Systematic Review and Meta-analysis of Randomized Controlled Trials Evaluating Intraoral Orthopedic Appliances for Temporomandibular Disorders

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Aims: *To conduct a systematic review with meta-analysis of randomized controlled trials (RCTs) that have assessed the efficacy of intraoral orthopedic appliances to reduce pain in patients with temporomandibular disorders affecting muscle and joint (TMJD) compared to subjects receiving placebo control, no treatment, or other treatments.* ***Methods:*** *A search strategy of MEDLINE, the Cochrane Library, the Cochrane CENTRAL Register, and manual search identified all English language publications of RCTs for intraoral appliance treatment of TMJD pain during the years of January 1966 to March 2006. Two additional studies from 2006 were added during the review process. Selection criteria included RCTs assessing the efficacy of hard and soft stabilization appliances, anterior positioning appliances, anterior bite appliances, and other appliance types for TMJD pain. Pain relief outcome measures were used in the meta-analyses, and the QUORUM criteria for data abstraction were used. A quality analysis of the methods of each RCT was conducted using the CONSORT criteria. The review findings were expressed both as a qualitative review and, where possible, as a mathematical synthesis using meta-analysis of results.* ***Results:*** *A total of 47 publications citing 44 RCTs with 2,218 subjects were included. Ten RCTs were included in two meta-analyses. In the first meta-analysis of seven studies with 385 patients, a hard stabilization appliance was found to improve TMJD pain compared to non-occluding appliance. The overall odds ratio (OR) of 2.46 was statistically significant (*P = .001*), with a 95% confidence interval of 1.56 to 3.67. In the second meta-analysis of three studies including 216 patients, a hard stabilization appliance was found to improve TMJD pain compared to no-treatment controls. The overall OR of 2.15 was positive but not statistically significant, with a 95% confidence interval of 0.80 to 5.75. The quality (0 to 1) of the studies was moderate, with a mean of 55% of quality criteria being met, suggesting some susceptibility to systematic bias may have existed.* ***Conclusion:*** *Hard stabilization appliances, when adjusted properly, have good evidence of modest efficacy in the treatment of TMJD pain compared to non-occluding appliances and no treatment. Other types of appliances, including soft stabilization appliances, anterior positioning appliances, and anterior bite appliances, have some RCT evidence of efficacy in reducing TMJD pain. However, the potential for adverse events with these appliances is higher and suggests the need for close monitoring in their use.* J OROFAC PAIN 2010;24:237–254

Key words: intraoral orthopedic appliances, systematic review, temporomandibular disorders

Intraoral orthopedic appliances have been historically advocated for managing temporomandibular disorders affecting muscle and joint (TMJD).[1,2] The most common types of intraoral appliances are the stabilization appliances of both hard and soft acrylic, anterior positioning appliances, and anterior bite appliances.[2] Despite their widespread use, there is still controversy regarding their efficacy in clinical trials, relative effectiveness in

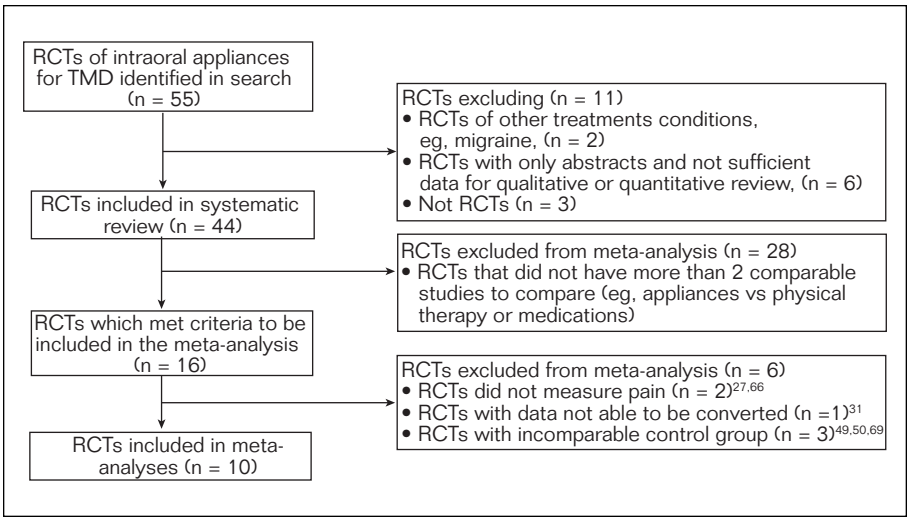


Fig 1 QUORUM diagram for inclusion and exclusion of studies in the meta-analyses of appliances versus control appliances and appliances versus no treatment. RCT studies excluded from the meta-analyses were still included in the systematic review. The detailed search strategy is included in Fricton et al.[5]

clinical use, and safety for TMJD pain with no cohesive single theory to explain the spectrum of their effects.[1] The efficacy of intraoral appliances for TMJD has been evaluated in randomized controlled trials (RCTs), but the outcomes of these studies vary and have never been synthesized in a meta-analysis. Thus, the aim of the present study was to conduct a systematic review of RCTs for appliances to assess the efficacy of intraoral orthopedic appliances to reduce pain in patients with TMJD compared to subjects receiving placebo control, no treatment, or other treatments.

Materials and Methods

This systematic review with meta-analysis was limited to English-language publications of RCTs for evaluating the efficacy of TMJD interventions. The QUORUM guidelines were used for reviewing quality of the reports and the Cochrane manual for design, conduct, and analysis of a systematic review and meta-analysis.[3,4] As noted in the Cochrane manual, a meta-analysis is the extraction of data from each individual study and the calculation of a result that can then be applied in a pooled average across studies. All RCTs that evaluated intraoral appliances, including soft and hard stabilization appliances, anterior positioning appliances, anterior bite appliances, and soft resilient appliances for TMJD, were eligible for inclusion in this review. The detailed methods for the search have been described by Fricton et al.[5] It is acknowledged that nonrandomized clinical trials and observational cohort studies also provide important information and may be the design of choice to demonstrate comparative effectiveness, widespread utility, adverse events, and risk assessment. However, they were not included in this search strategy because of their potential to introduce selection bias and dissimilar comparison groups in determining efficacy.

Search Strategy

MEDLINE, the Cochrane Library, and the Cochrane CENTRAL Register were searched to identify RCTs for TMJD and tension-type headache published during the years 1966 to March 2006.[5] The search strategy was based on the recommendations of the United States Agency for Health Care Policy, the Cochrane Collaboration, and the Oxford Centre for Evidence-based Medicine.[3,6] All English-language RCTs of intraoral appliances for treatment of TMJD, including tension-type headache, that were identified up to March 2006 were included and none were excluded. Two additional RCTs from 2006 were added during the manuscript review process. Figure 1 presents the QUOROM diagram on how trials were excluded from the meta-analyses. Abstracts were excluded from the review unless the data needed for the meta-analysis was available.[7] Studies that did not use pain as an outcome were also included in the review but not included in the meta-analysis. For the searches, the inclusion criteria included several MeSH terms to identify the published TMJD and headache literature relevant to this review and are listed in Fricton et al.[5] The MeSH terms included those referenced most frequently in the literature, including temporomandibular disorder, temporomandibular joint

disorder, craniomandibular disorder, myofascial pain, myofacial pain, tension-type headache, psychogenic headache, muscle headache, muscular headache, facial pain, orofacial pain, and chronic daily headache. Tension-type or muscular headache was included as a target population because the diagnosis of tension-type headache, as defined by the International Headache Society, has signs and symptoms that are the same as masticatory myofascial pain involving the temporalis muscle as defined by the American Academy of Orofacial Pain classification.[2,8]

Outcomes Assessed

Since pain is the major symptom of TMJD and the reason most patients seek treatment, it is often used as a measure of TMJD severity.[9,10] For this reason, this outcome was selected for determining the relative benefit of the study interventions. Methods for pain measurement were not strictly standardized between studies, but a reasonable comparison could be made by defining a successful outcome as approximately a 50% reduction in a self-report measure of pain (eg, 6 to 3 on 10-point scale) or a subjective report of at least an "improved" status based on an analysis of data that compared both measures of pain derived from TMJD patients in the TMJ Implant Registry and Repository of the United States National Institute for Dental and Craniofacial Research.

Validity Assessment

The methodological quality of the studies was assessed using the methods adapted from the CONSORT criteria and Cochrane handbook with results published in Fricton et al.[5,8,11] Three reviewers independently assessed the methodological quality of the RCTs, and any disagreements were resolved by consensus. The reviewer's inter-rater reliability was assessed by independent assessment of 10 studies and was found to be adequate with an Intraclass Correlation Coefficient (ICC) of 0.88 and a 95% confidence interval (CI). In addition, their agreement relative to another published quality assessment was found to be adequate.[12] These validity assessments were applied in a two-level process with the results presented in Tables 1 through 4.[5] Level I criteria for minimizing systematic bias were first evaluated to determine if *selection* bias, *measurement* bias, *comparison group* bias, and *attrition* bias as defined in the CONSORT criteria[13] and Fricton et al[5] were present. Second, the mean quality score with all CONSORT criteria were compared to determine if the quality of the methods or reporting may have explained differing results. These criteria included defining with specific criteria the study participants, outcome measures, sample size calculation, randomization, blinding, statistical methods, participant flow, recruitment and follow-up, use of baseline data, and numbers analyzed.

Data Abstraction

Five reviewers participated in selecting, reviewing, and abstracting data from the papers. All papers were independently and manually reviewed by at least two primary reviewers, and often three and four reviewers were used to ensure accuracy of the review. The intervention, baseline characteristics of the treatment and control groups (eg, age, gender, symptom severity, and diagnosis), and outcomes of studies included in the meta-analysis were extracted and presented in Table 1. Since the effect of splints occurs most often in the first 2 to 3 months, the closest time period to this cut-off was used in data abstraction.

Quantitative Data Synthesis

The pooled odds ratio (OR), absolute risk reduction (ARR), and number-needed-to-treat (NNT) were calculated, along with their associated 95% CI for rate of pain reduction. A fixed-effect model was used if no significant statistical heterogeneity was found and a random-effects model if significant statistical heterogeneity was shown. The mean and standard deviation (SD) were reported for the change in symptom scores. The event or success rate for the control group (CER) is the number of its successful outcomes divided by the number of subjects allocated to that group; the event rate for the experimental or active treatment intervention group is calculated likewise (EER). The NNT identifies how many people need to be treated with the study intervention to be associated with one more successful outcome than the number of successes in the group receiving the comparison treatment or placebo[14,15]: the lower the NNT estimate, the better the outcome associated with the intervention. NNTs of 2 to 4 are typically taken to indicate that the intervention is quite effective. Since the NNT is specific to the period of follow-up, the duration of follow-up must be similar in order for NNT values to be comparable.[11] This requirement was not met in many of the studies where the "duration of follow-up" of the studies varied considerably.

Table 1 Summary of RCTs Evaluating Stabilization Appliances Versus a Non-occluding Appliance for TMJD

Trial	Diagnosis	Group size	Treatment	Duration of follow-up	Measure	Outcome* ($P \leq .05$)	NNT†	Minimum criteria met?‡	Quality score§
Rubinoff et al, 1987[18]	TMJD muscle pain from general population	15 13	A: Stabilization appliance B: Palatal control appliance	Not reported	Pain (0 to 5) Muscle tenderness Inter-incisal opening	A = B A = B A = B	NA NA NA	no	37%
Dao et al, 1994[19]	TMJD muscle pain from general population	22 20 19	A: Stabilization appliance 24 hours/day B: Passive control: Stabilization appliance 30 min/visit C: Palatal control appliance 24 hours/day	7 visits over 10 weeks	Pain intensity VAS Pain unpleasant VAS Pain on chewing VAS Quality of life	A = B = C A = B = C A = B = C A = B = C	NA NA NA NA	yes	87%
Ekberg et al, 1998,[20] 1998,[21] and 1999[22] (1998 study with additional reports)	TMJD joint pain from clinic population	30 30	A: Stabilization appliance during sleep B: Palatal control appliance during sleep	10 weeks	Subjective improvement in overall pain and discomfort 50% of pain reduced TMJ pain-free with lateral palpation Change in condyle-fossa relationship	A > B A > B A > B	A:B 3 A:B 6 A:B 5 A:B 2	no	73%
Raphael et al, 2001[23]	TMJD muscle pain from clinic population	32 31	A: Stabilization appliance at night during sleep B: Palatal control appliance during sleep	5 visits over 6 weeks	Average pain Tenderness Jaw function Widespread pain present Days of pain interference	A > B A = B A = B A = B A = B	A:B 6 NA NA NA NA	yes	80%
Ekberg et al, 2003[24]	TMJD muscle pain from clinic population	30 30	A: Stabilization appliance during sleep B: Non-occluding palatal appliance during sleep	10 weeks	Subjective improvement in overall pain and discomfort 50% of pain reduced Reduced number of subjects with < 40 mm maximum opening	A > B A = B A > B	A:B 2 NA A:B 4	no	67%
Wassell et al, 2004[25]	TMJD from general dental practice	34 38	A: Lower stabilizing appliance full-time B: Non-occluding appliance full-time	6 weeks	Pain VAS Muscle tenderness Joint tenderness Inter-incisal opening	A = B A = B A = B A = B	NA NA NA NA	no	53%
Conti et al, 2006[26]	TMJD from clinic population	30 30 30	A: Maxillary stabilizing appliance with bilateral guidance at night B: Maxillary stabilizing appliance with canine guidance at night C: Maxillary non-occluding appliance at night	7 days to 6 months	Pain VAS Muscle and joint tenderness Mandibular range Joint sounds	B > C A = B= C A > C A = B= C	A:C 6 NA A:C 6 NA	yes	67%

NA = not applicable or could not be calculated; VAS = visual analog scale; TMJ = temporomandibular joint.
*Outcome defined by whether a statistical significance in outcome measure(s) between groups. A > B means that group A had significantly better outcomes that group B.
†NNT = The NNT number (eg, A:B6) means six patients need to be treated by treatment A in order for one person to experience a beneficial outcome, or for one more person to have a benefit than would be true for treatment B. The NNT was calculated if data showed a difference between groups, regardless of significance. However, when groups were equal or if appropriate data were not available, the NNT was not calculated.
‡ Minimum level I criteria for minimizing systematic bias includes selection bias, measurement (or detection) bias, comparison group (or performance) bias, and attrition bias.
§ The quality assessment score (%) was calculated to reflect the percent of all 11 CONSORT criteria that was met for each study, thus permitting an overall estimate of the quality of the evidence base for the treatment of TMJD.

Table 2 Summary of RCTs of Stabilization Appliance Versus No Treatment and Acupuncture

Trial	Diagnosis	Group size	Treatment	Duration of follow-up	Measure	Outcome ($P \leq .05$)	NNT	Minimum criteria met?	Quality score
Lundh et al, 1988*[31]	Disc displacement with reduction	20 21 22	A: Disc-repositioning onlays B: Stabilization appliance at night C: No treatment	6 months	Reduced chief complaint Reduced joint dysfunction Reduced joint pain to palpation	A > B > C A = B > C A = B A > C B = C	A:B 3 A:C 2 B:C 7	no	0.47
Johannson et al, 1991*[27]	TMJD with facial pain and headache	15 15 15	A: Acupuncture B: Stabilization Appliance C: No treatment	3 months	Reduced clinical dysfunction score (Pain not included)	A,B > C	A:C 2 B:C 2	no	60%
List et al, 1992, part I[28]	TMJD muscle pain	40 40 30	A: Acupuncture B: Stabilization appliance C: No treatment	6 to 8 weeks	Anamnestic Index Score to 0 Reduced subjective symptoms Pain intensity	A > B, C A > B A = B	A:C 5 A:B 3 NA	no	60%
List et al, 1992, part II[64]	TMJD muscle pain	22 25 30	A: Acupuncture B: Stabilization appliance C: No treatment	1 year follow-up	Subjective symptoms	A = B C: not analyzed	B:A 10	no	60%
Lundh et al, 1992[30]	Painful TMJ disc displacement without reduction	25 26	A: Stabilization appliance B: No treatment	12 months	Joint and muscle pain intensity	A = B	NA	no	53%
List et al, 1993[29]	TMJD	20 20 15	A: Acupuncture B: Stabilization appliance C: No treatment	6 to 8 weeks	Clinical dysfunction Pain intensity Pain intensity at 6 months	A = B > C A = B > C A = B	NA NA NA	no	47%

*These studies had a no-treatment control but were excluded in the meta-analysis due to the inability to convert the outcome measure into a comparable format.

Table 3 Summary of RCTs of Appliances Versus Other Treatment

Trial	Diagnosis	Group size	Treatment	Duration of follow-up	Measure	Outcome ($P \leq .05$)	NNT	Minimum criteria met?	Quality score
Dahlstrom et al, 1982[32]	TMJD	15 15	A: Flat appliance B: Biofeedback	6 weeks	Muscle pain at 1 month Pain in movement at 1 month Range of motion at 1 month	A = B A = B A = B	NA NA NA	no	0.47
Okeson et al, 1983[33]	TMJD	12 12	A: Stabilization appliance B: Simplified relaxation therapy	4 to 6 weeks	Muscle tenderness Incisal opening	A > B A > B	A:B 6 A:B 5	no	0.40
Dahlstrom et al, 1984[34]	TMJD	15 15	A: Stabilization appliance at night B: Biofeedback	6 week 12 months	Pain at 6 weeks Pain at 12 months	A = B A = B	NA NA	no	0.53
Raustia et al, 1985[65]	TMJD	25 25	A: Stabilization appliance B: Acupuncture	3 months	Pain (VAS)	A = B	A:B 4	no	0.27
Crockett et al, 1986[35]	TMJD muscle pain	7 7 7	A: Stabilization appliance and physical therapy B: Relax/stress management C: TENS	8 weeks	Pain	A = B = C	NA	no	0.53
Wenneberg et al, 1988[43]	TMJD with headache	15 15	A: Stabilization appliance B: Occlusal equilibration	2 months	Reduced subjective symptoms Reduced clinical dysfunction Headache frequency	A > B A > B A > B	NA A:B 3 NA	no	0.33
Schokker et al, 1990[41]	TMJD with headache	23 25	A: Stabilization appliance B: Standard headache medication management	6 weeks	Headache intensity Headache frequency Drug intake	A > B A > B A > B	A:B 3 NA NA	no	0.47
Turk et al,* 1993[66]	TMJD	28 30 20	A: Stabilization appliance full-time B: Stress management/biofeedback C: No treatment waiting list control	6 weeks 6 months	Pain at 6 weeks Muscle tenderness Depression Pain at 6 months Muscle tenderness Depression	A > B > C A > B > C A > B > C A = B > C A = B > C B > A > C	NA NA NA NA NA NA	no	0.53
Linde et al, 1995[67]	TMJ pain and disc displacement without reduction	15 16	A: Stabilization appliance 24 hours/day B: TENS	6 weeks	Muscle and TMJ pain 50% reduction in pain	A = B A > B	NA A:B 2	no	0.53
Turk et al, 1996[36]	TMJD	20 21	A: Stabilization appliance/stress management/biofeedback with cognitive therapy B: Stabilization appliance/stress management/ biofeedback with supportive counseling	6 months	Reduced muscle palpation pain Reduced TMJ palpation pain Unassisted opening without pain Unassisted opening regardless of pain Reduction in medication usage	A > B A = B A = B A = B A > B	NA NA NA NA A:B 4	no	0.60
Magnusson and Syren, 1999[68]	TMJD muscle pain	12 11	A: Stabilization appliance at night B: Jaw exercises	6 months	Pain	A = B	NA	no	0.40
Carlson et al, 2001[39]	TMJD muscle pain	23 21	A: Self-regulation B: Stabilization appliance with self-care instructions	6 weeks 6 months	Reduction in pain at 6 weeks Improved mouth opening Reduction in pain at 6 months Improved mouth opening	A = B A = B A > B A > B	NA NA NA NA	yes	0.87
Alvarez-Arenal et al, 2002[69]	TMJD pain with bruxism	24	A: Stabilization appliance B: TENS	4 months	Pantographic reproducibility index Joint clicking Pain to muscle palpation	A = B A = B A = B	NA NA NA	no	0.40

Wahlund et al, 2003[37]	Adolescents w/ TMJD pain	42 41 39	A: Stabilization appliance + brief information B: Relaxation therapy + brief information C: Brief information	6 months	50% improved pain intensity Improvement in mean pain index	A > B = C A = B > C	A:C 3 B:C 11 NA	yes	0.80
Tommaso et al, 2005[42]	Chronic tension-type headache	9 9	A: Stabilization appliance B: Amitriptyline	2 months	Total tenderness score Laser-evoked potential Severity and frequency of headache	A > B A < B A = B	NA NA NA	no	0.27

*This study had a no-treatment control but was excluded in the meta-analysis due to the inability to convert the outcome measure into a comparable format.

Table 4 Summary of RCTs of Various Designs and Applications of Appliances

Trial	Diagnosis	Group size	Treatment	Duration of follow-up	Measure	Outcome ($P \leq .05$)	NNT†	Minimum criteria met?	Quality score
Manns et al, 1983[38]	TMJD muscle pain	25 25 25	A: 1 mm stabilization appliance B: 4.42 mm appliance C: 8.15 mm appliance	3 weeks	Reduced subjective symptoms Reduced muscle/joint pain to palpation	B = C > A B = C > A	NA NA	no	0.60
Anderson et al,1985[48]	Disc displacement with reduction pain	10 10	A: Stabilization appliance 24 hours/day B: Anterior positioning appliance 24 hours/day	3 months	Subjective dysfunction Functional pain TMJ pain	B > A B = A B > A	B:A 2 B:A 5 B:A 2	no	0.40
Dahlstrom and Haraldson, 1985[46]	TMJD	10 9	A: Stabilization appliance night B: Anterior bite plate	6 weeks	TMJD pain and signs EMG activity	A > B A = B	A:B 7 NA	no	0.47
Manns et al, 1985[70]	TMJD	20 20 20	A: 1 mm stabilization appliance B: 4.25 mm appliance C: 8.25 mm appliance	3 weeks	Reduced EMG masseter activity	B = C > A	NA	no	0.27
Gray et al, 1991[47]	TMJD	34 21	A: Stabilization appliance B: Localized occlusal interference appliance with ball clasp	3 months	Number improving clinically and subjectively	A = B	B:A 8	no	0.40
Elsharkawy and Ali, 1995[50]	TMJD	23 22 23 17	A: Soft appliance night B: Acuhealth C: Acuhealth with appliance D: Placebo acuhealth	3 months	Percent reporting symptom free	A = B = C > D	A:D 1 B:D 2 C:D 1	no	0.53
Wright et al, 1995[49]	TMJD muscle pain	10 10 10	A: Soft appliance B: Palliative self-care C: No treatment	4 to 11 weeks	Subjective pain Pain-free opening Muscle pain threshold	A > B = C A > B = C A > B = C	NA NA NA	no	0.53
Davies and Gray, part I, 1997[44]	Disc displacement without reduction	25 25 20	A: Anterior positioning appliance 24 hours B: Anterior positioning daytime C: Anterior positioning nighttime	At 1 month: (during treatment) At 3 months: (posttreatment)	Joint sounds Joint pain to palpation Range of Motion Overall subjective and objective improvement	A > B = C A = B = C A > B = C A > B = C	NA NA NA A:B 3 A:C 5 C:B 8	no	0.47

Table 4 continued Summary of RCTs of Various Designs and Applications of Appliances

Trial	Diagnosis	Group size	Treatment	Duration of follow-up	Measure	Outcome ($P \leq .05$)	NNT†	Minimum criteria met?	Quality score
Davies and Gray, part II,1997[45]	TMJD	23	A: Stabilization appliance 24 hours	3 months	Joint sounds	A = B = C	NA	no	0.53
		19	B: Stabilization appliance day only		Pain	A = B = C	NA		
		28	C: Stabilization appliance night only		Limited opening	A = B = C	NA		
					Percent improved	A = B = C	A:B 5 A:C 7 C:B 12		
Shankland et al, 2001[52]	Tension type headache/ migraine	43	A: NTI anterior bite plane	8 weeks	Greater than 85% reduction in migraine	A > B	A:B 10	no	0.53
		51	B: Mandibular stabilization appliance		Percent reduction in tension-type headache	A > B	NA		
					Percent reduction in headache intensity	A = B	NA		
Carmeli et al, 2002[51]	Anterior disc displacement	18	A: Soft anterior positioning appliance	4 weeks	Reduced subjective pain	B > A	NA	no	0.47
		18	B: Exercises and therapist-performed mobilization		Improved mouth opening	B > A	B:A 2		
Fayed et al, 2004[71]	Anterior disc displacement with reduction	7	A: Anterior positioning appliance	3 months	MRI-TMJ disc recapture	B > A	B:A 7	no	0.60
		7	B: Stabilization appliance		TMJ disc size & position	B > A	NA		
Magnusson et al, 2004[53]	TMJD	14	A: Stabilization appliance	3 months	Subjective symptoms	A > B	A:B 3	no	0.60
					Anamnestic index	A > B	NA		
		14	B: NTI appliance	6 months	Subjective symptoms	A > B	A:B 5		
					Global improvement	A > B	A:B 2		
Jokstad et al, 2005[54]	TMJD	20	A: Stabilization appliance	3 months	Range of motion	A = B	NA	yes	0.73
		18	B: NTI appliance		Headache	A = B	NA		
					TMJ pain to palpation	A = B	NA		
					Jaw muscle tenderness	A = B	NA		
					Comfort	A = B	NA		
Schmitter et al, 2005[72]	Anterior disc displacement without reduction	38	A: Stabilization appliance	6 months	Success defined as 50% functional pain reduction and 20% increase in mouth opening	A > B	NA	no	0.67
		36	B: Anterior positioning appliance						
Stiesch-Scholz et al, 2005[73]	Anterior disc displacement without reduction	20	A: Stabilization appliance	3 months	Jaw mobility	A = B	NA	no	0.67
		20	B: Pivot appliance		Subjective pain	A = B	NA		
					Tenderness to palpation score (joint and muscle)	A = B	NA		
Truelove et al, 2006[40]	TMJD	64	A: Conservative self-care strategies	3 months	Pain intensity	A = B = C	NA	yes	0.87
					Range of motion,joint sound, etc.	A = B = C	NA		
		68	B: Conventional flat-plane hard acrylic appliance	12 months	Pain intensity	A = B = C	NA		
					Range of motion,joint sound, etc.	A = B = C	NA		
		68	C: Soft vinyl appliance						

MRI = magnetic resonance imaging.

Statistical Methods for Meta-analysis

The Comprehensive Meta Analysis version 2.0 was used for the meta-analyses and the random-effects model was selected. This is the model of choice when the true treatment effect is assumed to differ from one study to the next due to differences in subject characteristics, outcome measures, or the ways in which the study treatment may have been used. Averaging the effect estimates of such studies is useful for obtaining a meaningful estimate of the overall benefit associated with the treatment. When the main measure for the strength of effect is an OR, a multiplicative model is recommended for the synthesis, meaning that the combined effect for the studies is computed using the log of each individual OR, and the result is then transformed back to the original metric.[16] Studies having a continuous outcome measure such as pain severity of 0 to 10 were able to be included in the analysis by using the method of Chinn[17] to convert treatment group mean differences to an OR. To synthesize data from studies where different scales were used, the standardized mean difference (SMD) was used; this is the difference in means divided by the pooled SD. To combine studies that assessed the same outcome but differed in continuous versus dichotomous variables, the SD factor of $\pi/\ddot{o}3$ was used to convert from SMD to log OR. This approach is further discussed in the Cochrane Handbook for Systematic Reviews of Interventions 4.2.5.[12] Both the relative risk (RR) and OR were calculated to determine the clearest method of presenting the meta-analyses. The direction of the RR and OR was the same with consistent results. For the estimates of benefit in analyses of the meta-analyses, an OR greater than one (> 1) implies that the successful outcome (pain reduction) occurs more often in the study intervention group than in the control/comparison group. A *P* value for the test of heterogeneity between the studies was calculated to determine if combining data were reliable. Publication bias was evaluated using funnel plots and the Egger statistics for the study outcome.

Results

The review of the literature identified 47 publications citing 44 RCTs for intraoral orthopedic appliances for treatment of TMJD. The review included both a *qualitative* narrative synthese and, when possible, a *quantitative* meta-analyse employing the random-effects model. Combining these approaches allows readers to examine their relative agreement. Figure 1 presents the trial flow for the review and exclusion of studies to arrive at the final 10 studies for meta-analyses. Tables 1 to 4 list, in chronological order, the RCTs that were reviewed in the meta-analysis, including the authors, date, study sample and sizes, intervention groups, measures, outcome measures, NNT for each outcome, whether minimum quality criteria were met, and the overall quality score (0 to 1). Sufficient comparable studies were available to be synthesized in a meta-analysis to provide meaningful average estimates of the benefit of hard stabilization appliances relative to non-occluding appliances (Table 5) and no treatment (Table 6). RCTs with other types of appliances, including soft stabilization appliances, anterior positioning appliances, and anterior bite planes, as well as appliances compared to other treatments, such as self care, acupuncture, behavioral therapy, physical medicine, some pharmacological treatments, and occlusal therapies, were also reviewed.

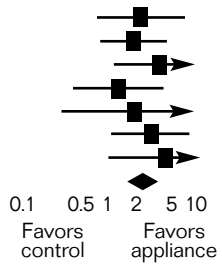
Meta-analysis for Stabilization Appliances Compared to Non-occluding Appliances

The seven RCTs[18–26] in Table 1 had data and methods that allowed meta-analysis of the results comparing hard stabilization appliances to an inactive non-occluding appliance intended to act as a control. The results varied considerably. Studies by Ekberg et al,[20–22] Raphael et al,[23] and Conti et al[26] found that stabilization appliances worn part-time while sleeping were better than the non-occluding appliances, taking into account pain outcomes. The NNT ranged from 2 to 6. The quality of these studies was good, with a mean of 73% of criteria met; both Ekberg et al[20] and Conti et al[26] studies met all level I criteria. In contrast, Dao et al,[19] Wassell et al,[25] and Rubinoff et al[18] studies used appliances full-time (24 hours) and reported no difference relative to non-occluding appliances at 6 to 10 weeks of follow-up. A mean of 59% of quality criteria was met, with only the Dao et al[19] study meeting all level I criteria.

Table 5 shows the forest plot associated with the meta-analysis of combining the seven studies. The estimated ORs for the overall treatment effect and the 95% CIs are plotted on a linear scale. In this plot, an OR > 1 implies that the successful outcome (pain reduction) occurs more often in the study intervention group than in the control group. The meta-analysis yielded a benefit in favor of the hard stabilization appliances when compared to the non-occluding appliances. The overall OR of 2.45 was statistically significant (*P* = .0001) with 95% CIs of

Table 5 Forest Plot Based on Seven Randomized Clinical Trials

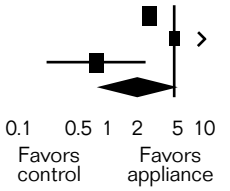
Study	OR	Lower limit	Upper limit	Z value	P	OR and 95% CI
Ekberg et al 1998–1999[20–22]	2.31	0.72	7.40	1.41	.15	
Raphael et al 2001[23]	1.98	0.80	4.89	1.48	.13	
Ekberg et al 2003[24]	3.82	1.15	12.71	2.18	.02	
Dao et al 1994[19]	1.30	0.37	4.48	0.41	.67	
Rubinoff et al 1987[18]	1.95	0.27	13.98	0.66	.50	
Wassell et al 2004[25]	3.12	1.09	8.91	2.12	.03	
Conti et al 2006[26]	4.71	0.96	22.93	1.92	.05	
Summary	2.45	1.56	3.86	3.89	0.00	



Forest plot based on seven randomized clinical trials totaling 385 subjects and evaluating the efficacy of hard stabilization appliances compared to palatal non-occluding appliances as a control treatment. In the figure on the right, the size of the squares suggest the size of the effect for each study, while the position of the parallelogram reflects the integrated TMJD of 2.46. A position to the right of "1" suggests more efficacy is demonstrated by the stabilization appliance over the control appliance and is plotted along a log scale.

Table 6 Forest Plot Based on Three Randomized Clinical Trials Including 216 Subjects

Study	OR	Lower limit	Upper limit	Z value	P	OR and 95% CI
List et al 1992, part I[28]	2.83	1.05	7.64	2.06	.03	
List et al 1992, part II[64]	5.00	1.10	22.72	2.08	.03	
Lundh et al 1992[30]	0.84	0.27	2.61	–0.29	.12	
Summary	2.14	0.80	5.75	1.51	.12	



Forest plot based on three randomized clinical trials including 216 subjects and evaluating the efficacy of stabilization appliances compared to no treatment as the control. In the figure on the right, the size of the squares suggests the size of the effect for each study, while the position of the parallelogram reflects the integrated TMJD of 2.15. A position to the right of "1" suggests more efficacy is demonstrated by the stabilization appliance over no-treatment control and is plotted along a log scale.

1.56 to 3.86. This analysis required converting the continuous data from one study (Raphael et al[23]) to the appropriate estimated OR in order to allow inclusion of that study. The test for heterogeneity between these studies was not significant ($P = .86$), suggesting that the study results can be reliably combined.

Meta-analysis for Stabilization Appliances Compared to No Treatment

Five studies compared hard stabilization appliances to no treatment. Three studies found appliances better than no treatment (Johannson et al[27] and List et al[28,29]), whereas two studies found appliances were equivalent to no treatment (Lundh et al [30,31]) (Table 2). The results of only three studies (List et al[28,29] and Lundh et al[30]) were able to be combined in a meta-analysis. RCTs excluded were the Johannson et al[27] study that did not measure pain and the Lundh et al[31] study that did not have data that allowed conversion.

Table 6 shows the forest plot associated with the meta-analysis of combining these three studies. This analysis required converting the continuous data from two studies (List et al[28,29]) to the appropriate estimated OR to allow their inclusion in the analysis. With an OR of 2.14, a positive net effect was demonstrated with stabilization appliance when compared to no-treatment controls with a 95% CI of 0.80 to 5.75, but this was not statistically significant. The test for heterogeneity between these studies was not significant, suggesting the results can be combined reliably ($P = .13$). Only one of the studies met all level I criteria and a mean of 58% of quality criteria was met, suggesting that systematic bias cannot be ruled out.

Review of Appliances Compared to Other Treatments

TMJD appliances were also compared to other treatments but, with the exception of acupuncture versus appliances, there were no sufficient numbers of RCTs for each type of study to be combined in a meta-analysis. Tables 2 through 4 present the characteristics of these studies.

Meta-analysis for Stabilization Appliances versus Acupuncture. Table 2 presents three RCTs in which data were synthesized in a meta-analysis comparing hard stabilization appliances to acupuncture. The studies reported a benefit associated with both acupuncture and stabilization appliances after several weeks of treatment.[27–29,64] The meta-analysis, combining data from all three studies, found a nonsignificant OR of 0.58, with 95% CI of 0.12 to 2.90. The test of heterogeneity between studies was also significant ($P = .008$) suggesting that combining the data may be unreliable.

Stabilization Appliances Versus Behavioral Therapy, Physical Therapy, and Self-care. Several short-term (4 to 6 weeks) studies found stabilization appliances equal to or more effective than behavioral therapies such as biofeedback and stress management.[32–38] The studies could not be combined in a meta-analysis due to differing study designs and interventions. However, when compared long-term (6 months) in a high-quality RCT, Carlson et al[39] found that behavioral therapy improved pain more than stabilization appliances. Stabilization appliances were found to be equal to physical therapies such as transcutaneous nerve stimulation (TENS) and jaw exercises. A high-quality study conducted by Truelove et al[40] found that the use of hard or soft stabilization appliances with self-care did not add any additional improvement in symptoms when compared to self-care treatment alone. Self-care included heat and cold packs, jaw exercises, reduction of parafunctional jaw activities, and muscle relaxation.

Stabilization Appliance versus Pharmacological Therapy. In a single RCT with tension-type headache patients, Schokker et al[41] found that stabilization appliances were more beneficial for reducing headache intensity, frequency, and amount of medication needed to control headache compared to standard headache medication management that included muscle relaxants and antidepressants. However, this single study did not meet level I quality criteria. In contrast, a study of 47 patients with tension-type headache found both stabilization appliances and amitryptyline (10 mg at night) improved headache severity and intensity equally, but the appliance had better improvement of tenderness scores.[42]

Stabilization Appliance versus Dental Therapy. Lundh et al[31] compared stabilization appliance therapy, disc-repositioning onlays over the mandibular teeth, and no treatment for managing short-term pain associated with TMJ disc displacement with reduction. Disc-repositioning onlays were better than stabilization appliances, and both treatments were better than no treatment for reduction of pain related to the subject's chief complaint. Wenneberg et al[43] compared the use of stabilization appliances to occlusal adjustment and concluded that appliances were more effective than occlusal adjustment. However, neither of these single studies meet level I quality criteria and met only 47% and 33% of quality criteria, respectively.

Different Stabilization Appliance Designs and Uses. Several RCTs compared appliance designs and uses. Davies and Gray[44,45] studied appliance use 24 hours per day, during the day only, or during the night only. There were no significant differences on pain outcomes among groups, suggesting that the efficacy of appliances is similar whether their use is part time or full-time. Manns et al[38] evaluated the thickness of stabilization appliances, concluding that 4-mm-thick and 8-mm-thick appliances were more effective than the thinner 1-mm appliances for the management of myofascial pain symptoms. Dahlström and Haraldson[46] compared stabilization appliances to anterior bite plates for management of TMJD and found stabilization appliances showed greater improvement in TMJD pain as well as signs. Gray et al[47] treated subjects with TMJ pain dysfunction syndrome with stabilization appliances compared to localized occlusal interference appliances and found no significant differences between groups. None of these studies met level I criteria.

Anterior Positioning Appliances. Two RCTs evaluating anterior positioning appliances were reviewed. Anderson et al[48] compared anterior positioning appliances to stabilization appliances for management of pain due to TMJ disc displacement with reduction and found anterior positioning appliances more effective in reducing jaw pain, joint noises, and locking. Both types of appliances were worn 24 hours per day. Davies and Gray[44] also compared the efficacy of anterior positioning appliances when worn 24 hours per day, at night only, or during the day only and found greater improvement in joint pain to palpation, joint sounds, and range of motion when worn 24 hours per day. The authors did note the possibility of occlusal changes,

such as posterior open bites, occurring when the appliances are used full-time. Since the occlusal changes reversed and symptoms continued to improve after terminating the use of the appliances, these authors suggested that there was no justification for completing "Phase II dental treatment," that is, a permanent change to restore the occlusion through restorative dentistry or orthodontics. Neither of these studies met level I criteria.

Soft Resilient Appliances. In two RCTs, soft resilient stabilization appliances were compared to no treatment or placebo. Wright et al[49] compared well-adjusted soft appliances with palliative treatment and no treatment in subjects with masticatory myofascial pain and found soft appliances were more effective than either palliative treatment or no treatment. Elsharkawy and Ali[50] compared four treatments for TMJD pain: soft appliance at night only, Acuhealth unit use only, the soft appliance combined with Acuhealth use, and placebo Acuhealth. The Acuhealth unit is an electronic acupuncture point stimulator. At 3 months, the three active treatment groups had a higher percent of pain-free patients than the placebo group. An RCT by Carmeli et al[51] compared a soft anterior positioning appliance to manual mobilization and exercises and found that the mobilization group was superior to the soft appliance group in total pain and range of motion. These single studies did not meet level I quality criteria. As noted earlier, the study by Truelove et al[40] found that soft stabilization appliances with self-care did not add any additional improvement in symptoms when compared to self-care treatment alone.

Anterior Bite Appliances. Four RCT studies evaluated the anterior bite plane and found conflicting results. Shankland et al[52] evaluated changes in tension-type and/or migraine headaches and found the nociceptive trigeminal inhibition (NTI) appliance, a small anterior bite plane, decreased headache frequency but not headache intensity compared to a control bleaching appliance with a high NNT of 10. Magnusson et al[53] compared the NTI appliance to stabilization appliance for TMJD symptoms including headache and found the stabilization appliance to be better than the NTI for improving TMJD pain, with an NNT of 3. Neither study met minimum criteria to reduce systematic bias. The adverse effects of the NTI included 1-mm mobility of the incisors in 12% of subjects and the development of an anterior open bite in one subject due to the appliance covering only the anterior teeth. Jokstad et al[54] also compared NTI to stabilization appliances in patients with TMJD and found that both groups had equal efficacy at 3 months. Dahlström and Haraldson[46] also compared the anterior bite plate to the stabilization appliance and found greater improvement in TMJD pain and clinical signs with the stabilization appliance.

Discussion

This systematic review and meta-analysis reviewed 47 publications of 44 RCTs involving 2,218 subjects and intraoral appliances. Of these, 10 studies were able to be combined in a meta-analysis that demonstrated that hard stabilization appliances have evidence of pain improvement in TMJD compared to both non-occluding control appliances (n = 7)[18–26] and no treatment (n = 3).[28–30] The NNT values in Tables 1 through 4 also provide some idea of the extent of benefit that an intervention can provide and is the number of patients that need to be treated for one to benefit compared with the control in a clinical trial. The NNT values ranged from 2 to 6, demonstrating that most patients improve with an appliance compared to the control appliance or no treatment.

The qualitative review of RCTs of different types and applications of appliances, including soft stabilization appliance, anterior positioning appliance, and anterior bite plane appliance, demonstrated some evidence of their efficacy in reducing pain, but the evidence is limited to single studies with small sample sizes and low-quality methods that make conclusions weak.

Anterior positioning appliances show some support for their use in reducing intermittent joint locking, but neither of the studies met level I criteria, suggesting that the results are preliminary. However, given that the use of anterior positioning appliances 24 hours per day have the potential for irreversible changes to the occlusion, such as posterior open bites, these appliances should be used part-time and closely monitored.

Anterior bite appliances may have some efficacy in reducing TMJD pain and headache, but since these are single studies that did not meet level I quality criteria, more studies are needed for definitive conclusions. However, considering these appliances have the potential for adverse events, including anterior open bites, tooth mobility, and accidental aspiration or ingestion, and have no better efficacy than stabilization appliances, the authors suggest caution in their use.

Furthermore, the comparison of appliances to other treatments including self-care, acupuncture, physical medicine, short-term behavioral therapies, and some pharmacological treatments found that

each has some evidence of equal efficacy to appliances and can be considered as initial or concurrent treatment for TMJD. Behavioral therapy has equal efficacy to appliances short-term but may have more positive effects than appliances in the long-term, perhaps due to its addressing of the underlying central etiologies more effectively than appliances. It is suggested that more studies with consistent methodology are needed for definitive conclusions of the efficacy of different types of appliances and their comparative effectiveness relative to other common TMJD treatments. In addition, since these treatments have different mechanisms associated with efficacy, delineating any additive effects of combining treatments within a multimodal intervention model is needed.

Although this review suggests that appliances have a positive therapeutic effect, the mechanism of this effect in reducing TMJD pain is still unclear, with few studies examining this matter. It is possible that multiple effects may be present, such as allowing an orthopedically comfortable jaw position, reducing masticatory muscle activity and joint loading, increasing patients' awareness and ability to reduce jaw and oral habits, and altering the functional relationships in the TMJ.

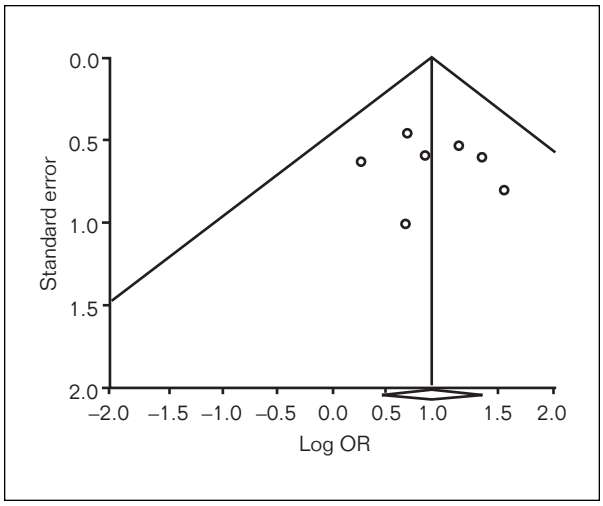


Fig 2 Funnel plot evaluating the potential for publication bias in the seven studies that are included in the Table 5 meta-analysis of stabilization appliances compared to control appliances. The plot is a scatterplot of the treatment effects estimated from individual studies (horizontal axis) against a measure of study size (vertical axis) based on OR. A symmetrical inverted funnel shape of results suggest that publication bias was unlikely in this meta-analysis.

Methodological Limitations

There are several weaknesses of this review that need to be considered. With any systematic review, the validity of results is based on both the ability to include all published reviews, the potential biases of reviews, and the quality of the RCTs reviewed. First, since this was an English-language review, there may be excellent studies in other languages that could have been included. While the review attempted to capture the majority of the published literature with both electronic and manual reviews, some literature that would have relevance to this review may have been missed. Furthermore, there have been many additional RCTs published since this review was completed. Two studies[26,40] from 2006 were added during the review process since they were high-quality studies with good sample sizes. Other RCTs beyond 2006 will be included in a future supplement to this review. Publication bias that makes it easier to publish and find studies with a "positive" result may affect the results of these meta-analyses. However, Figure 2 shows a funnel plot for the meta-analysis conducted in Table 5, suggesting publication bias was minimal. Another factor is that the outcome selected for comparison of studies was pain and that other outcomes may be as appropriate, such as dysfunction, disability, and adverse events. Pain is a subjective experience influenced by the patient's experiences, setting, and relationship to providers. Both the measurement of pain and its conversion to a comparable measure may have introduced bias into the meta-analyses. However, other outcome measures including disability and adverse events were not included in many studies, and thus were not able to be compared. Finally, it is important to note that the OR does not approximate the relative risk or outcomes in any of these studies but can illustrate an effect, either positive or negative with regard to the interventions. For example, an OR of 1.5 does not mean 50% more pain, but that the odds of having pain are 1.5 times higher in one group over another.

Methodological problems in the majority of the studies that were reviewed preclude definitive conclusions and point to the need for more well-controlled RCTs with improved methods. For example, the small sample sizes of almost all of the research limits conclusions and, in some cases, may generate type II errors and false negative results. The percent of CONSORT criteria that were met overall was low, with a mean of 55% of criteria met for RCTs of intraoral appliance treatment and only 45% of criteria met for RCTs of occlusal treatments. Only seven of the 44 stabilization appliance studies met all level I criteria.

In the meta-analysis of hard stabilization appliance versus non-occluding appliances, four studies demonstrated a benefit compared to non-occluding appliances, and three other studies showed no difference. Several factors in the study design may have contributed to these diverse results. In Table 2, the more positive studies favoring stabilization appliances had baseline pain levels of greater than 7 on a scale of 0 to 10, whereas the other studies had baseline pain levels less than 5 of 10. This suggests the possibility of a ceiling effect that occurs in studies having too low pain levels at baseline. Alternatively, the benefit associated with appliances may occur only in patients with more severe pain. Finally, these benefit estimates are limited to some extent by the fact that a palatal non-occluding appliance may not represent a true placebo; to the contrary, this appliance may also modify oral behavioral patterns and, thus, muscle pain as an active effect of the appliance. There have been no studies comparing stabilization appliances to other inactive placebos such as placebo medications. Other problems that may influence study results included drop-outs and loss to follow-up, lack of washout period for concomitant treatments, and possible differences in treatment compliance.[5]

Conclusions drawn from this systematic review, whether qualitative or the result of mathematical synthesis, are limited by the fact that outcomes associated with interventions can differ with respect to many methodological variables including the measures used, the chronicity of the condition, the specific diagnoses being treated, and comorbidities. For example, since most studies in this review were not designed to differentiate between joint versus muscle disorders, or use diagnostic criteria to define subtypes within these categories, the true treatment effects may be reduced by the lack of diagnostic precision. The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) had been developed to improve this situation.[55] In addition, there have been efforts to standardize outcomes in chronic pain clinical trials with use of IMMPACT recommendations, which is a collaboration between pain researchers, industry, and government agencies.[56,57]

Comparison to Other Reviews

There are several other systematic reviews involving appliances for TMJD that have been published.[12,58–61] In addition, two reviews were published involving electromyographic (EMG) biofeedback and acupuncture for TMJD that included appliance studies.[62,63] Although most of the same RCTs were reviewed, the present systematic review differs from the above reviews because it is the first to combine data from multiple RCTs into a meta-analysis. Despite differences in systematic review methods, the conclusions of these reviews are similar and provide support that appliances can consistently reduce TMJD pain.

Forssell et al[58] found that stabilization appliances were more effective for TMJD pain than no-treatment controls in three trials and were equal to no-treatment controls in 12 trials. The review by Kreiner et al[59] concluded that occlusal appliances do not function directly in reducing masticatory pain, but possibly as a behavioral intervention. The authors stated: "The behavioral effect of an occlusal appliance is likely the result of jaw function changes induced by both wearing a device and being in the study. In fact, when occlusal appliances were compared directly with a true behavior-modifying therapy, they were shown to be equal in efficacy." Turp and colleagues[60] also conducted a systematic review of 13 articles, representing nine RCTs, and also concluded that "most patients with masticatory muscle pain are helped by the incorporation of a stabilization splint" but was unclear whether success is due to the specific effect of the appliance. They found that a hard stabilization appliance appeared to yield a better clinical outcome than a soft appliance, a non-occluding palatal appliance, physical therapy, or body acupuncture. Al-Ani et al[61] also found evidence to suggest that the use of appliances for the treatment of TMJD may be beneficial for reducing pain severity and tenderness on palpation compared with no treatment. Each of these papers emphasized the need for further, rigorous RCTs that consider the method of allocation and outcome assessment, have large sample sizes, sufficient duration of follow-up, and standardization of the outcomes of the treatment of TMJD.

Clinical Considerations of Appliances

This review suggests several important clinical considerations about the rationale, implementation, and adverse events associated with the three general types of appliances including stabilization, anterior positioning, and anterior bite planes.

Hard Stabilization Appliances. These typically cover all maxillary or mandibular teeth and, in most studies, have bilateral posterior tooth contacts, canine lateral guidance, and incisal anterior guidance. Other terms for these appliances include splints, orthotic, bite guard, Michigan splint, and flat bite plane. There are no studies that suggest

maxillary or mandibular appliances have efficacy over the other but rather depend on patient and clinician preference and comfort. These appliances are intended to reduce TMJD pain and dysfunction by producing orthopedically comfortable jaw positions, reducing masticatory muscle activity and TMJ loading, and increasing patient awareness of oral parafunctional habits. They also can prevent tooth wear and periodontal trauma. Soft resilient full coverage appliances may be less expensive than hard stabilization appliances but need to be adjusted similar to hard appliances to allow comfort and efficacy.[49,50] In most cases, stabilization appliances are comfortable to wear unless they are bulky, tight, or ill-fitting, so they need to be well adjusted to facilitate patient comfort, stability, and compliance. Although the percent of adverse events was not provided in most of these studies, patients should be monitored regularly for evidence of mucosal ulceration or inflammation, tooth pain, mouth odors, speech difficulties, dental caries, tooth mobility, and occlusal changes.

Anterior Positioning Appliances. These appliances reposition the mandible and condyle anteriorly to improve the disc-condyle relationship and biomechanics of joint function. They have also been called mandibular orthopedic repositioning appliances, anterior positioning appliances, and disc-repositioning appliances. The primary indication for anterior positioning appliance therapy is TMJ disc displacement with reduction that is associated with painful clicking and/or intermittent locking. The appliance covers all teeth in the maxillary arch and provides occlusal indentations for the opposing posterior teeth. When the opposing teeth fully engage these occlusal guides, the condyle is held in a more anterior position during closing and opening movements, and the improved disc-condyle functional relationship results in a decrease in TMJ locking and noise and the associated joint or muscle symptoms. When this appliance is worn 24 hours per day for a prolonged period, it may cause a permanent anterior mandibular position and a posterior open bite. Thus, anterior positioning appliances are usually recommended to be worn part-time while sleeping.

Anterior Bite Appliances. These are usually fabricated for the maxillary arch and adjusted to provide occlusal contacts with the mandibular anterior teeth and no posterior tooth contact. Other terms for this include the NTI splint, anterior bite splint, and anterior jig appliance. The NTI and anterior jig appliances differ from anterior bite planes in that typically only the maxillary central incisors are covered, whereas the anterior bite plane usually covers all six maxillary anterior teeth with occlusal contacts with the six lower anterior teeth. It must be noted that partial coverage appliances may contribute to tooth movement and malocclusion as an adverse event if worn full-time.

Posterior Partial Coverage Appliances. These have occlusal contact on the posterior teeth only. Other variations of this appliance include the Gelb splint and pivotal, distraction, or localized occlusal interference splints. The posterior occlusal contacts are intended to change the biomechanics of the muscle and joints, as well as suppress muscle function and oral habits, thus decreasing pain due to repetitive strain. However, when partial coverage appliances are used full-time, adverse events of tooth mobility, tooth movement, and an anterior open bite can result.

This review also suggests that the efficacy of intraoral appliance therapy may depend not only on *appliance selection* but *patient selection* as well, since some patients benefit more from appliances than other patients. For example, the results from Raphael and Marbach[23] suggested that people with widespread pain are less likely to benefit from an appliance. Patients with TMJD may also have a number of comorbid conditions, such as fibromyalgia, neuropathic pain, migraine, depression, anxiety, bruxism, xerostomia, and other contributing factors that increase the risk for treatment failure.[2] Single treatment strategies such as an appliance can also fail due to long-standing maladaptive behaviors, attitudes, and lifestyles that accompany a chronic condition. For these reasons, clinicians need to determine the level of complexity and extent of comorbid conditions in each patient prior to treatment and match the complexity of the patient to the complexity of the treatment strategy. Patients with recent pain onset, limited treatment history, no comorbid conditions, and few behavioral and psychosocial contributing factors are simpler to manage by a single clinician with single treatments. Patients with comorbid conditions, persistent pain longer than 6 months, behavioral and psychosocial problems, frequent use of health-care services or medication, and lifestyle disturbances such as sleep and work interference are more complex to manage and require a multimodal treatment strategy with an interdisciplinary team.

Thus, appliances can be considered as part of a broader rehabilitation treatment program to encourage healing, normal function, and restoration of normal activities. In many TMJD cases, the use of other interventions such as self-care, exercise, physical therapy, and pharmacological treatments can improve the condition and preclude the

need for an appliance. Some of the RCTs reviewed suggest that the modest improvement that patients can receive with appliances can be enhanced with the addition of other evidence-based treatments, such as self-care, physical medicine, behavioral therapy, and pharmacological care. Complex patients with multiple contributing factors and comorbid conditions may require a team, such as a physical therapist and/or health psychologist, to improve the overall potential for success.

Future Research Agenda

In addition to the points noted above that still need to be addressed, other questions, such as what factors are involved with treatment failure and the mechanism of appliance efficacy, remain to be answered. Furthermore, the differential costs, comparative effectiveness with other treatments in diverse clinical settings, and frequency of adverse events are important to determine. When RCTs are conducted, careful attention should be given to methodological issues. Consistent outcomes, study designs, and multicenter populations will not only provide better evidence of efficacy, but also improve generalizability and synthesis for meta-analyses. Since RCTs are difficult and costly to conduct, it is recommended that future RCTs for TMJD be multisite and well-designed with adequate sample sizes and controlled for the specific diagnostic subtypes represented in the study samples. The comparison groups should include other treatments as well as placebo controls, when appropriate, measure multiple outcomes at both short-term and long-term follow-ups, and identify risk factors for delayed recovery.

Conclusions

The review concludes that hard stabilization appliances when adjusted properly have good evidence of modest efficacy in the treatment of TMJD pain when compared to non-occluding appliances and no treatment and are, at least, equally effective in reducing TMJD pain when compared to physical and behavioral therapies and pharmacological and acupuncture treatments. Other types of appliances, including soft stabilization appliances, anterior positioning appliances, and anterior bite appliances, have some RCT evidence that they are effective in reducing TMJD pain. However, the potential for adverse events with these appliances is higher and suggest close monitoring in their use.

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