Original Article

Comparative evaluation of clinical performance of different kind of occlusal splint in management of myofascial pain

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Abstract

Purpose: To determine the efficacy of hard, liquid, and soft splints in the management of myofascial pain dysfunction syndrome.

Materials and Methods: In this randomized clinical trial, 45 patients with myofascial pain were diagnosed and were randomly assigned into three groups of 15 patients each. Group 1 - subjects were given hard splint, Group 2 - soft splint, and Group 3 - liquid oral splint for 3 months. Subjective pain analysis using Modified Symptom Severity Index (Mod-SSI) and objective pain analysis muscle palpation was performed at 7 days, 1 month, 2 months, and 3 months after splint insertion. The changes in mean pain value by both methods, in all three groups, were analyzed with Tukey test and Kruskal–Wallis H-test, respectively ($P < 0.05$).

Results: Both Mod-SSI and palpation scores showed statistically significant reduction in pain for all three groups at the end of 3 months. However, the hard splints proved to be very effective in a shorter period of time, followed by liquid splints and finally soft splints.

Conclusion: The result of this study advocates the use of any one of the three types of the occlusal splints in the therapeutic management of myofascial pain due to temporomandibular disorders.

Key Words: Myofascial pain, occlusal splints, temporomandibular disorders

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INTRODUCTION

Patients with signs and symptoms of temporomandibular disorders (TMDs) are commonly treated with occlusal splint therapy.[1] Occlusal appliances are commonly used in the treatment of patients with TMDs and their effectiveness in reducing symptoms has been reported to vary between 70% and 90%.[2]

Hard acrylic-resin appliances have consistently been shown to be effective.[3-6] On the other hand, investigations have shown that soft appliances are effective for the reduction of muscle pain,[7-9] temporomandibular joint (TMJ) clicking,[8] and headache.[10] Hydrostatic appliance was designed by Lerman[11] over 30 years ago. In its original form, it consisted of bilateral water-filled plastic chambers attached to an acrylic palatal appliance, and the patient's posterior teeth would occlude with these chambers. Later, this was modified to become a device that could be retained under the upper lip, whereas the

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fluid chambers could be positioned between maxillary and mandibular posterior teeth.

Most of the occlusal splints currently in use are either the hard or soft splints. Hard splints have an advantage of having an occluding surface that is hard enough that does not lose; it is fit and thereby lasts longer.[12] Soft splints are simple to fabricate and have a soft occlusal surface that can be easily adjusted to adequate contact pattern. Hard splints can sometimes cause significant occlusal changes, which is not acceptable.[13] Soft splints can aggravate bruxism,[14] may be due to premature posterior contacts related to the fact that these splints cannot be balanced.

However, the hydrostatic occlusal splints have a flexible fluid layer that equalizes all bite forces by preventing tooth to tooth contact. It has a unique water system that immediately optimizes biomechanics, supports the jaw in a comfortable position, removes the teeth from dominance, placing bite and body in harmony, straightens the bite to maximize other structures, enables systemic function and balance, allows the body to naturally balance itself, and finds perfect occlusal balance after starting the treatment immediately.[15]

There are conflict of reports regarding the efficacy of different kinds of splints; it is difficult for clinicians to make evidence-based decisions regarding splint therapy because few randomized controlled clinical trials have compared different occlusal splint designs, including a "placebo" splint.[16,17] In this context, this study was carried out to study the efficacy of hard, liquid, and soft splints in the management of myofascial pain dysfunction syndrome.

MATERIALS AND METHODS

This study was conducted in the Department of Prosthodontics and Department of Oral Medicine and Radiology. Study sample consisted of 45 patients diagnosed with myofascial pain from the Department of Oral Medicine. Sample selection was based on a standardized and complete clinical examination based on the Research Diagnostic Criteria (RDC-TMDs).[18]

Ethical clearance was approved by the Institutional Review Board. Informed consent was obtained from each patient prior to participation in this study.

The inclusion criteria for selecting patients

- Group I: Muscle disorder
  - Myofascial pain
  - Myofascial pain with limited opening.
- Age: 18–65-year-old
- Should have at least six natural teeth in each quadrant.

Exclusion criteria

- Previous experience with occlusal splint therapy
- Any obvious dental decay or periodontal disease to which fascial pain could be attributed
- History of trauma in the pain area in <30 days
- Any systemic condition associated with widespread pain (e.g., fibromyalgia)
- Medical history of current drug addiction
- Any other disorders such as TMJ osteoarthritis or capsulitis
- Patient with psychiatric disorder
- Subject not willing to accept treatment.

Patients were randomly assigned using randomization table and categorized into three groups, with 15 patients in each group:

- Group 1: Hard splint
- Group 2: Soft splint
- Group 3: Liquid splint.

Group 1

The splints were fabricated with 3 mm thickness of acrylic between the maxillary and mandibular posterior teeth. These were stabilization type of splints. The splints were adjusted to create uniform occlusal contact of the centric cusps against the splint on all occluding posterior teeth, anterior teeth was in contact with the splint and provided a mutually protected occlusion [Figure 1].

Group 2

A soft occlusal splint was fabricated from a 3 mm thick, soft polyvinyl sheet. The fabrication was done in a vacuum former, pressure-molding device (BIOSTAR® SCHEU-DENTAL GmbH, Iserlohn, Germany) with a thermally controlled infrared heater over the mandibular cast and occlusal contacts were neutralized [Figure 2].

Group 3

Readily available liquid occlusal splints (Aqualizer™, BVM Meditech Pvt. Ltd., New Delhi, India) were given to these subjects [Figure 3].

Study period was for 3 months with evaluation at 7 days, 1 month, 2 months, and 3 months after splint insertion. Patients were instructed to wear splint for 24 h a day for 7 days and taken out during meals. Each patient was evaluated according to the subjective and objective assessment.

- Subjective pain analysis was done using Modified Symptom Severity Index (Mod-SSI). This scale has 28, characters for each of the three variables: Intensity, frequency, and pain duration. An average of the three variables was obtained, and final scores ranged from 0.035 to 1[19]

- Objective pain report analysis of muscular palpation (masseter, temporalis, and pterygoid muscles) was performed bilaterally with tight and constant pressure of approximately 1.500 g and were classified on a scale from 0 to 3 (0 - no pain; 1 - verbally reported pain; 2- pain or discomfort followed by fascial musculature contraction, and 3- when the patient backed away or showed lacrimation).[19]

Figure 1: Hard splint inserted in patient's mouth

Figure 2: Soft splint inserted in patient's mouth

Figure 3: Liquid supported splint inserted in patient's mouth

The obtained data were subjected to statistical analysis using IBM SPSS software (version 20.0, Chicago, IL, USA). Tukey test was used to compare the values of the Mod-SSI between three groups at all times. Kruskal–Wallis H-test was used to analyze the scores of digital palpation, both between groups and each groups at all times. Differences were considered statistically significant at $P \leq 0.05$.

RESULTS

The sample included 45 subjects (15 in each group) the Mod-SSI score showed statistically significant reduction for all three groups reflecting patients' improvement in muscle pain with hard, soft, and liquid supported splints. The hard splints proved to be very effective in a shorter period of time. From baseline to 7-day interval the curve for the hard splints showed a steep change. Whereas the soft and liquid splints showed much more gradual change from baseline to the 7-day interval and was rhythmic thereafter. However, from baseline to 90-day interval, all the three groups showed a considerable and comparable decrease in Mod-SSI scores.

The results for objective palpation also showed statistically significant difference between baseline and 90 days for all three groups, i.e., hard, soft, and liquid splints. For initial few days liquid splints was better followed by hard and soft splints. However, hard splints were more effective in shorter duration of time followed by liquid splints and lastly soft splints [Tables 1 and 2, Figures 4 and 5].

DISCUSSION

Treatments for TMDs are wide ranging and are directed primarily toward relief from persistent orofacial pain.[18,20,21] Due to difficulty in determining the etiology and the possibility that the symptoms are secondary to some other disorders of the TMJ or muscles of mastication initial treatment given should be reversible.

When a splint is inserted, there is an adaptation of the jaws to a new resting postural position. Occlusal splints that increase the occlusal vertical dimension beyond the freeway space cause an immediate adaptation to the new freeway space at an

Table 1: Means and SD for Mod-SSI and digital palpation for the three groups

Time	Mean±SD					
	Hard splint		Liquid splint		Soft splint	
	Mod-SSI	Digital palpation	Mod-SSI	Digital palpation	Mod-SSI	Digital palpation
Baseline	0.61±0.17	1.13±0.36	0.67±0.24	1.26±0.27	0.71±0.19	0.98±0.22
7 days	0.11±0.13	0.48±0.19	0.34±0.21	0.42±0.18	0.43±0.21	0.62±0.18
30 days	0.04±0.12	0.06±0.10	0.1±0.16	0.24±0.21	0.15±0.12	0.24±0.10
60 days	0.03±0.1	0.02±0.13	0.05±0.20	0.04±0.15	0.06±0.17	0.07±0.13
90 days	0.02±0.14	0±0	0.02±0.13	0±0	0.03±0.13	0±0

SD: Standard deviation, Mod-SSI: Modified Symptom Severity Index

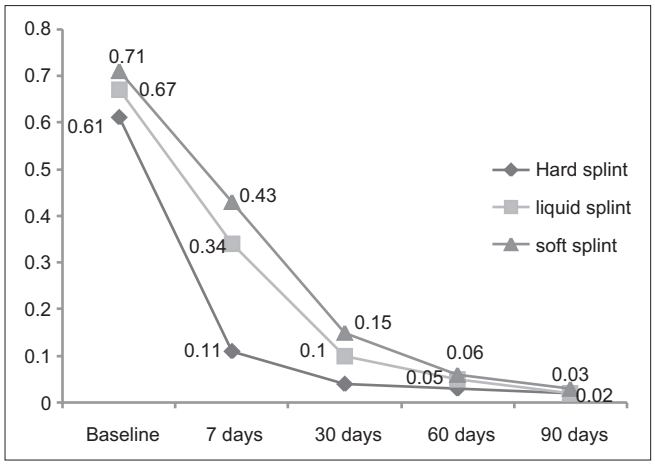

Figure 4: Mean of Modified Symptom Severity Index scores at each intervals for all three groups

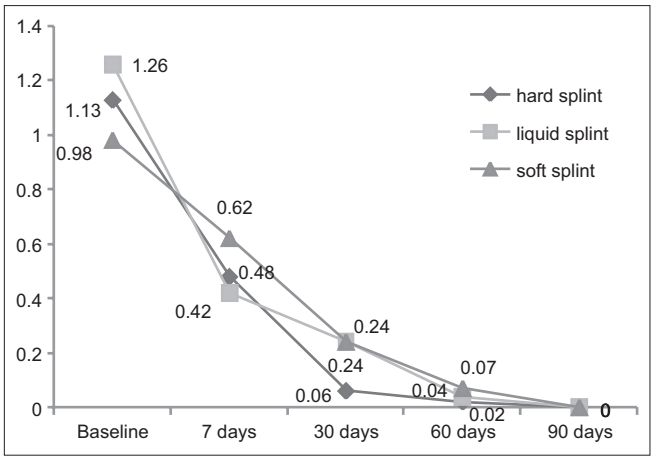

Figure 5: Mean of Digital Palpation scores of all muscles at each intervals for all three groups

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 the occlusal splint, muscular effort decreases resulting in the relaxing of the muscles and hence, TMJ.[22] Acrylic resin interocclusal appliances have been used in dentistry for the management and treatment of TMDs.[2,23-25]

Tsuga *et al.* (1989) had done a study on hard splints and found that it is ineffective in reducing muscle pain,[26] which is in contrast with our study. In the present study, hard splints were more effective compared to soft and liquid splints, showing significant difference throughout the study period. In 1988, a study done by Harkins *et al.* concluded that soft splints had a reduction in facial myalgia.[8] In our study, soft splints were effective, but when compared to liquid and hard splints it was less effective. For soft splints, the change was much more gradual from baseline to 7-day interval and was rhythmic thereafter. A study done by Nevarro *et al.* (1985) had concluded that soft splints are ineffective,[27] and in another study done by Okeson (1987) on nocturnal electromyogram comparison of hard and soft reported significantly less effect with soft splints,[14] but our study found that soft splints are effective in reducing the symptoms of myofascial pain although the time taken by them was slightly longer as compared to the hard and liquid splints.

Truelove *et al.* (2006) did a randomized trial in which they found that all the patients improved irrespective of splint design,[16] which is in accordance with our study, where there was both subjective and objective reduction in pain. Davies and Gray (1997) did an investigation on the pattern of splint usage found no advantage of any particular pattern of splint use.[28] Whereas in our study, we had an advantage of liquid

Table 2: *P* values for Mod-SSI and Digital Palpation scores between hard, liquid and soft splint groups at different intervals

	Hard splints	Liquid splints	Soft splints
Mod-SSI			
Baseline to 7 days	NS	NS	NS
Baseline to 30 days	≤0.05	NS	NS
Baseline to 60 days	≤0.05	≤0.05	NS
Baseline to 90 days	≤0.05	≤0.05	≤0.05
Digital palpation			
Baseline to 7 days	≤0.05	≤0.05	NS
Baseline to 30 days	≤0.05	≤0.05	NS
Baseline to 60 days	≤0.05	≤0.05	≤0.05
Baseline to 90 days	≤0.05	≤0.05	≤0.05

P≤0.05 is significant. NS: Nonsignificant, Mod-SSI: Modified Symptom Severity Index

and hard splints when compared to soft splints. A study done by Pettengill *et al.* (1998) found no difference between hard and soft splints.[29] However, in the current study, hard splint was more effective in comparison with the soft and liquid splints, though soft splints also showed a significant reduction in pain. Soft splints have been used as an interim appliance until acrylic-resin splints could be provided. These appliances have also been suggested as prognostic tool to evaluate whether an acrylic-resin splint would be advantageous. It has been postulated that the soft occlusal surface of soft splint may contribute to occlusal changes.[9] Liquid supported splints have been advocated for patients with TMDs. However, there are few trials that have evaluated efficacy and outcomes have been variable. Aqualizer™ works by allowing the muscles to automatically reposition the jaw. For relieving TMJ pain, restoring it is essential to restore this balance. Aqualizer™ is a new application of a basic physical law of nature called Pascal's law, which states that an enclosed fluid will apply equalized fluid pressure regardless of where the pressure is applied to the fluid. In other words, when a patient bites on the Aqualizer™, the fluid within it distributes bite forces evenly across the bite, reducing TMJ pressure and pain, and hence ensuring relief.[15]

Macedo and Mello (2002) evaluated the efficacy of the hydrostatic splint Aqualizer™, microcurrent electrical nerve stimulation (MENS) and transcutaneous electrical neural stimulation (TENS) therapies in patients with TMD in acute situations and concluded that the MENS and the hydrostatic splint were more effective than TENS,[30] which is consistent with our study, where liquid supported splint was more effective compare to the soft splints.

Research on TMD recommended the evaluation of pain in the masticatory muscle through subjective pain and digital palpation. The Mod-SSI is more complete than Visual Analog Scale because it takes into consideration, pain frequency and duration along with its intensity.[31]

Sample selection was based on a standardized and complete clinical examination based on the RDCs-TMD.[18]

Although the present study supports the use of hard, soft, and liquid splints in the management of myofascial pain dysfunction syndrome, further research is necessary to investigate the most appropriate usage regime of different types of splints, the different design of splints and also the EMG activity following the splint usage.

CONCLUSION

This study advocates the use of occlusal splint therapy for the management of myofascial pain. It is simple, with fewer side effects, cost effective, noninvasive, and better patient compliance. The results showed that all three types, i.e. hard, soft, and liquid occlusal splints reduced the Mod-SSI scores and Digital Palpation scores thereby proving that the type of splint did not have an effect on the overall results among the three groups. The findings from this study suggest the clinicians to consider occlusal splints as a therapeutic protocol when managing patients with myofascial pain dysfunction.

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Conflicts of interest
There are no conflicts of interest.

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