

THE USE OF THERAPEUTIC EAR PLUGS FOR TREATMENT OF MYOGENOUS TMD: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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Abstract

Objective: To assess the efficacy of therapeutic ear plugs in the treatment of myogenous TMD compared to stabilization splints.

Materials and Methods: 60 patients suffering from myogenous TMD according to DC/TMD criteria where divided into 2 group, stabilization splint group, and a group treated with therapeutic ear plugs. Pain was evaluated using visual analog scale VAS, and mouth opening was evaluated using a mouth opening index OI, after 1 and 3 months.

Results: Pain was reduced significantly in the ear plug group, dropping from 7.18 to 3.82 after 1 month and to 2.41 after 3 months. For the splint group there was significant drop in pain after 3 months where it decreased from 7.34 to 2.63, while it showed a non-significant decrease after 1 month (6.16). OI showed significant improvement in mouth opening in the ear plug group decreasing from 10.34 to 6.14 after 1 month and to 5.13 after 3 months. In the splint group the OI improved significantly from 11.06 to 4.87 after 3 months, while the improvement wasn't significant after 1 month (9.85).

Conclusions: Therapeutic ear plugs are a discrete, small, and effective alternative to stabilization splint in the treatment of myogenous TMD, and its full-time wear advantage over the splint makes its action more rapid.

Introduction

The term TMD refers to a group of disorders affecting the TMJ and/or muscles of mastication. Usual symptoms are; pain, limited mouth opening, and joint noises¹. The etiology of TMD is perplexing with many factors as psychological, muscular, and osteoarthritic

conditions in the play².

Diagnostic criteria for TMD as well as its classification are as confusing as its etiology, in 1992 Dworkin et.al.³ introduced research diagnostic criteria for TMD (RDC/TMD) that included Axis I physical assessment, and an Axis II psychological assessment. These criteria kept changing and refining over the time until 2014 when Schiffman et.al.⁴ revised the Axis I of the RDC/TMD and introduced the Diagnostic criteria for TMD (DC/TMD). In general, these classification schemes emphasis on the muscular role in TMD and categorized TMD broadly into group-1 (Muscle disorder), group-2 (Disc displacement), group-3 (Osteoarthritic problems).

Many therapeutic modalities have been advocated for treatment of TMD as medications⁵, physical therapy⁶, intra-oral splints, laser, ultra-sound⁷, and joint surgery⁸ with inconsistent reported results due to the multifactorial etiology of the disorder. The joint surgeries nowadays are on the decline with recent systematic reviews⁹ recommending non-invasive and reversible modalities of treatment.

Stabilization intra-oral splints are the most widely used and accepted treatment modality for myogenous TMD treatment being non-invasive, simple, easily fabricated, and reversible.¹⁰ Nevertheless, it has some drawbacks as being inconvenient for the patient due to its relatively large size, interferes with eating, and affects speech, therefore its use is mostly limited to sleeping time¹¹, thus decreasing its

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effectiveness. Furthermore, they do not prevent tooth clenching which could be a factor in TMD, and some patients may frequently break their splints due to excessive clenching¹².

The ear canal is very closely related to the TMJ both anatomically and physiologically; a study on human cadavers showed a communication between the middle ear and the TMJ with the discomalleolar ligament connecting the articular disc to the malleus bone of the middle ear running through the petrotympanic fissure, which also provided passage to the continuation of the sphenomandibular ligament which is also inserted to the malleus bone, explaining aural symptoms associated with TMD¹³. Another study by Tuz et.al¹⁴ found that TMD patients had more otological symptoms than normal subjects. The ear canal is not a rigid tube connecting to the middle ear, the outer 1/3 is highly deformable by mandibular and tongue movements, and this deformability was used in Japan to control some musical ear pads called “earable TEMPO” by using tongue movements and the amount of deformation was also measured¹⁵. Another study by Yu et.al¹⁶ showed that the ear is deformed with mandibular movements.

Recently some commercial ear plugs that claim to treat TMD have been introduced with very few published studies, namely the TMD'es™ (Ascentia Health, Inc., Rockford, IL, USA) which changed later to Cerezen™ (Renew Health Limited, Athlone, Ireland). The device is a hollow hard-plastic tube that fits into the patient's ear-canal. They have a metal handle for ease of insertion and removal by the patient. The only RCT that was found to date of writing this manuscript was one published by Tavera et.al.¹⁷ where they compared “TMDes” to splints and jaw exercises and found all three treatment modalities to be equally effective in reducing TMD symptoms in a group of patients classified with myofascial pain, arthralgia, and disc displacement with reduction all together.

Another study published by Pfeiffer et.al¹⁸ reported that “Cerezen™” showed promising results in treating bruxism, in a sample of 7 patients.

The aim of the current study is to assess the efficacy of using a custom-made ear plug in treating myogenous TMD patients compared to stabilization splints on pain and mouth opening.

Materials and methods

Study design

This study is a double arm open parallel active controlled randomized trial, with a 1:1 allocation ratio, with concealed randomization. Blinding of participants and care providers was not possible due to the nature of the interventions.

Study setting and population

The sample was selected from a population of patients seeking treatment of TMD at a private clinic specialized in diagnosis and treatment of TMD and orofacial pain in Alexandria, Egypt. Patients were informed about the study and agreed to participate, and a written consent was taken. 60 patients suffering from myogenous TMD according to DC/TMD criteria were recruited.

Inclusion criteria

To be included in the study the patient must meet the following criteria:

- Age (18-45) years.
- Presence of myogenous pain conforming to categories of local myalgia, myofascial pain and myofascial pain with referral according to the DC/TMD criteria for the last 30 days whether intermittent or constant.
- Full permanent dentition or fixed prosthodontic with normal occlusion.

Exclusion criteria

Any patient with the following criteria was excluded from the study:

- TMJ clicking or crepitations.
- Metabolic disease as diabetes
- Neurological disorders as trigeminal neuralgia
- Vascular disease (migraine and hypertension)
- History of psychological disease
- Rheumatoid arthritis or any connective tissue disease.
- Used narcotics or pain killers for the last week prior to examination.

Sample size estimation

G*Power software was used to estimate the sample size (Dusseldorf, Germany). Based on the calculations (57) cases were required, for a study with 80% power and an α of 0.05, using a population SD from Alquran et.al. study of 1.57 and a smallest effect of interest of 2 Thus, a total of 60 cases were used.

Randomization and concealed allocation

After clinical examination and eligibility for the study the patient picked an opaque sealed envelope containing one of the 2 study groups from a box having 30 envelopes for splint group, and 30 for ear plug group.

Interventions

A- Splint fabrication:

Upper arch stabilization splint was constructed as described by Okeson et.al.¹⁹, upper and lower casts were mounted on a semi adjustable articulator using a face bow, Whip Mix® (Whip Mix Corporation Louisville, KY 40217 USA) and a flat maxillary occlusal splint was fabricated to make even contact with all buccal cusps of lower teeth and incisal edges in centric relation, and provide canine and incisal

guidance to dis-occlude posterior teeth in lateral and protrusive excursions.

B- Ear plugs fabrication

Patients who were allocated to the ear plug group were sent to an ENT specialist to examine ear canal anatomy, remove any ear wax present and to make sure the patient is free from any ear pathology, before returning him to the TMJ center to take ear impressions. First an Otoblock sponge with pulling threads was placed halfway, just past the level of the 2nd bend of the ear canal to limit the flow of impression material towards the ear drum. (Amplifon Otoblock, Amplifon Italy), (Fig.1). Then the patient was asked to open his mouth as wide as he could, and a mouth gag was placed to help stabilize the mandible during the impression taking. Afterwards an ear impression using Otoform® AK addition vulcanizing ear impression silicone (Dreve Otoplastik GmbH, Germany) (Fig.2) was mixed into a special syringe (Fig. 3) and applied inside the ear canal filling it and extending outwards filling the helix bowl and tragus. After the material had set it was gently removed from the patient's ear (Fig. 4). The impressions were sent to a laboratory specialized in fabrication of hearing aids in Alexandria, Egypt and fabricated from Fotoplast® (Dreve Otoplastik GmbH, Germany). The plugs were marked with a red dot for right and blue for left. The plug had to sit flushed with the outer boarder of the ear canal, and were hollowed lengthwise to avoid hearing impairment, and had small metal handles to aid in their placement and removal by the patient. (Fig.5).

Patients in the splint group were instructed to use the splint only while sleeping, while the ear plug group were instructed to wear the plugs full time taking it out only during showering or swimming. Both groups were instructed to avoid any analgesics or pain killers. And were recalled after 1 and 3 months from the start of therapy. In addition, patients were assured that it

was expected for the ear plugs to cause slight initial discomfort that would disappear as the patients gets used to them.

Study outcomes and measuring scales

Primary outcome (Pain), the patient was asked to rate his pain on a visual analog scale VAS from 0-10cm where 0 was no pain and 10cm worst pain, and the distance was measured from the patient mark to 0 in cm. VAS was shown to be a reliable measurement tool for pain assessment²⁰.

Secondary outcome (Mouth opening index). For every patient the amount of active mouth opening (Opening made by the patient unassisted), and the amount of passive mouth opening (Opening assisted by the operator thumb pressure), was recorded using a Bowley gauge after correction for the initial overbite by taking it into consideration, in-order to calculate the opening index developed by miller et.al²¹. This opening index eliminates the effect of gender, ramus length, and gonial angle on linear mouth opening measurements. Using the formula:

$$OI = \frac{\text{passive opening} - \text{maximum voluntary opening}}{\text{Passive opening} + \text{maximum voluntary opening}} \times 100$$

Collection of data

Variables were collected before appliance insertion (T0), 1 month after (T1), and 3 months at the end of the study (T2) (end point)

Statistical analysis

Statistical analysis was performed using SPSS software, version 20 (SPSS Inc, Chicago, Ill) The significance level was set at $p \leq 0.05$. Data normality was tested using descriptive statistics, plots and Shapiro-Wilk test. 2-way repeated measure ANOVA was performed to determine significant differences between the different

time points for the primary and the secondary outcomes. Significant ANOVAs were followed by post hoc pairwise comparisons with Bonferroni adjustment.

Results

60 patients suffering from myogenous TMD were included in this study with a mean age of $30.2 \text{ years} \pm 10.3$, with 42 females (70%) and 18 males (30%).

All variables showed normal distribution, using Shapiro-Wilk test, so means, standard deviations (SD), were calculated, and parametric tests were used.

Table 1 shows that there was no significant difference in the VAS score between both groups at the base line. However. Significant reduction in pain compared to base line was observed in the ear plug group after 1 month of wearing while this was not the case with the splint group, as the pain score did not differ significantly after 1 month compared to the base line. Therefore, there was significant difference after 1 month in favor of the ear plug group. After 3 months both groups were not significantly different than each other and both had significant pain reduction compared to baseline.

Table 2 reveals that the mouth opening index showed a similar pattern as pain, as it shows that there was no significant difference in OI between both groups at the base line. However.

Significant reduction in OI -which means decreased passive opening and improvement of the muscular conditions- compared to base line was observed in the ear plug group after 1 month of wearing while this was not the case with the splint group, as the OI did not differ significantly after 1 month compared to the base line. Therefore, there was significant improvement in mouth opening after 1 month in favor of the ear plug group. After 3 months both groups were not significantly different than each other and both had significant better mouth

opening compared to baseline.

Discussion

The treatment of TMD should be started with reversible non-invasive methods⁹. The hard-occlusal splint is widely accepted as a reversible method for treatment with evidence of success¹⁰, although the exact mechanism of action of splints is still uncertain²², it is still widely used. The occlusal splint has some disadvantages as being unaesthetic, interferes with speech and eating, therefore mostly used while sleeping which limits its usefulness¹¹. The therapeutic ear plugs used in this study provide a discrete small alternative that could be used full time.

The results of the current study show a significant decrease in the pain score in the splint group, the reduction was about 16% after one month, and 64% after 3 months. This agrees with Miller et.al²¹, and Tavera et.al.¹⁷ who measured the pain also after 1 and 3 months and found pain reduction of 31% and 49% respectively. The difference in the 1-month pain reduction could be attributed to Tavera et.al. using double the number of patients as the current study, in addition they did not include myogenous TMD patients only, but included with them patients with arthralgia and disc displacement with reduction, which might have had more rapid relief than muscular pain. In addition, increasing the vertical dimension by the splint might have more effect in reducing the pain in patients with arthralgia and disc displacement^{23,24} initially, but as the stomatognathic system adapts to minor changes in the vertical dimension quickly²⁵ this increase had no effect on the pain reduction in the splint group after 3 months thus leading to comparable results between this study and Tavera et.al.

In the ear plug group there was significant reduction in pain after 1 and 3 months, where the pain reduction was 47% and 66.5% respectively, this is in total agreement with Tavera et.al.¹⁷ study that found pain reduction of

46% after 1 month and 58% after 3 months. This indicates that the ear plugs affect both patients with myogenous TMD and arthralgia and disc displacement with reduction equally.

In the current study there was significant difference in pain reduction after 1 month between the ear plug group and the splint group were as pain reduction was not statistically significant after 3 months, this could be attributed to the continuous wear of the ear plug versus the night time only wear of the splint, allowing the ear plug to have a faster effect.

The mouth opening index followed the same pattern as did the pain. As in the splint group there was significant increase in mouth opening only after 3 months, as evident by the reduction in the OI, this is in accordance with other studies^{21,26}. Whereas in the ear plug group there was significant improvement in mouth opening at 1 month and 3 months, this difference could be attributed to the more frequent use of the ear plug.

This trial demonstrated that ear plugs are comparable to splints in treating myogenous TMD as far as reducing pain and improving mouth opening are concerned and have an earlier on set of action. However, how the ear plugs work is somehow unclear, initially it was thought that they aid in stabilizing the TMJ being so close anatomically to the condyle, later studies^{15,16,27} showed that the outer part of the ear canal deforms upon mandibular movements, and it could be possible that the ear plugs work by biofeedback stimulation when the shape of the ear canal changes against its rigid body signaling to the muscles to stop the undesired movement.

Conclusions

Therapeutic ear plugs are a discrete, small, and effective alternative to stabilization splint in the treatment of myogenous TMD, and its full-time wear advantage over the splint makes its action more rapid.

Figures



Fig.1: Otoblock used to limit impression flow in the ear canal.



Fig.2: Otoform impression material.



Fig.3: Ear impression syringe.



Fig.4: Ear impression taken.



Fig.5: Finished therapeutic ear plugs.

Tables and charts

	T0 (mean \pm SD)	T1 (mean \pm SD)	T2 (mean \pm SD)	p-value
Ear plug group	7.18 (\pm 1.54) ^a	3.82(\pm 1.83) ^b	2.41(\pm 2.1) ^b	<0.0001*
Splint group	7.34(\pm 2.04) ^a	6.16(\pm 1.97) ^a	2.63(\pm 1.98) ^b	<0.0001*
P-value	0.168	<0.0001*	0.136	

Table 1: Comparisons of VAS scores in cm. between groups and across different time points. (T0) base line , after 1 month (T1) and after 3 months (T2).2-way repeated measure ANOVA. (Post-hoc is denoted by superscript letters)

*Statistically significant at $p \leq 0.05$

a, b: Different letters indicate statistically significant difference.

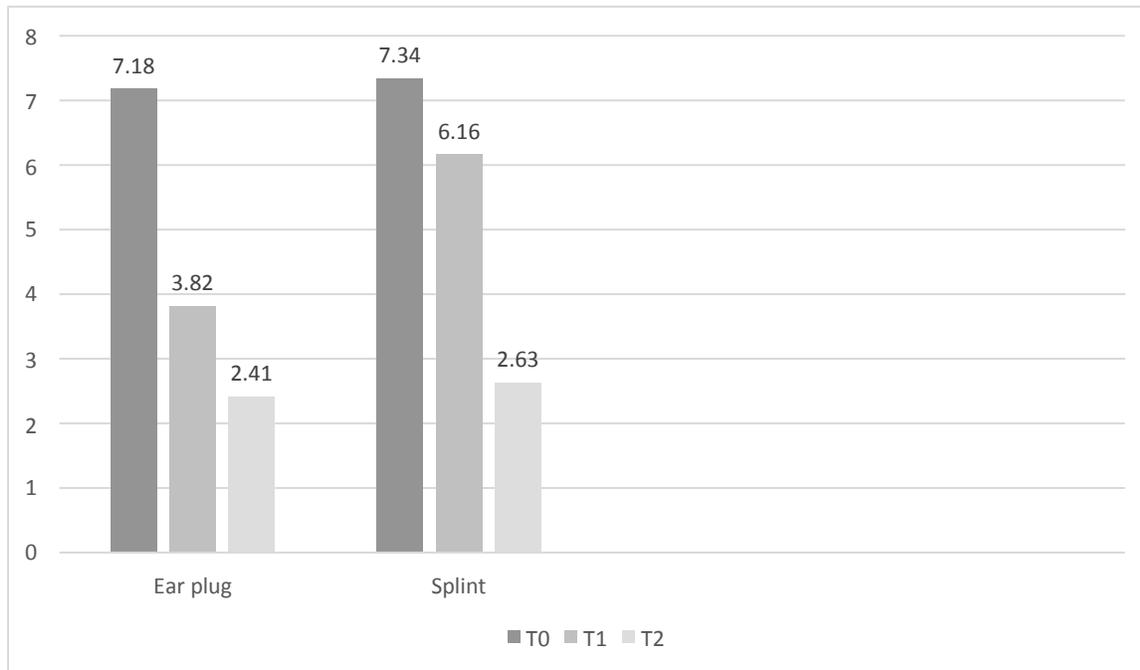


Fig.6: Bar chart showing mean values of VAS score in cm for the 2 groups across different time points.

	T0 (mean \pm SD)	T1 (mean \pm SD)	T2 (mean \pm SD)	p-value
Ear plug group	10.34 (\pm 4.16) ^a	6.14(\pm 1.26) ^b	5.13(\pm 1.16) ^b	<0.0001*
Splint group	11.06(\pm 3.87) ^a	9.85(\pm 2,23) ^a	4.87(\pm 1.43) ^b	<0.0001*
P-value	0.214	<0.0001*	0.173	

Table 2: Comparisons of opening index OI in percentage. between groups and across different time points. (T0) base line, after 1 month (T1) and after 3 months (T2).2-way repeated measure ANOVA. (Post-hoc is denoted by superscript letters)

*Statistically significant at $p \leq 0.05$

a, b: Different letters indicate statistically significant difference.

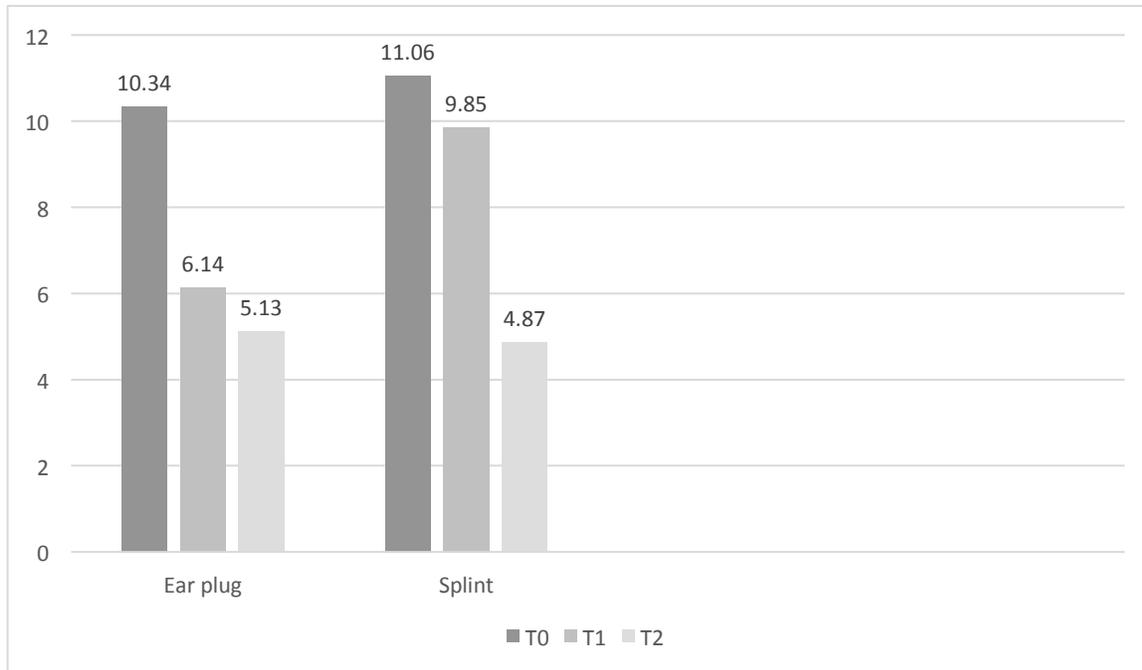


Fig.7: Bar chart showing mean values of opening index OI in percentage for the 2 groups across

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