

Digital occlusal splints for temporomandibular joint disorders: a systematic review

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ABSTRACT

Objectives. This systematic review aimed at assessing the therapeutic efficacy of computer-assisted or digitally constructed occlusal splints in comparison to conventional splint treatment for temporomandibular disorders or bruxism.

Material and methods. The study was prospectively registered in the Open Science Framework. Four electronic databases, PubMed, Embase, Web of Science, and Scopus, were searched comprehensively. The following keywords were employed: "3D-printed", "additive manufacture", "computer-aided design/computer-aided manufacturing", "temporomandibular joint", "temporomandibular joint dysfunction", "bruxism", "disc displacement", "temporomandibular disorder", "splint", "oral splint", "occlusal splint", "occlusal device", "bite splint", "occlusal appliance". Two risk of bias evaluation instruments were used to assess the quality of the included studies.

Outcomes. Following the application of the search strategy, a total of 557 publications were identified in the electronic databases. Seven eligible articles were finally included in the analysis. Six publications (85.7%) compared digitally manufactured occlusal splints to conventionally created splints, while one examined if the use of a facebow influences the performance of digital splints. Visual assessment scores or numerical rating scales of pain, optical axiography, tooth wear, and bruxism frequency were reported as outcomes.

Conclusions. Computer aided design occlusal splints provide equivalent outcomes to traditional splints. Some generated superior results, mainly probable as a result of the virtual articulator's greater precision and the splint materials' material qualities.

Keywords: occlusal splint, temporomandibular disorder, bruxism, computer-aided design, computer-assisted manufacturing, digital dentistry

List of abbreviations

3D – three-dimensional
BFB – biofeedback splint
CAD/CAM – Computer-aided design/computer-aided manufacturing
DC/TMD – Diagnostic Criteria for Temporomandibular Disorders
IOS – Intra-oral scanning
NRS – Numerical rating scale
OSF – Open Science Framework
PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols
RCT – Randomized Controlled Trials
RDC/TMD – Research Diagnostic Criteria for Temporomandibular Disorders
ROB – Risk of bias
ROB 2 – Cochrane Risk of Bias 2 tool
TMD – Temporomandibular disorder
TMJ – Temporomandibular joint
VAS – Visual assessment scale

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INTRODUCTION

Temporomandibular joint disorders (TMD) are a class of musculoskeletal conditions associated with pain and dysfunction involving the masticatory muscles and the temporomandibular joints (TMJ) [1]. TMD symptoms include myofascial pain, decreased range of motion of the mandible and clicking. Pain is often the defining feature of this disease and can be exacerbated with palpation of the TMJ or the surrounding musculature [2]. The prevalence lies between 3.2 and 17.6% and it affects women approximately 2.1 times more than men [3].

The treatment of TMD presents the following goals: decreasing joint and masticatory muscle pain, increasing the range of motion in the mandible, preventing degenerative changes in the articulating tissues [4]. Clinical management of TMD includes physical therapy, occlusal splints and/or adjustments, medication, and surgery [5,6]. Occlusal splint therapy is a well-established treatment option, that has shown positive results in alleviating symptoms of TMD [6]. It involves placing a custom-fabricated acrylic device over the incisal and occlusal surfaces of the teeth. This relaxes the muscles or allows the condyle to seat in centric relation, as well as protecting the teeth during bruxism [7]. Splints are traditionally manufactured by a dental technician using gypsum models mounted in a semi-adjustable articulator. This is a time-consuming process which is dependent on the experience of the technician, while also being susceptible to human error [8].

Recent advancements in the field of intra-oral scanning (IOS) and computer-aided design/computer-aided manufacturing (CAD/CAM) may have the potential to compensate for some of the shortcomings of conventional splint therapy and deliver improved clinical results, while simplifying the workflow. Several studies have shown the improved quality and material properties of CAD/CAM splints in comparison to conventional ones [9,10]. To the best of our knowledge, there is no review literature on topic of digital occlusal splints for TMD.

The aim of this research is examining the clinical effectiveness of computer-aided occlusal splint therapy, and how it compares to traditional methods in the treatment of TMD or bruxism. Our study is not limited only to milled or 3D printed devices but also examines clinical outcomes in cases where digital technologies were involved in splint manufacture.

MATERIAL AND METHODS

The systematic review was performed in accordance with the recommendations of the “Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA) Statement” [11]. It was prospectively registered in the Open Science

Framework (OSF). The protocol can be accessed using the following link: <https://osf.io/dc2h3>.

ELIGIBILITY CRITERIA

The inclusion criteria were as follows: original research (clinical trials, cohort studies, case-control studies) published in the English language; studies assessing the clinical outcomes of interventions involving occlusal splints produced using CAD/CAM technology or using digital sensors or other digital technologies embedded into the splint material.

The exclusion criteria were as follows: articles outside the area of interest, literature reviews, case reports/case series, in-vitro studies, commentaries, letters to the editor, editorials, conference abstracts, grey literature, or papers for which the full-text was not available or accessible.

SEARCH STRATEGY

The search strategy was based on MeSH and Emtree terms, adapted to other databases. A comprehensive electronic search was performed in July 2022 in the following databases: PubMed/MEDLINE, Embase, Web of Science, and Scopus. The following keywords were used: “3D-printed”, “additive manufacture”, “CAD/CAM”, “TMJ”, “temporomandibular joint”, “temporomandibular joint dysfunction”, “bruxism”, “disc displacement”, “temporomandibular disorder”, “splint”, “oral splint”, “occlusal splint”, “occlusal device”, “bite splint”, “occlusal appliance”. Original English language articles were sought. No restrictions were placed on the year of publication. The full search strategy is found in Table 2.

TABLE 1. PICO elements for guiding the search strategy

Research question: Is computer-aided splint therapy helpful in improving clinical outcomes in the management of temporomandibular joint disorders?	
Patient/Problem	Patients diagnosed with temporomandibular disorder (TMD)
Intervention	Digital, computer-aided or CAD/CAM manufactured occlusal splints
Comparison	Conventional splints, no treatment
Outcome	Pain relief, visual assessment score (VAS)/numerical rating scale (NRS) of pain, maximum mouth opening, TMJ clicking, tooth wear

STUDY SELECTION

The study selection was performed using the Rayyan AI platform [12], a web-tool to assist working on systematic reviews and scoping reviews. The publications were then independently examined by two calibrated researchers (S.M. and O.A.) who evaluated the titles and abstracts for relevance and the presence of the eligibility criteria, followed by assessing the full text of the retrieved articles. In case of a

TABLE 2. Search strategies for each database

PubMed (n = 42)
("Computer-Aided Design"[Mesh] OR "Printing, Three-Dimensional"[Mesh]) AND ("Temporomandibular Joint Disorders"[Mesh] OR "Temporomandibular Joint Dysfunction Syndrome"[Mesh] OR "Bruxism"[Mesh] AND "Occlusal Splints"[Mesh]. (3d-printed OR "additive manufacture" OR CAD/CAM) AND (tmj OR "temporomandibular joint" OR "temporomandibular joint dysfunction" OR bruxism OR "disc displacement" OR "temporomandibular disorder") AND (splint OR "oral splint" OR "occlusal splint" OR "occlusal device" OR "bite splint" OR "occlusal appliance")
Embase (n = 81)
('three-dimensional printing'/exp OR 'three-dimensional printing' OR 'computer aided design/computer aided manufacturing'/exp OR 'computer aided design/computer aided manufacturing') AND ('temporomandibular joint' OR 'temporomandibular joint disorder' OR disk) AND displacement OR tmj) AND ('occlusal splint'/exp OR 'occlusal splint' OR 'dental splint'/exp OR 'dental splint' OR 'splint'/exp OR 'splint'); (3d printed' OR 'additive manufacture' OR cad OR cam) AND (tmj OR 'temporomandibular joint' OR 'temporomandibular joint dysfunction' OR bruxism OR 'disk displacement' OR 'temporomandibular disorder') AND (splint OR 'oral splint' OR 'occlusal splint' OR 'occlusal device' OR 'bite splint' OR 'occlusal appliance')
Web of Science (n = 44)
(3d-printed OR "additive manufacture" OR CAD/CAM) AND (tmj OR "temporomandibular joint" OR "temporomandibular joint dysfunction" OR bruxism OR "disk displacement" OR "temporomandibular disorder") AND (splint OR "oral splint" OR "occlusal splint" OR "occlusal device" OR "bite splint" OR "occlusal appliance") ("Computer-Aided Design" OR "Printing, Three-Dimensional") AND ("Temporomandibular Joint Disorders" OR "Temporomandibular Joint Dysfunction Syndrome" OR Bruxism) AND "Occlusal Splints"
SCOPUS (N = 390)
(3d-printed OR "additive manufacture" OR CAD/CAM) AND (tmj OR "temporomandibular joint" OR "temporomandibular joint dysfunction" OR bruxism OR "disk displacement" OR "temporomandibular disorder") AND (splint OR "oral splint" OR "occlusal splint" OR "occlusal device" OR "bite splint" OR "occlusal appliance") ("Computer-Aided Design" OR "Printing, Three-Dimensional") AND ("Temporomandibular Joint Disorders" OR "Temporomandibular Joint Dysfunction Syndrome" OR Bruxism) AND "Occlusal Splints"

disagreement between researchers, a consensus was reached by discussion and differences in opinion were settled through debate and by consulting with a third researcher (M.H.).

DATA COLLECTION PROCESS

Two authors (S.M. and O.A.) extracted the data from the articles using a standardized template. The principal summary outcomes were authors, year of publication, setting, study design, sample size, age, gender, diagnostic, diagnostic criteria, intervention group, comparison group, treatment course, follow-up, outcome measurement, results, adverse effects, and dropout rate. This data is presented in Tables 3-4.

RISK OF BIAS ASSESSMENT

All studies were assessed for their methodological quality using two distinct tools, corresponding to their specific study design. Randomized Controlled Trials (RCTs) were analyzed using the Cochrane Risk of Bias 2 [13] (ROB 2) tool, while non-randomized studies were assessed using the ROBINS-I tool [14]. The risk of bias (ROB) assessments according to the ROB 2 and ROBINS-I tools are presented in Figures 2-5.

RESULTS

Study selection

After applying the search strategy, a total of 557 articles were identified in the electronic databases.

A number of 174 articles were eliminated as duplicates; 383 articles were screened based on their title and abstracts' relationship to the research question. The screening process generated 43 publications for retrieval. A total of 41 articles were retrieved as full text and assessed for eligibility. These were evaluated based on the inclusion and exclusion criteria. Finally, 7 eligible articles were included in the systematic review. The study selection process is illustrated in Figure 1.

Characteristics of included studies

Seven eligible studies, which included 244 patients, were analyzed in this paper. All studies had a parallel, two-arm design, with 3 being randomized controlled trials [15–17], one randomized crossover trial [18] and 3 non-randomized clinical studies [19–21]. In three studies, patients had a diagnostic of TMD [15, 19,20], the rest recruited patients with bruxism [16–18,21]. The diagnostic criteria included: RDC/TMD (Dworkin & LeResche [22]), DC/TMD (Schiffman & Ohrbach [23]) and the International consensus on the assessment of bruxism [24]. One study did not report the diagnostic criteria used [18].

Six papers (85.7%) compared CAD/CAM occlusal splints to conventionally manufactured ones, while one investigated if the use of a facebow affects the outcome of two CAD/CAM splints [16]. The reported outcomes were visual assessment scores (VAS) or numerical rating scales (NRS) of pain, optical axiography, tooth wear and bruxism frequency. One study reported an adverse effect of the therapy [17].

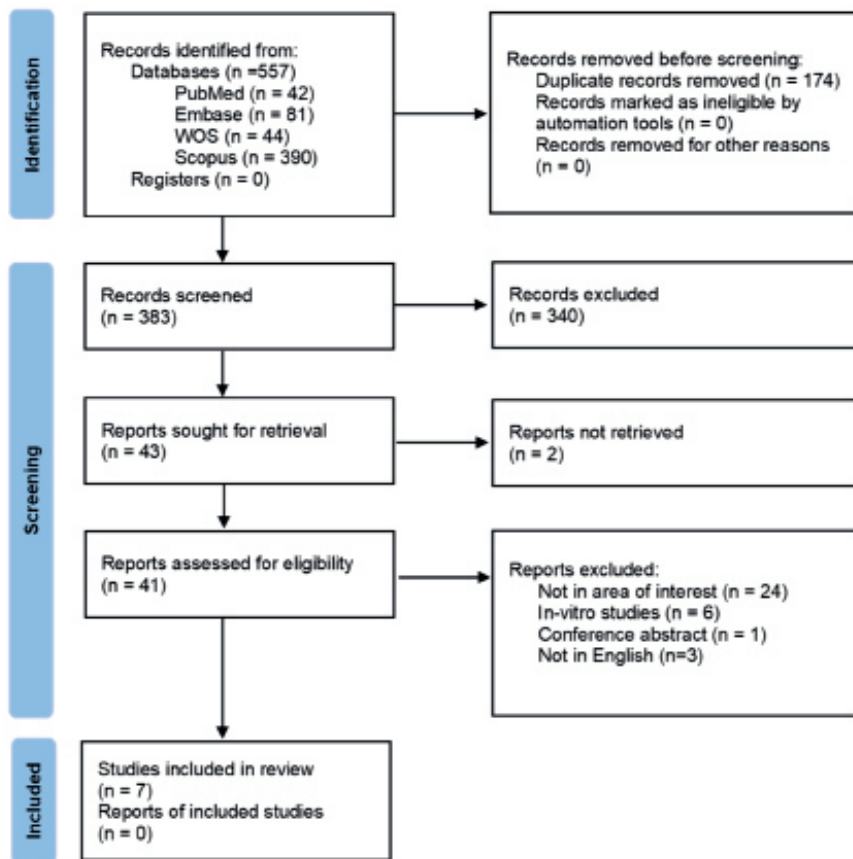


FIGURE 1. PRISMA flowchart summarizing the study identification and selection

In regard to setting, 3 studies were carried out in Germany [15,17,18], one in Egypt [16], Russia [19], Ukraine [20] and China [21], respectively.

Quality of the included studies

RCTs were evaluated based on the ROB 2 tool [13]. Studies were rated on a 3-point scale, reflecting concerns about risk of bias as low, some concerns or high risk. Two studies were rated as high ROB and two had some concerns for bias. The domains most affected by bias were measurement of the outcome (2/4) and reported results (2/4). All papers described adequate randomization.

Non-randomized studies were assessed according to ROBINS-I [14]. All studies presented a serious overall risk for bias, with the most affected domains being the selection of participants (3/3 severe ROB), selection of the reported results (3/3 severe ROB), confounding (2/3 severe ROB), and outcome measurement (1/3 severe ROB, 2/3 had some concerns).

DISCUSSION

Several systematic reviews have shown the efficacy of occlusal splint therapy in the treatment of TMDs [6,25,26]. Due to the rise of digitalization in dentistry [27], we considered it worthwhile to con-

duct a review specifically targeting occlusal splints fabricated using these methods. Digital workflows can provide several advantages to the clinician: a minimally invasive impression technique, in the case of IOS, increased time efficiency and the precision of the appliance.

Pho et al. [15] was the first published paper to compare the clinical effectiveness of CAD/CAM versus conventional stabilization splints for the treatment of TMD. They showed that a CAD/CAM splint was equally as effective as a conventional one in reducing pain symptoms but found no significant improvement in the mandibular movements. The studies by Chkhikvadze et al. [19] and Kostiuk et al. [20] found that splints manufactured using a digital protocol, which included the use of virtual articulators, produced better clinical outcomes in terms of the axiographic findings. These results suggest that placing models in a virtual articulator can significantly reduce the number of errors occurring when a facebow is used. This may be because virtual articulators are less prone to the deviations and measurement errors associated with the use of mechanical ones [28].

Early studies reported that occlusal appliances made using a facebow had more occlusal contacts and required less occlusal adjustments [29]. Alqutaibi et al. [16], however, showed that patient sa-

TABLE 3. Summary of included studies

Author, year	Study Design	Setting	Age (range/ mean)	Gender	Sample size	Diagnostic	Diagnostic criteria	Intervention group	Comparison group	Course/ Duration	Follow-up
Pho et al. 2016 [15]	Randomized controlled trial	Germany	28.51±7.13	75% F 25% M	48;32 completed (16/16)	TMD	RDC/TMD (Dworkin & LeResche [22])	CAD/CAM stabilization splint	Conventional stabilization splint	9m	9m
Brandt et al. 2019 [18]	Randomized crossover trial	Germany	22-33	19 F 11 M	30 (15/15)	Bruxism	N/A	CAD/CAM splint	Conventional splint	6m	3m, 6m
Chkhikvadze et al. 2019 [19]	Non-randomized controlled trial/ Observational study	Russia	23-39	40 F 7 M	47 (25/22)	TMJ disc displacement with reduction	DC/TMD (Schiffman & Ohrbach [23])	CAD/CAM muscle relaxation splint	Conventional splint	N/A	every 3w
Bergmann et al. 2020 [17]	Randomized controlled trial	Germany	IG 37.6±11 CG 41.3±14.2	21 F 18 M	41 (21/20)	Bruxism	RDC/TMD (Dworkin & LeResche [22])	Biofeedback splint (bruxXane)	Conventional splint	4.5m	1m, 2m
Kostiuk et al. 2020 [20]	Non-randomized controlled trial/ Observational study	Ukraine	N/A	27 F 11 M	38 (14/24)	Ventral articular disc dislocation with reduction	DC/TMD (Schiffman & Ohrbach [23])	3D printed muscle relaxation splint	Conventional muscle relaxation splint	N/A	1m
Wang et al. 2020 [21]	Non-randomized controlled trial/ Observational study	China	18-44	N/A	16 (8/8)	Bruxism	Lobbezoo et al. [24]	CAD/CAM PEEK splint	Conventional hard splint	12w	12w
Alqutaibi et al. 2021 [16]	Randomized controlled trial	Egypt	35.5 (IG: 34.8 CG: 36.2)	19 F 5 M	24 (12/12)	Bruxism	RDC/TMD (Dworkin & LeResche [22])	CAD/CAM splint with digital facebow	CAD/CAM splint w/o facebow	3m	1m, 3m

TMD-temporomandibular disorder, CAD/CAM-computer-aided design/computer-aided manufacturing, RDC/TMD-Research Diagnostic Criteria for Temporomandibular Disorders, DC/TMD-Diagnostic Criteria for Temporomandibular Disorders, PEEK-polyetherterketone, N/A-not applicable, F-female, M-male, m-month.

TABLE 4. Summary of reported outcomes

Author, year	Outcome measurement	Intervention group	Comparison group	Summary	Adverse effects	Dropout rate (%)
Pho et al. 2016 [15]	TMD/NS (headache, facial pain, joint pain, joint noises, mastication pain, neck pain, facial tension, limitation of mouth opening, tooth sensitivity)	Significant reduction in 10/13 variables	Significant reduction in 8/13 variables	No significant differences between treatments.	N	33%
Brandt et al. 2019 [18]	VAS (comfort, fit, retention, ease of handling) Missing occlusal contacts Retention Final preferences	65.5%* 41% 12 patients	67.7%* 38.5% 16 patients	The devices were not significantly different for wearing comfort (P=.235). Digitally fabricated occlusal devices are a viable alternative to conventional laboratory-made ones.	N	6.66%
Chkhikvadze et al. 2019 [19]	Axiography (no signs of subluxation of the articular disc)	88%*	81%*	The milled muscle relaxation splints were preferable to the splints made in a mechanical articulator.	N	0%
Bergmann et al. 2020 [17]	NRS (pain) Bruxing activity BPH AD	-50% 2.2±24.9 189.6±278.7	7% 1.8±11.3 283.7±785.2	Treatment with the biofeedback splint reduced the number of bruxing events (p=0.010) and their duration (p<0.001). Treatment with BFB splint led to significant improvement in symptoms compared to the control group (p=0.017).	Y	14.63%
Kostiuk et al. 2020 [20]	Axiography (no signs of subluxation of the articular disc)	92.80%*	85.70%*	The use of splints produced using the digital protocol was more advantageous compared to the splints produced using a mechanical articulator.	N	0%
Wang et al. 2020 [21]	VAS Comfort Retention	84.7 ± 3.4 86.7 ± 5.0	74.6 ± 4.0 82.2 ± 4.7	The comfort scores of the CAD/CAM group were significantly higher (p<0.001). Both types of splints showed clinically acceptable retention (p=0.086). The digital method had better time efficiency and less clinical wear.	N	0%
Alqutaibi et al. 2021 [16]	VAS (pain relief) Baseline 1m 3m	6.9±1.55 4.8±1.72 3.1±1.21	7.1±1.35 4.1±1.04 2.9±0.93	The use of a facebow in the construction of the CAD/CAM occlusal splint did not influence patient satisfaction.	N	0%

%-percentage of patients, TMD-temporomandibular disorder, VAS-visual assessment score, NRS-numeric scale for the signs and symptoms of TMD, BFB-biofeedback splint, BPH-bursts per hour, AD-average duration, CAD/CAM-computer-aided design/computer-aided manufacturing, Y=yes, N=no.

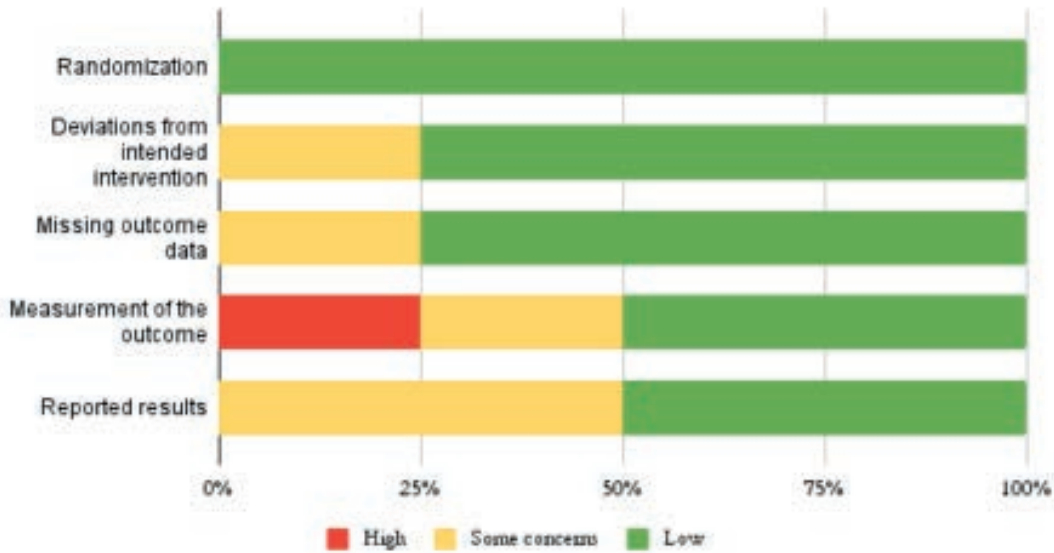


FIGURE 2. Summary of ROB 2 judgements across domains

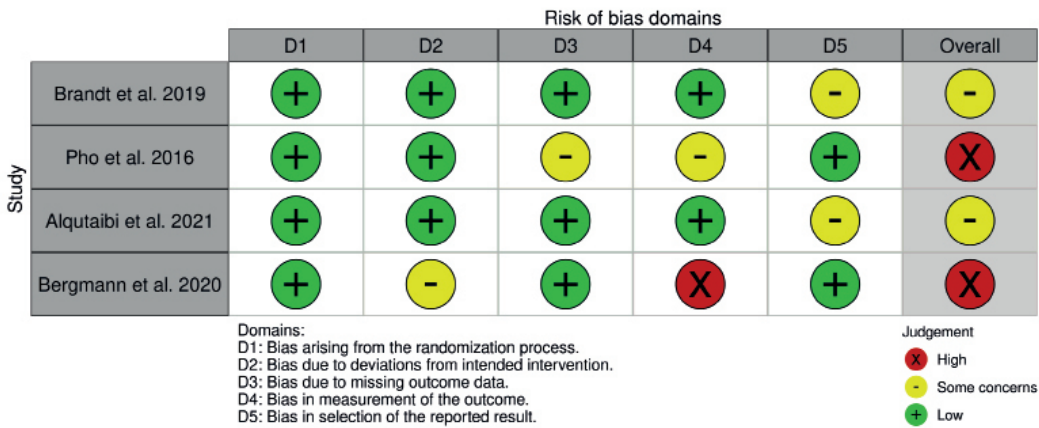


FIGURE 3. Summary of ROB 2 assessments for each study (n = 4)

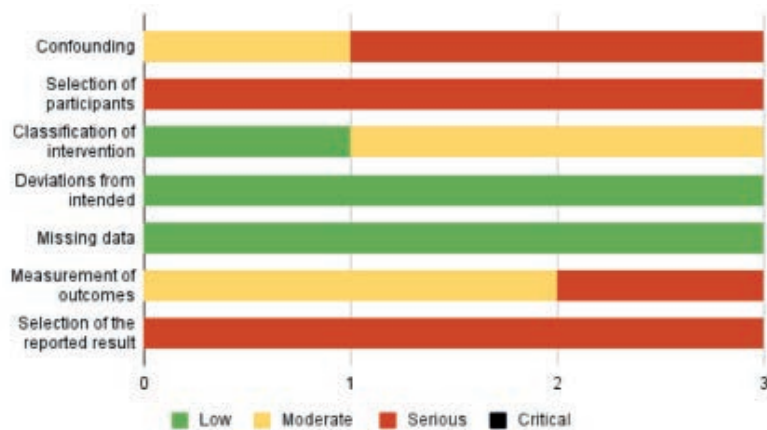


FIGURE 4. Summary of ROBINS-I judgements across domains

tisfaction was not influenced in the case of two types of CAD/CAM splints produced with or without a facebow. This is in line with recent research [30,31].

Several studies compared the clinical effects of digitally manufactured occlusal splints for the treatment of sleep bruxism. Bergmann et al. [17] analyzed

Study	Risk of bias domains							Overall
	D1	D2	D3	D4	D5	D6	D7	
Chkhikvadze et al. 2019	⊗	⊗	-	+	+	-	-	⊗
Kostiuk et al. 2020	⊗	⊗	+	+	+	-	-	⊗
Wang et al. 2020	-	⊗	-	+	+	⊗	-	⊗

Domains:
D1: Bias due to confounding.
D2: Bias due to selection of participants.
D3: Bias in classification of interventions.
D4: Bias due to deviations from intended interventions.
D5: Bias due to missing data.
D6: Bias in measurement of outcomes.
D7: Bias in selection of the reported result.

Judgement
⊗ Serious
- Moderate
+ Low

FIGURE 5. Summary of ROBINS-I assessments for each study (n = 3)

the effects of a full-occlusion biofeedback splint in the treatment of sleep bruxism and TMD. The tested appliance incorporated a pressure sensor and vibratory stimulus, with the objective of enabling a countervailing response to avoid the undesired effect. The studies by Brandt et al. [18] and Wang et al. [21] also showed that CAD/CAM splints were a viable alternative to conventional ones.

The studies that followed a randomized design were assessed for bias using the Cochrane ROB 2 tool [13]. In terms of bias attributed to the randomization process, we concluded that all the studies managed to adequately conceal the allocation sequence. Furthermore, the baseline differences between intervention groups did not suggest a problem with the randomization process. For two of the studies [15,17] blinding of the participants or assessor during the trial was not possible due to observable differences in splint materials or color. One study [17] was had a high ROB in the outcome measurement domain. The study used an appropriate outcome measurement (pain NRD), however the participant's knowledge of the intervention received is very likely to have introduced bias. In the study by Pho et al. [15] the assessor was aware of the intervention delivered. In this case the bias was considered less severe, as the measurement used was optical axiography, which is a more objective investigation method.

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Non-randomized studies were assessed for bias using the ROBINS-I tool [14]. The tool views each study as an attempt to emulate a hypothetical randomized trial. None of the papers provided sufficient information regarding the confounding and selection bias domains or provided statistical analyses that could adjust for the confounding factors. They were subsequently rated as having severe risk of bias.

Future researchers could consider also using passive controls, in order to rule out any natural or spontaneous remission of symptoms. Furthermore, longer follow-up times should be implemented to assess long term effect of the treatment.

CONCLUSION

The findings of the included studies suggest that CAD/CAM fabricated occlusal splints generate results comparable to conventional splints. Some even produced better results, most likely owing to the higher accuracy of the virtual articulator and the material properties of the splint materials. However, given the lack of high-quality evidence, and the large financial investment associated with digitally manufactured splints, we conclude that there is insufficient evidence to recommend this method over the conventional one.

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