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## Soft occlusal splint therapy in the management of myofascial pain dysfunction syndrome: A follow-up study in Kashmiri population

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### Abstract

**Background:** Psychological discomfort, physical disability and functional limitations of the orofacial system have a major impact on everyday life of patients with temporomandibular disorders (TMDs). A variety of therapies has been described in literature for its management. The present study is a prospective study carried out to evaluate the efficacy of occlusal splint therapy and compare it with pharmacotherapy (using analgesics and muscle relaxants) in the management of Myofascial Pain Dysfunction Syndrome.

**Materials and Methods:** Forty patients in the age range of 17-55 years were included in the study and randomly assigned to one of two equally sized groups, A and B. Group A patients received a combination of muscle relaxants and analgesics while Group B patients received soft occlusal splint therapy. All the patients were evaluated for VAS, maximum comfortable mouth opening, TMJ clicking and tenderness during rest and movement as well as for the number of tender muscles at the time of diagnosis, after the 1st week of initiation of therapy and every month for three months of follow-up.

**Results:** There was a progressive decrease in number of tender muscles, TMJ clicking and tenderness with various jaw movements and significant improvement in mouth opening in patients on occlusal splint therapy during the follow-up period as compared to the pharmacotherapy group.

**Conclusion:** Occlusal splint therapy has better long-term results in reducing the symptoms of MPDS. It has better patient compliance, fewer side effects, and is more cost-effective than pharmacotherapy; hence, it can be chosen for the treatment of patients with MPDS.

**Keywords:** Myofascial pain dysfunction syndrome, occlusal splint therapy, pharmacotherapy

### Introduction

Temporomandibular disorders (TMD) comprise a spectrum of conditions affecting the temporomandibular joints and muscles of mastication. These musculo-skeletal conditions have similar signs and symptoms including pain, limitation of movement, joint noises (clicking and crepitus), incoordination, headaches and occasionally tinnitus. In recent years, specific diagnostic criteria for sub-diagnoses of TMD have been introduced<sup>[1-3]</sup>, but most dentists may be more familiar with catch-all terminology such as 'temporomandibular joint dysfunction syndrome', facial arthromyalgia or Costen's Syndrome. Dentists are extensively involved in the management of TMD. A critical review has found that occlusal splints may be of benefit in TMD<sup>[4]</sup>.

Occlusal splint therapy is chosen for the treatment of dysfunctions in the orofacial region for several reasons. It is relatively simple, reversible, noninvasive and costs less than other treatments. Soft splints have been advocated for patients with TMD. They can be made for maxillary arches and are easily constructed and often inserted immediately at the initial examination. A high degree of patient acceptance has been reported with soft splints. The soft, resilient material may help in distributing the heavy load that occurs during parafunctional activity<sup>[5]</sup>.

A wide variety of drug classes have been described for chronic orofacial pain, ranging from short-term treatment with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and muscle relaxants for pain of muscular origin to long-term administration of antidepressants for less well-characterized pain.

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In this context, this study was carried out to evaluate the efficacy of conventional soft occlusal splint therapy in comparison to pharmacotherapy with a combination of analgesics and muscle relaxants in the management of Myofascial pain dysfunction syndrome.

## Materials and Methods

### Subjects

This prospective study was conducted in the Department of prosthodontics, Government Dental College & Hospital, Srinagar. Subjects were selected from a consecutive series of Myofascial pain dysfunction syndrome.

### Inclusion criteria

Adult patients suffering from chronic Myofascial pain for a minimum duration of three months and willing to participate in the study.

The diagnosis of Myofascial Pain Dysfunction Syndrome in these patients was based on the clinical features outlined by Eversole and Machado [6]. These include i) tender muscles of mastication, often accompanied by neck and strap muscles tenderness, ii) Restricted or deviated mandibular movement caused by muscular restriction, iii) No clinical or radiographic evidence of internal derangement [5].

### Exclusion Criteria

occlusal disharmony, those undergoing orthodontic treatment and/or occlusal corrections, any form of arthritis affecting the TMJ and patients undergoing treatment from a psychiatrist for psychological disorders associated with pain in the TMJ region.

The disease process and treatment procedures were fully explained to each patient and consent was obtained before the commencement of the study.

### Screening Procedure

A detailed history was recorded for each patient at the time of diagnosis regarding onset, duration and progress of symptoms. Pain characteristics like type, nature and severity were noted. Pain response to jaw activities such as mastication, phonation, and deglutition were also recorded. Intensity rates of pain were recorded on a Visual Analog Scale, 100 mm-long continuum (VAS) [7]. extremes were labeled as no pain and worst possible pain.

After taking history, maximum comfortable mouth opening of all patients was recorded. Temporomandibular joint examination included assessment of clicking, tenderness at rest and during various jaw movements (opening, closing, right and left lateral, protrusion and retrusion) and deviation during opening and closing movements. Both study and control groups were matched for mouth opening and TMJ clicking [Tables 1 and 2]. Tenderness of the muscles of mastication and the neck muscles was assessed by means of digital palpation, resistance testing and functional

manipulation of the muscles [8]. Tenderness in the muscle was recorded as being present or absent. Extraoral masticatory muscles such as the temporalis and masseter, were palpated with a digital pressure of 2 lb/ in<sup>2</sup>. The medial and lateral pterygoids were evaluated by functional manipulation [9].

### Group Assignment

Forty patients diagnosed with Myofascial Pain Dysfunction Syndrome were selected for the study and randomly assigned to two equally sized groups, A and B consisting of 10 patients each. The mean ages of the patients were 35.85 and 25.85 years in Groups A (pharmacotherapy group) and B (Occlusal splint therapy group), respectively. Group A was comprised of 40% males and 60% females, whereas Group B was comprised of 30% males and 70% females.

Group A (the positive control group) received an orally administered combination of muscle relaxants and analgesics comprising of Ibuprofen 400 mg, Paracetamol 325 mg, and Chlorzoxazone 250 mg in two doses daily for a period ranging from 5-7 days initially.

Group B was treated with Occlusal splint therapy for a period of three months. Patients were instructed to wear the splint at night to take care of parafunctional habits if any. In both the groups, subjective and objective assessments were evaluated at the time of diagnosis, after the first week of initiation of therapy and every month for three months of follow-up.

### Fabrication and adjustment of the occlusal splint

An alginate impression of the maxillary and mandibular arches was made. A soft occlusal splint was fabricated from a 3 mm-thick, soft polyvinyl sheet [Figure 1]. The sheet was adapted to a maxillary cast. The fabrication was done in a vacuum former, pressure moulding device [Figure 2] with a thermally controlled, infrared heater. This machine accomplished vacuum suctioning of the warmed sheet of thick, resilient mouthguard material over the maxillary cast [Figure 3]. When the sheet had properly adapted to the cast in the vacuum former, it was taken out. The splint was then separated from the cast with a laboratory knife/scissors, the edges were smoothed and the palatal area removed. The splint was then disinfected with 2% glutaraldehyde and placed in the patients mouth to check for retention. Chair side occlusal adjustment was made by evenly warming the occlusal surface of the splint with an alcohol torch before insertion into the patients mouth. A functional imprint was developed in centric using bilateral, centric relation manipulation such that it had evenly distributed bilateral, posterior contact with little or no contact with the anterior teeth when in centric occlusion. Anterior guidance provided posterior separation in excursive movement. A carbide bur was used to remove the excess material from the imprint to develop the desired occlusal pattern. The soft splint was then polished with pumice, disinfected and the appliance then placed in the patients mouth [Figures 4, 5].



Figure 1: BIOPLAST® polyvinyl sheet

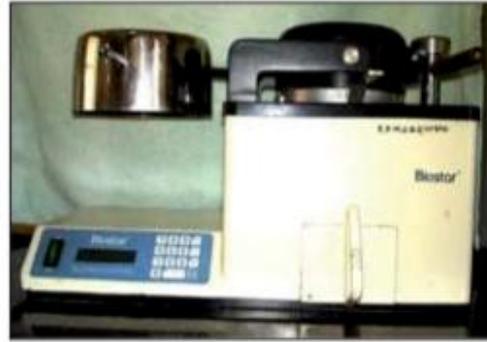


Figure 2: Biostar® vacuum former



Figure 3: Bioplast® polyvinyl sheet adapted on the maxillary cast



Figure 4: Frontal view of occlusal splint



Figure 5: Lateral view of occlusal splint

Time intervals	Group A	Group B	t-value	P	Significance
<b>GPI</b>					
At the time of diagnosis	1.95 ± 0.8048	2.20 ± 0.5231	-1.3981	0.1702	NS
After 1 <sup>st</sup> week of initiation of therapy	1.00 ± 0.5620	1.15 ± 0.8751	-0.6450	0.5228	NS
One month follow-up	1.40 ± 0.5982	0.90 ± 0.9119	2.0503	0.0473	S
Two months' follow-up	1.40 ± 0.5982	0.65 ± 0.8127	3.3236	0.0020	S
Three months' follow-up	1.60 ± 0.5026	0.65 ± 0.8127	4.4460	0.0001	S
<b>VAS</b>					
At the time of diagnosis	6.00 ± 1.0761	6.15 ± 0.4894	-0.5675	0.5737	NS
After 1 <sup>st</sup> week of initiation of therapy	4.00 ± 1.3377	5.15 ± 1.3485	-2.7076	0.0100	S
One month follow-up	4.85 ± 1.6631	4.85 ± 1.2680	0.0000	1.0000	NS
Two months' follow-up	4.85 ± 1.6631	4.00 ± 1.0260	1.9453	0.0605	NS
Three months' follow-up	5.05 ± 1.3169	4.00 ± 1.2566	2.5797	0.0138	S
<b>Number of tender muscles</b>					
At the time of diagnosis	2.40 ± 1.0463	2.85 ± 0.9333	-1.4353	0.1593	NS
After 1 <sup>st</sup> week of initiation of therapy	1.30 ± 0.8013	1.25 ± 0.9665	0.1780	0.8598	NS
One month follow-up	1.50 ± 0.9272	0.85 ± 1.0400	2.1875	0.0352	S
Two months' follow-up	1.55 ± 0.7592	0.85 ± 1.0400	2.4312	0.0203	S
Three months' follow-up	1.45 ± 0.8256	0.85 ± 1.0400	2.0208	0.0500	S
<b>Mouth opening (mm)</b>					
At the time of diagnosis	39.75 ± 7.3404	39.05 ± 6.4765	0.3197	0.7509	NS
After 1 <sup>st</sup> week of initiation of therapy	40.50 ± 6.1087	44.05 ± 7.3590	-1.6599	0.1053	NS
One month follow-up	40.30 ± 6.4734	45.00 ± 7.0188	-2.2014	0.0339	S
Two months' follow-up	40.30 ± 6.4734	45.75 ± 7.1516	-2.5267	0.0158	S
Three months' follow-up	40.30 ± 6.4734	46.70 ± 7.1311	-2.9718	0.0051	S

NS = Not Significant, S = Significant

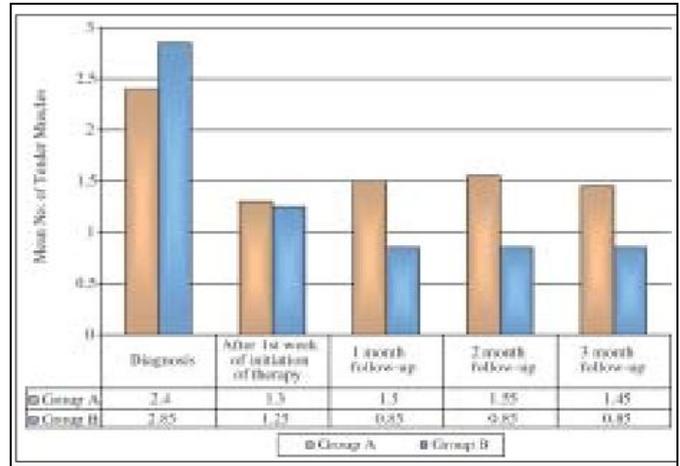
**Table 2: Chi square test for comparison of TMJ clicking between Groups A and B at the time of diagnosis and follow-up**

Time intervals	Group A	%	Group B	%	Chi-square	P	Significance
At the time of Diagnosis							
N	12	60	16	80	1.9047	0.1676	NS
Y	8	40	4	20			
After 1 <sup>st</sup> week of initiation of therapy							
N	12	60	20	100	10.0000	0.0016	S
Y	8	40	0	0			
One month follow-up							
N	13	65	20	100	8.4848	0.0036	S
Y	7	35	0	0			
Two months' follow-up							
N	12	60	20	100	10.0000	0.0016	S
Y	8	40	0	0			
Three months' follow-up							
N	13	65	20	100	8.4848	0.0036	S
Y	7	35	0	0			

N = No, Y = Yes, NS = Not Significant, S = Significant

**Results**

Table 1 shows the comparison of different variables measured between the two groups at various time intervals. Number of tender muscles [Graph 2] and TMJ clicking [Table 2] showed significant reduction in Group B (patients on occlusal splint therapy) compared to Group A (patients on pharmacotherapy) during the three months of treatment follow-up. Also, it can be noted here that a significant increase in mouth opening [Graph 3] was observed in Group B patients compared to Group A. VAS scores for pain intensity [Graph 1] showed significant reduction in Group A immediately after seven days of drug therapy, but no reduction during three months of treatment follow-up. On the other hand, Group B showed no reduction in VAS scores immediately after seven days of occlusal splint therapy, but significant reduction was seen in the 3rd month of treatment follow-up. Improvement in TMJ tenderness during rest and during movements, and jaw deviation revealed no significant difference between Group A and Group B during the course of the study.



**Graph 3:** Mouth opening in mm of Group A and Group B at time of diagnosis and during follow up.

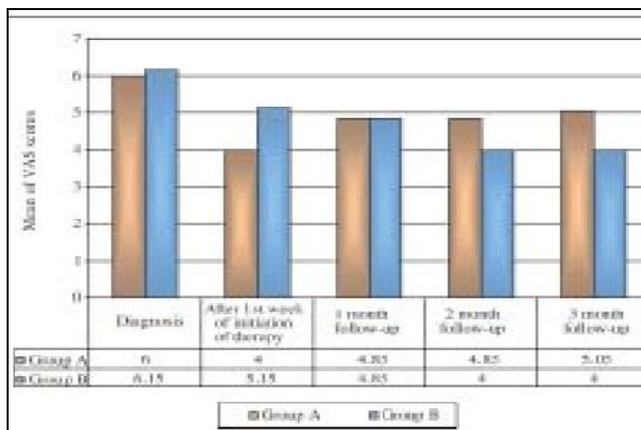
**Discussion**

The success for a treatment of any disorder relies on two considerations: relieving of symptoms and treating the cause. Choosing a specific conservative treatment modality for Myofascial Pain Dysfunction Syndrome patients depends on clinicians expertise, patient presentation, and elimination of possible etiologic factors. Till date, no single treatment modality has been proven to be better than any other for TMD.

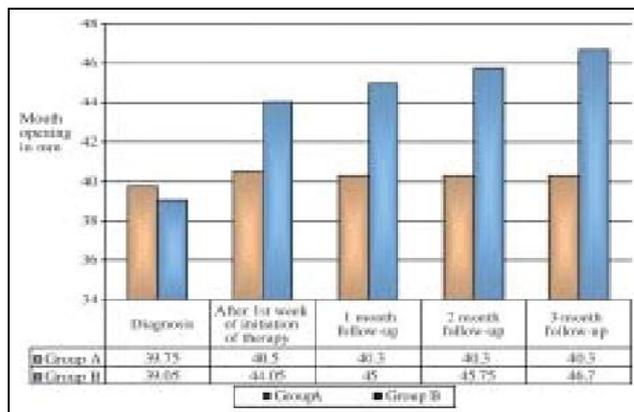
The present study evaluates the efficacy of occlusal splint therapy in the management of MPDS in comparison with pharmacotherapy, both being conservative treatment modalities.

In the current study, 55% of the patients of Group B had complete remission in VAS scores, the remaining 45% had significant reduction. TMJ clicking in Group B had also shown significant reduction as compared to Group A during the three months of treatment followup. Block *et al.*, 10 also found that after six weeks of using soft splints, 74% patients had complete or almost complete remission of their TMD symptoms.

In the present study, 11 out of 20 patients (55%) in Group B had complete reduction in muscle tenderness and the remaining nine had significant reduction. Four patients had clicking at the time of diagnosis, which had completely decreased by the third month of treatment follow-up. Kovaleski *et al.* [11] have also shown significant reduction in clicking, TMJ and muscle tenderness in response to occlusal splint therapy when patients were followed up for two months. In our study, 70% of the patients showed VAS scores of less than five on a 10-cm continuum scale. Tsuga *et al.* [12] concluded that 87% of their patients had reduced TMJ pain; VAS reduction was seen in 50% and clicking was reduced in 70% of the patients. Harkins *et al.* [13] found that 74% of the



**Graph 1:** Mean VAS scores of Group A and Group B at time of diagnosis and during follow up.



**Graph 2:** Mean scores of number of tender muscles of Group A and Group B at time of diagnosis and during follow up.

patients with soft splints had reduction in facial myalgia and reduction in or elimination of TMJ clicking. This improvement can be explained by the fact that occlusal splints with equal-intensity contacts on all of the teeth, with immediate disclusion of all posterior teeth by the anterior teeth and condylar guidance in all movements. This will relax the elevator and positioning muscles and contribute to the reduction of abnormal muscle hyperactivity<sup>[14]</sup>.

When a splint is inserted, there is an adaptation to a new resting postural position. Occlusal splints that increase the occlusal vertical dimension beyond the freeway space, cause an immediate adaptation to a new freeway space at an increased vertical dimension. Thus, an occlusal splint allows a muscle to function more efficiently during contact and be less active during postural functions. Hence, as the vertical dimension increases from the occlusal contact on the insertion of an occlusal splint, muscular effort decreases resulting in the relaxing of the muscles and hence, the TMJ<sup>[15]</sup>.

In the existing study, the VAS scores reduced significantly after pharmacotherapy immediately after seven days of treatment, but the effect was not sustained during three months of treatment follow-up. This is consistent with the study conducted by Minakuchi *et al.*, on the efficacy of occlusal splint therapy and pharmacotherapy on anterior disk displacement without reduction. They showed that both experimental groups had a significant improvement for most of the outcome variables, i.e., maximum mouth opening, VAS of pain and daily activity limitation<sup>[16]</sup> The only group effect seen was with the daily activity limitation variable wherein NSAIDs had a stronger effect than the splint. However, this difference was present only for one month and there were no significant group differences at the completion of the treatment.

In our study, the occlusal splint therapy did not result in any significant reduction in the VAS scores immediately after seven days of treatment, but significant and progressive reduction in VAS scores was seen in the third (last) month of treatment follow-up. This indicates that the occlusal splint causes a slow and steady improvement in TMJ symptoms in comparison to pharmacotherapy. This is in agreement with the conclusions of Raphael *et al.*<sup>[17]</sup> who found that occlusal splints had decreased the VAS scores and the number of painful muscles during a six-week follow-up study in patients with myofascial pain.

In our study, 65% of the patients showed an increase of 10.02 mm improvement in mouth opening with a mean increase of 7.4 mm. Suvinen *et al.*<sup>[18]</sup> have also shown a 7.4 mm improvement in mouth opening after splint therapy. Occlusal splint therapy decreased the pain and tenderness in the muscles and joints of the patients in the present study, apparently allowing an increase in their maximal mouth opening.

Davies *et al.*<sup>[19]</sup> in their study on the pattern of splint usage found no advantage of any particular pattern of splint use (i.e., day/night/day and night-time wear) in patients with myofascial pain dysfunction syndrome. In our study, the patients were instructed to wear the splint during the night to take care of any existing parafunctional habits. Results showed a progressive decrease in VAS scores, the number of tender muscles and TMJ clicking. In the present study, the patients in Group B experienced a decrease in the intensity of facial pain and a progressive improvement in TMJ disorder symptoms in comparison to Group A patients.

In the current study, 11 out of 20 patients in group B had bruxism, of these 11, eight patients showed significant

reduction in parafunctional habits. The other three patients found the occlusal splint to be ineffective in reducing bruxism. Raphael *et al.*<sup>[17]</sup> found an improvement in pain related measures but the severity of bruxism did not moderate the therapeutic effect of the occlusal splints in their study. This could be explained due to the compressible nature of the soft occlusal splint in patients who are dedicated bruxists and who are so aware of having something compressible in the mouth that they actually increase the activity rather than decrease it<sup>[18]</sup>.

Nonsteroidal anti-inflammatory analgesics (NSAIDs) are known to be effective in the management of mild-to moderate inflammatory conditions, particularly of the musculoskeletal system<sup>[20]</sup>. Muscle relaxants are administered to reduce skeletal muscle tone and are often administered to patients with muscle tone and chronic orofacial pain to help prevent or alleviate the increased muscle activity<sup>[20]</sup>. They are thought to decrease muscle tone without the impairment of motor function by acting centrally to depress polysynaptic reflexes.

Andrade *et al.*<sup>[21]</sup> have reported pharmacological guidelines for the treatment of TMD. For acute spasm or Myofascial pain, Dypirone 500 mg can be given with a muscle relaxant, three times daily for two days whereas NSAIDs (oral route) can be given for 5-7 days for myositis and TMJ inflammatory disorders. A lack of therapeutic effect after a 7-10 days trial or the development of any Gastro Intestinal (GI) symptoms should lead to prompt discontinuation of the NSAIDs<sup>[22]</sup>.

Due to the lack of standard recommended dosages of any form of pharmacotherapy, a commercially available combination of a muscle relaxant and analgesics consisting of Ibuprofen 400 mg, Paracetamol 325 mg, and Chlorzoxazone 250 mg was administered orally twice a day for 5-7 days initially in the present study. When patients reported with recurrence of pain during their post treatment follow-up, they were advised to repeat the same treatment regimen.

There was no report of serious side effects due to drug intake in any patient. In Group B, a few patients had initial side effects such as dryness of mouth, occasional feeling of tightness of the appliance, and a feeling of queasiness and presence of foreign object, which gradually decreased within few days. The results of the present study infer that a soft occlusal splint therapy is a commonly used conservative treatment modalities and is useful in the reduction of pain and tenderness in the muscles and also in an improvement in mouth opening. This is in agreement with various studies supporting the usefulness of occlusal splints in the management of Myofascial Pain Dysfunction Syndrome<sup>[9, 11, 12, 16, 19, 20, 23-38]</sup>.

The present study supports the use of conventional soft occlusal splints in the safe management of patients with myofascial pain dysfunction syndrome. But the present study does have certain limitations.

## Conclusions

The conventional soft occlusal splint therapy is a much safer and effective mode of a conservative line of therapy in comparison to long-term pharmacotherapy in patients with myofascial pain dysfunction syndrome. The advantages of occlusal splint therapy include reversible therapy, better results, fewer side effects, cost-effectiveness and better patient compliance than pharmacotherapy, which has many adverse side effects. The occlusal splint may also have placebo effects. This study supports the use of occlusal splint therapy in the management of Myofascial Pain Dysfunction Syndrome for better long-term results.

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