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The Comparison of Efficacy of Soft and Hard occlusal Splints in Management of Temporomandibular Joint Disorders and Bruxism: A Systematic Review of Randomized Control Trials

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ABSTRACT

Background and aim: Temporomandibular disorders (TMDs) and Bruxism both often bring patients to seek treatment in a dental clinic. The first line of treatment for such patients is non-invasive therapy in the form of occlusal splints. This systematic review aimed to compare the efficacy of soft and hard occlusal splints in the management of temporomandibular disorders (TMD) and Bruxism.

Material and methods: A total of 798 studies were searched using online databases, including PubMed, MEDLINE, Google Scholar, and Embase, employing a PICOS strategy and relevant keywords. Following the described inclusion and exclusion criteria, 11 randomized controlled trials (RCTs) were selected, which compared soft and hard occlusal splints in the treatment of temporomandibular disorders (TMD) and Bruxism. Titles and abstracts were screened, data extraction was done, and studies were assessed for risk of bias and quality of reporting using the Jadad score.

Results: The findings suggest that both soft and hard occlusal splints have been demonstrated to effectively reduce pain, improve mandibular movement, and alleviate symptoms associated with TMDs and Bruxism.

Conclusions: The results for both types of splints were similar in all aspects. Thus, the reported superiority of either type of splint over the other is inconclusive.

1. Introduction

Temporomandibular disorders (TMD) include a broad range of conditions associated with oro-facial, head, and neck pain and dysfunction.[1] These conditions may be related to the masticatory or neck muscles, the central and peripheral nervous systems, or the temporomandibular joint (TMJ), potentially affecting the social, vocational, and emotional lives of patients.[2] TMDs affect approximately 6%–12% of the adult population.[3] Females are suffering twice as much as males, and this ratio in the patient population is as high as 10:1.6.[4] The prevalence of Bruxism ranges from 8% to 31% within the general population, wherein sleep bruxism affects 16%, and awake Bruxism is observed in 24% of the adult population.[5, 6] The understanding of the etiopathogenesis of TMDs is limited, and so is the definitive diagnostic and therapeutic approach. However, there are numerous treatment options available to patients, including both surgical and non-surgical therapies, to alleviate their symptoms.[7] Surgical management may include TMJ arthrocentesis, arthroscopy, and arthrotomy as per the indications. However, surgery is usually considered after non-surgical therapy proves ineffective. Non-surgical management of TMDs includes counseling, physiotherapy, pharmacotherapy, and intra-oral occlusal splints. A literature review indicates that the success rate of non-surgical treatment is approximately 70%, while the success rate of surgical treatment is approximately 83%. However, some studies report self-improvement rates of 40%–70% without any treatment.[8-10] The occlusal splints are designed to increase vertical dimension and cause posterior dis-occlusion during lateral excursions and are effective because they also alter the condylar position.[11, 12] They also help manage the tooth wear caused by Bruxism. The occlusal splints can be permissive or non-permissive, hard or soft occlusal splints. The advantages of soft splints over rigid splints are their immediate and convenient use in patients.[13] The soft splints help distribute heavy occlusal loads and are suggested to alleviate symptoms associated with TMD and parafunctional habits.[14] Among the various non-surgical treatment modalities suggested for TMDs and Bruxism, the most efficacious approach remains unclear to date, which may result in management based more on experience than evidence. The purpose of the current systematic review, therefore, is to find and suggest evidence-based effectiveness of soft occlusal splints over rigid occlusal splints when used in the management of TMDs and Bruxism.

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Table 1. TMD classification.

Axis	Classification Group	Specific Diagnostic Criteria (Examples)	Key Features
Axis I: Physical Diagnoses	Group I: Pain-Related Diagnoses	-----	Focuses on physical conditions Based on clinical examination and patient symptoms.
	Myalgia	- Pain in masticatory muscles (e.g., masseter, temporalis) upon palpation or during jaw movement. - Absence of joint sounds as a primary complaint.	Most common TMD pain diagnosis. Localized muscle pain.
	Arthralgia	- Pain in the temporomandibular joint (TMJ) area upon palpation or during jaw movement. - Often associated with inflammatory processes in the joint.	Joint pain, often without clear mechanical derangement.
	Headache attributed to TMD	- Headache located in the temporal region, often associated with masticatory muscle pain and/or TMJ pain. - Pain is influenced by jaw function.	Secondary headache related to TMD.
	Group II: Intra-Articular Diagnoses (Joint Disorders)	-----	Focuses on structural and mechanical issues within the TMJ.
	Disc Displacement with Reduction (DDwR)	- Reciprocal clicking or popping sounds in the TMJ during opening and closing movements. - Normal range of motion, but sometimes with a "catch" sensation.	The disc moves out of place but returns to its normal position upon opening.
	Disc Displacement without Reduction (DDwoR) with Limited Opening	- History of clicking that has stopped, followed by persistent limitation of mouth opening. - Deflection of the mandible to the affected side during opening.	The disc remains displaced, obstructing condylar movement.
	Disc Displacement without Reduction (DDwoR) without Limited Opening	- History of clicking that has stopped. - Normal or near-normal range of mouth opening. - Crepitus may or may not be present.	The disc remains displaced, but adaptation allows for normal movement.
	Degenerative Joint Disease (Osteoarthritis/Osteoarthrosis)	- Crepitus (grating sound/sensation) in the TMJ during jaw movement. - Radiographic evidence of degenerative changes (e.g., flattening, osteophytes, erosion).	Chronic, progressive breakdown of joint tissues.
	Subluxation	- Recurrent, transient dislocation of the condyle beyond the articular eminence, followed by spontaneous reduction.	Hypermobility occurs when the joint "pops out" but returns to its original position on its own.
	Dislocation	- Condyle moves beyond the articular eminence and gets "locked" in an open position, requiring manual reduction.	Complete displacement of the condyle that requires assistance to return.
Axis II: Psychosocial and Functional Status	Pain-Related Disability	- Assessed using tools like the Graded Chronic Pain Scale (GCPS). - Measures pain intensity and its interference with daily activities.	Provides a biopsychosocial context for the physical diagnosis. Identifies contributing psychological and behavioral factors.
	Psychological Distress	- Assessed using questionnaires like the Patient Health Questionnaire (PHQ-4, PHQ-9, PHQ-15) and Generalized Anxiety Disorder (GAD-7) scale. - Measures symptoms of depression, anxiety, and somatization.	Identifies psychological factors impacting pain perception and function.
	Jaw Functional Limitation	- Assessed using tools like the Jaw Functional Limitation Scale (JFLS). - Measures difficulty with specific jaw movements and functions (e.g., chewing, speaking, yawning).	Quantifies the impact of TMD on daily oral activities.
	Oral Parafunctional Behaviors	- Assessed via self-report checklists (e.g., Oral Behaviors Checklist). - Identifies habits like clenching, grinding, nail-biting.	Identifies potential exacerbating factors.

2. Material and Methods

Protocol and registration

The International Prospective Register of Systematic Reviews (PROSPERO) database was searched for any registered protocols on a similar topic. In addition, the current systematic review was registered as a protocol in PROSPERO (CRD42023392424). The Preferred Reporting Items reported the systematic review for Systematic Reviews and Meta-Analyses (PRISMA) statements.

Eligibility criteria

Inclusion criteria

The PICOS framework (population, intervention, comparison, outcomes, studies) was used to formulate the focused question of the review:

(P) patients diagnosed with TMD and Bruxism;
(I) soft occlusal splints;
(C) hard occlusal splints;
(O) Intensity of pain and harmful effects of TMD, tooth wear in bruxism;
(S) Randomized clinical trials.

The included clinical trials recruited adult patients aged 18-70 years with signs and symptoms of TMD, such as myofascial pain, osteoarthritis, TMJ clicking, and anterior disc displacement with or without reduction. For Bruxism, the patients included in the trials had intra-oral and extra-oral physical signs of Bruxism as well as measured sleep bruxism activity. The patients did not receive any treatment for TMD and Bruxism prior to the study. The outcomes of TMD were measured with one of the following:

1. Subjective pain analysis using:
    a) Modified symptom severity index (Mod-SSI);
    b) Visual analog scale (VAS);
    c) Characteristic pain intensity (CPI);
2. Improvement in clinical measures such as:
    a) range of motion,
    b) extraoral muscle palpation

Outcomes of bruxism

1. Electromyography
2. Maximal mouth opening
3. Bite force

Exclusion criteria

The following exclusion criteria were applied:

1) Population less than 18 years and above 70 years of age,
2) Patients with primary psychiatric diagnoses,
3) ongoing dental, medical, or physiotherapeutic treatments for TMD,
4) participants undergoing orthodontic treatment focusing on development and not treatment of TMD,
5) surgical treatment/dual treatments

Search strategy

A detailed, automated literature search was conducted across PubMed, MEDLINE, Embase, ProQuest, Google Scholar, and Scopus, with no time restrictions. Any information about clinical trials in progress was also checked on www.clinicaltrials.gov. The reference lists of all identified studies were manually searched to identify any potentially relevant studies. Mendeley desktop software was used to manage the relevant downloaded articles and remove any duplicates. Various combinations of descriptors extracted from Medical Subjects Headings (MeSH) and free terms were used. (Table 2).

Table 2. Full search strategy.

Search #1	Soft vs. rigid occlusal splints and facial pain or Oro-facial pain or myofascial pain
Search #2	Soft vs. rigid occlusal splints and temporomandibular disorders or TMD or temporomandibular joint dysfunction syndrome.
Search #3	Soft vs. hard occlusal splints in TMD and facial pain, oro-facial pain, or myofascial pain.
Search #4	Soft vs. hard occlusal splint therapy and temporomandibular disorders or TMD temporomandibular joint dysfunction syndrome or bruxism.
Search #5	Soft vs. hard occlusal splints in bruxism or clenching or sleep bruxism.

Study selection and data extraction

The study selection process was completed in three stages. First, titles and abstracts of all identified articles were screened by two independent reviewers (PS and PN) using the standardized guide. This was followed by the retrieval of full texts of studies that met eligibility criteria and were reviewed by two reviewers (SK and PS). Any disagreements regarding study selection were mutually discussed, and a consensus was reached before the study was included in the analysis. Reviewers (SK and PS) collected the data on study characteristics such as author name, year of study and country, study design, type of intervention, observation period, number of patients, and outcome measures such as muscle tenderness score, pain scale, electromyography of muscles, maximal mouth opening and bite force.

Risk of bias assessment and methodological quality

In our systematic review, the methodological quality and potential for bias of each included study were rigorously assessed by two independent reviewers (PS and SK), with any discrepancies resolved through mutual discussion to ensure consistency. Initially, the reporting quality of the studies was evaluated using the Jadad scale, which assigns a score from 0 to 5 based on the reporting of randomization, double-blinding, and participant withdrawals or dropouts, with higher scores indicating better reporting of these aspects of internal validity.[15] Building upon this initial assessment, a more comprehensive and detailed risk of bias evaluation was conducted using the Cochrane Risk of Bias (RoB) 2.0 tool.[16] This advanced tool allowed for a granular assessment across five distinct domains: bias arising from the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. For each domain, and subsequently, for the study's overall risk of bias, judgments were assigned as "low risk," "some concerns," or "high risk," with detailed rationales provided that often leveraged insights gained from the Jadad scoring and other reported study characteristics. (Table 3).

Table 3. Cochrane risk of bias.

Author and Year	D1: Randomization Process (Randomized)	D2: Deviations from Intended Interventions (Blinding of P/P)	D3: Missing Outcome Data (Withdrawals/Dropouts)	D4: Measurement of Outcome (Blinding of Outcome Assessor)	D5: Selection of Reported Result (Protocol/Pre-specification)	Overall RoB (Speculative)	Rationale/Assumptions based on Jadad
Pettengill et al., 1998 [17]	High risk (No randomization reported)	Some concerns (Yes, but the method is not appropriate/described for blinding)	Some concerns (Yes, n=5 reported; unclear if reasons are outcome-related or if appropriately handled)	High risk (No blinding of outcome assessor)	High risk (No info on protocol/pre-specification; potential for selective reporting given overall low quality)	High risk	No randomization is a direct high risk. Blinding is described as "Yes" but "No" for the appropriate method, suggesting issues in D2/D4. Missing data was mentioned, but the handling and reasons are unclear. Given the age and low Jadad, selective reporting is likely.
Truelove et al., 2006 [18]	Low risk (Yes, Yes - randomized & method appropriate)	Low risk (Yes, Yes - blinding and method appropriate, likely dual)	Low risk (No withdrawals/dropouts, ideal)	Low risk (Yes, Yes - likely blinded outcome assessment)	(A High Jadad score implies good reporting, though protocol is still assumed)	Low risk	A high Jadad score (5) strongly suggests a low risk across most domains, particularly in terms of randomization and blinding. No dropouts are excellent for D3.
Nilner et al., 2008 [19]	Low risk (Yes, Yes - randomized & method appropriate)	Some concerns (Yes, but No for blinding method appropriateness/description, suggests P/P aware)	Low risk (Yes, n=1 reported; small, unlikely to bias)	High risk (No blinding of outcome assessor)	Some concerns (No info on protocol; potential for selective reporting)	High risk	Randomized and method appropriate is suitable for D1. "Yes" for blinding but "No" for appropriate method points to issues in D2 (performance) and D4 (detection). Lack of protocol info for D5.
Alencar et al., 2009 [20]	Some concerns (Yes, but No for method appropriateness – likely sequence generation issues)	Low risk (Yes, Yes - blinding and method appropriate)	Some concerns (Yes, n=3 reported; unclear if reasons are outcome-related or if appropriately handled)	Low risk (Yes, Yes - likely blinded outcome assessment)	Some concerns (No info on protocol; potential for selective reporting)	Some concerns	"Yes" for randomized but "No" for method implies issues in D1. Good blinding for D2/D4. Missing data requires additional information for D3. Lack of protocol info for D5.
Christidis et al., 2014 [21]	Low risk (Yes, Yes - randomized & method appropriate)	Low risk (Yes, Yes - blinding and method appropriate)	Some concerns (Yes, n=15 reported; unclear if reasons are outcome-related or if appropriately handled)	Low risk (Yes, Yes - likely blinded outcome assessment)	Some concerns (No info on protocol; potential for selective reporting)	Some concerns	A high Jadad score (5) suggests a low risk for D1, D2, and D4. Fifteen dropouts might lead to "Some concerns" for D3, depending on reasons and handling. Lack of protocol for D5.
Seifeldin et al., 2015 [22]	High risk (No randomization reported)	High risk (No blinding reported)	Low risk (No withdrawal or dropouts - ideal)	High risk (No blinding reported)	High risk (No info on protocol/pre-specification; potential for selective reporting	High risk	Not randomized nor blinded, are direct high risks for D1, D2, and D4. A Low Jadad score (1) indicates overall severe limitations.

					given overall low quality)		
Amin et al., 2016 [23]	Low risk (Yes, Yes - randomized & method appropriate)	High risk (No blinding reported)	Low risk (No withdrawal or dropouts - ideal)	High risk (No blinding reported)	Some concerns (No info on protocol; potential for selective reporting)	High risk	No blinding leads to a high risk for D2 (performance) and D4 (detection). D1 and D3 appear low risk. Lack of protocol info for D5.
Giannakopoulos et al., 2016 [24]	Low risk (Yes, Yes - randomized & method appropriate)	High risk (No blinding reported)	Some concerns (Yes - withdrawals reported; unclear if reasons are outcome-related or if appropriately handled)	High risk (No blinding reported)	Some concerns (No info on protocol; potential for selective reporting)	High risk	Similar to Amin et al., no blinding directly translates to high risk for D2 and D4. D1 seems a low risk. Withdrawals warrant some concern for D3. Lack of protocol info for D5.
Raza et al., 2018 [25]	Some concerns (Yes, but No for method appropriateness – likely sequence generation/concealment issues)	High risk (No blinding reported)	Some concerns (No info on withdrawals, implies missing data issues)	High risk (No blinding reported)	High risk (No info on protocol/pre-specification; very low Jadad)	High risk	A Jadad score of 0 is a strong indicator of high risk across multiple domains, including D1 (inappropriate randomization method), D2/D4 (lack of blinding), D3 (insufficient information on missing data), and D5 (lack of transparency and reporting).
Raval et al., 2022 [26]	High risk (No randomization reported)	High risk (No blinding reported)	Some concerns (No info on withdrawals, implies missing data issues)	High risk (No blinding reported)	High risk (No info on protocol/pre-specification; very low Jadad)	High risk	Similar to Raza et al., a Jadad score of 0 and an explicit "No" for randomization and blinding points indicate a high risk across the board.
Benli et al., 2022 [27]	Low risk (Yes, Yes - randomized & method appropriate)	High risk (No blinding reported)	Some concerns (Yes, n=11 reported; unclear if reasons are outcome-related or if appropriately handled)	High risk (No blinding reported)	Some concerns (No info on protocol; potential for selective reporting)	High risk	D1 is low risk. However, "No" for blinding immediately flags a high risk for D2 (performance) and D4 (detection). Withdrawals (n=11) lead to some concern for D3. Lack of protocol info for D5.

3. Results

Study selection

Fig. 1 displays a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram, which systematically illustrates the process of literature search and study selection for a review on temporomandibular disorder (TMD) and Bruxism. It follows the standard phases of identification, screening, eligibility, and inclusion.

A . Identification Phase:

- The initial search across various databases yielded 876 records.
- An additional 10 records were identified through other unspecified sources.
- This resulted in a total of 886 records before duplicate removal.

B . Screening Phase:

- After removing duplicates, 100 records remained for screening. This indicates that a significant number of duplicates were removed from the initial 886.
- From these 100 records, 786 records were screened. (There seems to be a discrepancy here: if 100 records remained after duplicates, and 786 were screened, it implies an error in the "Records after duplicates removed" box. Assuming "Records screened (n=786)" refers to the actual unique records for screening, then the initial "Records after duplicates removed (n=100)" might be a typo or miscalculation, or "Records screened" should be 100. Given the rest of the flow, assume that 786 is the correct number of records that were assessed at the title/summary level).
- During this screening, 15 full-text articles were excluded based on their title and summary due to non-relevance. (Again, if 786 were screened and 15 excluded, the number of records moving to full-text assessment would be 771, not 20+6=26, as shown below. There is a clear inconsistency in the numbers provided in the diagram. I will explain the diagram *as it is presented* while noting the numerical inconsistencies.)

C. Eligibility Phase:

- A smaller subset of full-text articles was assessed for eligibility. The diagram states 20 for TMD and 6 for Bruxism, totaling 26 articles that proceeded to full-text review.
- From these, 15 full-text articles were excluded because they did not match the eligibility criteria. Reasons for exclusion included being irrelevant to the intervention, review articles, case reports, or not fitting the scope for TMD and Bruxism.

D. Included Phase:

- Following the eligibility assessment, 10 studies were included in the qualitative analysis for TMD, and 1 study was included for Bruxism. This brings the total number of included studies to 11.

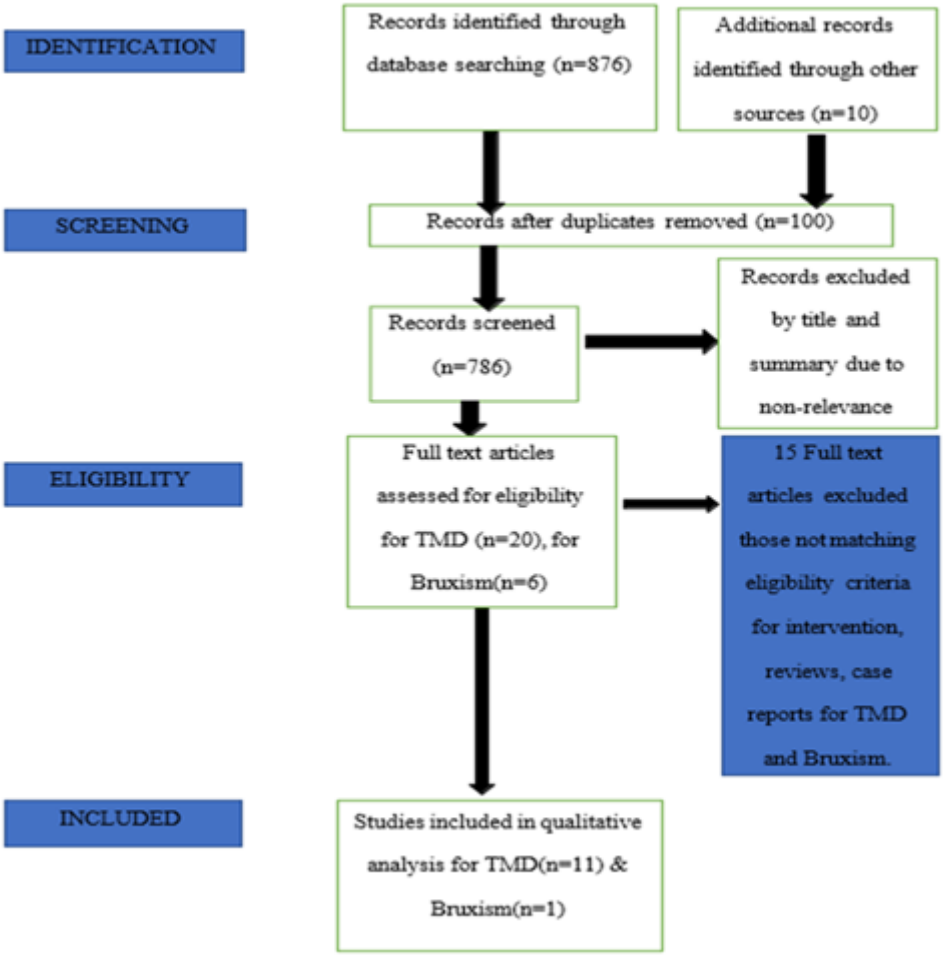

Fig. 1. Flow diagram of literature search and selection criteria.

Study characteristics

The study characteristics, including study design, age of subjects, number of subjects included, intervention, subjects per group, and outcome measures, have been summarized in Table 4 (TMD) and Table 5 (Bruxism).

Risk of bias assessment

Among the included studies, eight studies had a high risk of bias, two studies showed some concerns, and only one study was found to be low risk.

Table 4. Characteristics of included Studies for TMD.

Study Characteristcs (Author, Year & Place)	Study Design	Age (Gender)	Follow-up/ Period	Problem	No. of Subjects	Intervention	No. of Subjects Per Group	Outcome Measured
Pettengill et al., 1998[17]	RCT	=18 (6M, 12F)	10-15	Myofascial pain, disk displacement, with reduction, osteoarthritis & TMJ inflammation	18	Soft splint	7	Objective pain analysis, muscle pain score.
						Hard splint	11	
Truelove et al., 2006[18]	RCT	18-60	12 MONT HS	Myofascial pain & disc displacement with reduction	200	Soft splint	68	CPI, improvement in muscle pain and rangeof motion.
						Hard splint	68	
						Usual treatment	64	
Nilner et al., 2008[19]	RCT	=18 (7M, 58F)	10 weeks	Myofascial pain with or without limited opening	65	Prefabricated splint (relax, soft)	32	Subjective evaluation ofpain using the verbal scale, visual analog scale VAS.
						Stabilization splint (hard)	33	
Alencar et al., 2009[20]	RCT	18-65 (3M,25F)	3 months	Myofascial pain dysfunction syndrome	28	Soft splint	14	Subjective pain analysis using Mod-SSI & objective pain analysis using muscle palpation.
						Hard splint	14	
Christidis et al., 2014[21]	RCT	⩾18 (45F,3M)	12 months	Myofascial pain with or without limited opening, disc displacement with or without reduction, osteoarthrosis in contralateral TMJ & episodic or chronic tension type headache	48	Prefabricated appliance (relax)	24	Pain intensity measured using VAS, physical functionin g classified using GCPS, Emotional functioning using modified symptom checklist- 90-Revised (SCL-90-R).
						Stabilization appliance	24	
Seifeldin et al., 2015[22]	RCT	24-47 (21M,29 F)	4 months	Myofascial pain dysfunction or internal derangement of TMJ with reduction	50	Soft splint	25	VAS, tenderness of masticatory muscle, clicking and tenderness of TMJ & maximum mouth opening.
						Hard splint	25	

Amin et al., 2016[23]	RCT	18-65	3 months	Myofascial pain dysfunction syndrome	30	Soft splint	15	Subjective pain analysis Using Mod-SSI & objective pain analysis muscle Palpation.
						Hard splint	15	
Giannakopou los et al., 2016[24]	RCT	41.6±16.7 (25F,11 M)	2 weeks	Myofascial pain non-dysfunctional syndrome	36	Prefabricated splint(Aqualizer)	NR	Current Pain Intensity by GCPS on NRS, Active Maximum Mouth opening without pain.
						Co-polyester splint	NR	
						Michigan type Hard splint	NR	
Raza et al., 2018[25]	RCT	20-45 (24M,26 F)	6 months	Myofascial pain, restricted or deviated mandibular movements	50	Soft splint	NR	Mouth opening range, VAS for pain, tenderness of masticator y muscles & TMJ.
						Hard splint	NR	
Raval et al., 2022[26]	RCT	NR	6 months	Myofascial pain dysfunction or internal disc derangement	70	Soft splint	NR	Mouth opening, VAS, clicking sound evaluation.
						Hard splint	NR	

*Mod-SSI= Modified Symptom Severity Index, VAS= Visual Analog Scale, CPI=Characteristic Pain Intensity, GCPS= Graded Chronic Pain Scale, EMG= Electromyography, NRS=Numerical Rated Scale.

Table 5. Characteristics of study included in bruxism.

Author	Study Type	Duration	Condition	Intervention	No. of Subjects	Outcome
Benli t al., 2022[27]	RCT	21-24 months	Sleep bruxism	Soft splint (2mm)	23	Bite force, sleep quality
				Soft splint (3mm)	23	
				Hard splint (2mm)	23	
				Hard splint (3mm)	23	

4. Discussion

With the use of hard and soft occlusal splints, there is an improvement in signs and symptoms of TMDs reported in various studies. Among these signs and symptoms, pain represents the most common reason for seeking treatment in the dental clinic. Various pain assessment tools are used to quantify the pain experienced by patients for baseline pain assessment and to measure the effect of any intervention, such as hard and soft splints, in this systematic review. The assessment tools used to evaluate the effects of hard and soft splints in TMDs and bruxism, as well as their inferences, are discussed below.

1. Subjective pain analysis using

A) Modified symptom severity index (Mod-SSI)

Mod-SSI is considered superior to VAS in assessing pain frequency, intensity, and duration. There are statistically significant differences between the baseline and the 3-month follow-up for both the rigid splint and soft splint groups.[20] The splints, regardless of type, were effective in alleviating symptoms of myofascial pain dysfunction syndrome and increasing the muscle pain threshold over time. Though rigid splints demonstrated a rapid improvement in muscle pain threshold, the soft splints exhibited a slower but statistically significant improvement. This delayed response could indicate that the soft splint required a more extended period to exert its beneficial effects on pain reduction and muscle function.[20, 23] Similar findings were reported by Amin et al. However, the smaller sample size may limit the generalizability of the findings.[23]

B) Visual analog scale (VAS)

Several studies have evaluated the effectiveness of various types of splints in managing myofascial pain, with or without limited mouth opening, in patients with temporomandibular disorders (TMDs). The primary outcome measure used in these studies was the subjective evaluation of pain, assessed using a visual analog scale (VAS). Their results suggest that neither soft splints nor hard stabilization splints demonstrated superiority over the other in terms of pain reduction in patients with myofascial pain and limited opening.[19, 21, 22, 25, 26]

C) Characteristic pain intensity (CPI)

Truelove et al. found no statistically significant effects of soft splint or rigid splint on the signs and symptoms of TMD as compared to self-care treatment without any splint.[18] On the other hand, Giannakopoulos et al. showed that after 2 weeks of treatment, there was a significant reduction in current pain intensity for the group using soft splints compared to the prefabricated splint and Michigan-type rigid splint.[24]

2. Improvement in clinical measures

A) Range of motion

Only one RCT studied the range of motion where both soft and hard splints were equally effective in improving the range of mandibular movement.

B) Maximum mouth opening

Giannakopoulos et al. found that all the splint groups exhibited a significant increase in active maximum mouth opening compared to baseline measurements.[24] Seifeldin and Elhayes found that the soft splint group exhibited a significant increase in mouth opening compared to the hard splint group. In contrast, Raval et al. found soft splints to exhibit improvement earlier than rigid splints.[22, 26] On the contrary, another study observed a statistically significant improvement initially with the use of rigid splints, but eventually, both the groups showed significant mouth opening range; results should be cautiously interpreted as this study has a high risk of bias.[25]

C) Tenderness of muscles

The measurement of the tenderness of muscles and TMJ about the use of the soft splint and rigid splint has shown inconclusive findings. Some studies have favored rigid splints over soft splints.[23, 25] Pettengil et al. found both to be equally effective, whereas Alencar & Becker found similar results but also observed that rigid splints improved the symptoms earlier than soft splints.[17, 20] Seifeldin and Elhayes found a significant decrease in muscle tenderness with soft splints as compared to rigid splints.[22]

Bruxism

For patients with Bruxism, soft splint therapy is more effective than rigid splints, as evaluated by parameters including maximum bite force and sleep quality at three different time intervals. Maximum bite force significantly decreased for soft splints while offering significant improvement in sleep quality.[27]

5. Conclusion

In this systematic review, 876 studies were screened, and 11 articles were selected based on qualitative information about the management of TMD and Bruxism using hard and soft splints in Adult population using defined inclusion criteria. Four studies showed equal effectiveness of both splint groups for TMD; three studies showed more effectiveness of rigid occlusal splints, whereas an equal number of studies showed significant relief of signs and symptoms of TMD with the use of soft splints. For patients with Bruxism, one relevant study has shown that soft occlusal splints can decrease associated symptoms. There is a consensus on the use of occlusal splints for both temporomandibular disorder (TMD) and Bruxism. However, the comparative efficacy between soft and hard splints could not be definitively determined due to the limited number of studies directly comparing these two types. Further research is warranted in this direction, as well as to assess the long-term outcomes and potential side effects associated with their use. Additionally, future studies should consider larger sample sizes and standardized outcome measures to provide more robust evidence for clinical decision-making.

Conflict of Interest

The authors declared that there is no conflict of interest.

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