No evidence on the effectiveness of oral splints for the management of temporomandibular joint dysfunction pain in both short and long-term follow-up systematic reviews and meta-analysis studies

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Abstract (J Korean Assoc Oral Maxillofac Surg 2020;46:87-98)

The aim of this study was to determine the efficacy of oral splints in reducing the intensity of pain in patients with temporomandibular joint dysfunction in both short and long-term treatment durations. Electronic databases, Cochrane Library, MEDLINE via PubMed, Web of Science, Egyptian Knowledge Bank, and EMBASE were searched for randomized controlled trials comparing different types of splints to non-occluding splints, behavioral therapy, pharmacotherapy, counseling, and no treatment. The risk of bias was assessed by using Cochrane risk of bias recommendations. Fixed and random effects were used to summarize the outcomes. The effect estimates were expressed as standardized mean differences (SMD) or risk ratios with a 95% confidence interval (CI). Subgroup analyses were carried out according to the treatment duration. Twenty-two studies met the inclusion criteria. A meta-analysis of short-term studies up to three months revealed no significant difference between the study groups. However, long-term studies exhibited a significant difference in pain reduction in favor of the control group. Total analysis revealed that the control group resulted in significant pain reduction (SMD 0.14, 95% CI 0.05-0.23, P=0.002, I^2=0%). Oral splints are not effective in reducing pain intensity or improving function in patients with temporomandibular joint dysfunction.

Key words: Occlusal splints, Pain, Review, Meta-analysis

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I. Introduction

Psychologic, social, and biologic factors are several causes of temporomandibular joint dysfunction (TMJD). The relief of pain and the ability to masticate are considered the principal concerns for patients. An understanding of the psychological conditions with proper treatments for chronic pain and dysfunction must be considered[1]. The ultimate success was achieved when the operator met the patients' expectations by improving their quality of life[2].

Successful treatment of TMJD depends on an accurate diagnosis followed by the selection of proper treatment. Treatment modalities applied to relieve pain and other symptoms of this disorder are classified into non-invasive physical therapy[3], pharmacotherapy[4], counseling assurance[5], and occlusal splint therapy[6]. Minimally invasive arthrocentesis[7], acupuncture[8], and lasers[9] are among the invasive surgical intervention methods[10].

Occlusal splints are considered a simple, chair-side, and less invasive treatment. Occlusal splints are the favorable treatment of choice in our institute after medications. The clinical findings of occlusal splints for the treatment of both myofascial pain dysfunction (MPD) syndrome and disk displacement are controversial and they may act as a placebo rather than a specific therapeutic mechanism[11].

Regardless of the splint mode of action, many old and several recent clinical trials and systematic reviews have documented its therapeutic effectiveness in reducing pain intensity and improving masticatory function in patients with painful temporomandibular disorder (TMD)[12,13]. However, most of the current literature did not demonstrate any beneficial effect in short-term[14] and long-term follow-up[15].

Among the causes of variability between the results, pa-

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tients with TMJD cannot be considered a homogeneous group and will respond differently, with investigators relying on subjective symptoms reported by the patients. Moreover, studies can present with inadequate sample sizes, short follow-up periods, poor quality of the control group, and bias in data reporting. Proper evaluation of splint appliance therapy is achieved by applying long-term follow-ups, randomized controlled study designs, recruitment of a homogeneous population, and blinding in data extraction.

The investment in evidence-based medicine and its role in improving the acceptance of studies for publication, besides the natural progress of the disease, recent diagnostic measures, and improvement of communication between clinicians and patients means it is likely these account for changes in the old concepts that previously guided temporomandibular joint (TMJ) treatment.

This review was conducted to shed light on doubts about the therapeutic value of oral splints through a meta-analysis of data from different relevant randomized controlled trials (RCTs) and studies of different types of occlusal splints. Our purpose was to evaluate the effectiveness of splint therapy in ameliorating pain issues in patients with TMJD.

II. Materials and Methods

The recommendations from the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement were followed[16].

1. Eligibility criteria

1) Inclusion criteria

RCT studies that were conducted in humans over the past twenty years. Patients with TMJD that included myofascial pain with the source of pain being either muscular or from the joint, and patients with disk displacements with or without reduction. Studies that compared splints to non-invasive treatment (medications-biofeedback, counseling, and non-occluding splints). Patient diagnosis was either based on Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) or clinical examination.

2) Excluded from the study

Published studies older than twenty years, studies on animals, uncontrolled studies comparing different types of splints with each other, or studies with minimally invasive treatment modalities (low-level laser, arthrocentesis, acu-

puncture, and physiotherapy). If there were multiple comparisons within the same study, each comparison was included separately. Moreover, various intervals within the related research were recorded in each relevant subgroup.

2. Population

Patients with myofascial pain and/or disk displacement with or without reduction were included. Patients with arthritis or neuralgias were excluded.

3. Intervention

The study included all types of splints (stabilizing splint, Michigan splint, centric relation appliance, flat occlusal appliance, soft or hard splints, vinyl appliances, and positioning splints).

4. Control group

The patients in the control group underwent medical treatment, biofeedback, non-occluding splints, massages, behavioral therapy, cognitive, counseling, or no treatment.

5. Outcome

1) Primary outcome

Pain intensity was estimated with any recognized, validated pain scale: visual analogue scale, numeric rating scale, characteristic pain intensity, and symptom severity index. Subgroup analyses were carried out for the outcomes based on the follow-up duration classified into one, two, three, six, and twelve months.

2) Secondary outcome

Maximum mouth opening (MMO) was evaluated by interincisal opening measured in millimeters.

6. Search methods for studies identification

The search for studies in the English language was conducted up to August 2018. The following databases were searched individually from 1998 to the present: MEDLINE, Web of Science, EMBASE, and Egyptian Knowledge Bank. Manual searches, references from primary studies, and systematic reviews for relevant data were obtained. The search used a combination of controlled vocabulary: 'temporomandibular

joint disorders'[MeSH Terms] OR 'temporomandibular'[All Fields], AND 'joint'[All Fields], AND 'disorders'[All Fields], OR 'temporomandibular joint disorders'[All Fields], OR ('temporomandibular'[All Fields] AND 'disorders'[All Fields]) OR 'temporomandibular disorders'[All Fields], OR 'mouth'[MeSH Terms] OR 'mouth'[All Fields] OR 'oral'[All Fields]) AND ('splints'[MeSH Terms] OR 'splints'[All Fields] OR 'splint'[All Fields]). 'temporomandibular joint'[MeSH Terms] OR ('temporomandibular'[All Fields] AND 'joint'[All Fields]) OR 'temporomandibular joint'[All Fields] OR 'TMJ'[All Fields], AND 'pain'[MeSH Terms] OR 'pain'[All Fields].

7. Data extraction and management

Both continuous (mean, standard deviation) and dichotomous (event, control) studies were included in the analysis.

8. Assessment of study risk of bias

All included studies were evaluated with consent from the Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0[17]. The risk of bias was assessed using Cochrane Collaboration's tool with response options of 'low risk', 'unclear risk', and 'high risk' for the following criteria: sequence generation, allocation concealment, blinding, incomplete outcome data, reporting bias, and other biases.

9. Measurements of the treatment effect

1) Pain intensity
Standardized mean difference (SMD) with 95% confidence interval (CI) and fixed effects were used for continuous outcomes. For dichotomous outcomes, the estimate of the effect was expressed as a risk ratio (RR) together with 95% CIs and random effects.
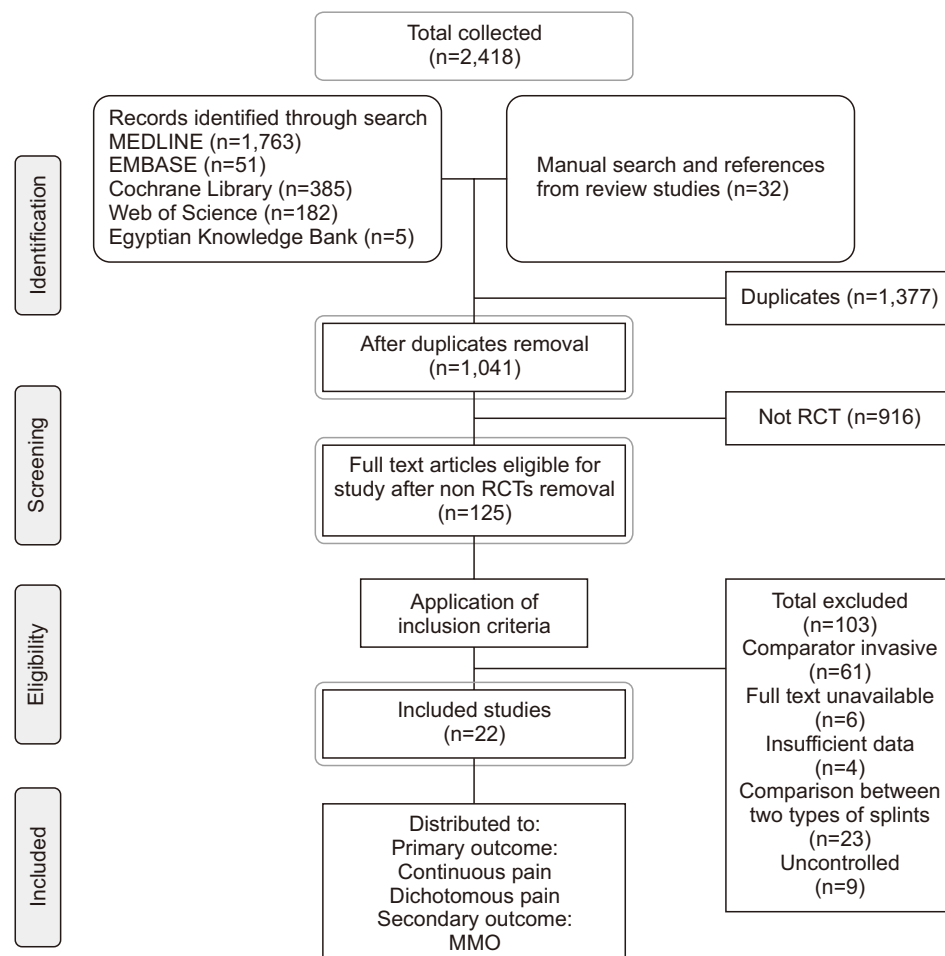
Fig. 1. Flow chart diagram. Adapted from the article of Moher et al. (PLoS Med 2009;6:e1000097)[38] in accordance with the Creative Commons Attribution license. (RCT: randomized controlled trial, MMO: maximum mouth opening)
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2) Maximum mouth opening

The mean difference (MD) with 95% CI and fixed effects was used for the assessment of the outcomes.

3) Assessment of heterogeneity

Chi-square testing for heterogeneity was performed, and the extent of the inconsistency of the treatment effects (I^2)

across the trials was measured. We considered heterogeneity substantial if I^2 was greater than 30%, or if there was a low *P*-value (less than 0.10) in the chi-square test for heterogeneity. We used a fixed-effect meta-analysis for combining the data, but clinical heterogeneity random-effect was used in the subgroup analyses.

Fig. 2. Forest plot of continuous pain analysis at different intervals with risk of bias for the included studies. (SD: standard deviation, CI: confidence interval, df: degree of freedom)

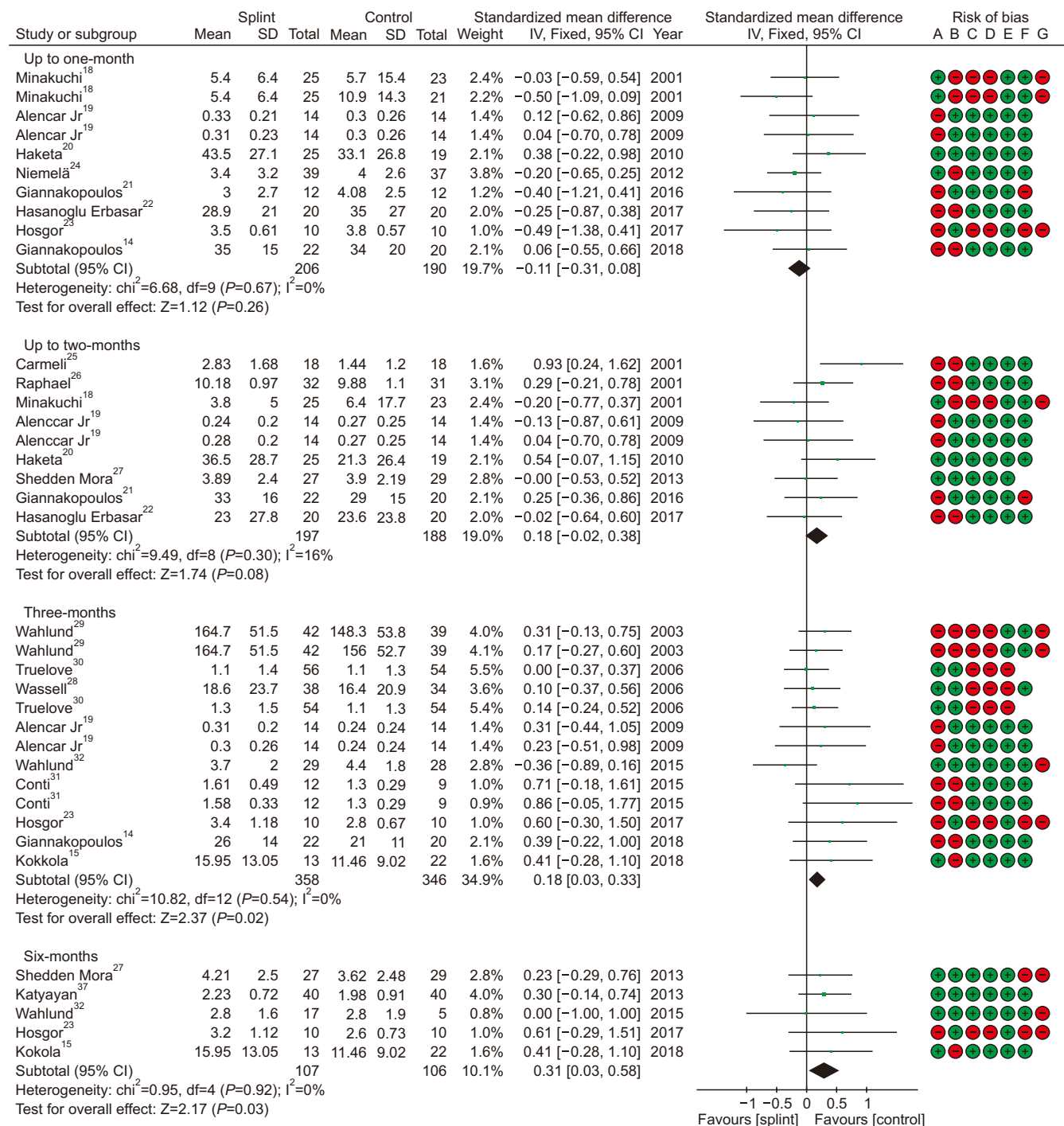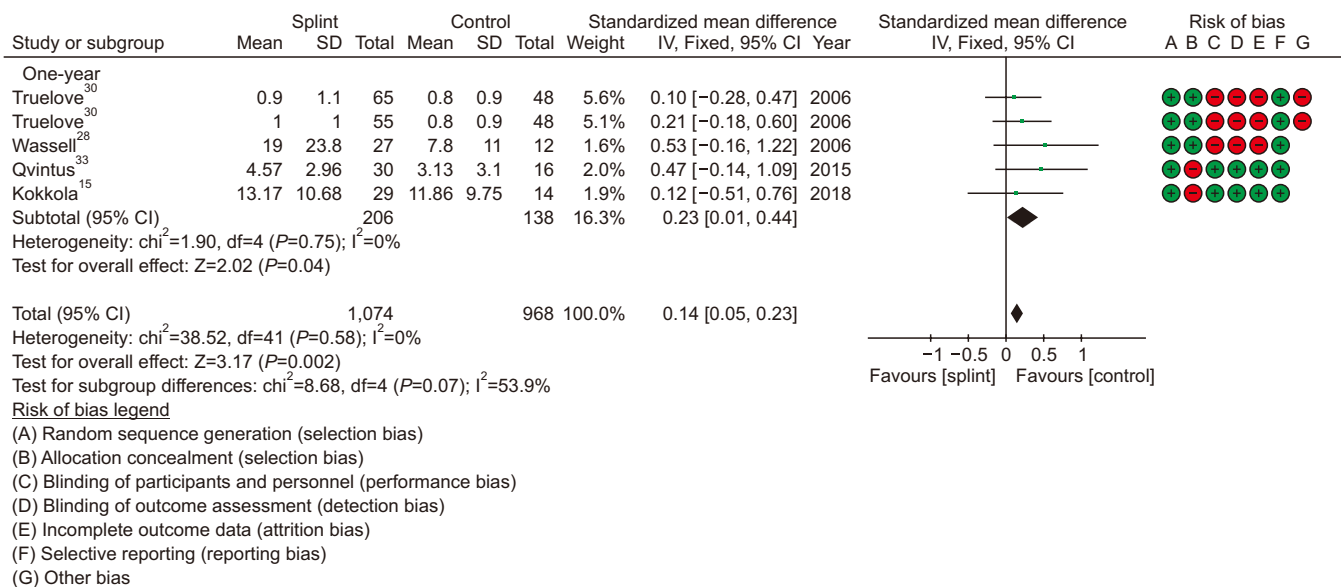| Study or subgroup | Splint | | | Control | | | | Standardized mean difference | | Standardized mean difference | Risk of bias |
	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	Year	IV, Fixed, 95% CI	A B C D E F G
One-year											
Truelove[30]	0.9	1.1	65	0.8	0.9	48	5.6%	0.10 [−0.28, 0.47]	2006		
Truelove[30]	1	1	55	0.8	0.9	48	5.1%	0.21 [−0.18, 0.60]	2006		
Wassell[28]	19	23.8	27	7.8	11	12	1.6%	0.53 [−0.16, 1.22]	2006		
Qvintus[33]	4.57	2.96	30	3.13	3.1	16	2.0%	0.47 [−0.14, 1.09]	2015		
Kokkola[15]	13.17	10.68	29	11.86	9.75	14	1.9%	0.12 [−0.51, 0.76]	2018		
Subtotal (95% CI)			206			138	16.3%	0.23 [0.01, 0.44]			

Heterogeneity: chi^2=1.90, df=4 (*P*=0.75); I^2=0%
Test for overall effect: Z=2.02 (*P*=0.04)

Total (95% CI)			1,074			968	100.0%	0.14 [0.05, 0.23]			

Heterogeneity: chi^2=38.52, df=41 (*P*=0.58); I^2=0%
Test for overall effect: Z=3.17 (*P*=0.002)
Test for subgroup differences: chi^2=8.68, df=4 (*P*=0.07); I^2=53.9%

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Fig. 2. Continued.

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4) Assessment of reporting biases

Publication bias was appraised using the symmetry of the funnel plots. We visually assessed funnel plot asymmetry. When asymmetry was detected, investigations were performed using exploratory analyses.

5) Methodological quality assessment

Data synthesis and meta-analyses were performed according to the rules adopted by the Cochrane Collaboration reviewer's handbook[17]. All statistical analyses were conducted using Review Manager software (RevMan 5.3).

III. Results

The initial search yielded a total of 2,418 titles: 1,763 from PubMed, 51 from EMBASE, 385 from the Cochrane Central library, 182 from the Web of Science, 5 from Egyptian Knowledge Bank (ClinicalKey), and 32 through manual searches.

After reviewing the abstracts, 1,377 studies were excluded from the analysis, and 1,041 were considered for further full-text screening. Finally, a total of 22 studies[14,15,18-37] were included in this systematic review[38].(Fig. 1)

1. Results and study characteristics

1) Primary outcome (pain intensity) (Fig. 2)
(1) Short follow-up period: up to one month

Table 1 reviews the summary of the included subgroup studies. Studies starting from the one week follow-up period up to one month included a total of eight studies with ten comparisons[14,18-24], two of them comparing occlusal splints with medications[18,23], and two comparisons of soft and hard occlusal splints with a non-occluding palatal splint[19]. Two studies compared occlusal splints versus exercise[14,20], two studies compared them with counseling[22,24], and the last two compared them with no treatment[18,21].

Control groups in four comparisons reported better pain reduction compared to splint therapy[14,19,20]; however, the other six comparisons favored splint therapy[18,21-24].

Total subgroup analysis of the eight identified studies with a total of 396 participants revealed non-significant overall effects on pain reduction (SMD −0.11, 95% CI −0.31 to 0.08, *P*=0.67, I^2=0%).

(2) Short term evaluation: up to two months

Studies with a follow-up period greater than one month and up to two months were included. Subgroups included eight studies with nine comparisons[18-22,25-27]. Three comparisons involved non-occluding palatal splints[19,25,26], three comparisons involved exercise[20,21,25], and one study compared occlusal splints versus counselling[22] with a single comparison for every medical treatment[18] and cognition[27].

In five comparisons, the control group exhibited better results than splints[18-20,25,26], with four comparisons in favor of splints[18,19,22,27]. The total subgroup analysis of the identified studies with a total of 385 participants revealed non-

Table 1. Summary of the included studies

Study (first author)	Publication year	Diagnostic mean	Diagnosis	Pain measurement tool	Study splint type	Control	No. of participants	Follow-up period
Minakuchi[18]	2001	Clinical	DD	VAS	OS	NSAID	48	4 wk
Minakuchi[18]	2001	Clinical	DD	VAS	OS	No treatment	46	4 wk
Alencar Jr[19]	2009	Clinical	MPD	SSI	Soft splint	NOS	28	1 mo
Alencar Jr[19]	2009	Clinical	MPD	SSI	Hard splint	NOS	28	1 mo
Haketa[20]	2010	Clinical	DD	VAS	OS	Exercise	44	4 wk
Niemelä[24]	2012	RDC/TMD	MPD	VAS	SS	Counseling	76	1 mo
Giannakopoulos[21]	2016	RDC/TMD	MPD	NRS	Soft splint	No treatment	24	2 wk
Hasanoglu Erbasar[22]	2017	RDC/TMD	MPD	VAS	NTI-tss	Counseling	40	3 wk
Hosgor[23]	2017	RDC/TMD	DD	VAS	SS	NSAID	20	1 mo
Giannakopoulos[14]	2018	RDC/TMD	MPD	NRS	Michigan splint	Exercise	42	2 wk
Raphael[26]	2001	RDC/TMD	MPD	PI	Hard splint	NOS	63	6 wk
Carmeli[25]	2001	Clinical	DD	PI	Soft splint	Exercise	36	5 wk
Minakuchi[18]	2001	Clinical	DD	VAS	OS	NSAID	48	2 mo
Alencar Jr[19]	2009	Clinical	MPD	SSI	Soft splint	NOS	28	2 mo
Alencar Jr[19]	2009	Clinical	MPD	SSI	Hard splint	NOS	28	2 mo
Shedden Mora[27]	2013	RDC/TMD	DD	VAS	OS	Cognition	56	2 mo
Giannakopoulos[21]	2016	RDC/TMD	MPD	NRS	Soft splint	No treatment	24	6 wk
Hasanoglu Erbasar[22]	2017	RDC/TMD	MPD	VAS	NTI-tss	Counseling	40	6 wk
Haketa[20]	2010	Clinical	DD	VAS	OS	Exercise	44	8 wk
Wahlund[29]	2003	RDC/TMD	MPD	PI	SS	BI	81	3 mo
Wahlund[29]	2003	RDC/TMD	MPD	PI	SS	Relaxation	81	3 mo
Truelove[30]	2006	RDC/TMD	MPD	PI	Hard splint	Self-care	108	3 mo
Truelove[30]	2006	RDC/TMD	MPD	PI	Soft splint	Self-care	110	3 mo
Wassell[28]	2006	Clinical	MPD	VAS	SS	NOS	72	3 mo
Alencar Jr[19]	2009	Clinical	MPD	SSI	Soft splint	NOS	28	3 mo
Alencar Jr[19]	2009	Clinical	MPD	SSI	Hard splint	NOS	28	3 mo
Wahlund[32]	2015	RDC/TMD	MPD	NRS	SS	Relaxation	57	3 mo
Conti[31]	2015	RDC/TMD	DD	PI	ARS	Counseling	21	3 mo
Conti[31]	2015	RDC/TMD	DD	PI	NTI-tss	Counseling	21	3 mo
Hosgor[23]	2017	RDC/TMD	DD	VAS	SS	NSAID	20	3 mo
Giannakopoulos[14]	2018	RDC/TMD	MPD	NRS	SS	Exercise	42	3 mo
Kokkola[15]	2018	RDC/TMD	MPD	OHIP	SS	Counseling	39	3 mo
Shedden Mora[27]	2013	RDC/TMD	DD	VAS	SS	Cognition	56	6 mo
Katyayan[37]	2014	RDC/TMD	MPD	VAS	SS	Counseling	80	6 mo
Wahlund[32]	2015	RDC/TMD	MPD	NRS	SS	Relaxation	22	6 mo
Hosgor[23]	2017	RDC/TMD	DD	VAS	SS	NSAID	20	6 mo
Kokkola[15]	2018	RDC/TMD	MPD	OHIP	SS	Counseling	35	6 mo
Truelove[30]	2006	RDC/TMD	MPD	PI	Hard splint	Self-care	113	1 yr
Truelove[30]	2006	RDC/TMD	MPD	PI	Soft splint	Self-care	103	1 yr
Qvintus[33]	2015	RDC/TMD	MPD	VAS	SS	Counseling	46	1 yr
Wassell[28]	2006	Clinical	MPD	VAS	SS	No treatment	39	1 yr
Kokkola[15]	2018	RDC/TMD	MPD	OHIP	SS	Counseling	43	1 yr
Ekberg[34]	2004	Clinical	MPD	VAS	SS	NOS	40	1 yr

(DD: disk displacement, VAS: visual analogue scale, OS: occlusal splint, NSAID: nonsteroidal antiinflammatory drugs, MPD: myofascial pain dysfunction, SSI: symptom severity index, NOS: non-occluding splint, RDC/TMD: research diagnostic criteria of temporomandibular dysfunction, SS: stabilizing splint, NRS: numeric rating scale, NTI-tss: nociceptive trigeminal inhibition-tension suppression system, PI: pain intensity, BI: brief information, ARS: anterior reposition splint, OHIP: oral health impact profile)

significant overall effects on pain reduction (SMD 0.18, 95% CI –0.02 to 0.38, *P*=0.08, I²=16%).

(3) Intermediate follow-up period: three months

Nine studies with thirteen comparisons at the three months' follow-up period were included[14,15,19,23,28-32]. One study compared occlusal splints with medications[23], two studies involved occlusal splints with a non-occluding palatal splint[19], and three studies compared occlusal splints with counsel-

ling[15,31]. Two studies by Wahlund et al.[29,32] compared splints with relaxation, and two comparisons with self-care[30].

In twelve studies, the control group exhibited better results than the splints[14,15,19,23,28-31], with one study in favor of splints[32].

Total subgroup analysis of the identified studies with a total of 704 participants revealed a significant overall effect on pain reduction in favor of the control (SMD 0.18, 95% CI

0.03-0.33, P=0.02, I^2=0%).

(4) Long term evaluation

(i) Six months

Five studies at the six months' follow-up period[15,23,27,32,37] were included with one study comparing occlusal splints with medications[23]. Two comparisons between splint and counselling[15,37] One study compared splints with relaxation[32], while the remaining study compared occlusal splints versus cognition[27].

All five studies in the control group showed better results

than splints regarding pain reduction.

Total subgroup analysis of the identified studies with total of 213 participants revealed a significant overall effect on pain reduction in favor of the control (SMD 0.31, 95% CI 0.03-0.58, P=0.03, I^2=0%).

(ii) One-year follow-up

Four studies with five comparisons at the one-year follow-up period[15,28,30,33] were included. One study compared occlusal splints with no treatment[28], two studies compared splints and counselling[15,33], and two comparisons of Truelove et al.[30]
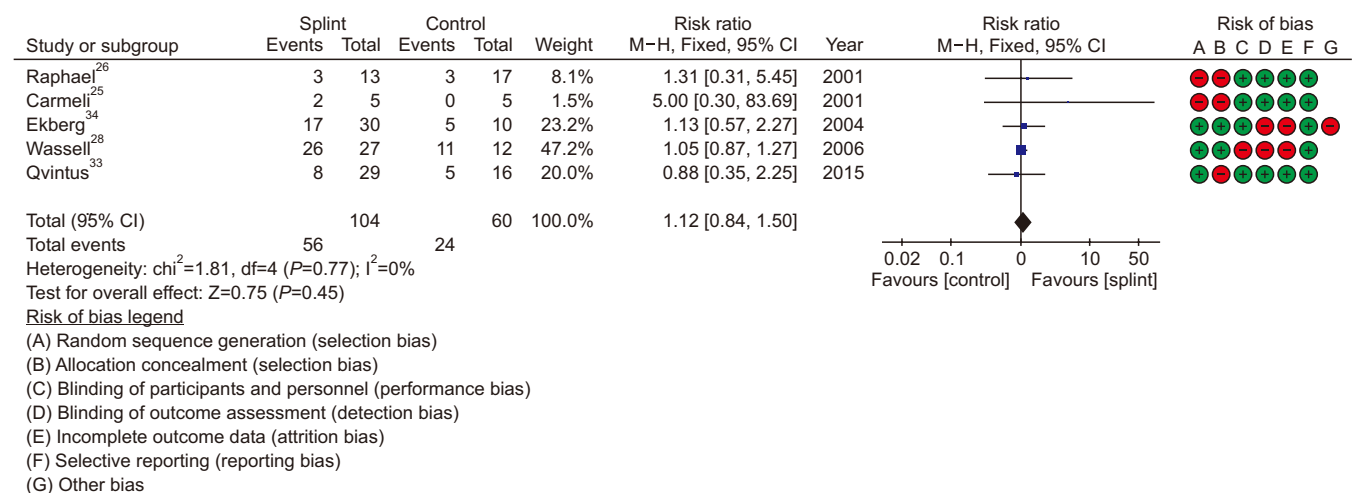

Fig. 3. Forest plot of dichotomous pain analysis at different intervals with risk of bias for the included studies. (M–H: Mantel-Haenszel test, CI: confidence interval, df: degree of freedom)

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Table 2. Summary of the included studies of short- and long-term maximum mouth opening (MMO) subgroup analysis

Study (first author)	Publication year	Diagnostic mean	Diagnosis	Pain measurement tool	Study splint type	Control	No. of participants
Carmeli[25]	2001	Clinical	DD	MM	Soft splint	Exercise	36
Minakuchi[18]	2001	Clinical	DD	MM	Flat OS	NSAID	50
Minakuchi[18]	2001	Clinical	DD	MM	Flat OS	No treatment	46
Niemelä[24]	2012	RDC/TMD	MPD	MM	SS	Counseling	76
Gomes[35]	2014	Clinical	MPD	MM	OS	No treatment	28
Gomes[35]	2014	Clinical	MPD	MM	OS	Massage	28
Wassell[28]	2006	AAOFP	MPD	MM	SS	NOS	39
Wassell[28]	2006	AAOFP	MPD	MM	SS	NOS	72
Wahlund[29]	2003	RDC/TMD	MPD	MM	OS	BI+relaxation	83
Wahlund[29]	2003	RDC/TMD	MPD	MM	SS	BI+relaxation	83
Wahlund[32]	2015	RDC/TMD	MPD	MM	SS	Relaxation	57
Conti[31]	2015	Clinical	DD	MM	SS	Relaxation	22
Conti[31]	2015	Clinical	DD	MM	ARS	Counseling	21
Conti[31]	2015	Clinical	DD	MM	NTI-tss	Counseling	21

(DD: disk displacement, MM: inter-incisal opening in millimeters, OS: occlusal splint, NSAID: nonsteroidal antiinflammatory drugs, RDC/TMD: research diagnostic criteria of temporomandibular dysfunction, MPD: myofascial pain dysfunction, SS: stabilizing splint, BI: brief information, NTI-tss: nociceptive trigeminal inhibition-tension suppression system, AAOFP: American Academy of Orofacial Pain, ARS: anterior reposition splint, NOS: non-occluding splint)

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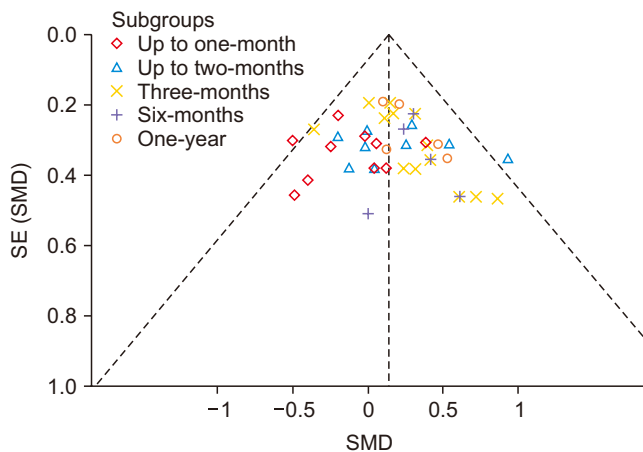
compared soft and hard splints with self-care.

In all five comparisons, the control group exhibited better results than splints regarding pain reduction.

Total subgroup analysis of the identified studies with total of 344 participants revealed a significant overall effect on pain reduction in favor of the control (SMD 0.23, 95% CI 0.01-0.44, *P*=0.04, I²=0%).

(5) Total analysis

The five included subgroups reveal moderate heterogeneity between them (I²=53.9%). However, no heterogeneity between the individual studies (I²=0%) was observed. The overall effect of the meta-analysis with a total of 2,042 participants revealed a significant difference between the control and splint therapy in favor of the control group (SMD 0.14, 95% CI 0.05-0.23, *P*=0.002, I²=0%).

(6) Dichotomous studies (Fig. 3)

Five studies were included[25,26,28,33,34]. Two studies compared manual mobilization and active exercises[25,33], two studies compared splints with a palatal non-occluded splint[26,34], and one study compared splints with no treatment[28].

Total analysis of the identified studies with a total of 164 participants revealed no significant overall effects of splint therapy on pain reduction (RR 1.12, 95% CI 0.84-1.50, *P*=0.45, I²=0%).

2) Secondary outcome

(1) Maximum mouth opening

(i) Short-term evaluation

Table 2 presents a summary of the included subgroup studies. Included studies involved a follow-up period up to three months. Subgroups included five studies with nine comparisons[18,24,25,35,36]. In five comparisons, the splint group exhibited

Study or subgroup	Splint Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, Fixed, 95% CI	Year
Short									
Minakuchi[18]	39.8	10.1	25	38.5	9.68	21	2.9%	1.30 [-4.43, 7.03]	2001
Minakuchi[18]	37.5	9.91	25	37	10.5	25	3.0%	0.50 [-5.16, 6.16]	2001
Minakuchi[18]	39.8	10.1	25	38.1	10.5	25	2.9%	1.70 [-4.01, 7.41]	2001
Minakuchi[18]	37.5	9.91	25	37.9	9.84	21	2.9%	-0.40 [-6.13, 5.33]	2001
Carmeli[25]	37.6	6.13	18	37.5	6.1	18	5.9%	0.10 [-3.90, 4.10]	2001
Niemelä[24]	45.9	8.7	39	46.5	7.8	37	6.9%	-0.60 [-4.31, 3.11]	2012
Gomes[35]	47.17	3.53	14	49.75	5.35	14	8.4%	-2.58 [-5.94, 0.78]	2014
Gomes[35]	47.17	3.53	14	50.32	5.63	14	7.8%	-3.15 [-6.63, 0.33]	2014
Ahmed[36]	41.92	4.79	13	41.92	5.3	13	6.3%	0.00 [-3.88, 3.88]	2016
Subtotal (95% CI)			198			188	47.0%	-0.87 [-2.29, 0.55]	
Heterogeneity: chi²=4.66, df=8 (*P*=0.79); I²=0%									
Test for overall effect: Z=1.20 (*P*=0.23)									
Long									
Wahlund[29]	49.3	8.8	42	49.4	6.4	41	8.7%	-0.10 [-3.40, 3.20]	2003
Wahlund[29]	49.5	7.3	42	50	5.5	41	12.3%	-0.50 [-3.28, 2.28]	2003
Wahlund[29]	43.1	8	29	45.3	9.2	28	4.7%	-2.20 [-6.68, 2.28]	2003
Wassell[28]	45.7	8.3	38	46.6	7.3	34	7.3%	-0.90 [-4.50, 2.70]	2006
Wassell[28]	47.7	4.1	27	48.9	4.1	12	12.2%	-1.20 [-3.99, 1.59]	2006
Conti[31]	41.2	7.2	12	39.3	6.1	9	2.9%	1.90 [-3.80, 7.60]	2015
Conti[31]	42.2	6.4	12	39.3	6.1	9	1.5%	2.90 [-2.48, 8.28]	2015
Wahlund[32]	46.4	8.4	17	52.4	7.8	5	53.0%	-6.00 [-13.92, 1.92]	2015
Subtotal (95% CI)			219			179		-0.62 [-1.96, 0.72]	
Heterogeneity: chi²=4.94, df=7 (*P*=0.67); I²=0%									
Test for overall effect: Z=0.90 (*P*=0.37)									
Total (95% CI)			417			367	100.0%	-0.74 [-1.71, 0.24]	
Heterogeneity: chi²=9.66, df=16 (*P*=0.88); I²=0%									
Test for overall effect: Z=1.48 (*P*=0.14)									
Test for subgroup differences: chi²=0.06, df=1 (*P*=0.80); I²=0%									

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Fig. 4. Forest plot result of comparisons of the splint group vs control group in maximum mouth opening at both short and long term durations according to the total subgroup analysis. (SD: standard deviation, CI: confidence interval, df: degree of freedom)

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Fig. 5. Funnel plot comparison: splint group vs control group in continuous pain assessment to detect publication bias of the studies. (SE: standard error, SMD: standardized mean difference)
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better results than the non-splint group[18,25,36] and four comparisons were in favor of the control[18,24,35].

Total subgroup analysis of the identified studies with a total of 386 participants revealed non-significant overall effects on the improvement in mouth opening (MD –0.87, 95% CI –2.29 to 0.55, P=0.23, I^2=0%).

(ii) Long-term evaluation

Included studies involved a follow-up period up to one year. Subgroups included four studies with eight comparisons[28,29,31,32]. In two comparisons, the splint group exhibited better results than then control[30], and six comparisons were in favor of the control group[28,29,32].

Total subgroup analysis of the identified studies with a total of 398 participants revealed non-significant overall effects on the improvement of mouth opening (MD –0.62, 95% CI –1.96 to 0.72, P=0.37; I^2=0%).

Total analysis of the identified studies with a total of 784 participants revealed no significant overall effects of splint therapy on MMO (MD –0.74, 95% CI –1.71 to 0.24, P=0.14, I^2=0%).(Fig. 4)

3) Methodological quality assessment

(1) Risk of bias across all the included studies

Nine studies had a high risk for selection bias (random sequence generation) (41%), eleven studies were at high risk of selection bias (allocation concealment) (50%), five studies had performance bias (23%), eight studies exhibited detection bias (36%), three studies had attrition bias (14%), and finally two studies exhibited reporting bias (1%).

The funnel plots declared no publication bias for the two primary outcomes, continuous and dichotomous, in both short and long-term follow-up periods (Fig. 5) and also no publication bias for the secondary outcome (MMO).

IV. Discussion

Systematic reviews are a critical assessment tool in evidence-based decision-making. This study was assigned to PRISMA[16] statements for systematic reviews. Well-structured PICO (Problem Intervention-Comparison-Outcome) questions with clearly outlined inclusion and exclusion criteria were also included. A publication bias analysis was performed for every outcome using funnel plots.

Pain is considered the most common reason for medical consultation. Therefore, it was selected as the primary outcome of this review. However, restoring the normal range of mouth opening, and subsequently, normal masticatory and jaw function was the secondary outcome examined.

We investigated the effects of splint therapy as a conservative TMD treatment modality in reducing pain intensity and improving mouth opening through the analysis of twenty-two included studies.

There is no gold standard control to compare the different types of splints. Therefore, all the splints included in the current review were compared with no treatment or behavioral therapy.

Over-estimation of the effect of treatment resulted from an improper means of randomization, neglecting concealment of treatment allocation, not adequately blinded assessments, short follow-ups, or lacking of study power due to small sample sizes being the most serious problems.

Although several studies investigated splint therapy, the results remain controversial. Methodological differences among the studies are evident, and a comparison of the results is often difficult due to heterogeneity. The clinical relevance of these findings shows a need for more well-designed RCTs.

Studies that were older than twenty years were excluded due to the introduction of RDC/TMD classification which decreases diagnostic pitfalls and improves population selection. The use of recent materials and continuous changes in splint design all may confound the results associated with the classification's effectiveness.

In this systematic review, we tried to minimize bias across the studies and obtain maximal homogeneity among the subgroups by using appropriate eligibility criteria and selecting only studies with the control group receiving no treatment or

palliative treatment. Subsequently, meta-regression analysis was not required.

In the current review, subgroups were selected according to the recommendation of Pficer et al.[39] who studied confounding factors with meta-regression analysis and found that that duration of treatment is one of the parameters that could affect the outcome of using oral splints. He reported that investigators should pay attention not only to the short-term but also long-term therapeutic effects in their studies.

Continuous outcome data was obtained using SMD, 95% CI, and applying inverse variance with a fixed effect for accurate analysis. For dichotomous pain intensity data, we used relative risk and random effects because of the low number of included studies and heterogeneity.

For secondary outcomes based on continuous data, we used MD because of using the same scale in measurements and 95% CI. Inverse variance and fixed effects were applied to achieve sensitive analysis.

In short-term follow-ups, oral splints exhibited no significant effect on pain reduction. However, in long-term follow-ups, behavioral therapy was associated with significant pain reduction.

These findings do not mean that behavioral therapy is better than oral splints, but that the effect of splint therapy was abolished or equal to no treatment after an extended period of time.

The findings of the conducted review follow the individual studies[18-20,24,26-28,30,33,40] that did not observe any difference between splint therapy and placebos.

Most of the reviews that compared splints with lasers, arthrocentesis, acupuncture, or physiotherapy resulted in fake estimations because such comparisons depend on the power of the comparator and do not provide a clue about the actual estimation.

There are several articles that included studies comparing splints with behavioral treatment, pharmacologic treatment, arthroscopy, surgical intervention, or no treatment[41].

This review showed that there is no evidence to suggest that splint therapy is beneficial for pain reduction measured with different scales or even effective in reducing symptoms in patients with myofascial pain when compared with placebo or no treatment. These findings are in agreement with the systematic review by Al-Ani et al.[42].

There was no evaluation of each splint type separately, and the populations were mixed including disk displacement with myofascial pain participants. Non-occluding splints were considered as controls which may have some effects through the repositioning of the tongue and patient awareness issues.

We recommend an evaluation of each type of splint separately and subgroup analysis separating cases of myofascial pain from cases of disk displacement.

V. Conclusion

Based on the limitations of the included studies in this systematic review due to considerable bias in selection, concealment, and blinding, the present outcome suggests that oral splints are not effective for either the reduction of pain intensity or improvement in MMO compared to control groups in patients with TMJD.

Further assessment with a higher level of evidence including studies with proper selection randomization, concealment, calculated sample size, and blinding for better estimation of the effectiveness of splint therapy in patients with TMJD are needed.

Apparent improvements observed in most of the studies on oral splints are due to the placebo effect or the natural remission of symptoms.

Oral splints can be used only as an adjunct to other non or minimally invasive treatments for TMJD management. Furthermore, oral splints could be helpful in blocking bad habits and bruxism in order to inhibit dental damage potentially induced by that disorder.

Our results confirmed that the effect of splint therapy for pain reduction in short-term durations is better than that seen in control groups, but that results becomes insignificant with fading effects in long-term studies.

Author's Contributions

The author designed the study, collect the data, and did the statistical analysis.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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