

# Stabilisation Splint versus Other Conservative Therapies for the Treatment of TMD: A Systematic Review

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## ABSTRACT

The purpose of this systematic review was to compare the effectiveness of stabilisation splint (SS) with other conservative treatment modalities in the management of temporomandibular disorders (TMD). An electronic search in PubMed, Google Scholar, and Cochrane was conducted to find randomised control trials published on the management of temporomandibular disorders in English language from March 2000 to June 2023 along with manual search in the relevant Journal of Prosthetic Dentistry, the American Journal of Prosthodontics, and the Journal of Oral Rehabilitation. A total of 64 studies were initially considered, out of which eight studies fulfilled the inclusion criteria. Furthermore, RoB-2 analysis tool was used for checking the risk of bias in the included studies. On comparing the readings and outcomes, only one study showed that the SS was better than the comparators. The review identified that there is weak evidence of effectiveness of SS splint therapy over other conservative therapies for the treatment of TMD.

**Key Words:** Splints, Conservative treatment, Pain measurement, Temporomandibular disorders.

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## INTRODUCTION

The term temporomandibular disorders (TMD) is used to define a group of clinical issues in temporomandibular joints, masticatory muscles, and associated structures. TMD falls in the category of musculoskeletal disorders.<sup>1</sup> Symptoms of TMD follow a chronic pattern showing variation over the period of time.<sup>2</sup> Common complaints associated with TMD include pain, joint sounds, limited mouth opening, and deviations or deflections in mandibular movements.<sup>1</sup> In many cases these signs and symptoms show reduction with time without any treatment.<sup>1,3</sup> Common aetiological factors for TMD include stress, direct or indirect trauma, parafunction, any source of deep pain input, and occlusal disturbances.<sup>1</sup>

The main goal in the treatment of TMD is to reduce or eliminate pain and restore normal jaw function. Different treatment methods prescribed for the treatment of TMD include reversible and conservative as well as irreversible and non-conservative surgical methods.<sup>4</sup>

Conservative options for the treatment of TMD include psychological counselling, behavioural therapies, medications, jaw rest, occlusal appliances, muscle relaxing exercises, physiotherapy, acupuncture, and biofeedback techniques. Different occlusal appliances are used among which the stabilisation splint (SS) therapy is the most suggested treatment option.<sup>5</sup> It is a removable appliance made of hard acrylic resin which provides reversible ideal occlusion and decreases abnormal muscle activity providing neuromuscular balance.<sup>6,7</sup> According to a review, it was found that there was a lack of evidence regarding SS being more effective than other types of soft and placebo splints or other conservative modalities employed.<sup>8</sup> Furthermore, the literature has reported the use of a combination of different approaches to be more effective in treating TMD.<sup>4,9</sup>

A number of clinical studies have evaluated the effectiveness of SS therapy in TMD patients, and few of them have compared SS therapy with other treatment modalities including surgical and non-surgical. Numerous studies have suggested that SS is superior in efficacy over other treatments.<sup>10-13</sup> Though, few studies have reported otherwise.<sup>14,15</sup> There is a lack of consensus in selecting the most appropriate conservative treatment option for treating the TMD. The objective of this systematic review article was to compare the effectiveness of SS with other conservative treatment modalities (including physiotherapy, exercises, laser, medicines, and dry needling / trigger point injections) in the management of temporomandibular disorder keeping a decrease in pain intensity as a parameter of effectiveness.

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## METHODOLOGY

This review article is registered with Prospero (CRD no: CRD42023428771) and is reported according to PRISMA guidelines for reporting of systematic reviews and meta-analyses. Criteria followed the PICO(S) (patient or population, intervention, control or comparison, outcome, and study) framework as suggested by the PRISMA checklist (Table I). This review included all clinical trials comparing the effectiveness of the SS with other conservative therapies published in the English language from March 2000 to June 2023. Further inclusion criteria applied for the studies to be included in the review; studies including patients from all races and ethnicities, 15-40 years of age with diagnosis of TMD established on the basis of research diagnostic criteria (RDC), absence of any comorbid condition (odontogenic pain, bone pathology, rheumatoid arthritis, osteoarthritis, condylar resorption, and trigeminal neuralgia) that may deteriorate the condition and affect the bone or intensity/tolerance to pain. Exclusion criteria were articles not in the English language, reviews, abstracts, letters to the editor, editorials, animal studies, and *in vitro* studies, data from conference abstracts and studies involving any odontogenic pain, bone pathology, trigeminal neuralgia, or any other comorbid condition in addition to TMD.

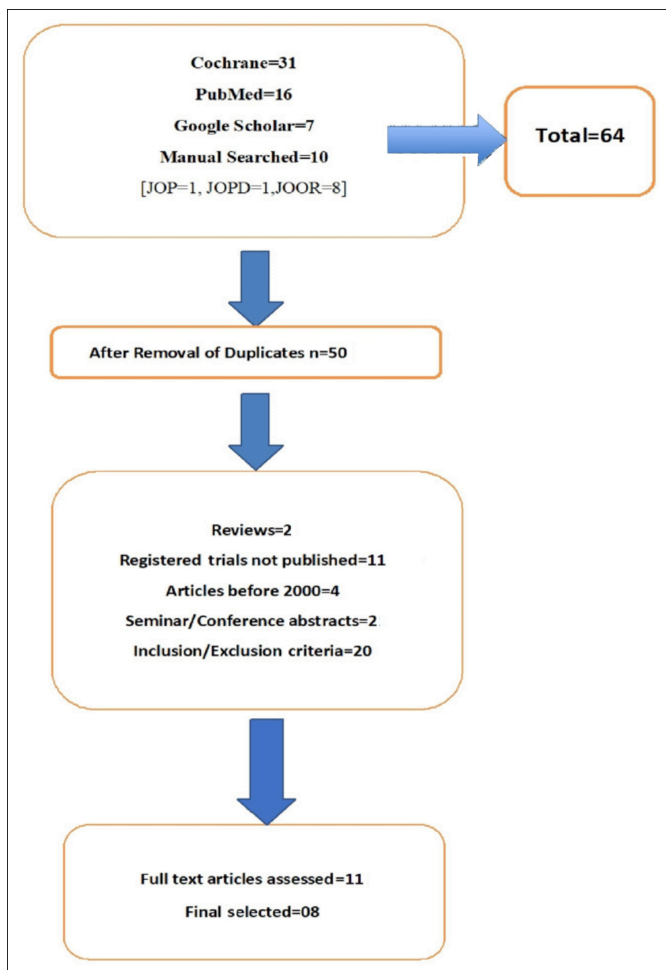


Figure 1: Flowchart for study identification.

An electronic search in databases PubMed, Google Scholar, and Cochrane was performed with the following MeSH key terms: Oral splints or stabilisation splints or occlusal splint or splint, and supportive therapy or conservative therapy, and TMD or myofascial pain. Further manual search in Journal of Prosthetic Dentistry, the American Journal of Prosthodontics, and Journal of Oral Rehabilitation was done to ensure all the essential material was gathered (Figure 1). After removing the duplicates, all the articles found relevant were assessed by two independent reviewers (MK and SA) using predetermined criteria. After going through the titles and abstracts, 11 full-text articles selected, were reviewed in detail. The results were compared after the assessment of both reviewers. In case of disagreement, a third reviewer (HS) was consulted, and consensus was reached after the discussion. Reviewers used the Cochrane risk-of-bias tool for randomised trials (RoB-2) for bias analysis as per the official document of guidance from the RoB-2 developmental group (Figure 2). Any disagreement between the authors was resolved in a comparable manner followed during the inclusion/exclusion process. Pain intensity data for the included studies were analysed to assess the main differences in the mean scores, SD and keeping confidence intervals of 95% on VAS.

Due to inconsistencies in the reported results, with few studies quoting quantitative data and others using figures, the data were analysed in a thematic way on the basis of descriptive statistics and VAS score. In the descriptive statistics, data were compared on the basis of objective, modality, number of participants / dropouts, number of groups i.e. intervention and controls, duration of follow-up, results, and treatment outcome parameters used. Table II compares the VAS scores before and after the intervention.

## RESULTS

A total of 11 clinical trials were selected to be included in the study. Three articles were excluded after the detailed study as they included patients suffering from TMD due to bone disease, such as osteoarthritis or rheumatoid arthritis, which was the exclusion criteria for the systemic review. Bone disorders were excluded as they may alter the course of TMD. The remaining eight RCTs satisfied the inclusion criteria. None of the published studies were registered clinical trials, rather they were approved by the local ethical review board. All the studies included cases that were referred to the special department for the clinical diagnosis and treatment fulfilling the criteria set for the diagnosis of TMD. The number of participants included in the studies ranged from 21-80 with a minimum number of participants in one group as 13.<sup>16</sup> All the studies had male and female patients enrolled except for one study.<sup>17</sup> The methodology covered both inclusion and exclusion criteria for every study in detail except for one study.<sup>18</sup> The objective of the studies was similar, to find out the efficacy / effectiveness of comparators with SS.

Furthermore, all the studies described in detail about the occlusal prescription of SS except the one by Ozkan *et al.*<sup>5</sup> Details of the studies and their results are compared in Table II.

**Table I: Systemic research strategy.**

Population	Clinical trials reporting the comparison of SS therapy with any conservative / supportive technique.
Intervention	Stabilisation splint therapy.
Comparison	Supportive / conservative treatments (physiotherapy, exercises, laser, medicines, placebo, and dry needling / trigger point injection).
Outcome	Decrease in the intensity of pain on visual analogue scale (VAS).
Search combination	Oral splints or stabilisation splints or occlusal splint or splint and supportive therapy or conservative therapy, and TMD or myofascial pain.

**Table II: Descriptive data of the studies included.**

Author / Year	Objective	Modality compared	No. of participants/ dropouts	No. of groups	Duration of follow-up	Result	Treatment outcome parameter*
Vrbancovic et al. 2019 <sup>17</sup>	To compare the effectiveness of SS with placebo splint.	Placebo splint (PS)	34 F / dropouts not available	Two	6 months	SS was more effective in reducing pain, improving OHIP, and functional limitation.	VAS, MMO, OHIP, and MCO.
Alajbeg et al. 2018 <sup>16</sup>	To evaluate the effectiveness of amitriptyline in the treatment of chronic TMD patients and to compare the obtained treatment results with SS.	Amitriptylin (A) SS	21 / 8 dropouts	Three A = 4 B = 4 C = 5	1 <sup>st</sup> week, 6 <sup>th</sup> week 12 <sup>th</sup> week	Amitriptyline and SS are more effective than placebo. VAS and OHIP showed better result while MCO were improved in Group B.	VAS, MCO, OHIP.
Qvintus et al. 2015 <sup>18</sup>	To assess the efficacy of SS tyhe treatment on TMD-related facial pain during a 1-year follow-up.	SS+C+ME ME+C	80 / dropouts not available (18 M 62 F)	Two	1 month 3 months 6 months 1 year	No difference between the two groups.	VAS patient own satisfaction.
Katyayan et al. 2013 <sup>22</sup>	To assess the efficacy of SS therapy on TMD related facial pain and mandibular mobility.	SS+ME+C ME+C	80 / dropouts not available 77.5 % F	Two A = 40 B = 40	6 months	No difference between the two groups on VAS and decreasing painful sites.	VAS AMO, mandibular right laterotrusion, mandibular left laterotrusion, mandibular protrusion, and number of painful muscle sites.
Niemela et al. 2012 <sup>21</sup>	To examine the efficacy of the SS treatment on TMD-related facial pain and mandibular mobility.	SS muscle exercises (ME) counselling (C)	80 / dropouts not available (18M 62 F)	Two	1 month	VAS and other values were similar for both groups.	VAS, MO, laterotrusion protrusion active maximal opening pain on palpation.
Conti et al. 2012 <sup>19</sup>	To test the hypothesis that treatment with intra-oral appliances with different occlusal designs was beneficial. In the management of the pain of masticatory muscles compared with a control group.	SS+C NTI+C C	51 / 12 dropouts	Three A = 21 B = 16 C = 14	2 weeks 6 weeks 3 months	No difference between the groups	VAS, pressure pain threshold.
Michelotti et al. 2012 <sup>20</sup>	To compare the effectiveness of an education programme with that of occlusal splint therapy for the treatment of myofascial pain of the jaw muscles across a short period.	Counselling SS	44 / 3 dropouts (10M 34F)	Two A = 23 B = 21	Every 3 <sup>rd</sup> week for 3 months	No difference between pain-free mouth opening, headache, and pain during chewing	VAS, MO, spontaneous muscle pain, and pain during chewing headache.
Ozkan et al. 2011 <sup>5</sup>	To compare combination treatment.	Trigger point injection (TPI) plus SS	50 / dropouts not available (44 F 06 M)	Two	3 months	Combo more effective	VAS

\* The review included the studies in which diagnosis of TMD was established using the research diagnostic criteria for TMD (RDC / TMD) developed by Dworkin et al.<sup>23</sup> Comparison groups included placebo splint, trigger point injection, amitriptyline, muscle exercises, counselling, and tension suppression system. The history of any previous treatment for TMD was not considered in any study. Almost all the studies had two groups except for two studies.<sup>16,19</sup> Also, the duration of follow-up was different for each study ranging from one week to one year.

**Table III: Comparison of VAS score before and after intervention.**

Author / Year	Intervention	Duration	Baseline VAS score			Post-treatment VAS findings			Outcome
			Group A	Group B	Group C	Group A	Group B	Group C	
Vrbancovic et al. 2019 <sup>17</sup>	Group A = SS Group B = PS	6 months	6.52 ± 2.03	5.53 ± 1.7	-	0.56 ± 1.25	2.4 ± 3.5	-	SS group showed greater decrease in VAS score.
Alajbeg et al. 2018 <sup>16</sup>	Group A = A Group B = P Group C = SS	12 weeks	80.25 ± 14.15	72.75 ± 21.71	70.0 ± 12.5	56% reduction.	No Significant change.	58% reduction.	Group A and C showed similar results.
Qvintus et al. 2015 <sup>18</sup>	Group A = SS + ME Group B = ME	1 year	5.22	4.59	-	4.24	3.37	-	SS is not as effective as muscle exercises alone.
Katyayan et al. 2013 <sup>22</sup>	Group A = SS Group B = Counselling	6 months	6.04	6.72	-	3.8	4.73	-	No additional benefit was found of using splint over a 6-month period.
Niemela et al. 2012 <sup>21</sup>	Group A = SS + C + ME Group B = C + ME	1 month	5.3 ± 2.8	4.8 ± 2.4	-	3.4 ± 3.2	4.0 ± 2.6	-	No difference.
Conti et al. 2012 <sup>19</sup>	Group A = SS + C Group B = NTI + C Group C = C	3 months	Value between 60-70 (graphical presentation).	Value ≤60 (graphical presentation).	Value between 55-60 (graphical presentation).	82% responsive.	76.9% responsive.	33.3% responsive.	Significant difference between Group A and Group C.
Michelotti et al. 2012 <sup>20</sup>	Group A = ME + C Group B = SS	3 months	41.6 (mean)	39.1 (mean)	-	F = 12.1; p = 0.001 (changed significantly over time).	F = 1.7. p = 0.197 (No change)	-	Education (counselling) was slightly more effective than occlusal splint without education.
Ozkan et al. 2011 <sup>5</sup>	Group A = SS Group B = SS + TPI	12 weeks	7.20 ± 1.50	7.48 ± 1.71	-	3.16 ± 1.52	1.40 ± 1.16	-	Combination therapy showed better results.

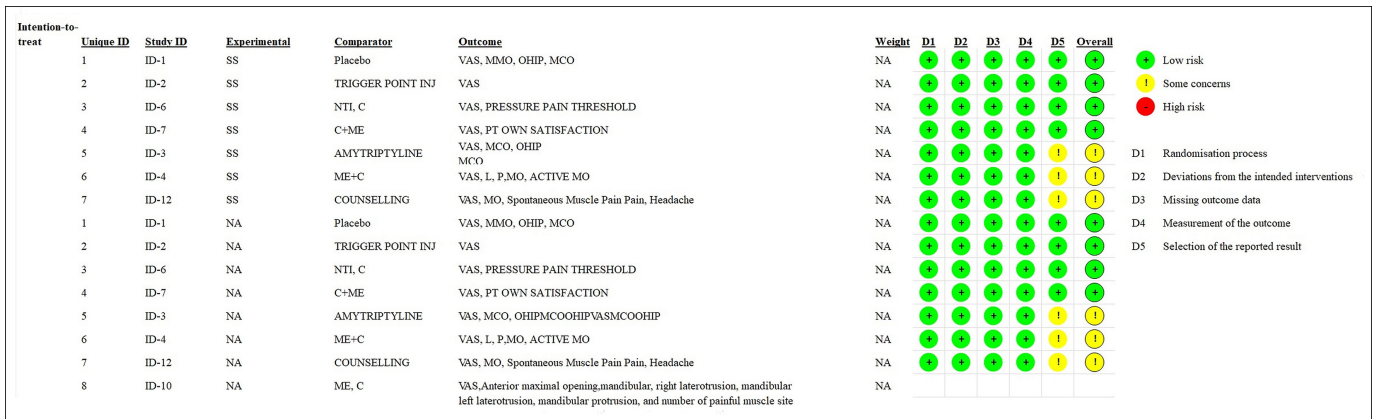


Figure 2: RoB-2 analysis chart.

The baseline finding was VAS score, though only one study lacked that (Table III).<sup>19</sup> While, the results after the treatment were measured but presented variedly in articles, in the form of graphs presentations or tables.<sup>16,19</sup> On comparing the readings and outcomes, only one study showed that SS was better than the comparators.<sup>16</sup> Similarly, only amitriptyline used in combination with splint showed better results in comparison to using SS alone.

The treatment outcome measured was observed to be different for every study, with VAS common for all studies as described for inclusion criteria. Other measured outcomes included MMO (maximal mouth opening), MCO (maximal comfortable mouth opening, OHIP (oral health impact factor performa), GCPS (graded chronic pain scale), patient's own satisfaction, AMO (anterior maximal opening), mandibular right laterotrusion and left laterotrusion, mandibular protrusion, and active maximal opening, pain on palpation, pressure pain threshold, spontaneous muscle pain, and measurement of painful muscle sites.

The bias was low for all the studies except three studies showing some concerns (Figure 2).<sup>16,20,21</sup> Furthermore, only two studies were discussed regarding the blindness of the study i.e. the procedure was though performed by a single clinician, the post-treatment values were checked by another clinician who had no idea about the treatment provided to the patient he was evaluating.<sup>18,19</sup> Dropouts were reported in only three studies (Table II and Figure 2).<sup>16,19,20</sup>

On comparing SS to placebo splint, VAS scores showed decrease in the pain in SS group (Wilks' Lambda = 0.58, F = 5.78, p = 0.004, and effect size = 0.22), also PSS (perceived stress scale) scores, OHIP scores, MCO were significantly lower for SS compared to PS group while MMO and GCPS scores were similar for both groups. On Post hoc analysis, the mean VAS values for SS group were significantly lower at 1<sup>st</sup>, 3<sup>rd</sup>, and 6<sup>th</sup> month of the treatment (p = 0.0007, p <0.0001, and p <0.0001, respectively), while for PS group significant difference was observed only at the 6<sup>th</sup> month of the treatment (p = 0.006). There were no different VAS scores present between TMD subgroups.<sup>17</sup>

Three clinical trial studies compared the effectiveness of SS with counselling or education and muscle exercises. All three of them found that the VAS and overall pain during mandibular movements decreased, but there was no significant difference in the findings within the control group. Their follow-up period was one month, six months, and one year, respectively.<sup>18,21,22</sup>

Clinical trials were conducted to compare the NTI device with the SS. Three groups were made. Group A received an NTI device, Group B received SS, and Group C only had counselling. On follow-up visits at two, six weeks and three months, VAS and pressure pain threshold of the muscles were recorded and revealed that Group A showed improvement in the pain on the first follow-up visit (significance level of 5%), while Group B and C showed progress at 6<sup>th</sup> weeks and 3 months. In contrast the PPT values had no significant effect on them.<sup>19</sup>

Pain significantly decreased in both amitriptyline (Group A) and in the SS group (Group C) over time. In Group A, the decrease was more significant (F = 11.326, p = 0.002, effect size = 0.791) in comparison to Group C (F = 7.343, p = 0.005, effect size = 0.647). Similarly, OHIP improved significantly for Group A (F = 4.417, p = 0.036, effect size = 0.596). While in placebo group (Group B) both VAS and OHIP-14 scores showed no significant change (p >0.05). MCO was increased for all the groups, though Group C had better results in comparison to Group A and B (p >0.05). At the 12<sup>th</sup> week, Group A and C showed improved but non-significant change in VAS scores while OHIP showed a reduction comparatively to Group B.

Both groups with and without trigger point injection showed significant reduction in the frequency of pain, and intensity of pain (p <0.001). Also, significant decrease in myofascial pain at rest (Group 1 p = 0.001, Group 2 p <0.001), during mandibular movements (p = 0.002 in Group 1 and p <0.001 in Group 2) was observed. Patients from both groups reported improvement in symptoms (significant at p = 0.033). While MIO showed a slight increase in Group 2 (36.6 ± 1.7, 40.1 ± 1.6) as compared to Group 1 (37.5 ± 2.38,

39.9 ± 1.7) at 3-month follow-up. There was no significant difference in VAS scores between two groups at 4<sup>th</sup> and 12 weeks' follow-up with Group 2 showing statistically significant reduction in VAS scores ( $p < 0.001$ ).<sup>5</sup>

## DISCUSSION

TMD are commonly encountered in practice. This systematic review was conducted after 20 years of previous systematic reviews.<sup>4,8</sup> The review was registered with Prospero to decrease the chances of duplication of topics and increase transparency.

All studies were analysed through the Cochrane RoB-2 tool for risk of bias analysis, and it was found that none of the trials were registered with any of the clinical trial registries (Figure 2). Though the bias of the studies was low, but the quality assurance details were lacking in all. Studies lacked clarification on randomisation process and blindness. Only two studies mentioned blindness but failed to describe the process. The objective was the same for the studies, and the outcome was measured by different scales lacking standardisation, but all included VAS scale. Hence, the analysis included in the review was based on post-treatment VAS scores. Baseline investigations were mentioned in all the studies except one.<sup>19</sup> Similarly, outcome was described in percentage of decrease of the VAS score in one study, while two showed VAS values on the line graph.<sup>16,19</sup> The duration of the studies was short with the longest being one year. Findings are summarised in Table III.

Only two studies had results supporting that the SS has significant effect on pain and management of TMD symptoms.<sup>16,17</sup> Other studies had shown no significance of SS in comparison to counselling / education and muscle exercises.<sup>18,21,22</sup> The results have been summarised according to the comparative therapies used in the study.<sup>18,21,22</sup>

Previous systematic reviews have concluded that there is a supportive evidence for the use of SS in TMD for decreasing severity of pain at rest and during the movement of mandible when it is compared to placebo. The reviews had reported lack of data, short duration of the study, and no standardisation of outcomes in the included studies.<sup>4,8</sup> The authors of the described studies had agreed that further trials with an ample number of participants and longer duration should be done to find out the effectiveness of the SS for concrete evidence in its favour.

After the comparison of the eligible clinical trials published comparing the SS with other modalities, it was found that there is a lack of sufficient clinical trials to establish the use of SS therapy as superior to other conservative treatment options and there is a need for further RCTs. Most published studies have inadequate sample sizes, short duration of study (less than three months), and control groups which were exposed to different treatment modalities. Hence, it is

concluded that further studies with adequate sample size and long-term follow-up are required to support the effectiveness of SS over counselling and muscle exercises.

## CONCLUSION

This systematic review identified that there is weak evidence that SS splint therapy may be beneficial in the treatment of TMD over other conservative options in terms of pain reduction measured on VAS. Further well-conducted RCTs are needed to identify the effectiveness of SS therapy over other conservative therapies with emphasis on randomisation, long duration of follow-up, blind treatment outcome assessment, and distinct criteria for diagnosis of TMD.

### ETHICAL APPROVAL:

This study is registered with Prospero (CRD no: CRD42023 428771).

### COMPETING INTEREST:

The authors declared no conflict of interest.

### AUTHORS' CONTRIBUTION:

MK: The conception and design of the study.

SA: Drafting the manuscript.

SS, JA: Acquisition, analysis, and interpretation of data.

HS: Critical review for important intellectual content.

All author approved the final version of the manuscript to be published.

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