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## LITERATURE REVIEW

**EFFECTIVENESS OF DIGITAL OCCLUSAL SPLINTS IN MANAGING TEMPOROMANDIBULAR JOINT DISORDERS: A SYSTEMATIC REVIEW AND META ANALYSIS**

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**Abstract**

**Background:** This systematic review aims to assess the effectiveness of 3D occlusal splints (OS) for managing pain and improving maximum mouth opening in temporomandibular joint disorders (TMDs) via randomized controlled trials (RCTs).

**Materials and Methods:** Searches were conducted in PUBMED, SCOPUS, and the COCHRANE library. Eligible studies were evaluated for risk of bias (RoB) by two reviewers based on predetermined criteria: generation of random sequences, implementation of single-operator protocol, inclusion of a control group, blinding of testing machine operator, uniformity in sample preparation, evaluation of failure modes, adherence to manufacturer's instructions for materials, and explanation of sample size calculation. If the author provided information about the examined parameter, the study was categorized as having a "YES." Conversely, if the information was absent, the parameter was marked as "NO." The RoB for each study was then determined according to the total number of "YES" responses: 1 to 3 indicated a high RoB, 4-6 signified a medium risk, and 7 to 8 indicated low RoB. Out of 14 articles, 5 RCTs underwent qualitative analysis.

**Results:** Results indicate that OS therapy effectively manages TMD-related pain and reduces TMJ clicking. Additionally, it improves mouth opening in patients with initial limitations. Better symptom management correlates with improved quality of life in TMD sufferers.

**Conclusions:** Further comparative clinical trials are necessary due to remaining uncertainties regarding how specific OS design and fabrication methods may impact TMD outcomes.

**Keywords:** Temporomandibular Joint, Temporomandibular Joint Disorders, Occlusal therapy, Occlusal Splint, Pain, Maximum mouth opening.

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## INTRODUCTION

Temporomandibular Joint Disorders (TMD) encompass various clinical issues impacting the TMJ, myofascial muscles, and associated structures. The primary manifestations involve pain and clicking in the TMJ, discomfort in facial and masticatory muscles, and irregular jaw movements. TMDs represent a significant health challenge since they are a primary cause of persistent orofacial pain, disrupting everyday tasks. It is interesting to note that while around 60 to 70 percent of the population displays signs of TMD, only about one in four individuals who show these signs are aware of experiencing any symptoms.<sup>1-6</sup> The origins of TMD remain somewhat enigmatic, but factors that seem to play a part include various factors like occlusal abnormalities, emotional stress, orthodontic procedures, minor repetitive injuries, suboptimal health and dietary habits, joint looseness, and increased estrogen. The multifaceted etiology of TMD involves neuromuscular, neurobiological, biomechanical, and biopsychosocial factors, resulting in broader classifications as Articular and Muscular Disorders. From an anatomical perspective, the disc assumes a pivotal role, contributing to articulating surfaces in both joint compartments. Disc displacements serve as a central aspect in the diagnosis of TMDs, elucidating various clinical signs and symptoms. Disc derangement disorders constitute 30% to 39% of the overall TMD prevalence. TMDs are also frequently linked to additional symptoms affecting the head and neck area, including headaches, ear-related issues, dysfunction in the cervical spine, and changes in the position of the head and neck.<sup>7-12</sup>

Treatment for TMDs is deemed necessary in only 5% to 10% of instances, with 40% witnessing spontaneous resolution of symptoms. Extended follow-up investigations suggest that conservative therapy achieves pain relief in 50% to 90% of cases, often employing a conservative approach to alleviate pain and enhance functionality. Strategies for managing TMD include non-pharmacologic management, pharmacologic drug therapy, and in severe cases, surgical interventions. The initial therapeutic options for treating TMDs include occlusal splint therapy (OS), physical therapy and medication.<sup>13-19</sup> In practical terms, an OS is typically made from resin, and is commonly crafted to cover either the upper or lower jaw, encompassing all the

biting and cutting surfaces of the teeth. Occlusal splint therapy, the prevailing clinical method due to its simplicity, affordability, and wide applicability,<sup>20</sup> plays a crucial role in alleviating tension, mitigating muscle hyperactivity, and preventing adverse effects associated with temporomandibular disorders. They are designed to alter the occlusal relationship between maxillary and mandibular arches, thereby preventing complete intercuspatation of teeth. This intentional interference prompts patients to readjust their jaw position to achieve an optimal occlusion, thereby facilitating the natural alignment of the temporomandibular joint.<sup>21</sup> The efficacy of occlusal splints lies in their ability to promote neuromuscular adaptation and proprioceptive feedback. By encouraging patients to adopt a more harmonious jaw position, occlusal splints contribute to improved muscular coordination and joint stability. Additionally, the alteration in occlusal contact patterns induced by the splint serves to disrupt maladaptive habits, such as bruxism or clenching, which can exacerbate TMJ symptoms. Furthermore, occlusal splints function to distribute occlusal forces more evenly across the dental arches, thereby mitigating excessive loading on specific teeth and reducing the risk of dental attrition, fracture, or temporomandibular joint overloading.<sup>20</sup> This redistribution of forces helps to alleviate strain on the TMJ and surrounding structures, promoting a more balanced muscle and joint environment conducive to healing and rehabilitation in TMD patients. Occlusal splints are traditionally crafted using the conventional compression molding technique with heat cure acrylic resin, but this method has drawbacks such as monomer leakage and shrinkage, leading to biocompatibility issues.<sup>22</sup>

The advent of Computer-Aided Design and Computer-Assisted Manufacturing (CAD/CAM) technology has revolutionized the traditional fabrication methods for occlusal splints, offering a novel and sophisticated alternative. Recent advancements in 3D printing have demonstrated potential in creating customized splints with enhanced precision and efficiency.<sup>22</sup> However, additional research is crucial to evaluate the efficacy and long-term results of 3D printed splints, as current literature on the success rates of splints created with this method is sparse.<sup>23</sup> This systematic review explored how effective 3D printed occlusal splints are in treating

temporomandibular joint disorders, particularly in relieving pain. It aimed to answer questions about the overall success rate, pain reduction, enhancement of mouth opening, and the pros and cons of this therapy. This comprehensive review delves into the effectiveness of 3D printed occlusal splints for treating TMD, aiming to uncover insights and pinpoint any gaps in current research. The null hypothesis suggested that there would be no difference in subjective and objective outcomes between those receiving 3D printed occlusal splints and those with conventional occlusal therapy.

## MATERIALS AND METHODS

### Protocol and eligibility criteria

The systematic review followed the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) guidelines. The methodology was crafted according to the standards set in the Cochrane Handbook for Systematic Reviews of Interventions. The inclusion criteria were specifically constructed following the PICOS criteria: P (population) = Patients with Temporomandibular Joint Disorders; I (intervention/exposure) = Use of 3D printed Occlusal Splint; C (Comparison) = Conventional Occlusal splint /No treatment/Placebo; O (Outcome) = Visual Analogue scale (VAS), Maximal mouth opening, Tekscan (T Scan), Joint Vibration Analysis (JVA); and S (Study design) = clinical trials written in English. The review question was "Does the use of 3D printed Occlusal Splint reduce Pain and has an effect on maximal mouth opening?". No restrictions were imposed on setting, country, or time period for the included studies. However, any publications that didn't align with the review's objectives or weren't original research were excluded.

### Search strategy

The search spanned up to January 2024, covering electronic databases such as Web of Science, PUBMED Central, Google Search, and COCHRANE, utilizing diverse search terms via the PUBMED search builder tool. This review incorporated articles featuring Randomized Control Trials (RCTs) but excluded *in vitro* studies, narrative reviews, systematic reviews, animal research, and studies not published in English. Two independent reviewers

evaluated the studies' eligibility according to the inclusion criteria.

### Screening

Two reviewers, M.V and S.M, conducted independent screenings of the collected papers, achieving a notable agreement level of 0.81, suggestive of robust alignment in their assessments. Subsequent to the initial data compilation, a thorough screening process was enacted, resulting in the exclusion of articles that failed to adhere to the specified inclusion and exclusion criteria. These criteria were delineated in four distinct phases. In the first step, irrelevant publications and citations were eliminated. Then, in the second step, a single reviewer carefully went through the titles and abstracts of the selected studies, picking out only the ones considered relevant. Any studies lacking statistics or factual data were promptly set aside. If there were any lingering doubts, the entire article was retrieved and compared with a second reviewer's assessment for further consideration. During Stage 3, both examiners undertook a reassessment of the articles identified in Stage 1 to confirm their relevance to review. This phase involved the exclusion of incomplete publications and those with insufficient data, along with articles that had not been cited. The publications that survived this stage were subjected to meticulous scrutiny. Stage 4 was dedicated to identifying research that aligned with our PICOS criteria, resulting in the exclusion of certain articles from our review.

### Study selection

EndNote™ (v. 9.0) software was employed to remove duplicates and conduct initial screening based on titles and abstracts. Eligible articles meeting inclusion criteria were further assessed by two investigators accessing their full texts independently. Discrepancies if any were resolved by a third investigator.

### Data extraction

Two authors extracted, reviewed, and analyzed data from the retained studies, employing a structured format delineating population demographics, investigated variables, data collection timelines, and noteworthy discoveries. A third author corroborated the extracted data, with any disparities in data collection addressed through collaborative discourse.

*Methodological quality assessment*

Two authors assessed the risk of bias using the RoB 2.0 tool for all included studies. The evaluation of bias risk relied on various criteria, including the generation of random sequences, the utilization of a single-operator protocol, the incorporation of a control group, the blinding of the testing machine operator, the uniformity in sample preparation, the scrutiny of failure modes, compliance with manufacturer instructions for materials, and the elucidation of sample size calculation rationale. The studies were classified according to whether information about the examined parameter was present ("YES") or absent ("NO"). The risk of bias (ROB) for each study was assessed based on the total number of "YES" responses. A score of 1 to 3 denoted a high ROB, 4 to 6 indicated a medium risk, and 7 to 8 suggested a low

ROB.

RESULTS

Search results

In total, the researchers found 20 articles through electronic database searches and manual exploration. After reviewing 14 studies met the criteria for a comprehensive examination of their full texts, ultimately resulting in the identification of 9 randomized control trials for in-depth qualitative analysis. The study screening and selection of articles are explained in Figure 1.

The methodological quality of the studies included in this systematic review was assessed, as shown in Table 1.

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only

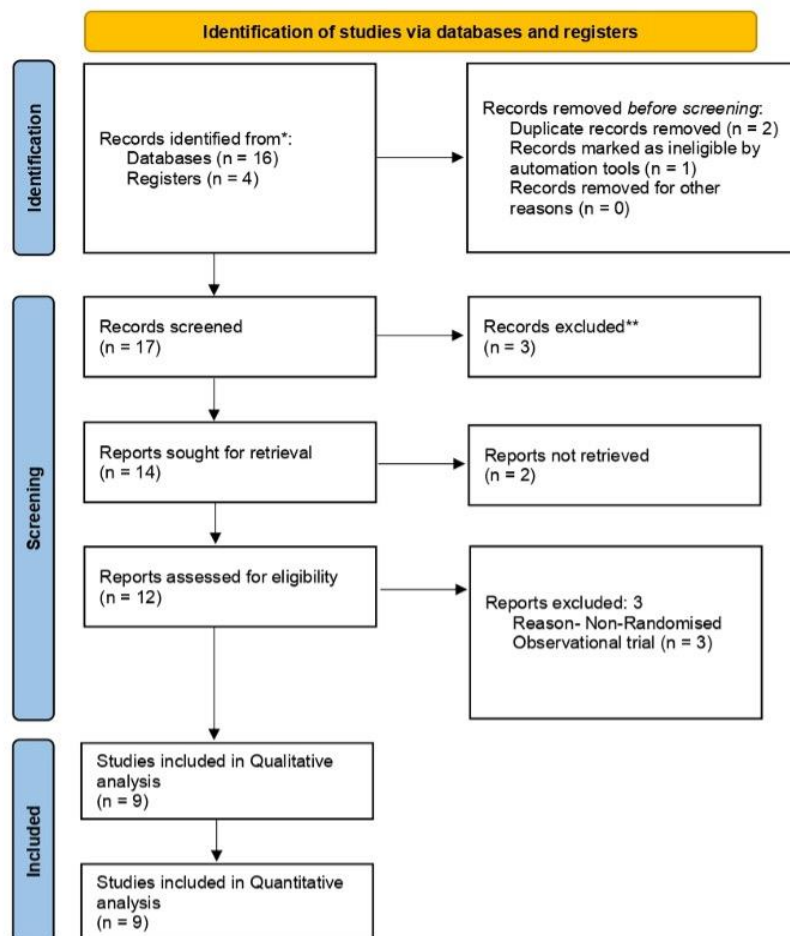


Figure 1. PRISMA 2020 flow chart for identifying studies of this systematic review and meta-analysis

STUDY CHARACTERISTICS

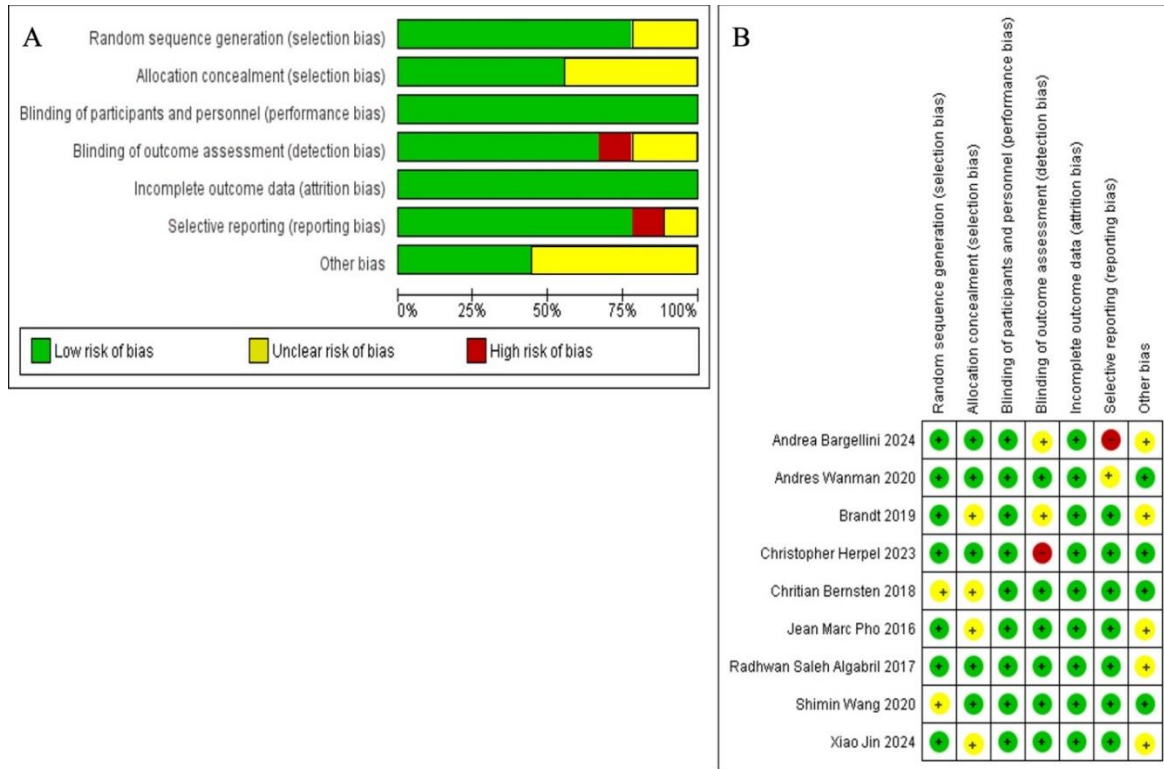


Figure 2. A. Risk of Bias assessment graph and B. Risk of Bias assessment summary

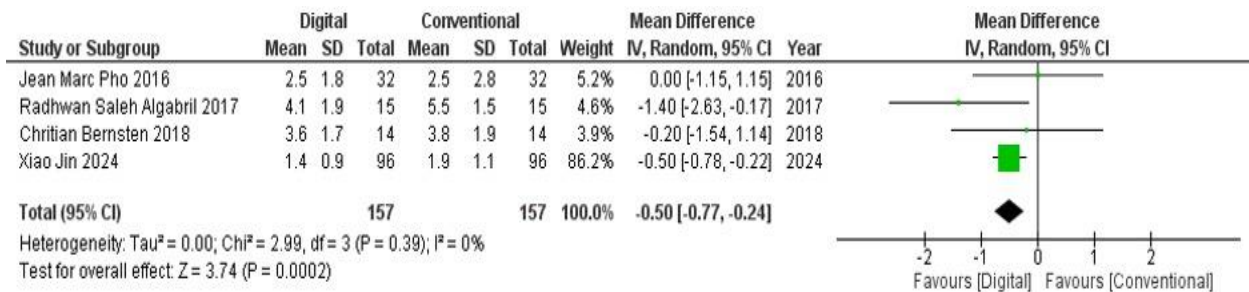


Figure 3. Forest Plot favoring digital occlusal splint therapy for pain reduction

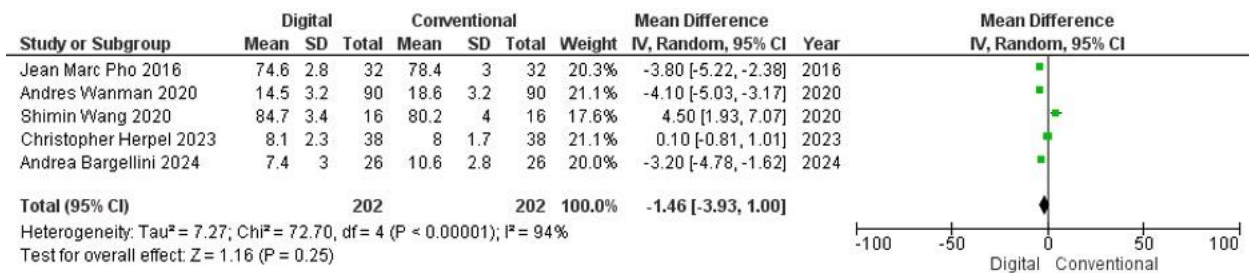


Figure 4. Forest Plot showing no significant results among the groups suggesting comparable patient acceptability and comfort levels

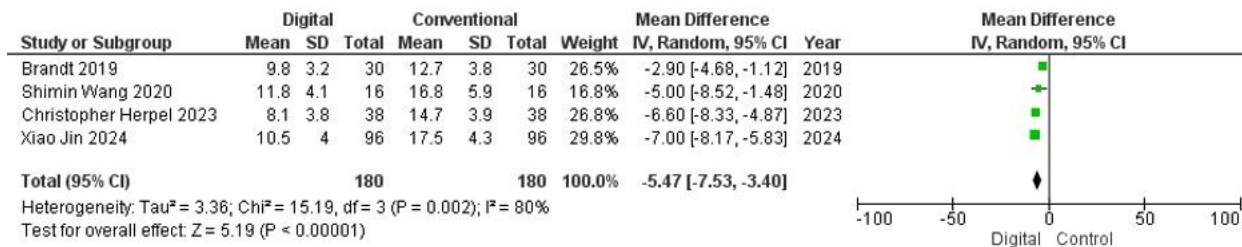


Figure 5. Forest Plot showing reduced chair time appointment timing required for adjustment and fitting of digital occlusal splint

Table 1. Risk of Bias assessment

Author	Chritian Bernsten et al.	Andres Wanman et al.	Jean Marc Pho et al.	Christoph er Herpel et al.	Andrea Bargellini et al.	Xiao Jin et al.	Shimin Wang et al.	Radhwan Saleh Algabril et al.	Brandt et al.
Random sequence generation	Unclear	Low risk	Low risk	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk
Allocation concealment	Unclear	Low risk	Unclear	Low risk	Low risk	Unclear	Low risk	Low risk	Unclear
Selective Reporting	Low risk	Unclear	Low risk	Low risk	High risk	Low risk	Low risk	Low risk	Low risk
Blinding of participants and personnel	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Blinding of outcome assessment	Low risk	Low risk	Low risk	High risk	Unclear	Low risk	Low risk	Low risk	Unclear
Incomplete outcome data	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Other bias	Low risk	Low risk	Unclear	Low risk	Unclear	Unclear	Low risk	Unclear	Unclear
Quality	Fair quality	Good quality	Good quality	Fair quality	Fair quality	Good quality	Good quality	Good quality	Fair quality

Out of the nine studies included, four were judged to have a moderate level of quality, while one was deemed to be of low quality. Table 2 illustrates

the fundamental attributes and methodological elements of the studies that were retained.

Table 2. Characteristics of Included Studies

DATA CHARACTERISTICS											
STUDY REFERENCE	YEAR OF STUDY	LOCATION OF STUDY	STUDY DESIGN	POPULATION			INTERVENTION	COMPARISON	OUTCOME ASSESSED	FOLLOW UP	CONCLUSION
				SAMPLE SIZE	AGE	GENDER					
Chritian Bernsten et al.	2018	South east Norway	Randomized controlled trial	14	21-55 years	1-Male, 13-females	Additive manufactured occlusal stabilization splint	Conventional occlusal stabilization splint	VAS pain scale DC/TMD SCORES	Every 6 weeks for 4 months	Both traditional and 3D-printed splints were found to provide a high level of comfort after three months of use. When combined with the DC/TMD score, this suggests that both types of splints produce similar treatment outcomes.
Andres Wanman et al.	2020	Clinical Oral Physiology department in Umeå, Sweden	Randomized controlled trial	90	18-70 years	40-Males, 50-Females	Heat and vacuum pressed resilient occlusal splint	Home exercises and Supervised exercises	TMJ clicking, TMJ locking, Jaw pain, Maximal jaw movement	Baseline and 3 months	About half the participants saw their jaw clicking improve, with no big difference between treatments. In both the supervised exercise and bite splint groups, around two-thirds felt their jaw sounds got better by at least 30%, and half by 50% or more. The supervised exercise group also felt less jaw pain, neck stiffness, mood swings, and stress. Both jaw exercises and bite splints helped reduce jaw clicking. The supervised exercise program also made people feel better overall, possibly helping them cope better.
Jean Marc Pho et al.	2016	Ludwig Maximilian University Prosthodontic Department in Munich, Germany	Randomized controlled trial	32	20-40 years	12-Males 20-Females	CAD/CAM occlusal splint	Conventional occlusal splint	Pain was measured using a numeric scale (TMD/NS, 10 cm), while right and left condyle movements (mm) were measured using optical axiography.	Baseline and then monthly for 9 months	The CAD/CAM splint showed a significant reduction in 10 out of 13 TMD/NS items, compared to 8 out of 13 with the conventional splint. However, neither treatment significantly improved mandibular movements. Overall, both treatments were equally effective, with no discernible difference between them.
Christopher Herpel et al.	2023	Germany	Randomized controlled trial	38	18-55 years	All female participants	3D printed occlusal splint	Milled occlusal splint	Survival, Adherence, Technical complications, Patient satisfaction on a 10-point Likert scale, and Maximum wear using superimposition of optical scans.	2 weeks and 3 months post insertion	All splints survived the trial. Minor cracks occurred in 6 printed and 4 milled splints. Patient satisfaction averaged 8 for printed and 8.1 for milled splints. Wear varied, with printed splints showing median maximum wear of 153 in posterior segments and 195 in frontal segments, while milled splints showed 96 in posterior and 123 in frontal segments. Despite minor differences, both types performed similarly in patient satisfaction, complication rates, and wear behavior.
Andrea Bargellini et al.	2024	University of Torino, Italy	Randomized controlled trial	26	8-20 years	19-Males 7-Females	3D printed Occlusal splint	Conventional Occlusal splint	SB index, the total amount of surface masseter muscle activity (sMMA), and general and SB-related phasic and tonic contractions	Baseline, 1 month and 3 months	3D printed splints appear to influence electromyographic activity associated with sleep bruxism more significantly, though they do not notably affect the overall sleep bruxism index. The smoother surfaces provided by 3D splints might contribute to stabilizing phasic contractions.
Xiao Jin et al.	2024	Wenzhou Medical University, China	Randomized controlled trial	96	20-40 years	24-Males 72-Females	3D printed Occlusal splint	Conventional Occlusal splint	Pain score and mouth opening before and after treatment	Baseline and 6 months	Digitally designed and 3D-printed repositioning splints outperformed conventional occlusal splints in reducing pain and enhancing mouth opening. They emerge as highly effective treatments for temporomandibular joint disc displacement.
Shimin Wang et al.	2020	Peking University School and Hospital of Stomatology, Beijing, PR China.	Randomized controlled trial	16	18-44 years	6-Males 10-Females	3D printed digital splints	Conventional hard acrylic splint	Manual time encompassing impression acquisition, splint fabrication, and clinical occlusal adjustment was documented. Visual analog scale. Maximum	Baseline and 12 weeks	Digitally produced splints offered improved comfort and time efficiency compared to conventional hard splints. Additionally, PEEK milled digital splints demonstrated superior wear resistance in comparison with acrylic resins.

									depth loss and volumetric loss of the occlusal surface of splints in the posterior teeth.		
Radhwan Saleh Algabril et al.	2017	Department of Prosthodontics, Cairo University, Egypt	Randomized controlled trial	30	20-40 years	6-Males 24-Females	CAD/CAM stabilization occlusal splint	Conventional hard acrylic splint	Patient's satisfaction (TMD/NS), Muscle's activity, e time needed for adjustment of splint	Baseline, 1 month and 3 months	CAD/CAM occlusal splints require less adjustment time and enhance TMD patient satisfaction significantly more than conventional splints. However, both types of splints yield similar improvements in muscle activities.
Brandt et al.	2019	Germany	Randomized controlled trial	30	22-33 years	15-Males 15-Females	CAD/CAM splint	Conventional hard acrylic splint	VAS, Missing occlusal contacts, Retention, Preference	Baseline every 3 weeks for 3 months	No significant difference among the splint for outcome measured. CAD/CAM splint can serve as a reasonable alternative to Conventional splint.

The dataset encompasses a range of randomized controlled trials (RCTs) conducted across various geographical regions between 2016 and 2024. Numerous investigations have delved into the efficacy of various occlusal splint types in managing temporomandibular disorders (TMDs). Retained studies encompasses Stabilization and Anterior repositioning splints as the treatment modality for the temporomandibular joint disorders. Bernsten et al. (2018) conducted a randomized controlled trial (RCT) comparing additive manufactured occlusal stabilization splints to conventional ones, finding that both types provided high comfort levels after three months of use.<sup>23</sup> Wanman et al. conducted an RCT comparing heat and vacuum pressed resilient occlusal splints to home and supervised exercises, observing improvements in TMJ clicking, pain reduction, and overall well-being in both groups.<sup>24</sup> Pho et al. compared CAD/CAM occlusal splints to conventional ones, finding significant reductions in TMD pain with both treatments.<sup>25</sup> Herpel et al. compared 3D printed to milled occlusal splints, noting similar patient satisfaction levels and complication rates.<sup>26</sup> Bargellini et al. evaluated the effects of 3D printed occlusal splints on sleep bruxism, finding significant impacts on electromyographic activity.<sup>27</sup> Jin et al. compared 3D printed repositioning splints to conventional ones, observing better pain reduction and mouth opening with the former.<sup>28</sup> Wang et al. examined digitally produced occlusal splints, highlighting their enhanced comfort and time efficiency.<sup>29</sup> Algabril et al. found that CAD/CAM splints improved TMD patient satisfaction more than conventional splints.<sup>30</sup> Brandt et al. found no significant differences between CAD/CAM and conventional splints in various outcome measures. These findings collectively

indicate that both conventional and digitally manufactured occlusal splints offer effective treatment options for TMDs, with each approach having its own advantages and considerations.<sup>31</sup>

### Outcome assessment

The studies followed The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT 7) and CONSORT guidelines, evaluating symptoms like TMJ clicking, locking, and jaw pain severity using graded scales and Numeric Rating Scale (NRS). Moderate improvement was defined as a reduction of 30% or more, while substantial improvement was considered a reduction of 50% or more. Additional evaluations encompassed the Jaw Functional Limitation Scale-20, indicators of depression and somatization, the Neck Disability Index (NDI), and the Patient Global Impression of Change (PGIC). Changes in maximal jaw movement were measured in millimeters. Numeric scales (TMD/NS, 10 cm) assessed symptoms monthly for 9 months. Optical axiography tracked condyle movements. Patient satisfaction was gauged through a questionnaire. Surface electromyography (EMG) recorded masseter and temporalis muscle activity during clenching. Manual time for impression, splint production, and occlusal adjustment was noted. Visual analog scale captured subjective evaluations, while depth and volumetric loss of splints were measured. Main outcomes included the overall SB index, surface masseter muscle activity (sMMA), and phasic/tonic contractions. Electromyography provided precise diagnosis, complemented by Visual Analog Scale (VAS) scoring for subjective pain assessment, ensuring a comprehensive evaluation of treatment efficacy.

## Effects of Occlusal splint on TMD

All studies included in the review reported a significant decrease in pain and an increase in maximal mouth opening. This significant reduction was observed in the Occlusal splint group at the two- and the four-month follow-ups. Pain was notably reduced in both the compared groups in all studies. Occlusal splint was effective in improving the quality of life in one study. However, a study reported an irrelevant result between the occlusal splint and the control group.<sup>32</sup> Christian Bernsten et.al reported both traditional and 3D-printed splints were found to provide a high level of comfort after three months of use. When combined with the DC/TMD score, this suggests that both types of splints produce similar treatment outcomes.<sup>23</sup> A study compared acupuncture with flat occlusal plane appliances in 40 women with myogenic temporomandibular dysfunction. They found that after 4 weeks of treatment, both groups showed equally reduced pain intensity measured by VAS ( $p < 0.001$ ) and significant increase in mouth opening range. This led the authors to conclude that both therapies are equally effective in managing chronic pain associated with TMD.<sup>33</sup> A study juxtaposed Low-Level Laser Therapy (LST), oral appliance (OA), and conservative splint therapy (CSL) in alleviating jaw muscle pain. The LST group exhibited diminished pain levels at the 3-week mark ( $p = 0.018$ ), with all groups demonstrating amelioration at the 6-month juncture. Conversely, a study uncovered no distinction between device-supported sensorimotor training and traditional splint therapy for myofascial TMD pain over a 3-month duration. EMG activity increased during maximum biting, notably in temporal muscles for sensorimotor training. The training was more challenging than splints, preferred by patients. A limitation was the absence of an untreated control group.<sup>34</sup> Another study assessed LED therapy combined with OS in six patient groups, finding significant pain reduction and EMG signal decreases in combined therapy groups compared to controls ( $p < 0.05$ ). In the study, they found that having two LED therapy sessions per week significantly helped reduce blood lactate levels.<sup>35</sup> Few studies looked into orofacial muscle activity therapy (OMT) in patients dealing with painful joints and TMDs, and they split them into four groups randomly. After 120 days, they noticed that the group receiving OMT had better outcomes compared to the OS group.

They also noticed a big difference in how often people got headaches among the different groups ( $p < 0.05$ ). All the groups experienced less muscle pain, better movement in their jaw, and fewer signs and symptoms, except for the control group. To sum up, OMT seemed to work better than OS in helping manage TMD symptoms.<sup>36,37</sup>

## Digital vs Conventional Occlusal splint - Assessment of Pain

The figure 3 summarizes findings from four studies conducted between 2016 and 2024, comparing Digital occlusal splints with Conventional occlusal splints. Each study compares Pain scores (VAS) means and standard deviations in two groups. For instance, Jean Marc Pho's study, which involved 32 participants in each group, revealed mean values of 2.5 and 2.8. This resulted in an effect size of 0.00 with a confidence interval of [-1.15, 1.15], indicating no substantial difference between the groups [25]. In Radhwan Saleh Algabril's study, which included 15 participants per group, mean values of 4.1 and 5.5 were observed. This yielded an effect size of -1.40, with a confidence interval of [-2.63, -0.17], indicating a notable advantage for the Digital Occlusal splint group<sup>30</sup>. In Bernsten et al.'s study, with 14 participants per group, mean values of 3.6 and 3.8 were found, resulting in an effect size of -0.20 with a confidence interval of [-1.54, 1.14], indicating no significant difference between the groups.<sup>23</sup> Conversely, Xiao Jin's study, which had a larger sample size of 96 participants per group, showed mean values of 1.4 and 1.9, resulting in an effect size of -0.50 with a confidence interval of [-0.78, -0.22], suggesting a significant difference favoring the Digital occlusal splint group.<sup>28</sup> The comprehensive meta-analysis, encompassing all four studies with a total of 157 participants in each group, revealed a pooled effect size of -0.50, with a 95% confidence interval of [-0.77, -0.24]. Heterogeneity analysis indicated minimal variability among the study results ( $\text{Tau}^2 = 0.00$ ;  $\text{Chi}^2 = 2.99$ ,  $\text{df} = 3$ ,  $P = 0.39$ ;  $I^2 = 0\%$ ). The overall effect test was significant ( $Z = 3.74$ ,  $P = 0.0002$ ), indicating that Occlusal splint therapy has a considerable effect across the analyzed studies.

## Digital vs Conventional Occlusal splint - Assessment of Comfort levels

The figure 4 presents the results of five studies

conducted between 2016 and 2024, each examining the effects of a treatment by comparing the mean values of an outcome measure between two groups. Jean Marc Pho et al.<sup>25</sup> study, with 32 participants in each group, found a significant difference favoring the Digital occlusal splint group (effect size -3.80, 95% CI [-5.22, -2.38]). Andres Wanman<sup>24</sup> study, which included 90 participants per group, also found a significant difference favoring the Digital occlusal splint group (effect size -4.10, 95% CI [-5.03, -3.17]). In contrast, Shimin Wang<sup>38</sup> study of 16 participants per group observed a significant difference favoring the Conventional occlusal splint group (effect size 4.50, 95% CI [1.93, 7.07]). Christopher Herpel<sup>26</sup> study, involving 38 participants per group, found no significant difference between the groups (effect size 0.10, 95% CI [-0.81, 1.01]). Lastly, Andrea Bargellini<sup>27</sup> study with 26 participants per group identified a significant difference favoring the Digital occlusal splint group (effect size -3.20, 95% CI [-4.78, -1.62]). When these studies are combined in a meta-analysis with a total of 202 participants in each group, the overall effect size is -1.46 (95% CI [-3.93, 1.00]), indicating no significant overall effect of the treatment. The heterogeneity analysis ( $Tau^2 = 7.27$ ;  $Chi^2 = 72.70$ ,  $df = 4$ ,  $P < 0.00001$ ;  $I^2 = 94\%$ ) reveals substantial variability among the study results. The test for the overall effect ( $Z = 1.16$ ,  $P = 0.25$ ) further confirms that there is no significant overall effect. This suggests that the treatment's impact varied considerably across the different studies, with no consistent overall benefit observed.

### Digital vs Conventional Occlusal splint - Assessment of Appointment timing

The figure 5 summarizes the results of four studies conducted between 2019 and 2024, each assessing the impact of a treatment by comparing mean outcomes between two groups. Brandt study [31], involving 30 participants per group, found a significant difference favoring the Digital occlusal splint group (effect size -2.90, 95% CI [-4.68, -1.12]). Shimin Wang's study<sup>29</sup>, with 16 participants per group, also indicated a significant difference favoring the Digital occlusal splint group (effect size -5.00, 95% CI [-8.52, -1.48]). Christopher Herpel study,<sup>26</sup> including 38 participants per group, showed a significant difference favoring the Digital occlusal splint group (effect size -6.60, 95% CI [-8.33, -4.87]).

Xiao Jin's study<sup>28</sup>, with a larger sample size of 96 participants per group, identified a significant difference favoring the Digital occlusal splint group as well (effect size -7.00, 95% CI [-8.17, -5.83]). When these studies are combined in a meta-analysis, with a total of 180 participants in each group, the overall effect size is -5.47 (95% CI [-7.53, -3.40]), indicating a significant overall effect favoring the Digital occlusal splint group. The heterogeneity analysis ( $Tau^2 = 3.36$ ;  $Chi^2 = 15.19$ ,  $df = 3$ ,  $P = 0.002$ ;  $I^2 = 80\%$ ) shows substantial variability among the study results, suggesting that the treatment effects differ across studies. The test for the overall effect ( $Z = 5.19$ ,  $P < 0.00001$ ) confirms that the combined results are statistically significant, favoring Digital Occlusal splint group.

## DISCUSSION

In this systematic review (SR), we examined the results of 9 RCTs involving individuals aged 18 and older who had TMD. Our analysis revealed both traditional and 3D-printed splints demonstrated high levels of comfort even after three months of use, indicating similar treatment outcomes when combined with the DC/TMD score. About half of the participants experienced improvements in jaw clicking, with two-thirds reporting better jaw sounds by at least 30% in both supervised exercise and bite splint groups, along with reduced jaw pain, neck stiffness, mood swings, and stress in the supervised exercise group. The CAD/CAM splint exhibited a significant reduction in 10 out of 13 TMD/NS items compared to 8 out of 13 with the conventional splint, although neither significantly improved mandibular movements. Both splint types showed comparable patient satisfaction, complication rates, and wear behavior, with minor differences observed. 3D-printed splints influenced electromyographic activity associated with sleep bruxism more significantly, possibly due to smoother surfaces stabilizing phasic contractions. Digitally designed and 3D-printed repositioning splints proved highly effective for temporomandibular joint disc displacement, offering improved comfort and time efficiency compared to conventional hard splints, with PEEK milled digital splints showing superior wear resistance. CAD/CAM occlusal splints required less adjustment time and significantly enhanced TMD patient satisfaction

compared to conventional splints, while both types showed similar improvements in muscle activities. Overall, CAD/CAM splints serve as reasonable alternatives to conventional splints for various outcomes. But due to fair-quality of studies involved with bias likely to affect the outcome in few studies. Hence the findings should be considered cautiously. And that more high-quality research is needed to validate these SR.

In dentistry, occlusal splints are frequently used for TMD patients.<sup>7</sup> Occlusal splints are reported to have a success rate of 70–75% in treating TMD.<sup>39</sup> Their main objectives are to modify biomechanical pressure on the TMJ and reduce parafunctional activity.<sup>40</sup> By raising the vertical dimension, occlusal splints can change the TMJ's position. Moreover, they modify activity patterns of the jaw closing muscles, influencing motor control. The therapeutic benefits of occlusal splint therapy may be attributed to a decrease in the electrical activity of the masticatory muscles.<sup>41,42</sup> According to certain researchers, occlusal splint therapy only results in short-term decreases in electromyographic activity; however, following prolonged usage of occlusal splints, no decreases are shown because of the muscles' adaptation mechanisms.<sup>43</sup> According to Alajbeg et al.<sup>39</sup> stabilizing splints significantly reduced pain intensity when compared to alternative devices. When it comes to disc displacements, anterior repositioning splints can restore discs to their initial position in cases when the disc displacement has been reduced, but they cannot be used in cases where the disc displacement has not been reduced.<sup>44</sup> The mechanism of occlusal splints and the indications for each kind cannot be determined with high-quality evidence, nevertheless. Among individuals diagnosed with myogenous TMDs, treatments such as OS, nociceptive trigeminal inhibition tension suppression system (NTI-tss), and counseling, either alone or in combination, demonstrated a substantial reduction in the perception of intensity of the pain after treatment than the control group.<sup>13</sup> In contrast to using a complete hard stability splint and not receiving any treatment (the control group), the utilization of anterior repositioning splints along with counseling therapy resulted in considerable decrease in the occurrence of TMJ clicking.<sup>20</sup> Treatment approach that proved most effective in reducing pain among individuals primarily affected by arthrogenous TMDs was the use of an anterior

repositioning splint (ARS), followed by counseling and self-management involving a hard stabilization splint (HSS).<sup>20</sup> NTI-tss approach proved to be more efficient in managing pain in patients with TMD, followed by the use of HSS and a combination of counseling and HSS. For patients dealing with TMJDs that involve both the TMJ and masticatory muscles, the most successful treatment method was anterior midline stop devices along with counseling and HSS following as less effective options.<sup>45</sup> Subgroup analyses uncovered noteworthy pain alleviation when using a complete HSS for short period follow-up and exclusively during nighttime, as opposed to follow-up for longer periods and continuous use of a full HSS. Numerous studies have explored treatments for various forms of TMD, aligning with this review's conclusions. However, previous research often encompassed mixed patient profiles, including myalgia, TMJ degeneration, and disk pathology. Moraissi et al.<sup>20</sup> in a systematic review with meta-analysis, found repositioning splints combined with CSL therapy most effective for TMD management. Low-quality evidence suggests that hard stabilization splints alone alleviate myogenic TMD symptoms compared to no treatment or non-OS treatments. Additionally, combining hard stabilization splints with CSL therapy yields comparable pain relief to splints alone, with some studies suggesting added benefits. Some research indicates similar outcomes between hard and soft stabilization splints. Zhang et al.<sup>32</sup> reported equivalent effectiveness between OS therapy and exercise therapy for pain relief and mandibular movement improvement in painful TMD patients.

Pain is a multifaceted sensation that involves different aspects, encompassing both physiological and psychological dimensions. Within the realm of psychological factors, it has been observed that a prior experience of postoperative pain can affect how pain is perceived and experienced following a surgical procedure. Although the level of evidence was Fair for included trials, the small sample size and the lack of thorough relevant protocols make us question the quality of data available to make an informed decision. A larger number of clinically relevant, clinician-oriented outcomes should be measured.

### Limitations of the study

All the studies included in the review were RCTs

conducted exclusively in English, and they exhibited a high risk of bias due to lack of allocation concealment. Pain was assessed using different methods and at varying time points across the studies, and authors employed different statistical approaches, limiting the ability to conduct a meta-analysis. Moreover, the initial pain intensity of study groups was not characterized, potentially influencing the results. Long-term effects of therapy on TMD-related pain were not investigated, and there was a lack of studies with large sample sizes and balanced gender distributions. Future investigations may benefit from incorporating passive control groups to eliminate the possibility of natural or spontaneous symptom remission. Additionally, extending the follow-up duration would be valuable for evaluating the long-term effects of the treatment.

## CONCLUSION

The results from the studies indicate that CAD/CAM fabricated occlusal splints offer outcomes similar to traditional splints, with some demonstrating even better results, possibly due to the enhanced precision of virtual articulators and material characteristics. As pain and symptoms related to TMD decreased, there was a considerable positive impact among the patients post digitally fabricated occlusal splint therapy. Given this evidence, we suggest the utilization of digitally fabricated splints as a treatment and management option for TMD in adults. However, there is still uncertainty regarding how the specific design and manufacturing process of digital occlusal splints impact TMD. Further clinical trials comparing these factors are needed to gain a clearer understanding. Due to limited high-quality evidence and the significant financial investment required for

digitally manufactured splints, it is concluded that there isn't enough evidence to prefer this method over the conventional approach.

## DECLARATIONS

### *Conflicts of interest and financial disclosures*

The author declares that he has no conflict percent and there was no external source of funding for the research in question.

### *Ethical approval*

The study was approved by the Institutional Ethics Committee and was conducted in accordance with the Declaration of the World Medical Association.

### *Informed consent*

Informed consent was obtained from all individual participants included in the study.

### *Source of funding*

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## AUTHOR CONTRIBUTIONS

Conceptualization, S.M., M.M.M. and G.L.; Methodology, M.V., A.S. and D.N.; Formal analysis, M.V. and M.M.M.; Investigation, M.V., A.S. and M.D.B.; Data curation, G.M. and M.M.M.; Writing—original draft preparation, M.V., S.M., A.S. and D.N.; Writing—review and editing, M.M.M., M.C. and G.M.; Visualization, G.M. and M.M.M.; Supervision, M.C. and G.M.; Project administration, M.C. and G.M. All authors have read and agreed to the published version of the manuscript.

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