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ORIGINAL ARTICLE

Efficacy of occlusal splints in the treatment of temporomandibular disorders: a systematic review of randomized controlled trials

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ABSTRACT

Objective: This systematic review aimed to assess the efficacy of occlusal splints in the treatment of temporomandibular disorders (TMDs).

Material and Methods: This systematic review was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Four databases (Medline *via* Pubmed, Web of Science, Embase and Scopus) were searched, the last search was conducted on April 2020. Randomised controlled trials (RCTs) employing the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) or Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) as diagnostic criteria and including occlusal splint as one of the experimental groups were included in the present study. The data from the included studies were extracted and assessed for risk of bias.

Results: Eleven studies were included. The sample size ranged from 12 to 96 subjects. The male to female ratio was 0 to 25%. The mean length of follow-up was 4 months. Occlusal splint had a positive effect on mandibular movements in all included studies. Seven studies showed a positive effect of occlusal splint on chronic pain reduction and pain intensity, while two others showed improvement of temporomandibular joint clicking sounds and locking of the jaws. Moreover, improvements in mouth opening, depression, and anxiety symptoms, were reported in four studies.

Conclusions: An occlusal splint can be considered as a non-invasive treatment approach for patients with TMD, especially those with signs and symptoms of restriction of mandibular movement and pain. Moreover, the present findings highlighted an urgent need of a standardised consensus regarding the prognostic evaluation of TMD.

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Introduction

Temporomandibular disorder (TMD) is a pathological condition involving the temporomandibular joint (TMJ), temporomandibular muscles, and nervous system [1]. The prevalence of TMD across countries ranges from 10.5% to 54% [2–4]. The large variation of prevalence rates between countries may be due to different populations or examination methods, but more importantly, to different diagnostic criteria. Therefore, the International Network for Orofacial Pain and Related Disorders Methodology has recommended the uniform use of the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) [5] and Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) [6] in TMD clinical research and diagnosis. According to DC/TMD and RDC/TMD, common TMD symptoms are TMJ noise, limitation of mandibular movement and pain, including arthralgia, myalgia, local myalgia, myofascial pain, myofascial pain with referral, headache attributed to TMD, which affect individual's quality of life and require treatment.

The treatment options for TMD can be divided into three categories: non-invasive, minimally invasive, and invasive. Conventionally, non-invasive approaches include occlusal splints, pharmacotherapy, and physical therapy; minimally invasive approaches include interarticular injections and arthrocentesis; and invasive approaches include arthroplasty and TMJ replacement [7]. Non-invasive approaches are the most commonly used because of their safety and convenience [7]. However, invasive approaches may be more beneficial for patients with serious TMD, such as degenerative osteoarthritis [7]. However, high technical sensitivity limits the use of invasive approaches. Thus, many innovative solutions, such as acupuncture [8] and bio-oxidative ozone therapy [9], have been developed and tested.

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An occlusal splint is a removable device affecting the relationship of the mandible to the maxillae. It is one of the most widely used therapeutic methods among the above-mentioned approaches [10], in part due to its low cost [7]. It can be used to reconstruct neuromuscular balance through stabilisation of the occlusion, release of stress from the TMJ, and repositioning of the TMJ in a reversible way [11].

Previous randomised controlled trials (RCTs) have reported contradictory results regarding the effects of occlusal splints on the improvement of pain, movement function of mandible, and psychological aspects in patients with TMD [12–16]. The efficacy of occlusal splints in the treatment of TMDs has been systematically reviewed previously [10,17–19]. However, those reviews have reported inconsistent evidences, which might be due to the methodological errors: for instance, including studies other than RCTs [17], not using the DC/TMD or RDC/TMD as diagnostic criteria [10,18,19], and using different evaluation methods. All of these factors brought difficulties to the choice of treatment approaches in clinical practice.

Therefore, this systematic review was designed to assess the efficacy of occlusal splints versus other approaches to treat TMDs and then provide evidence-based recommendations for clinical practice.

Materials and methods

Protocol

This systematic review was reported following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist [20].

Search strategy

Specific search terms and their combinations were used to search four databases: Medline *via* Pubmed, Web of Science, Embase and Scopus. Only included studies published after 1992. Keywords such as occlusal splint, temporomandibular joint disorders were used to search. Two authors (He KX and Zhang SH) performed the literature search independently.

Inclusion criteria

The eligibility criteria of studies were as follows: including subjects older than 18 years [21]; diagnosed with TMD using well-established diagnostic criteria (DC/TMD or RDC/TMD); including an occlusal splint group and a proper control group; studies in English and were RCTs.

Exclusion criteria

The exclusion criteria were as follows: studies from which we were unable to extract detailed data; duplicated studies; studies that included subjects who had received treatment for TMD prior to the study; and studies that included animal subjects.

Study selection

Two authors (He KX and Zhang SH) screened the studies' titles and abstracts independently. The level of agreement between the reviewers was determined by Cohen's kappa test, with $\kappa = 0.61$ being considered an acceptable agreement score. Any disagreement was resolved by discussion or by consulting a senior reviewer (Chen J).

Data extraction

Two authors (He KX and Zhang SH) collected the following data from the selected studies: publication year, location, occlusal splint design, mean age, sex, sample size, dropout rate, diagnostic criteria, TMD classification, groups, follow-up, outcomes, results, and conclusions. Studies were excluded if the required information could not be obtained. A senior reviewer (Chen J) resolved any conflicts.

Assessment of methodological quality

Joanna Briggs Institute's Critical Appraisal Checklist for Randomised Controlled Trials [22] was used to assess the methodological quality of the included studies. The checklist contains 13 items as follows:

1. Was true randomisation used for assignment of participants to treatment groups?
2. Was allocation to treatment groups concealed?
3. Were treatment groups similar at the baseline?
4. Were participants blinded to treatment assignment?
5. Were those delivering treatment blinded to treatment assignment?
6. Were outcome assessors blinded to treatment assignment?
7. Were treatment groups treated identically other than the intervention of interest?
8. Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analysed?
9. Were participants analysed in the groups to which they were randomised?
10. Were outcomes measured in the same way for treatment groups?
11. Were outcomes measured in a reliable way?
12. Was appropriate statistical analysis used?
13. Was the trial design appropriate and any deviations from the standard RCT design (individual randomisation, parallel groups) accounted for in the conduct and analysis of the trial?

If the authors reported a parameter, the item received a "YES". The more items marked as YES, the more reliable the study is. Articles that included 9 to 13 "YES" items were classified as having high methodological quality. Articles that included 5 to 8 "YES" items were classified as having moderate methodological quality. Articles that included 1 to 4

"YES" items were classified as having low methodological quality.

Results

Study selection

The electronic database search yielded 1021 records. No additional records were identified by screening references of included studies. After removal of duplicates, the titles and abstracts of 481 records were evaluated comprehensively. Of those, 414 records were excluded. The remaining 67 records were assessed for eligibility through full-text screening. Finally, eleven articles [9,23–32] were included in this systematic review. Details about study selection are show in Figure 1.

Study characteristics

The eleven included studies were published between 2010 and 2020. All studies were RCTs. Two studies were from Turkey [9,23], three from Brazil [27,28,31], and the remaining from Italy [24], Germany [25], Croatia [26], Finland [29], Portugal [32], and Sweden [30]. The sample size ranged from 12 to 96 subjects. The majority of participants were female (82.37%); three studies [9,27,28] only included female patients. Only two studies [29,32] used DC/TMD as diagnostic criteria; the other studies used RDC/TMD. The length of follow-up ranged from 1 week to 12 months.

The objectives of the eleven studies varied. Six studies [9,23–25,28,32] aimed at investigating patients with painful TMD (such as myofascial pain). Two studies [26,30] aimed at investigating disc displacement. Three studies [27,29,31] aimed at researching patients with any diagnosis of TMD. Different outcomes were evaluated, such as pain condition, pain location, and mandibular movements. In addition, only one study [30] evaluated the effect of soft resilient occlusal splint on TMD. The dropout rate ranged from 0% to 20.53%, except in one study (58%) [29]. Details about the characteristics of the included studies are shown in Table 1.

Methodological quality

The methodological quality of the included studies is described in Table 2. None of the included studies showed low methodological quality. Four studies [26–28,32] showed moderate methodological quality. Seven studies [9,23–25,29–31] showed high methodological quality. Furthermore, the four studies [9,29–31] published during 2019 and 2020 showed high methodological quality. The

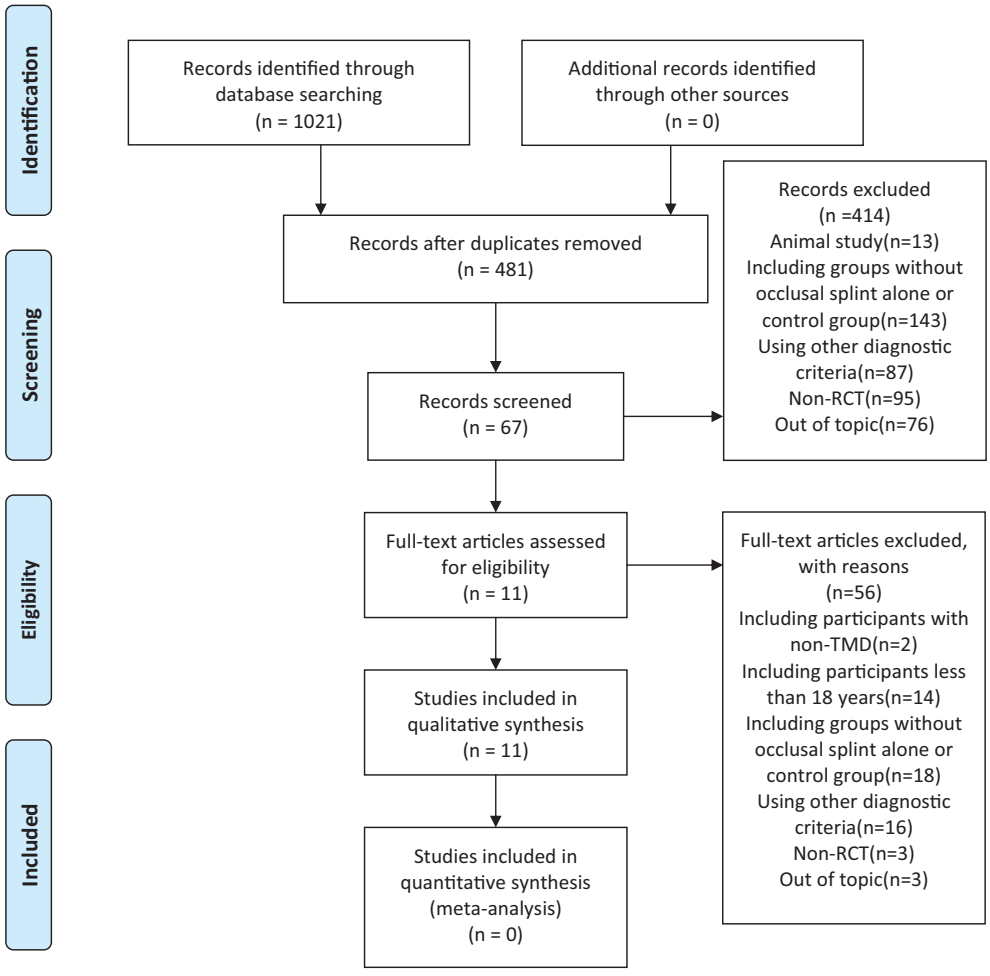

Figure 1. Flow diagram of study selection. Abbreviations: TMD, temporomandibular disorder; RCT, randomised controlled trial.

Table 1. Characteristics of the included studies.

First author	Location	Publication year	Occlusal splint design	Mean age, years	Sex	Total sample size	Dropout rate	Diagnostic criteria	TMD classification	Groups	Follow-up	Outcomes	Results (between groups)	Results (before VS after)	Conclusion
Öz	Turkey	2010	Okeson stabilisation splint	32.84 ± 10.70	34F/6M	40	9.09%	RDC/TMD	Myofascial pain dysfunction syndrome	G1: occlusal splint G2: low-level laser	G1: 3 months G2: 10 weeks	#1: pain condition #2: pain location #3: mandibular movement (UOP/MUO/MAO) #4: pain upon palpation in masticatory muscles #5: tenderness upon palpation in masticatory muscles #6: PPT #7: overall pain ratings on a VAS #8: RDC/TMD axis II evaluation	#1: no significant difference #2: no significant difference #3: no significant difference #4: no significant difference #5: no significant difference #6: no significant difference #7: significant difference #8: no significant difference	#1: no significant difference #2: no significant difference #3: significant difference #4: no significant difference #5: significant difference #6: significant difference #7: significant difference #8: NR	Low-level laser therapy was as effective as an occlusal splint in the treatment of MPS
Michelotti	Italy	2012	Maxillary Michigan splint (rigid, including all off maxillary teeth, flat occlusal plane)	31.2 ± 11.8	34F/10M	44	6.81%	RDC/TMD	Myogenous pain (Ia and Ib in the RDC/TMD)	G1: occlusal splint G2: education	3 months	#1: effect of treatment on pain-free maximal mouth opening #2: effect of treatment on spontaneous muscle pain score #3: pain during chewing and headache scores	#1: no significant difference #2: significant difference #3: no significant difference	#1: significant difference #2: G1: no significant difference G2: significant difference #3: no significant difference	Education was slightly more effective than an occlusal splint in treating spontaneous muscle pain
Shedden Mora	Germany	2013	Acrylic occlusal splint (flat occlusal plane)	G1: 34.3 ± 12.5 G2: 36.3 ± 13.4	44F/12M	56	3.45%	RDC/TMD	Painful axis I TMD diagnosis	G1: occlusal splint G2: biofeedback-based cognitive behavioural treatment	6 months	#1: characteristic pain intensity #2: pain-related disability #3: jaw use limitations #4: depressive symptoms #5: general anxiety symptoms #6: cognitive and behavioural pain strategies #7: somatoform complaints #8: TMD-related symptoms #9: participant ratings of global improvement #10: satisfaction with treatment #11: adverse events #12: demographic and health history measures #12: NMMA	#1: no significant difference #2: no significant difference #3: no significant difference #4: no significant difference #5: no significant difference #6: no significant difference #7: no significant difference #8: no significant difference #9: significant difference #10: significant difference #11: no significant difference #12: no significant difference	#1: significant difference #2: significant difference #3: significant difference #4: significant difference #5: significant difference #6: significant difference #7: significant difference #8: significant difference #9: NR #10: NR #11: NR #12: no significant difference	Biofeedback-based cognitive behavioural treatment might be sufficient and even more cost-effective than occlusal splint
Alajbeg	Croatia	2015	Maxillary acrylic stabilisation occlusal splint (in centric relation, at the level of first molar)	30.5 ± 13.97	9F/3M	12	0%	RDC/TMD	Anterior disc displacement without reduction	G1: stabilisation splint G2: stabilisation splint + physical therapy	6 months	#1: pain level #2: MCO #3: MAO #4: path of mouth opening	#1: NR #2: NR #3: NR #4: significant difference	#1: significant difference #2 G1: no significant difference G2: significant difference #3 G1: no significant difference G2: significant difference #4: NR	Simultaneous use of stabilisation splint and physical therapy was more efficient in reducing deviations and improving range of mouth opening than stabilisation splint used alone; both treatment options were efficient in reducing pain in patients with anterior disc displacement without reduction
Ferreira	Brazil	2015	Acrylic occlusal splint	38.65 ± 11.71	20F/0M	20	20%	RDC/TMD	TMD	G1: occlusal splint G2: occlusal splint + articular acupuncture	5 weeks	#1: muscle pain intensity	#1: significant difference	#1: significant difference	Occlusal splint combined with ear acupuncture reduced pain symptoms of muscle and joint TMD, more rapidly and more significantly so than isolated occlusal therapy
Grillo	Brazil	2015	Acrylic occlusal splint (flat occlusal plane)	30.0 ± 6.59	40F/0M	40	0%	RDC/TMD	Myogenic TMD (Ia or Ib)	G1: occlusal splint G2: acupuncture	4 weeks	#1: pain intensity in muscle #2: RMO #3: PPT #4: electromyographic assessment	#1: no significant difference #2: no significant difference #3: no significant difference #4: no significant difference	#1: significant difference #2: significant difference #3: significant difference #4 G1: significant difference G2: no significant difference	Both treatments reduced pain intensity of myogenic TMD in the short term and may be considered strategies to control chronic pain related to TMD

(*continued*)

Table 1. Continued.

First author	Location	Publication year	Occlusal splint design	Mean age, years	Sex	Total sample size	Dropout rate	Diagnostic criteria	TMD classification	Groups	Follow-up	Outcomes	Results (between groups)	Results (before VS after)	Conclusion
Celakil	Turkey	2019	Maxillary Okeson occlusal splint (acrylic, at the level of first molar, in centric relation)	G1: 34.70 ± 10.13 G2: 33.00 ± 9.66	40F/0M	40	2.44%	RDC/TMD	Diagnosis of pain	G1: occlusal splint G2: bio-oxidative ozone therapy	G1: 1 month G2: 2 weeks	#1: average pain on palpation scores #2: UOP #3: MUO #4: MAO #5: left lateral excursion #6: right lateral excursion #7: protrusion #8: PPT-temporal #9: PPT-masseter #10: PPT-lateral pole #11: VAS score of pain	#1: no significant difference #2: significant difference #3: no significant difference #4: no significant difference #5: significant difference #6: significant difference #7: no significant difference #8: significant difference #9: significant difference #10: no significant difference #11: no significant difference	#1: significant difference #2: significant difference #3: significant difference #4: significant difference #5 G1: no significant difference G2: significant difference #6 G1: no significant difference G2: significant difference #7 no significant difference #8: significant difference #9: significant difference #10: significant difference #11: significant difference	Occlusal splint treatment is still the gold treatment modality for objective pain relief in patients with TMD pain. Occlusal splint treatment statistically provided better improvements than ozone therapy in the PPT scores.
Huhtela	Finland	2019	Acrylic occlusal splint (in centric relation)	G1: 26 G2: 25	80F/16M	96	58%	DC/TMD	Any diagnosis of TMD	G1: occlusal splint G2: applied relaxation	12 months	#1: TMD signs #2: mean total score of depressive symptoms #3: mean total score for NSPS with or without pain #4: mean number of body pain sites	#1: no significant difference #2: no significant difference #3: significant difference #4: significant difference	#1: no significant difference #2: NR #3: NR #4: NR	Neither of the treatments showed more benefit in decreasing local TMD pain; applied relaxation gave more benefit on psychological well-being and general pain symptoms.
Wänman	Sweden	2019	Resilient occlusal splint	39.00 ± 15.00	63F/27M	90	16.67%	RDC/TMD	Symptomatic disc displacement	G1: occlusal splint G2: home exercise G3: supervised exercise	3 months	#1: TMJ clicking sounds #2: locking of the jaw #3: pain in jaw, TMJ, temples #4: pain in jaw, TMJ, temples during jaw movement #5: severity of TMJ sounds #6: severity of TMJ locking #7: severity of jaw pain #8: NDI #9: depression #10: somatization #11: jaw opening #12: right laterotrusion #13: left laterotrusion #14: protrusion #15: PGIC of TMJ clicking #16: PGIC of TMG locking #17: JFLS-20	#1: no significant difference #2: no significant difference #3: no significant difference #4 G2 vs G3: significant difference #5 G1 vs G2/G2 vs G3: significant difference #6: no significant difference #7: no significant difference #8: no significant difference #9 G2 vs G3: significant difference #10: no significant difference #11: no significant difference #12: no significant difference #13: no significant difference #14: no significant difference #15: no significant difference #16: no significant difference #17: no significant difference	#1: no significant difference #2 G1: significant difference G2/G3: no significant difference #3 G1/G2: no significant difference G3: significant difference #4 G1/G2: no significant difference G3: significant difference #5: significant difference #6 G1/G3: significant difference G2: no significant difference #7 G1/G3: significant difference G2: no significant difference #8 G1/G2: no significant difference G3: significant difference #9 G1/G2: no significant difference G3: significant difference #10 G1: no significant difference G2/G3: significant difference #11: no significant difference #12: no significant difference #13 G1: significant difference G2/G3: no significant difference #14: no significant difference #15: NR #16: NR #17: no significant difference	Jaw exercise programmes and bite splint treatments had positive effects on TMJ clicking; the supervised exercise programme had an additional effect on the subject's wellbeing, and thus may help to encourage patient's empowerment and coping strategies

(*continued*)

Table 1. Continued.

First author	Location	Publication year	Occlusal splint design	Mean age, years	Sex	Total sample size	Dropout rate	Diagnostic criteria	TMD classification	Groups	Follow-up	Outcomes	Results (between groups)	Results (before VS after)	Conclusion
Melo	Brazil	2020	Okeson splint	28 ± 9.34	72F/17M	89	20.53%	RDC/TMD	Any diagnosis of TMD	G1: occlusal splint G2: manual therapy G3: counselling G4: occlusal splint + counselling	1 month	#1: pain scale #2: HADS #3: BAI #4: STAI	#1: no significant difference #2: no significant difference #3: no significant difference #4: no significant difference	#1: significant difference #2: significant difference #3: significant difference #4: significant difference	The therapies used were effective in reducing pain and anxiety in patients diagnosed with TMD. However, no treatment was superior to the other in reducing the studied variables.
Sousa	Portugal	2020	Occlusal splint with contact points in all teeth and canine guidance in laterality and protrusion movements	43.1 ± 13.7	64F/16M	80	0%	DC/TMD	TMJ arthralgia	G1: occlusal splint G2: occlusal splint + betamethasone G3: occlusal splint + sodium hyaluronate G4: occlusal splint + platelet-rich plasma	6 months	#1: pain value #2: maximum pain-free mouth opening	#1: no significant difference #1: NR	#1: significant difference #2: significant difference	All the treatments used caused a reduction in pain and increased pain-free mouth opening. The splint combined with the platelet-rich plasma injection achieved long-term success.

F: female; M: male; DC/TMD: Modified Diagnostic Criteria for Temporomandibular Disorders; RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders; G: group; NR: not recorded; MPS: myofascial pain syndrome; UOP: unassisted opening without opening; MUO: maximum unassisted opening; MAO: maximum assisted opening; PPT: pressure pain threshold; VAS: visual analogue scale; NMMA: nocturnal masseter muscle activity; MCO: maximum comfortable opening; RMO: maximum mouth opening without pain; NSPS: non-specific physical symptoms; NDI: neck disability index; PGIC: patient global impression of change; JFLS-20: Jaw Function Limitation Scale-20; HADS: hospital anxiety and sepression Scale; BAI: beck anxiety inventory; STAI: state-trait anxiety inventory.

most frequent missing items were as follows: (1) Were those delivering treatment blinded to treatment assignment? (2) Were participants blinded to treatment assignment?; and (3) Was allocation to treatment groups concealed?

Efficiency of occlusal splints

Occlusal splints in patients with painful TMD

Öz et al. [23] evaluated 40 patients with myofascial pain dysfunction syndrome for 3 months and reported that occlusal splints can improve mandibular movements, reduce overall muscle pain and tenderness upon palpation, and increase pressure pain threshold (PPT) significantly. In addition, low-level laser therapy was as effective as occlusal splints in the treatment of myofascial pain dysfunction syndrome.

Another study with 44 subjects with myogenous pain for 3 months reported that occlusal splints fail to significantly relieve spontaneous muscle pain and pain during chewing [24]. Self-care driven by professional education was slightly more effective than an occlusal splint in function improvement and pain relief. Moreover, in a study with 6 months of follow-up, Shedden Mora et al. [25] found that biofeedback-based cognitive behavioural therapy is sufficient to reduce pain, disability, depressive and anxiety symptoms, and jaw use limitations, when compared with an occlusal splint. Two other studies [9,28] included patients with painful myogenic TMD experienced for 4 weeks and 1 month, respectively. Grillo et al. [28] found that both occlusal splint and acupuncture could significantly reduce pain intensity and PPT as well as improve maximum mouth opening without pain. However, the significant reduction of right temporal muscle electrical activity was only observed in the occlusal splint group. Celakil et al. [9] compared occlusal splint and bio-oxidative ozone therapy and found that occlusal splint is more effective. Occlusal splints can improve mandibular movements, increase PPT, and relieve pain on palpation. Sousa et al. [32] revealed that occlusal splint combined with platelet-rich plasma injection can achieve long-term clinical success by pain reduction and increased pain-free mouth opening, and occlusal splint combined with betamethasone or sodium hyaluronate can gain short-term positive effect.

Occlusal splints in patients with disc displacement

Alajbeg et al. [26] found that both a stabilisation splint and physical therapy could decrease the level of pain within 6 months. Furthermore, a stabilisation splint combined with physical therapy was shown to improve the range of mouth opening significantly. Wänman et al. [30] set three groups to evaluate the efficiency of occlusal splints to treat symptomatic disc displacement during a period of 3 months and found that both occlusal splints and exercise have a positive effect on TMJ clicking sounds. Supervised exercise may have an additional effect by making patients willing to participate in treatment. However, only occlusal splint was helpful for locking of the jaw.

Table 2. Assessment of methodological quality.

Items	Sousa 2020	Melo 2020	Wanman 2019	Huhtela 2019	Celakil 2019	Grillo 2015	Ferreira 2015	Alajbeg 2015	Mora 2013	Michelotti 2012	Oz 2010
1. Was true randomisation used for assignment of participants to treatment groups?	U	Y	Y	Y	Y	U	U	U	U	U	Y
2. Was allocation to treatment groups concealed?	U	Y	Y	Y	U	U	U	U	Y	U	Y
3. Were treatment groups similar at the baseline?	Y	Y	Y	Y	Y	Y	U	U	Y	Y	Y
4. Were participants blind to treatment assignment?	U	U	N	U	Y	U	U	U	N	N	Y
5. Were those delivering treatment blind to treatment assignment?	U	U	N	U	Y	U	U	U	N	N	N
6. Were outcomes assessors blind to treatment assignment?	U	U	Y	Y	Y	U	U	U	Y	Y	Y
7. Were treatment groups treated identically other than the intervention of interest?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed?	Y	Y	Y	Y	N	U	U	U	Y	Y	N
9. Were participants analysed in the groups to which they were randomised?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
10. Were outcomes measured in the same way for treatment groups?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
11. Were outcomes measured in a reliable way?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
12. Was appropriate statistical analysis used?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomisation, parallel groups) accounted for in the conduct and analysis of the trial?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Y: Yes, N: No, U: Unclear, NA: Not Applicable.

Occlusal splints in patients with any diagnosis of TMD. Melo et al. [31], Ferreira et al. [27] and Huhtela et al. [29] evaluated patients with any diagnosis of TMD (such as myofascial pain, disc displacement, etc.) for 5 weeks to 12 months. Ferreira et al. [27] found that occlusal splint can significantly reduce muscle pain intensity. However, it can achieve the same goal more rapidly and significantly, when combined with ear acupuncture. Huhtela et al. [29] reported that occlusal splint is not effective for TMD-related symptoms. However, applied relaxation was shown to benefit psychological well-being. Considering the high dropout rate (58%) of this RCT [29], this conclusion should be explained with caution. Melo et al. [31] revealed that occlusal splint can reduce pain value and anxiety in patients diagnosed with TMD.

Discussion

Current research situation

The pathological factors of TMD include mental factors, dental occlusion relationship, joint overload, and bad habits [33]. The most common treatment approach, occlusal splint, does not completely solve TMD with non-occlusal factors. In fact, in current clinical research, physiotherapy may be preferred to an occlusal splint in the initial phase of treatment [34]. However, in another clinical trial, Tatli et al. [15] found that occlusal splints have no additional effect on improving functional performance. To the best of our knowledge, the latest systematic review on this topic was published in 2017 [35]. However, the included studies did not use DC/TMD and RDC/TMD as diagnostic criteria. In addition, two high-quality, well-designed RCTs [9,30] published in 2019 were not included. The above limitations may affect the credibility of its conclusion. Therefore, the present systematic review was conducted to provide more compellent evidence by controlling inclusion criteria and including the latest well-designed RCTs.

Present results

This present review showed strong evidence of the positive effect of occlusal splints. Seven studies [9,25–30] found that occlusal splints are superior to other treatment solutions. Two study [23,31] reported an equal treatment effect between occlusal splint and low-level laser therapy or manual therapy, respectively. One study [24] found that education is slightly more effective in managing myofascial pain. And one study [32] revealed that occlusal splint combined with platelet-rich plasma injection can be considered as a clinical acceptable therapy, especially for the long-term clinical success.

Regarding individual outcomes, eight studies [9,25–29,31,32] reported that occlusal splint can significantly decrease the level of TMD-related pain, while two others [24,30] reported no significant difference. In addition,

improvements of mandibular movements were reported in all eleven included studies. Of the four studies [25,29–31] that evaluated depressive and anxiety symptoms, only two studies [25,31] reported that occlusal splint can significantly improve depressive and anxiety symptoms.

Regarding the mechanism of occlusal splints, many studies have focussed on the changes of blood flow before and after treatment with an occlusal splint. An occlusal splint can significantly increase the temperature of masticatory muscles in patients with TMD. This increase may be due to the return of blood supply to its normal level [36]. Furthermore, load on masticatory muscles may act as a compressor in the blood vessels and increase the blood flow. Increasing oxygen transport through blood vessels may occur to support the normal function of the muscle system [37,38].

TMD is a multifactorial disease, which may explain the differences in results across studies. In an 11-year follow-up study, Banafa et al. [33] found that female patients and patients with a low level of education might be more susceptible to TMD. In a prospective cohort study, Fillingim et al. [39] revealed that the psychological condition is strongly associated with TMD. Furthermore, none of the included studies divided the patients based on pain intensity at baseline. Subjects with different pain intensity may gain different benefits from occlusal splints. However, this needs to be confirmed in further studies. In addition, none of included studies performed subgroup analysis by type of occlusal splint. Different types of occlusal splint have been used in the treatment of TMD with different clinical symptoms and aetiological factors, which may lead to differences in treatment effectiveness [40]. The variation in the characteristics of the included subjects may be explained as reason of the contradictions and inconsistencies of the results among these studies.

Limitations and recommendations

Limitations at review level

This systematic review only included studies written in English, which may indicate publication bias. Furthermore, the limited number of studies may also cause bias.

Limitations at study level

All included studies were RCTs with acceptable methodological quality. However, the lack of a standardised consensus about the prognostic evaluation of TMD resulted in a high number of inconsistent outcome measures. Thus, accurate quantitative analysis was not possible. Of all subjects included in this systematic review, 82.37% were female and three studies [9,27,28] only included female patients with TMD. Kim et al. [41] found sex differences among patients with TMD: quality of life and TMD symptoms are more likely to be affected among women than among men. In addition, an epidemiological study revealed that female patients with TMD seek treatment more frequently than do male patients with TMD. Differences in oestrogen level may explain these findings [42]. Thus, our conclusions may not be generalised to men. Furthermore, all included studies were from Europe and South America, and these data may provide weak evidence for clinical practice in Asia and Australia. There were no high-quality studies comparing the effect between occlusal splints and invasive approaches, such as arthroplasty. The effectiveness of occlusal splint is highly associated with the frequency of follow-up and accurate occlusal adjustment in clinical practice. However, none of the included studies describes this information specifically, and this remains a possible bias against the reliability of studies. The effect of soft and hard occlusal splints on TMD still remain controversial. Alpaslan C et al. [43] reported that the soft and hard occlusal splint gain equal short-term effectiveness as an additional therapy of temporomandibular joint arthrocentesis. However, Sameh et al. [44] reported that soft occlusal splint exhibited superior results in reducing the tenderness of masticatory muscles and improving mouth opening after 4 months follow-up. In addition, well-designed RCTs compared the effect of soft and hard occlusal splint is required for subjects with TMD.

Recommendations

Within the above-mentioned limitations, some recommendations for clinical practice can be drawn. For patients with signs and symptoms of restriction of mandibular movement, occlusal splint is the treatment of choice. Education combined with physical therapy and occlusal splint is recommended for patients with signs and symptoms of TMD-related pain. In addition, for patients with anxiety and other psychological problems, cognitive behavioural therapy can be used. Combined therapy may provide more benefits to patients with TMD.

We recommend further studies: 1) include more male subjects; 2) be multicenter RCTs with patients in particular in the area of Asia and Australia; 3) compare the effect of various occlusal splint designs and materials, and 4) report as per the CONSORT statement to obtain high-quality evidence. In addition, a consensus approach to evaluate TMD as per DC/TMD or RDC/TMD must be adopted for further accurate quantitative analysis.

Conclusion

Within the limitations of the present study, an acrylic occlusal splint with flat occlusal plane can be considered a non-invasive treatment approach for patients with TMD, especially those with signs and symptoms of pain and restriction of mandibular movement.

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