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Effectiveness Of Hard Versus Soft Occlusal Splints In The Management Of Patients With Temporomandibular Disorders: A Systematic Review

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Abstract

Introduction: Temporomandibular disorders (TMDs) are the most common non-dental orofacial pain that has major impact on the quality of life. Management of TMD can be either conservative or surgical treatments. Occlusal splint therapy is chosen for the treatment of dysfunctions as it is relatively simple, reversible, non-invasive and costs less than other treatments. Hard splints are fabricated from self or heat cured acrylic resin, forming hard and rigid occlusal surface while the soft or resilient splints forming somewhat flexible occlusal surface that can be easily adjusted to adequate contact pattern.

Objectives: With continuous debate and lack of consensus regarding which are more effective in managements of the TMD, soft or hard occlusal splint, this paper presentation attempts to review the current literature regarding effectiveness of hard v/s soft occlusal splints in patients with TMDs.

Methods : PubMed, Cochrane CENTRAL databases, Google Scholar, Embase and Google searches were performed using PICO strategy. Randomized Controlled Trials (RCTs) which compared hard versus soft occlusal splint were only articles to be included. Titles and abstract screened, data extracted and articles were assessed for risk of bias and quality of reporting. A thorough systematic review was performed for relevant RCTs.

Results: Six out of 2708 articles were selected based on the defined criteria set for the review. Four articles suggested the patients improved over time and both the hard and soft splints offered the benefit equally. One report suggested hard splint to be superior, while another suggested soft splint to be more effective.

Conclusion: Both hard and soft occlusal splints proved to be effective in patients with TMDs. The scarcity of current external evidence emphasizes the need for more clinical research.

Key words: Myofascial Pain, Temporomandibular Disorders, Hard Occlusal Splint, Soft Occlusal Splint, Systematic Review

1 | INTRODUCTION

Temporomandibular disorder (TMD) is a group of musculoskeletalconditions that involve the temporomandibular joints (TMJs), the masticatory muscles and all associated tissues (1). The TMD is included in the sub-classification of musculoskeletal disorders; it is one

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of the primary causes of pain of non-dental origin. Temporomandibular joint disorders (TMD) have a major impact on the quality of life. TMD is characterized by several signs and symptoms that include facial muscle and joint pain, limitation and/or mandibular deviation in the trajectory, joint noises, earaches, and pain of cervical origin.

The studies on the prevalence of TMD in children and adolescents have shown that subjective symptoms and clinical signs are rather common and increase with age (2). Various studies suggested that almost 40-70% of the population is having one detectable sign associated with TMD (3,4). Women represent the majority of patients with TMJ dysfunction (5–9). Although there is not a defined etiology for TMD; functional, structural, and psychological factors characterize the multifactorial origin of this dysfunction. Some conditions, such as malocclusion, parafunctional habits, emotional stress, trauma, sleep disorders, postural abnormalities, systemic factors, are present with particular frequency in patients with TMD signs.

The main treatment options for TMD include occlusal therapy (10), psychotherapy (11) , physical therapy (12), medication (13), manual therapy (14), and surgery (15). The occlusal therapy is defined as any therapy that alters a patient's occlusal condition, which can be used to improve function of the masticatory system through the influence of the occlusal contact patterns and by altering the functional jaw position (3) It is classified as reversible occlusal therapy which includes occlusal splints; and irreversible occlusal therapy consisting of selective grinding, fixed prosthesis and orthodontic therapy. Occlusal splint therapy is chosen for the treatment of dysfunctions as it is relatively simple, reversible, non-invasive and costs less than other treatments. Hard splints are fabricated from self or heat cured acrylic resin, forming hard and rigid occlusal surface, that resist wearing and last longer time. But with the long use, a significant occlusal change can occur. On the other hand, the soft or resilient splints forming somewhat flexible occlusal surface that can be easily adjusted to adequate contact pattern. However, this pliable splints can aggravate bruxism because the soft material cannot be balanced, leading to premature posterior contacts (16).

There are differences of opinion as well as lack of consensus regarding which one amongst hard and soft occlusal splint is more effective in the TMD patients. To further explore the clinical effectiveness of hard and soft splint therapy in the management of TMD, we performed the present systematic review by comparing the clinical effects reported in all relevant randomized controlled trials.

2 | METHODS

2.1 | Search strategy

The publications were searched from 5 electronic databases and websites like PubMed, Cochrane central register of controlled trials, EMBase and Google search for eligible randomized or parallel-group design clinical trials that evaluated the effectiveness of hard and soft splints in patients suffering from Temporomandibular disorders. The PICO (Population, Intervention, Comparator, Outcomes) strategy was employed as shown in Table 1.

Table 1: PICO criteria for the systematic review

PICO CRITERIA	
Population	1)MeSH term: (temporomandibular disorders) OR (temporomandibular joint disc) OR (temporomandibular joint) OR (temporomandibular disorders) OR (myofascial pain dysfunction) OR (myofascial pain) 2)Text word: (temporomandibular joint dis*) OR (dis*, temporomandibular) OR (disc*, temporomandibular joint) OR (joint dis*, temporomandibular) OR (TMJ disorders) OR (disorder, TMJ) OR (disorders, TMJ) OR (TMJ dis*) OR (temporomandibular disorder*) OR TMD OR (myofascial pain dysfunction) OR (myofascial pain)
Intervention/comparison	3) MeSH term: splints OR (occlusal splints) 4) Text word: hard occlusal splint* OR soft occlusal splint* OR resilient occlusal splint* OR hard and soft occlusal splints* OR hard and resilient occlusal splints* OR (splints, occlusal) OR (occlusal splint*) OR (splint, occlusal)
Outcomes	5) MeSH term: pain OR (pain measurement) 6) Text word: (maximal mouth opening) OR (MMO) OR pain OR (pain measurement) OR (visual analogue scales of pain) OR (VAS of pain) OR (healing from TMJ clicking) OR (pain relief)
Study design	7) MeSH term: randomized controlled trials AND controlled clinical trials
Search combination	1 AND 2 AND 3 AND 4 AND 5 AND 6 AND 7
Language	English
Electronic database	Electronic database Medline/PubMed, EMBase, Cochrane Central Register of Controlled Trials (CENTRAL) and Google search upto July 2021
Focused question	Which one, hard or soft occlusal splint therapy, is effective in the management of patients with temporomandibular disorders (TMDs)?

2.2 | Selection Criteria

All studies were selected in accordance with the following selection criteria:

1) Randomized Control Trials.

2) TMD patients older than 18 years.

3) Studies comparing the effectiveness of hard and soft splint therapy.

4) Only patients who should have been diagnosed with TMD (e.g., myofascial pain, osteoarthritis, TMJ clicking or anterior disc displacement with or without reduction).

5) Patients who had not been administered a TMD treatment prior to the study.

6) Outcome investigated with one of the following: i) Subjective pain analysis using Mod-SSI (modified symptom severity index), VAS (visual analog scale) ii) Objective pain analysis muscle palpation (muscle pain score), iii) Characteristic pain intensity (CPI) and, iv) improvement in clinical measures such as range of motion, muscle palpation (extraoral muscles).

2.3 **Data extraction**

The relevant information, including study design, patient characteristics, interventions, comparisons, and outcomes, were independently extracted and entered into a database by investigators. The following information was extracted from each study: publication year, region, age, gender, sample, diagnostic criteria, classification of diseases, history, intervention and control groups, course, follow-up, and outcomes. When relevant research information was missing, particularly study design or outcome information, the study was excluded.

2.3 | Quality assessment of included studies

The methodological quality of eligible trials was evaluated using the Cochrane collaboration tool for assessing risk of bias (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias). Also the reporting quality of the studies were evaluated using Jadad score (17).

3 | RESULT

3.1 | Outcome of the literature search

2078 publications were identified in the electronic databases (Figure 1). The data for systematic review were obtained after employing the selection criteria summarized in Methods section after reading all titles, abstracts and full texts. 6 eligible studies (16,18–22) from 6 publications were included in our final analysis.

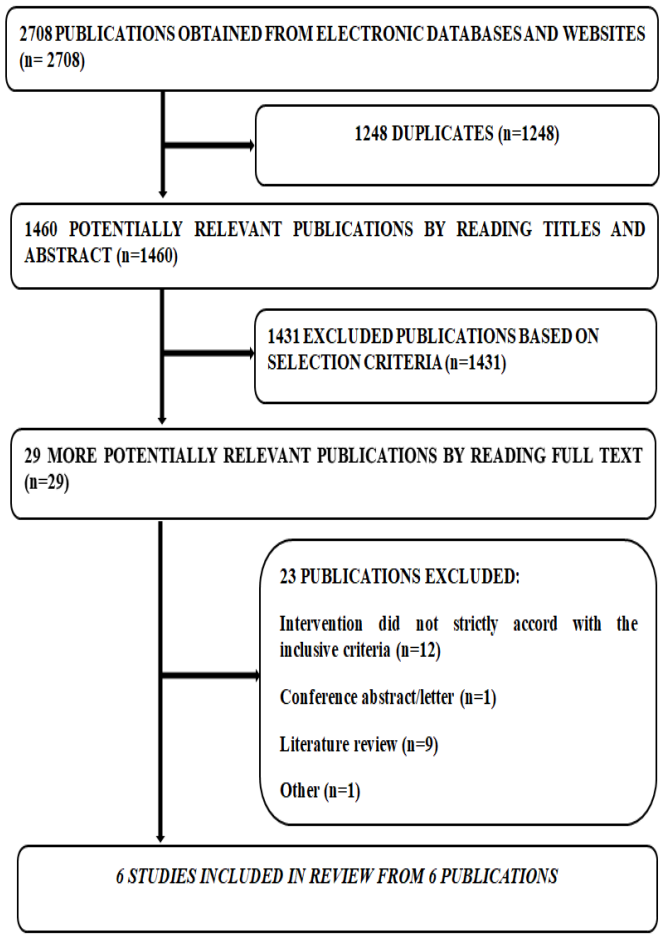

Fig. 1: TRIAL IDENTIFICATION AND SELECTION

3.2 | Study Characteristics

The study characteristics like age, number of subjects included, intervention, subjects per group and outcome measured have been summarized in Table 2.

Table 2 : Characteristics of included Studies

Study ID	Follow-up	Age (gender)	Problem	No. of subjects	Intervention	Subjects per group	Outcome measured
Amin et al 2016 (India)	3 months	18-65	Myofascial pain dysfunction syndrome	30	Hard splint	15	Subjective pain analysis using Mod-SSI and objective pain analysis muscle palpation (Digital palpation score)
					Soft splint	15	
Alencar and Becker 2009 (Brazil)	3 months	18-65 (3M,25F)	Myofascial pain dysfunction syndrome	28	Hard splint	14	Subjective pain analysis using Mod-SSI and objective pain analysis muscle palpation (Digital palpation score)
					Soft splint	14	
Seifeldin Jr and Elhayes 2015 (Egypt)	4 months	24-47 (21M, 29F)	Myofacial pain dysfunction or internal derangement of TMJ with reduction	50	Hard splint	25	Pain VAS*, tenderness of masticatory muscles, clicking and tenderness of TMJ, and range of mouth opening.
					Soft splint	25	
Truelove et al 2006 (USA)	12 months	18-60	Myofascial pain and Disk displacement with reduction	200	Hard splint	68	Characteristic pain intensity (CPI), improvement in clinical measures such as range of motion, muscle palpation (extraoral muscles)
					Soft splint	68	
					Usual treatment	64	
Nilner et al 2008 (Sweden and Finland)	10 weeks	= 18 (7M, 58F)	Myofascial pain with or without limited opening	65	Stabilization appliance	33	Subjective evaluation of pain using verbal scale, treatment outcomes regarding pain on mouth opening and chewing using VAS.
					Prefabricated appliance (Relax)	32	
Pettengill et al 1998 (USA)	10-15 weeks	= 18 (6M, 12F)	Myofascial pain, disk displacement with reduction, osteoarthritis, and TMJ inflammation (more than one was acceptable).	18	Hard splint	11	Objective pain analysis muscle palpation (muscle pain score)
					Soft splint	7	

*Mod-SSI= Modified Symptom Severity Index, VAS=Visual Analog Scale

3.3 | Quality of the included studies

The risk of bias in the included studies was strictly evaluated. Details of methodological approach are presented in Table 3. The reporting quality of the studies was assessed by using the quality score developed by Jadad et al. (17) as presented in Table 4. The Jadad scale consists of five items which focus on three dimensions of internal validity (randomization; double blinding; description of withdrawals and drop-outs). Uncertainties on data interpretation and discrepancies in scoring the reporting quality were resolved by discussion between the reviewers.

Table 3: Risk of Bias Assessment of the Studies

Study ID	Random sequence	Allocation concealment	Blinding	Incomplete outcome data	Selective reporting	Others
Amin et al 2016	Low risk	Unclear	Unclear	Low risk	Low risk	Low risk
Alencar and Becker 2009	Unclear	Unclear	Low risk	Low risk	Low risk	Low risk
Seifeldin Jr and Elhayes 2015	High risk	High risk	High risk	Low risk	Low risk	Low risk
Truelove et al 2006	Low risk	Low risk	Unclear	Low risk	Low risk	Low risk
Nilner et al 2008	Low risk	Low risk	Unclear	High risk	Low risk	Low risk
Pettengill et al 1998	High risk	High risk	Unclear	High risk	Low risk	Low risk

Table 4 : Jadad Score for Assessing Reporting Quality of the Studies

STUDY ID	Study described as randomized?	Method described and appropriate?	Study described as (double) blind?	Method described and appropriate/ inappropriate?	Description of withdrawals/ dropouts?	Jadad score
Amin et al 2016	Yes	Yes	No	-	No withdrawal or dropout	3
Alencar and Becker 2009	Yes	No	Yes	Yes	Yes (n=3)	4
Seifeldin Jr and Elhayes 2015	No	-	No	-	No withdrawal or dropout	1
Truelove et al 2006	Yes	Yes	Yes	Yes	No withdrawal or dropout	5
Nilner et al 2008	Yes	Yes	Yes	No	Yes (n=1)	4
Pettengill et al 1998	No	-	No	-	Yes (n=5)	1

3.4 | Results of outcome

Based on the identified publications, following results can be drawn:

Amin et al. (16): Both Mod-SSI and palpation scores showed statistically significant reduction in pain for both groups at the end of 3 months. However, the hard splints proved to be very effective in a shorter period of time followed by soft splints.

Alencar Jr and Beckar (18): The results for muscle pain threshold assessed with digital palpation showed statistically significant differences between baseline and 90 days for both groups. Significant differences were first seen at 7 days for hard splint and 90 days for soft splint.

Seifeldin Jr and Elhayes (19)**:** At 4 months, the soft splint group showed significantly higher values of mouth opening. VAS scores for pain

significantly decreased in both groups throughout the entire follow-up period. Clicking scores significantly decreased in both groups throughout the follow-up period, starting from 2 months with the hard splint and 3 months with the soft splint. However, there were no statistically significant differences in VAS scores and Clicking scores between the two groups at any follow-up interval. Tenderness of the masticatory muscles and neck muscles showed a significantly greater percentage of improvement in the soft compared to the hard splint group, with complete disappearance of tenderness of masticatory muscles and neck muscles at 3 months versus 4 months.

Truelove et al. (20): No significant differences among the groups in TMD-related pain levels or other common signs and symptoms of TMD at baseline (BL) or at any follow-up.

Nilner et al. (21): The authors observed no significant differences among the groups in TMD-related pain levels or other common signs and symptoms of TMD at baseline (BL) or at any follow-up.

Pettengill et al. (22): There was no statistically significant difference in muscle palpation scores between the hard and soft appliances at each visit.

4 | DISCUSSION

Occlusal therapy alters a patient's occlusal condition, which can be used to improve function of the masticatory system through the influence of the occlusal contact patterns and by altering the functional jaw position (3). A properly balanced splint results in an occlusion associated with relaxed positioning elevator muscles, allowing the articular disc to obtain its antero-superior position over the condylar head.

The present article investigated the effectiveness of hard and soft occlusal splints in the management of TMD patients. In this systematic review, we evaluated 6 clinical trials that included TMD patients older than 18 years of age using defined criteria. 4 of these studies (20–22) found hard and soft occlusal splints to be equally effective in management of TMD. The results of the studies should be interpreted with caution as they might have been affected by many factors: High risk of bias, selected number of studies, and small sample size (22) . It was impossible to blind the clinicians treating the patients and to determine whether they inadvertently modified their treatment approach (20). Another limitation of the study could be the decision to enroll patients with different types of TMD as long as they also had a concurrent diagnosis of myofascial pain (20).

In one included study (16), although the results showed that the type of splint did not have an effect on the overall results, the improvements are seen earlier in hard splints group. The hard splints proved to be very effective in relieving pain at shorter period of time when compared to soft splints. Hard occlusal splints can be used as permissive splints (muscle deprogrammers) that allow teeth to glide over biting surface, which leads to loss of neuromuscular reflex while closing in maximum intercuspation causing muscle deprogramming; and also, as non-permissive (directive) splints that have ramps or indentations on occluding surface, limiting the movement of mandible and also position the condylar-disk assemblies to a more stable position.

In contrast to the previous studies, the results of another study(19) showed significantly greater muscle tenderness reduction and mouth opening improvement in the soft compared to the hard splint group, with complete disappearance of tenderness at 3 months. This is supported by study of Kovaleski and de Boever (23), which showed statistically significant muscle improvement after 2 months of soft occlusal splint therapy. Soft splint therapy have also shown to reduce facial pain by 74% (24). Soft rubber splints that functions by separation of teeth. Hydrostatic splints cushioned with fluid (Aqualizer^{TM}) redistribute occlusal forces evenly, thereby reducing TMJ pressure and pain and ensuring relief.

Moreover, 4 of the 6 reviewed studies had Jadad score of 3 or more. The other 2 articles had an unacceptably low reporting quality of 1. It has been shown that studies with Jadad score of 2 or less tend to give an overoptimistic picture of the real treatment effect than studies with a higher score (25).

5 | CONCLUSION

Due to the limited number of available studies considered with high risk of bias and low reporting

quality, our clinical question can only be answered tentatively: Based on the currently best available evidence, it appears that most patients with TMDs are helped equally by incorporation of hard and soft occlusal splints. More clinical studies will be required to confirm the results. Nevertheless, evidence is equivocal that improvement of pain symptoms after incorporation of an intraoral appliance is caused by a specific effect of the splint.

6 | RECOMMENDATION

Well-designed RCTs, reporting on patient related outcomes, are highly recommended to evaluate the effectiveness of the hard and soft occlusal splint therapy.

7 | CONFLICT OF INTEREST

There was no conflict of interest.

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