

Comparative evaluation of occlusal splint therapy and muscle energy technique in the management of temporomandibular disorders: A randomized controlled clinical trial

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Abstract

Background: Contradicting evidence regarding the effects of occlusal splint therapy in the management of Temporomandibular disorder (TMD) and promising results shown by muscle energy technique.

Aim: To determine and compare the effects of occlusal splint therapy, muscle energy technique, and combined treatment with education for self-management and counseling in the management of TMD.

Study Design and Settings: Randomized clinical trial.

Methodology: A total of 160 participants diagnosed with TMD according to Diagnostic Criteria/TMD axis I were randomly allocated into four treatment groups with equal allocation ratio using random numbers table. The main inclusion criteria were the presence of pain in the preauricular area, TMJ and/or muscles of mastication and maximum mouth opening <40 mm. Group A participants received muscle energy technique, Group B participants received occlusal splint therapy, Group C participants received combined treatment, and Group D participants received education for self-management and counseling (control). Control group treatment was provided to all the trial participants.

Statistical Analysis: Intragroup comparison was made using Friedman test and Wilcoxon test while intergroup comparison was done using Kruskal–Wallis test and Mann–Whitney U test.

Results: Intensity of pain on a visual analog scale and maximum mouth opening were measured at baseline, at 1 week, at 2 weeks, at 1 month, and after 3 months.


Conclusion: Muscle energy technique, occlusal splint therapy and combined treatment significantly reduce pain compared to controls and muscle energy and combined treatment are superior to other groups for mouth opening improvements in patients with TMD.

Keywords: Counseling, muscle energy technique, orofacial pain, self-management, stabilization splint, temporomandibular joint disorders

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INTRODUCTION

Temporomandibular disorders (TMD) is a collective term that includes many clinical conditions involving the masticatory muscles or temporomandibular joints and associated structures which can be characterized by pain in the preauricular area, TMJ, or muscles of mastication; limitation or deviation in the mandibular range of movements; and TMJ sounds like clicking, popping and crepitus during mandibular function.^[1] Other symptoms associated with TMD can be a headache, earache, poor quality of sleep, and depression.^[2-4] TMD generally affect 5%–12% of the population.^[1] It is estimated that 5%–6% of the population reporting clinically significant TMD-related jaw pain during their lifetime.^[5,6] The etiology of TMD is multi-factorial and predisposing factors can be anatomical, traumatic, pathophysiological, or psychosocial.^[7]

Muscle energy technique is an osteopathic manipulative therapy used in the treatment of musculoskeletal disorders. It has many subtypes; two commonly used subtypes are Postisometric relaxation and Reciprocal inhibition. Muscle energy technique is frequently used in treating excessively tensed muscle which restricts joint movements and causes pain.^[8] The muscle energy technique is effective in reducing pain and improving motion in different parts of the body.^[8,9] However, there is a lack of enough evidence regarding the use of muscle energy techniques in the management of TMD. Recently two studies have reported significant improvement in the symptoms of TMD with the use of muscle energy technique.^[10,11]

In the literature, few studies have documented higher clinical success with the use of stabilization splint in the management of TMD.^[12-20] Few have reported the role of stabilization splint in reducing muscle activity of temporalis and masseter muscle.^[21-23] However, several studies have reported that the effects of stabilization splints in TMD are similar to nonoccluding control splints.^[24-30] Because of this contradicting evidence in the literature regarding effects of stabilization splint therapy and promising results shown by the muscle energy technique in the management of TMD; this trial was initiated to determine and compare the effects of stabilization splint therapy, muscle energy technique, combined treatment, and education for self-management and counseling in the management of TMD. The null hypothesis states that there are no significant differences in the effects obtained by stabilization splint therapy, muscle energy technique, combined treatment, and education for self-management and counseling in the management of TMD after 3 months.

METHODOLOGY

Study design and settings

A prospective, multi-arm, multicenter, participants and analyst blinded randomized controlled trial was conducted at four different institutes from Dec 28, 2015 to March 12, 2020.

Sample size

A total sample size of 160 ($n = 160$) was obtained to achieve the required power of the study with 40 subjects in each group.

Ethics committee approval

Presentation of research protocol was done in front of the two institutional Ethics committees and approvals were received IRB no:- ECR/236/Indt/GJ/2015.

A total of 387 patients were diagnosed with TMD using DC/TMD (Axis I)^[31] by the principal investigator and three other dentists. Those who fulfilled the inclusion criteria [Table 1] were given a brief explanation about the research and participants who signed the informed consent were included in the study [Figure 1].

Allocation sequence generation and allocation concealment

A person independent of the principal investigator and screening dentists had generated four comparison groups for 160 patients ($n = 160$) with simple randomization using equal allocation ratio by referring to a random numbers table, written it on the cards, and concealed the cards in sequentially numbered, sealed (with tamper-proof tape), opaque envelopes, and kept in a locker and opened only after envelopes had been irreversibly assigned to the participants.

Blinding

In this study, participants were blinded by not revealing to them detail about the treatment group they belonged to and recalling the participants of the same group on the same day. The statistical analyst was blinded by hiding from him the group names until data were analyzed.

Procedure

Group A ($n = 40$): Muscle energy technique

In the muscle energy technique following two techniques were used.

Post isometric relaxation

Patients were asked to lay supine on the dental chair with mouth open. The dentist placed gloved thumbs on the occlusal surface of patients' lower back teeth and patients were asked to close the jaw using 20% of total effort while

Table 1: Inclusion and exclusion criteria for trial participants

Inclusion criteria	Exclusion criteria
Patients diagnosed with TMD according to DC/TMD axis I	Patients who were under treatment of analgesics, NSAIDs, muscle relaxants or antidepressants
Pain in temporomandibular joint, muscles of mastications, or both plus any one/more of the following	Patients with the absence of maxillary and/or mandibular central incisors
Presence of joint sounds like clicking or crepitus	Patients who were unable to attend the hospital for the prescribed treatment period
A history of jaw lock or limitation of opening or deviation	The patient who insisted on for a specific treatment (e.g., occlusal adjustments, medication)
TMJ or masticatory muscle tenderness to palpation	Presence of complete or removable partial prostheses with distal extension
Reduced mouth opening including the vertical overlap of <40 mm	Patients with malignant tumours of the face and jaw
Sign and symptoms present for >4 weeks	History of fracture or surgery of jaw or TMJ
Patients of both gender	Patients who had received any form of treatment for TMD in past
Patients willing to participate in the research	Patients who had received orthodontic treatment in past
Age >20 years	Patients with oral submucous fibrosis

TMD: Temporomandibular disorders, DC: Diagnostic criteria, NSAIDs: Nonsteroidal anti-inflammatory drugs, TMJ: Temporomandibular Joint

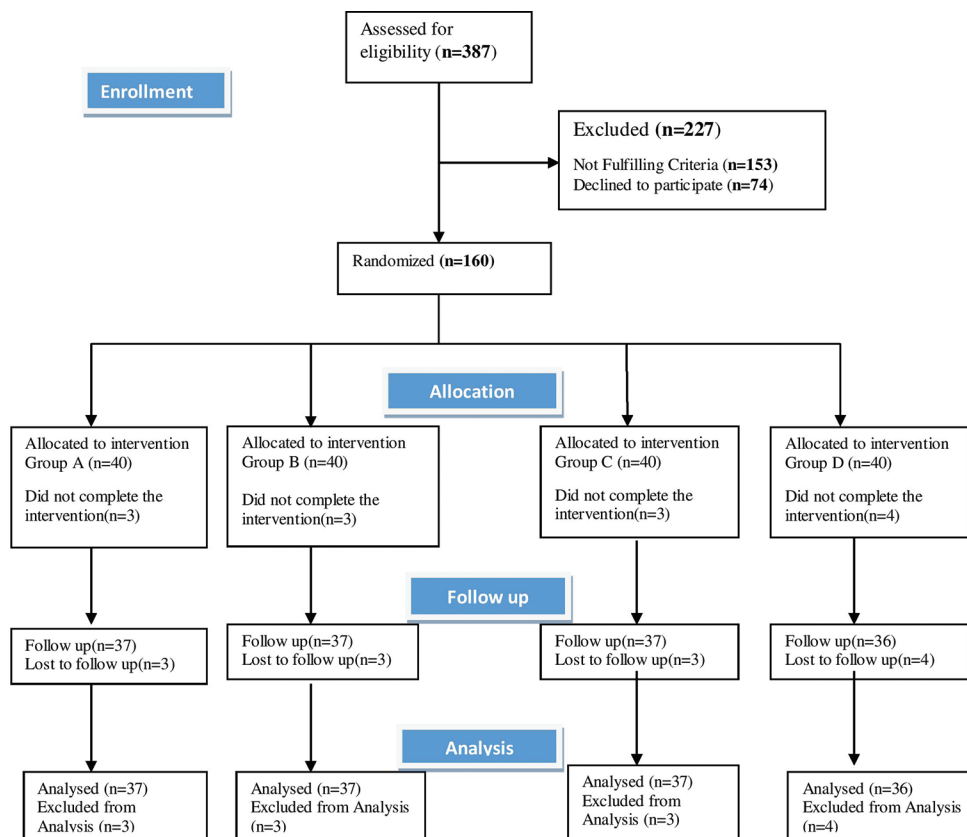


Figure 1: Flow chart of trial participants according to CONSORT guidelines

the dentist provided equal resistance with the thumb so that no movement could occur [Figure 2]. After a 5 s hold, patients were asked to relax and the dentist gently opened the jaw to the maximum possible distance.^[8] This procedure was repeated five times in 30 min session.

Reciprocal inhibition

Patients were asked to sit in the dental chair in an upright position and to open the mouth to its comfortable limit. The dentist from behind the dental chair placed one hand below the mandible of the patient and grasped the forehead with another hand for stability [Figure 3]. Patients were then asked to attempt to open the mouth against the resistance

applied by the dentist’s hand placed below the mandible for 10 s. Then, patients were asked to open the mouth to its new barrier before repeating the procedure.^[8] This procedure was repeated 5 times in 30 min session.

This muscle energy technique was given three times a week for four weeks.

Group B (n = 40): Occlusal splint therapy

Impressions of the patient’s maxillary and mandibular arches were taken in perforated stock metal trays using irreversible hydrocolloid impression material and casts were obtained by pouring the impressions with dental



Figure 2: Position of operator and patient during post isometric relaxation

stone. Facebow relation was recorded and the maxillary cast was mounted to a semi-adjustable articulator (Hanau wide view). Patients were guided to close the jaw in centric relation using bimanual manipulation and this relation was transferred to the articulator using bite registration wax.

Stabilization splints were constructed by adapting ethylene-vinyl acetate sheets (2 mm thickness) on maxillary casts using a vacuum form machine and occlusal surfaces were modified with auto polymerizing acrylic resin to incorporate the contact of all mandibular teeth in centric relation [Figure 4], anterior guidance for disclusion of posterior teeth during protrusion and canine guidance for disclusion during lateral movements. Fit and occlusion of stabilization splints were verified in patients' mouths. Patients were advised to wear the splint at night for a minimum of 12 h. All patients were recalled for adjustments and follow-up at 24 h, 1 week, 2 weeks, 1 month, and 3 months.

Group C (n = 40): Muscle energy technique + Occlusal splint therapy (combined treatment)

This group of patients received occlusal splint therapy and muscle energy technique.

Group D (n = 40):-Education for self-management, and counseling (control group)

In this group, patients were treated by education for self-management and counseling alone.

Patients were educated regarding the diagnosis and generally favorable prognosis of TMD when appropriate which included reassurance that TMD is a typically benign condition and self-limiting in the vast majority of cases. Patients were educated regarding the biopsychosocial etiology of TMD, sleep practices, time-limited use of



Figure 3: Position of operator and patient during reciprocal inhibition

analgesics, anatomy, and functions of TMJ and associated musculature.^[32]

Patients were educated regarding identification, monitoring, and avoidance of any parafunctional behavior that can exacerbate the pain and were made conscious to avoid daytime clenching, clicking, or grinding of teeth.^[32]

Patients were advised to avoid unilateral chewing, excessive talking, and chewing gum, to take proper rest and sleep, to do deep breathing exercises.

Advised a pain-free diet for 2 weeks followed by a review to check the tolerance to firmer consistency food.^[32]

Instructed to apply moist heat to the area of discomfort for 10 min each time for 2–3 times/day.

All the trial participants received education for self-management and counseling in addition to the treatment specified for a particular group.

Outcome measurements and data collection

The primary outcome was measured as intensity of pain on a visual analog scale (VAS) and the secondary outcome was measured by maximum mouth opening as inter incisal opening plus the vertical overlap at baseline, at the end of 1 week, end of 2 weeks, end of 1 month, and follow-up at 3 months.

The VAS is a 10 cm horizontal line with marking from 0 to 10. The left end of the VAS is marked as 0 which describes no pain and the right end of VAS is marked as 10 which describes the worst pain. All patients were asked to mark the intensity of pain perceived by them, on VAS in data sheets provided to them, at described time intervals.



Figure 4: Stabilization splint in Centric relation position in patient's mouth

For maximum mouth opening, participants were asked to open the mouth as much as possible without pain, and the distance between labioincisal edges of maxillary and mandibular central incisors was measured vertically using calibrated, millimeter ruler and added by vertical incisal overlap to calculate maximum mouth opening.^[1,33] Measurement of MMO was repeated twice and averaged to minimize error.

Statistical analysis

Intragroup comparison according to time interval was made using the Friedman test and if found significant a *post hoc* test was done by the Wilcoxon test. Intergroup comparison was made using the Kruskal–Wallis test and *post hoc* analysis was performed by the Mann–Whitney U-test. The Statistical Package for the Social Science (SPSS ver 22, IBM Corp., Armonk, N.Y., USA) was used for statistical analysis. The level of significance was kept at 5% (Confidence Interval 95%).

RESULTS

The age- and gender-wise distribution of trial participants are described in Table 2. The group-wise distribution of diagnostic subgroups of TMD is described in Table 3. The maximum number of patients were of Myofascial pain (28.12%) followed by Disc displacement with reduction (22.5%) and the least number of patients were of Disc displacement without reduction without limited opening (00).

Results are presented in detail in Tables 4, 4.1-4.3,5, 5.1-5.3 and Figures 5 and 6 Pain decreased and maximum mouth opening increased for all the groups after 3 months in comparison to baseline [Tables 4 and 5]. However, the intragroup comparison shows that pain reduction was highly significant ($P < 0.001$) in three treatment groups (Group A, B, and C) as compared to the control group after 3 months [Table 4.3]; there was no significant ($P > 0.05$) difference in pain reduction between Group A, B and C after 3 months [Table 4.3]. Intragroup comparison has shown

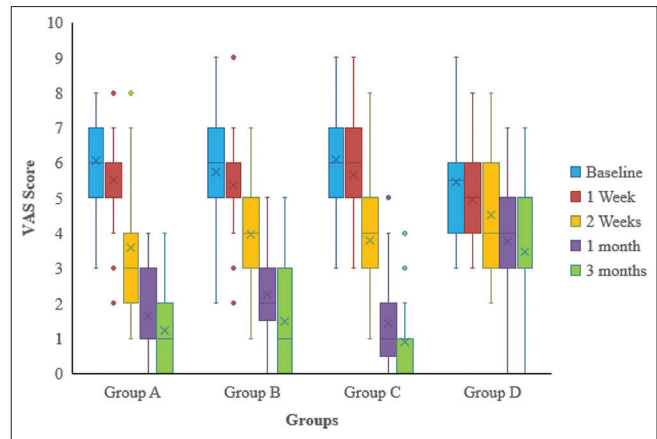


Figure 5: Graphical presentation for comparison of VAS score at different time interval among groups

Table 2: Group wise age and gender distribution of trial participants

Groups	Age (years)	Gender	
		Male, n (%)	Female, n (%)
Group A (n=40)	37.60±10.55	23 (14.37)	17 (10.63)
Group B (n=40)	42.25±9.85	14 (8.75)	26 (16.25)
Group C (n=40)	40.42±10.41	18 (11.25)	22 (13.75)
Group D (n=40)	37.48±10.15	18 (11.25)	22 (13.75)
Total (n=160)	39.44±10.34	73 (45.63)	87 (54.37)

that there was a highly significant ($P < 0.001$) improvement of mouth opening for Group A and Group C patients as compared to Group B and Group D patients after 3 months. There was no significant ($P > 0.05$) difference between Group B and Group D in the improvement of mouth opening after 3 months. There was no significant ($P > 0.05$) difference between Group A and Group C in mouth opening improvement [Table 5.3].

DISCUSSION

The present trial was initiated to find quality evidence regarding the effects of occlusal splint therapy and muscle energy technique in the management of TMD. Pain decreased and maximum mouth opening increased in all four treatment groups, but intragroup comparisons revealed that experimental groups improved pain significantly more than the control group, and muscle energy technique and combined treatment groups improved mouth opening significantly more than occlusal splint therapy and education for self-management and counseling groups. Hence, null hypothesis is rejected. However, there was no significant difference in pain improvement between the muscle energy group, splint group, and combined treatment group after 3 months.

Patients treated by muscle energy technique reported a significant reduction in pain and significant improvement in maximum mouth opening at 2 weeks, 1 month, and

Table 3: Group wise distribution of temporomandibular disorders sub groups

TMD sub classification	Groups				Total (n=160), n (%)
	Group A (n=40), n (%)	Group B (n=40), n (%)	Group C (n=40), n (%)	Group D (n=40), n (%)	
Local myalgia	3 (1.87)	3 (1.87)	2 (1.25)	2 (1.25)	10 (6.25)
Myofascial pain	9 (5.62)	11 (6.87)	14 (8.75)	11 (6.87)	45 (28.12)
Myofascial pain with referral	5 (3.12)	3 (1.87)	3 (1.87)	2 (1.25)	13 (8.12)
Arthralgia	2 (1.25)	5 (3.12)	5 (3.12)	4 (2.5)	16 (10)
Headache	1 (0.62)	0	1 (0.62)	0	2 (1.25)
Disc displacement with reduction					
Right	4 (2.5)	5 (3.12)	6 (3.75)	6 (3.75)	36 (22.5)
Left	4 (2.5)	6 (3.75)	6 (3.75)	3 (1.87)	
Disk displacement with reduction with intermittent locking					
Right	4 (2.5)	2 (1.25)	2 (1.25)	3 (1.87)	15 (9.37)
Left	2 (1.25)	1 (0.62)	1 (0.62)	3 (1.87)	
Disk displacement without reduction with limited opening					
Right	2 (1.25)	1 (0.62)	1 (0.62)	2 (1.25)	13 (8.12)
Left	3 (1.87)	2 (1.25)	1 (0.62)	3 (1.87)	
Disk displacement without reduction without limited opening	0	0	0	0	0
Degenerative joint disease	3 (1.87)	2 (1.25)	0	2 (1.25)	7 (4.37)
Subluxation	2 (1.25)	0	0	1 (0.62)	3 (1.87)

TMD: Temporomandibular disorders

Table 4: Comparison of Visual Analog Scale at different time interval among groups

Groups	Minimum	Maximum	Mean±SD	Median	P ^a
Baseline					
Group A (n=40)	3.00	8.00	6.05±1.32	6.00	0.11
Group B (n=40)	2.00	9.00	5.75±1.41	6.00	
Group C (n=40)	3.00	9.00	6.10±1.53	6.00	
Group D (n=40)	3.00	9.00	5.45±1.28	5.50	
After 1 week					
Group A (n=40)	2.00	8.00	5.50±4.40	6.00	0.08
Group B (n=40)	2.00	9.00	5.37±1.29	5.00	
Group C (n=39)	3.00	9.00	5.64±1.42	6.00	
Group D (n=40)	3.00	8.00	4.95±1.26	5.00	
After 2 weeks					
Group A (n=38)	1.00	8.00	3.58±1.59	3.00	0.02*
Group B (n=39)	1.00	7.00	3.97±1.39	4.00	
Group C (n=38)	1.00	8.00	3.79±1.34	4.00	
Group D (n=39)	2.00	8.00	4.51±1.47	4.00	
After 1 month					
Group A (n=37)	0	4.00	1.62±1.23	1.00	<0.001**
Group B (n=37)	0	5.00	2.24±1.30	2.00	
Group C (n=37)	0	5.00	1.43±1.37	1.00	
Group D (n=36)	0	7.00	3.75±1.70	4.00	
After 3 months					
Group A (n=37)	0	4.00	1.22±1.20	1.00	<0.001**
Group B (n=37)	0	5.00	1.49±1.45	1.00	
Group C (n=37)	0	4.00	0.89±1.17	1.00	
Group D (n=36)	0	7.00	3.47±1.98	3.00	

^aKruskal-Wallis test, *P<0.05 significant, **P<0.001 highly significant. SD: Standard deviation

3 months' time intervals in comparison to baseline. These findings are in accordance with the findings of Rajadurai^[10] and Trivedi *et al.*^[11] This reduction in pain and improvement in maximum mouth opening can be attributed to the fact that muscle energy technique by stretching the muscle fibers stimulates the Golgi tendon receptors which inhibits the muscle tension leading to relaxation.^[34] When the muscle actively contracts its antagonists reflexively relax because of which opening the mouth against resistance relaxes the

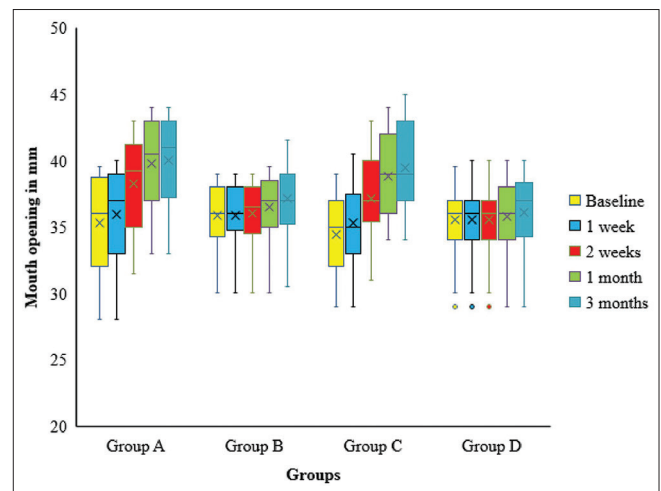


Figure 6: Graphical presentation for comparison of mouth opening (in mm) at different time interval among groups

elevator muscle and vice versa for depressor muscle which can increase MMO.^[35] However, these findings are not in accordance with the findings of Freshwater and Gossling.^[36] This type of contradictory findings might be because both asymptomatic and symptomatic participants with a limited range of mouth opening were recruited by Freshwater and Gossling so the participants without pain at the start of treatment may not have reported improvement in pain. The sample size of the study was also relatively small.

For Occlusal splint therapy, a significant reduction in pain and improvement in maximum mouth opening was observed after 3 months as compared to baseline. These findings are in accordance with the previous studies by several authors who also reported similar findings with the use of stabilization splint therapy.^[12-20,37,38] For the combined treatment group also there was a significant

Table 4.1: Pair wise comparison of Visual Analog Scale after 2 weeks between groups

Groups	Mean difference	P ^a
Group A versus Group B	-0.39	0.09
Group A versus Group C	-0.21	0.27
Group A versus Group D	-0.93	0.004*
Group B versus Group C	0.18	0.41
Group B versus Group D	-0.54	0.21
Group C versus Group D	-0.72	0.04*

^aMann-Whitney U test, *P<0.05 significant

Table 4.2: Pair wise comparison of Visual Analog Scale after 1 month between groups

Groups	Mean difference	P ^a
Group A versus Group B	-0.62	0.04*
Group A versus Group C	0.19	0.36
Group A versus Group D	-2.13	<0.001**
Group B versus Group C	0.81	0.004*
Group B versus Group D	-1.51	<0.001**
Group C versus Group D	-2.32	<0.001**

^aMann-Whitney U test, *P<0.05 significant, **P<0.001 highly significant

reduction in pain and improvement in maximum mouth opening observed after 3 months as compared to baseline.

There was a statistically significant reduction in pain and no significant improvement in mouth opening for the occlusal splint therapy group in comparison to the control group at 1 month and 3 months. These findings are in accordance with the study by Wahlund *et al.*^[39] and Alajbeg *et al.*^[40] who had reported similar results. Present findings are partially supported by previous studies which have shown superior results with splint therapy in comparison to controls.^[18,37,38,41-43,47] Present findings are not in accordance with some previous studies^[19-25,33,44-46,48-53] according to which treatment provided in the control groups are similar in effects or superior to occlusal splint therapy. Possible reasons for this type of contradictory findings with the use of stabilization splint therapy could be due to the difference in sample size, different types of treatment in control groups (Some had used control splints, some had used exercise, brief information, or no treatment), no standard protocol for fabrication of stabilization splint used and difference in the duration of studies.

Occlusal splints when fabricated and adjusted properly improves the symptoms of TMD but the exact mechanism by which it works is still not very clear. However, it is believed that splint relaxes the muscles and allows the condyle to seat completely in centric relation, and reduces the overloading of the joint thereby improving the symptoms of TMD.

There was a highly significant reduction in pain and improvement in maximum mouth opening for the patients of counseling group after 3 months in comparison to baseline. These findings are similar to the findings by

Table 4.3: Pair wise comparison of Visual Analog Scale after 3 months between groups

Groups	Mean difference	P ^a
Group A versus Group B	-0.27	0.53
Group A versus Group C	0.33	0.14
Group A versus Group D	-2.25	<0.001**
Group B versus Group C	0.60	0.08
Group B versus Group D	-1.98	<0.001**
Group C versus Group D	-2.58	<0.001**

^aMann-Whitney U test, *P<0.05 significant, **P<0.001 highly significant

Table 5: Comparison of mouth opening (mm) at different time interval among groups

Groups	Minimum	Maximum	Mean±SD	Median	P ^a
Baseline					
Group A (n=40)	28.00	39.50	35.31±3.42	36.00	0.22
Group B (n=40)	30.00	39.00	35.85±2.61	36.00	
Group C (n=40)	29.00	39.00	34.45±3.10	35.00	
Group D (n=40)	29.00	39.50	35.51±2.69	36.00	
After 1 week					
Group A (n=40)	28.00	40.00	35.94±3.37	37.00	0.55
Group B (n=40)	30.00	39.00	35.90±2.59	36.00	
Group C (n=39)	29.00	40.50	35.27±3.04	35.00	
Group D (n=40)	29.00	40.00	35.55±2.71	36.00	
After 2 weeks					
Group A (n=38)	31.50	43.00	38.24±3.48	39.00	0.002*
Group B (n=39)	30.00	39.00	36.04±2.58	36.50	
Group C (n=38)	31.00	43.00	37.13±3.06	37.00	
Group D (n=39)	29.00	40.00	35.54±2.75	36.00	
After 1 month					
Group A (n=37)	33.00	44.00	39.74±3.26	40.50	<0.001**
Group B (n=37)	30.00	39.50	36.48±2.35	37.00	
Group C (n=37)	34.00	44.00	38.84±3.20	39.00	
Group D (n=36)	29.00	40.00	35.76±2.90	36.00	
After 3 months					
Group A (n=37)	33.00	44.00	39.98±3.27	41.00	<0.001**
Group B (n=37)	30.50	41.50	37.16±2.61	37.00	
Group C (n=37)	34.00	45.00	39.47±3.17	39.00	
Group D (n=36)	29.00	40.00	36.07±2.91	37.00	

^aKruskal-Wallis test, *P<0.05 significant, **P<0.001 highly significant. SD: Standard deviation

Pimental *et al.*,^[54] Aggarawal VR *et al.*,^[55] De Barros Pascoal *et al.*^[56] However, the findings of the counseling group were not significant as compared to other groups.

Pain reduction was significant after 1 month and not significant after 3 months for the muscle energy group in comparison to the splint group. However, mouth opening improvement was highly significant for the muscle energy group as compared to the splint group after 1 month and 3 months. There was no statistically significant difference in pain reduction and mouth opening improvement between the muscle energy technique group and the combined treatment group at specified time intervals. These findings suggest that there are no additional benefits of using combined treatment over muscle energy technique alone.

Pain reduction on VAS for patients of combined treatment was statistically significant at 1 month but not significant at

Table 5.1: Pair wise comparison of mouth opening (mm) after 2 weeks between groups

Groups	Mean difference	P ^a
Group A versus Group B	2.20	0.003*
Group A versus Group C	1.11	0.13
Group A versus Group D	2.70	0.001*
Group B versus Group C	-1.09	0.14
Group B versus Group D	0.50	0.41
Group C versus Group D	1.59	0.04*

^aMann-Whitney U test, *P<0.05 significant

Table 5.2: Pair wise comparison of mouth opening (mm) after 1 month between groups

Groups	Mean difference	P ^a
Group A versus Group B	3.36	<0.001**
Group A versus Group C	0.91	0.24
Group A versus Group D	3.98	<0.001**
Group B versus Group C	-2.35	0.003*
Group B versus Group D	0.72	0.29
Group C versus Group D	3.07	<0.001**

^aMann-Whitney U test, *P<0.05 significant, **P<0.001 highly significant

Table 5.3: Pair wise comparison of mouth opening (mm) after 3 months between groups

Groups	Mean difference	P ^a
Group A versus Group B	2.82	<0.001**
Group A versus Group C	0.51	0.49
Group A versus Group D	3.92	<0.001**
Group B versus Group C	-2.31	0.003*
Group B versus Group D	1.09	0.13
Group C versus Group D	3.40	<0.001**

^aMann-Whitney U test, *P<0.05 significant, **P<0.001 highly significant

3 months follow-up in comparison to occlusal splint therapy group patients. However, mouth opening improvement was statistically significant for the combined treatment group in comparison to the occlusal splint group after 1 month and 3 months. These findings are partially supported by the findings of Espi Lopez *et al.*^[57] who reported that combined treatment protocol based on manual therapy plus splint therapy tends to improve pain, pain-induced dysfunction, and patients' self-perception of change in patients with TMD.

In the present study, we have used education for self-management and counseling as a treatment for the control group because it is reported that counseling was equally effective in improving muscle tenderness and maximum mouth opening as compared to the occlusal appliance, and counseling and self-management-based therapies are conservative, low cost, and beneficial treatment alternatives.^[48]

To avoid inter-examiner error, all the treatments were provided and outcomes were measured by the principal investigator. However, because of that, it was not possible to blind the investigator and assessor which can be the possible limitation of the trial. In this trial, participants and statistical

analysts were blinded. The possible heterogeneity of patients could not be taken into account in this study however homogeneity was increased by excluding the diseases or conditions which might have an effect on the treatment outcome of the research.^[53] Because of the high number of patients with myofascial pain and disc displacement with the reduction in all groups and overlap of different diagnoses, groups were not homogeneous according to subclassification of TMD which is a limitation of the present study.

CONCLUSION

Within the limitation of this randomized controlled trial, we can conclude that;

1. Muscle energy technique is effective in reducing pain and increasing maximum mouth opening in patients with TMD at 3 months in comparison to education for self-management and counseling. Muscle energy technique is also effective in improving maximum mouth opening in patients with TMD at 3 months in comparison to occlusal splint therapy; however, its effects on pain reduction are similar to occlusal splint therapy at 3 months. Muscle energy technique provides reduction in pain and improvement in mouth opening similar to combined treatment in the management of TMD at 3 months
2. Occlusal splint therapy (stabilization splint) is effective in reducing the pain of TMD at 3 months in comparison to education for self-management and counseling; however, its effects on maximum mouth opening are similar to education for self-management and counseling. Occlusal splint therapy and combined treatment do not vary significantly in terms of pain reduction in patients with TMD at 3 months; however, combined treatment significantly improves maximum mouth opening in patients with TMD at 3 months in comparison to occlusal splint therapy
3. Combined treatment significantly reduces the pain and improves the maximum mouth opening in patients with TMD at 3 months in comparison to education for self-management and counseling.

Future recommendation

Further studies as randomized controlled trials are recommended for a longer duration to assess the effects of Muscle energy technique, occlusal splint therapy, and combined treatment on distinct subgroups of TMD.

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Conflicts of interest

There are no conflicts of interest.

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