed the study. The mean values of ages were 18.900 ± 2.315 and 18.950 ± 2.038 for the first and second groups respectively. The standard error values were 0.518 and 0.456 for the first and second study groups respectively. Variance values were 5.358 and 4.155 for the first and second study groups respectively, while the coefficient of variance values were 12.25 and 10.76 for the first and second study groups respectively, the range values were 7.000 respectively for the two groups. As observed in table (1) there was non-significant differences between the first and second study groups (P>0.05).

There was a greatly significant increase in MMO (P = 0.0001) as the mean value of the maximum mouth opening (MMO) of the first study group (A) was (28.2 ± 1.11) mm, while after management it was (66.3 ± 2.55) mm. In the second group (B), the mean value of the MMO pretreatment was (27.1 ± 1.54) mm, while after treatment it was (62.6 ± 2) mm (table 1).
The mean VAS in degrees of the first study group pretreatment was (8.2 ± 1.44) degrees, however post treatment it was (4.3 ± 1.21) degrees. These results showed a highly significant decrease in VAS (P= 0.0001). In the second study group, the mean value of the VAS pretreatment was (8.2 ± 1.12), whereas after treatment it was (6.2 ±1.54) degrees. The results showed a highly significant decrease in MFIQ (P = 0.0001). In the second study group, the mean value of the MFIQ in pretreatment was (65.6 ± 2.41), but post treatment was (48.35 ± 1.39) degrees (table 3).

DISCUSSION
This study compared the effectiveness of TherBite exercises and ketoprophen phonophoresis on MMO, VAS and MFIQ on TMJD after tonsillectomy. The outcomes of the current study displayed an extremely significant rise of the means of the second record of MMO and a highly significant drop of the means of the second record of VAS. There was also a highly significant decrease of the means of the second record of MFIQ (after three weeks of the TherBite exercises application and ketoprophen phonophoresis) compared to pre-application of the TherBite exercises and ketoprophen phonophoresis (the first record). So, these results support the anticipation that both TherBite exercises and ketoprofen 2.5% gel phonophoresis were significantly effective in decreasing tempromandibular joint pain and trismus after tonsillectomy as demonstrated by the extremely significant increase in MMO and the highly significant decrease in VAS and MFIQ. But TherBite exercises were more beneficial than the ketoprofen 2.5% gel phonophoresis.

The results were steady with those documented by Buyukkurt et al. [8]. Forty-five patients in their study were to make surgical elimination of lower third molars. Subjects were allocated into 3 groups. In group A, everyone was given intramuscular 25 mg prednisolone directly post-surgery. In group B, everyone was given intramuscular 25 mg prednisolone and diclofenac instantly post-surgery, and in group C everyone was given sterile saline solution as control group. Postoperative pain was assessed by visual analogue scale on the day of operation. Facial swelling and trismus were assessed on 2nd and 7th days postoperatively. Results showed that the mixture of a distinct dosage of prednisolone and diclofenac is compatible for handling of postoperative pain, trismus, and swelling post dental surgery and can be utilized when widespread postoperative swelling of soft tissue is predictable.

Cagnie et al.[9] examined the effect of ultrasound on the transdermal distribution of ketoprofen in humans and compared the concentrations post continuous and pulsed use. Twenty-six subjects having knee conditions needing arthroscopy were accidentally allocated to 3 groups. Immediately pre operatively, phonophoresis of a ketoprofen (Fastum gel) was applied to group A by continuous US (1 MHz, 1.5 W/cm2, for 5 minutes). Group B had the similar management using pulsed US (100 Hz, 20% duty cycle). Group C had 5 minutes of sham US using ketoprofen gel. The US head was applied above a ten cm² region via slight, constant, circular motion. Their study confirmed that ketoprofen phonophoresis permits achievement of greater local concentrations, while systemic coverage is lesser. Outcomes indicated that ultrasound can elevate the transdermal transfer of ketoprofen.

Carriches et al. [10] compared the efficiency of methylprednisolone (corticoid) against diclofenac (nonsteroidal anti-inflammatory drugs) for the management of inflammation and trismus post-operative elimination of lower third molars. Subjects were divided in two groups randomly: the diclofenac and the methylprednisolone group. A recording card was completed with pre and postoperative epidemiological and clinical documents about
inflammation and trismus. 24 hours postoperatively, diclofenac group displayed a severe inflammation in one of the facial dimensions. Trismus was actually alike in the 2 groups. Corticoid group reported little inflammation.

**Hoppenrath and Ciccone** [6] examined a 48-year-old female suffering from right elbow pain. Grip strength was measured at $90^\circ$ of elbow flexion utilizing a Jamar hand dynamometer. Three scores were recorded, and the average was documented. They utilized US in their program. They were concerned in the research literature that is providing proof to upkeep the idea that phonophoresis is better than US in handling situations such as lateral epicondylitis.

**Hsieh** [16] investigated the exterior effects of US and phonophoresis on the variation of spinal induced nitric oxide synthase (iNOS). Inflammatory arthritis was brought in 18 male Wistar rats. Serial alterations in inflammatory pain responses, comprising hind-limb edema, and the locomotion of the arthritic animals were evaluated. Arthritic rats received US (n=6), diclofenac phonophoresis (n=6), or sham treatment (n=6). At 20 hours post injection, spinal induced nitric oxide synthase–like immunoreactive (iNOS-LI) cells were inspected. Results: The rearing behavior of arthritic animals was significantly better after US and diclofenac phonophoresis usages. Ultrasound and phonophoresis actually modify and inhibit the brought rise in total and regional iNOS-LI neurons. Peripheral usage of diclofenac phonophoresis produces a benefit compared to US only in influencing the central mechanisms of nociception.

On the other hand, McNeely et al. [14] produced a suggestion supporting acupuncture to decrease pain compared with no treatment, significant progresses in oral opening were established with muscular awareness relaxation treatment, biofeedback training, and low-level laser therapy usage. Yano et al. [18] stated that limitation of the mouth opening after a pathogenic disorder exterior to the TMJ is called a pseudo- or extra-articular ankylosis. Single case exhibited fibrous degeneration of the bilateral masseter muscles with no facial bone fracture that produced severe trismus, a mouth opening of lesser than 2 mm, and progressively occurred post blunt injuries to the face. The other was a rare condition followed by the bone formation in the masseter muscle and was detected as myositis ossificans traumatica, that similarly exists as severe trismus, with a maximal mouth opening of 5 mm post facial ferocity. Both were operatively managed with cutting up of the diseased muscles. In addition, a hemicoronidotomy was done in the circumstance of myositis ossificans traumatica. Though a traditional treatment with physical rehabilitation is the main strategy of managing pseudoankylosis of the TMJ, a surgery should be well-thought-out when the source of the troubles is osteogenic or severe extra-articular ankylosis.

**Baranano et al.** [19] assessed Dynasplint Trismus System (DTS) for relieving trismus caused by treatment of head and neck cancer on 26 subjects. Though the first improvement was 0.36 mm/day throughout the 1st 6 weeks, enhancement demolished with time, and the whole advance was 0.16 mm/day. They stated that the DTS was useful in elevating the mandibular ROM at a degree of modification maximizing through original management. **Cohen et al.** [20] assessed the usage of a mechanical stretching maneuver, the TheraBite, for the primary postsurgical treatment of trismus. Subjects used TheraBite mechanical jaw mobilization apparatus, they were taught in the appropriate usage, and initiated within 6 weeks post-surgery. Maximum interincisor opening (MIO) was evaluated at the start of usage and at the utmost recently postsurgical visiting. Results: The average MIO was 30mm (21–38mm) at the start of the study and 40mm (30–57mm) at the final visit. No obstacles were accompanying usage of the device.
Kamstra et al. [15] evaluated the influence of TheraBite exercises on mouth opening and analyzed elements prompting this effect on patients. Outcome of exercises with a TheraBite to manage trismus was assessed in 69 head and neck cancer subjects of two university medical centers. Mouth opening was evaluated as interincisal distance in millimeters. Results: mean preliminary mouth opening was 22.0 mm (SD 6.4); mean rise in mouth opening was 5.4 mm (SD 5.7). Following TheraBite exercises, mouth opening improved on average 5.4 mm.

LIMITATION
The study limitations include a small number of patients and longer period than three weeks was needed for better results.

CONCLUSION
Application of TherBite exercises and ketoprofen 2.5% gel phonophoresis were significantly effective in decreasing TMJD and trismus after tonsillectomy as demonstrated by the highly significant increase in MMO and highly significant decrease in VAS and MFIQ. But TherBite exercises were more beneficial.

Disclosure statement
No author has any financial interest or received any financial benefit from this research.

Conflict of interest
The authors state no conflict of interest.

Funding
This study did not receive any form of funding.

REFERENCES


Table (1): Comparing the MMO mean values in mm before and after treatment in both study groups.

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<td>62.6</td>
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Table (2): Comparing the VAS mean values in degrees pre and post treatment in the two study groups.

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Table (3): Comparing the MFIQ mean values in degrees pre and post treatment in both study groups.

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