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REVIEW

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Efficacy of stabilization splints for the management of patients with masticatory muscle pain: a qualitative systematic review

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Abstract This study aimed at providing an answer to two clinical questions related to patients with masticatory muscle pain: 1) Does the use of a full-coverage hard acrylic occlusal appliance (stabilization splint) lead to a significant decrease of symptoms? and 2) Is the treatment success achieved with a stabilization splint more pronounced than the success attained with other forms of treatment (including placebo treatment) or no treatment? A systematic search was carried out in different electronic databases, supplemented by handsearch in four selected dental journals and by examination of the bibliographies of the retrieved articles. Thirteen publications, representing nine controlled clinical studies, could be identified. Reporting quality of most studies as assessed with the Jadad score ranged from 1 to 5. Based on the currently best available evidence it appears that most patients with masticatory muscle pain are helped by the incorporation of a stabilization splint. Nevertheless, evidence is equivocal if improvement of pain symptoms after incorporation of the intraoral appliance is caused by a specific effect of the appliance. A stabilization splint does not appear to yield a better clinical outcome than a soft splint, a non-occluding palatal splint, physical therapy, or body acupuncture. The scarcity of current external evidence emphasizes the need for more and better clinical research.

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Introduction

Muscle pain has been known for some time to be the leading cause of discomfort in the head and neck area [5], and masticatory muscle pain (myofascial pain) is the most common diagnosis among the various conditions encompassed by the term *temporomandibular disorders* (TMDs) [58, 81]. For about 40 years [76], stabilization splints have been one of the preferred modalities in the management of TMDs [72], although a great variety of other treatments are currently in use among clinicians [3, 96].

In the early 1990s, David Sackett and his colleagues from McMaster University, Hamilton (Ontario, Canada), introduced the concept of evidence-based medicine (EBM), "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" [82]. The practice of EBM relies on three equally important elements: the best research evidence from a systematic search of the literature (mostly from patient-centered clinical research), individual clinical expertise (clinical skills and past experience), and patient values (preferences, concerns, expectations) [83]. The application of EBM comprises several steps: formulation of an important and answerable clinical question derived from a clinical problem; selection of the most appropriate information source(s) and the most appropriate search strategy; and appraisal and application of the evidence found. In many editorials and articles, the introduction of EBM into dentistry has been encouraged. However, the incorporation of EBM into clinical decision-making depends heavily on the availability of external clinical evidence.

Over the past two decades, a few reviews about the effect of occlusal appliances for the management of TMDs have been published (e.g., [2, 10, 11, 30, 31, 52]). In these

publications, however, no distinction among specific TMD diagnoses such as masticatory muscle pain was made. The present paper, therefore, focuses on the most common clinical scenario in the management of TMDs by dentists: the management of a patient, who suffers from pain in the masticatory muscles, with a bite splint. Specifically, by systematically searching the literature, we want to provide an answer to the following two clinical questions. In patients with masticatory muscle pain:

1. Does the use of a full-coverage hard acrylic occlusal appliance (stabilization splint, Michigan splint) lead to a significant decrease of symptoms?
2. Is symptom improvement achieved with a stabilization splint more pronounced than the success attained with other forms of management (including placebo treatment) or no treatment?

Considering the great number of patients suffering from myofascial face pain, an answer to our questions would be of considerable clinical relevance.

Methods

To identify all relevant articles and dental congress abstracts of randomized controlled clinical trials (RCTs), in which stabilization splint therapy was used and compared to no therapy or concurrent treatments, the following information sources and search strategies were used:

Search in electronic databases

- *Ovid Medline* (online database). The subject terms included in the search as well as the search strategy are listed in Table 1.
- *Cochrane Library* (online database). The search term was "splint."
- *ISI Web of Science* (Science Citation Index Expanded) (online database). The option "Full Search" was chosen. The keywords included in the search were "bite splint," "occlusal appliance," "occlusal splint" and "splint."
- *Japana Centra Revuo Medicina* (CD-ROM). The search in this database was carried out in a similar way as in Medline.

The following Japanese terms were used:

- Randomized controlled trials: *Musakui taisyo shiken, Musakui hikaku shiken*
- Clinical trials: *Rinsyo shiken*
- Random allocation: *Randamu waritsuke*
- Double-blind method: *Nijuu mouken shiken*
- Controlled clinical trials: *Hikaku rinsho shiken*, *Hikaku taisho rinsho shiken*
- Myofascial pain dysfunction (MPD) syndrome: *Kinmaku totsuu kinoushogai shoukougun*, *MPD shoukougun*
- Temporomandibular joint (TMJ) dysfunction syndrome: *Gaku-kansetsusho*, *Gaku-kinouijo*, *Gaku-kinoushogai*, *Tougai kagakushogai*
- Masticatory muscle: *Soshaku-kin*
- Myofascial pain syndrome: *Kinmaku-totsuu shoukougun*, *Kinmakutsuu shoukougun*
- Pain: *Totsuu*
- Bite splint: *Baito supurinto*, *Baito purein*, *Kougou kyojo*
- Occlusal appliance: *Okuruuzaru apuraiansu*
- Occlusal splint: *Okuruuzaru supurinto*
- Splint: *Supurinto*

Handsearch in selected journals

The most important, peer-reviewed journals of Austria, France, and Germany, which are currently not included in Medline, namely *Actualités odonto-stomatologiques* (Medline listing discontinued in 1991), *Stomatologie* (formerly—until 1996—*Zeitschrift für Stomatologie;* discontinued in Medline in 1990), and *Deutsche Zahnärztliche Zeitschrift* (listing in Medline discontinued in 1992), were handsearched through December 2003.

In addition, the abstracts published in the special issues of the *Journal of Dental Research*, which relate to the annual General Session and Exhibition of the International Association for Dental Reseach (IADR), were reviewed for the years 1990–2003.

Bibliography search of the identified publications and reviews

The references listed in the relevant articles were perused to identify additional publications pertinent to our clinical question. In addition, the reference lists of relevant review articles were checked.

Inclusion/exclusion criteria

Only trials in which patients had explicitly been diagnosed with masticatory muscle (myofascial) pain were considered. Studies in which additional diagnoses were allowed (e.g., TMJ arthralgia/osteoarthritis; disk interference disorders), were excluded from further analysis. Similarly, articles in which unspecific terminology was used to characterize the investigated patient samples (e.g., "mandibular dysfunction", "[TMJ] pain dysfunction syndrome" or "temporomandibular disorders") were not considered because these terms may also include TMJ-related conditions.

There were neither age restrictions of study participants nor language restrictions for inclusion. The last update of the search was made on 11 December 2003.

Table 1 Search strategy and results in Ovid Medline (date of the search: 11 December 2003)

	Search terms	Hits	Relevant
#1	trial$.mp. or Clinical Trials/ or Randomized Controlled Trials/	328835	–
#2	Temporomandibular Joint Disorders/ or Masticatory Muscles/ or Craniomandibular Disorders/ or Temporomandibular Joint Dysfunction Syndrome/ or myofascial pain dysfunction syndrome.mp. or Myofascial Pain Syndromes/	15178	–
#3	Occlusal Splints/ or bite splint$.mp. or Splints/	6140	
#1 AND #3		151	[17, 28, 98]
#2 AND #3		964	[7, 17, 28, 47, 80, 86, 98]

Assessment of reporting quality

The reporting quality of the identified articles of RCTs was assessed independently by two reviewers (J.C.T, A.H.). For this purpose, the quality score developed by Jadad et al. [46] was used. The Jadad scale consists of five items which focus on three dimensions of internal validity (randomization; double blinding; description of withdrawals and drop-outs). Uncertainties on data interpretation and discrepancies in scoring the reporting quality were resolved by discussion between the two reviewers.

Results

Altogether, 13 relevant publications, representing nine clinical studies, were identified by the two reviewers. The articles of six studies were published in English, the rest in Dutch [98], German [86], and Japanese [84]. Two studies were carried out in Sweden, two in the USA, one in Canada, one in Germany, one in Italy, one in Japan, and one in the Netherlands. Only two trials [91, 98] were conducted over an observation period of at least 1 year.

The results of the search in Ovid Medline are displayed in Table 1. Seven articles listed in this database are relevant to our question [7, 17, 28, 47, 80, 86, 98].

The search in the Japanese database yielded one hit [84]. The searches in the Cochrane Library and in ISI Web of Science identified no additional publications.

The handsearch in the special issues of the *Journal of Dental Research* yielded five meeting abstracts [42, 43, 44, 90, 91]. All five abstracts referred to the same prospective trial. In the following, only the two most recently published abstracts, which complement each other, are considered [44, 91].

The bibliography search of the identified publications identified no additional publication. (In one article [78], a paper from an Argentinean dental journal was cited [79] in which it was allegedly reported "that splint therapy associated with diazepam, in this order, produced more effective TMD pain relief when these therapies were applied exclusively." In the cited article by Roldan et al. [79], however, bite splints were not mentioned.)

The major characteristics (patients, inclusion and exclusion criteria, treatment groups, number of participants, study duration, outcome variables for treatment success) and findings (improvement of signs and symptoms, authors' conclusions, reviewers' comments) of the publications are summarized in Tables 2 and 3. In all but one study [86], stabilization splints were fabricated in the maxilla. Masticatory muscle pain was an outcome variable in every study. In all but two trials [7, 17], functional parameters such as mandibular mobility and TMJ sounds were also considered. In three articles [28, 47, 86], Helkimo's Clinical Dysfunction Index (CDI) [38] was used.

The methodology of the clinical investigations differed in several important aspects:

1. Recruitment of study participants: in all but two trials, study participants were restricted to patients seeking care at or referred to clinical centers specialized for the diagnosis and management of orofacial pain. In the remaining two studies, participants were exclusively [80] or partly [17] recruited by notices in local newspapers or journals.
2. Number of participants: the number of participants included in most studies was small. The total number of participants lay between 26 [86] and 168 individuals [91] (Table 2).
3. Description of randomization/blinding: the method of randomization was described only in two publications [28, 86]. Five studies [17, 28, 47, 80, 98] used a blinded design: the examiner who evaluated the treatment was blind to the type of treatment the patient received. Lack of (double-)blinding leads to an overestimation of the treatment effect [85]. (It is controversial whether or not double-blinding is possible in trials comparing active and "placebo" appliances.) The publication by Ekberg et al. [28] is the only one with an appropriate description of both randomization *and* blinding, and with a Jadad score of 5 (Table 4). (It has to be considered that the reported information about the randomized studies of Huggins/Truelove et al. [44, 91] as well as Sakuma et al. [84] was limited in the available meeting abstracts.)
4. Appliance use: in three trials [17, 80, 86], the appliance was worn (nearly) 24 h/day. In four other studies, the splint was worn only at night [7, 28, 47, 98]. In the published meeting abstracts [44, 84, 91], no pertinent information was given.
5. Treatment provided in the control group(s): Michigan splints were compared with the following alternative approaches:

- Non-occluding palatal appliance [17, 28, 80, 84]
- Anteriorly occluding maxillary splint [86]
- Full-covering maxillary soft appliance [44, 91]
- Occlusal adjustment [98]
- Physical therapy [98]
- Body acupuncture [47]
- Different treatments [44, 91]
- No treatment [7, 47]

In one study [80], physical therapy and verbal support were given to each patient included in the trial.

Based on the results described in the identified publications, our two clinical questions can be answered as follows:

1. Management of myofascial face pain with a stabilization splint worn at night is likely to lead to a statistically significant short-term improvement when compared with no treatment [47].
2. Current evidence is inconclusive about the question of whether the observed improvement during and after stabilization therapy is greater than the one achieved by a non-occluding palatal appliance (i.e., a "placebo" splint). In two recently conducted trials [28, 84], there was a statistically more significant decrease of pain and functional impairment in the group that received a

Table 2 Characteristics of RCTs in which stabilization appliance therapy in patients with masticatory muscle pain was investigated

Study	Patients	Inclusion criteria	Exclusion criteria	Treatment groups	n	Study duration
Rubinoff *et al.* [80]	Patients responding to a notice in a newspaper (Buffalo, New York, USA)	• Diagnosis of MPD: "a complaint of facial pain and one or more of the following: limited jaw opening, joint sounds, deviation on opening, and tenderness on muscle palpation."	• Clinical or radiological evidence of TMJ pathology • Complete upper or lower denture • Recent major occlusal changes • Third molar problems (*e.g.*, pericoronitis) • Previously worn a appliance • Alternative diagnosis	(1) Maxillary stabilization appliance (24h/day) (2) Non-occluding palatal appliance (24h/day) • Additional treatment in both groups: - support by the dental therapist - physical therapy (moist heat; daily home exercise)	(1) 15 (2) 11/15	6 weeks
Siegert & Gundlach [86]	From the clinic population of the Dental School, University of Hamburg (Germany)	• Myofascial pain • Possibly: No satisfactory pain reduction by previous patient education and physical therapy (n=26/72)	• Evidence of TMJ pathology	(1) Mandibular (!) stabilization appliance (use: as often as possible) (2) Maxillary anterior appliance (Sved appliance; "relaxing appliance") (use: as often as possible)	(1) 12 (2) 12/14	2.2 months (average)
Johansson *et al.* [47]	Consecutive series of patients referred to the Department of Stomatognathic Physiology, Faculty of Odontology, University of Gothenburg (Sweden), for TMD treatment	• History including signs and symptoms of TMD • Complaints of headache and/or facial pain • Clinical examination demonstrating tenderness to palpation in the masticatory muscles • Complete natural dentition (single crown permitted)	• Individuals with psychologic / psychogenic factors, trauma, surgery, or systemic joint, muscle, or skin diseases influencing the symptoms • Radiologic evidence of TMJ, facial skeleton, or tooth pathology • Previous acupuncture or stomatognathic therapy for the treatment of the disorder in the individuals selected	(1) Maxillary stabilization appliance (at night) (2) Body acupuncture (3) No treatment	(1) 15 (2) 15 (3) 15	(1) 3 months (2) 3 months (3) 2 months

Table 2 (continued)

Study	Patients	Inclusion criteria	Exclusion criteria	Groups	n	Study duration
Dao *et al.* [17]	(a) Recruited through announcements published in local journals; or (b) referred by dentists to the research clinic, University of Montreal (Canada)	• Men and women between 16 and 45 years seeking treatment • Chief complaint of frequent pain (at least four times/week) in the masticatory muscles of at least 12 weeks duration • Positive report of tenderness to palpation of at least three sites in the masticatory muscles	• Clinical or radiological evidence of TMJ pathology • Previous occlusal treatment with or without appliances • Complete dentures or removable partial dentures with distal extensions • Metabolic disease • Neurologic disorders • Vascular disease • Neoplasia • History of psychiatric disorders • History of drug abuse • Recent facial or cervical trauma • Currently receiving medication or other treatments	(1) Stabilization appliance (24h/day) (2) Stabilization appliance (restricted use: 30 minutes at each appointment = passive control) (3) Non-occluding palatal appliance (= active control) (24h/day)	(1) 22 (2) 19/20 (3) 20/21	2 weeks baseline + 8 weeks treatment
Cane *et al.* [7]	Patients referred to the Physical Medicine and Rehabilitation Service, S. Giovanni-Molinette Hospital, Turin (Italy)	• Cervical pain • Contractures of the neck muscles • Reduction of cervical mobility • Masticatory muscle pain (n=33)	• Clinical or radiological evidence of arthrosis • Previous treatment for pain in the neck region • History of trauma to the cervical region • Cervical pain related to tumor • Congenital malformation of the cervical-occipital junction	(1) Maxillary stabilization appliance (night only) (2) No treatment	(1) 18 (2) 15	2 months

Table 2 (continued)

Study	Patients	Inclusion criteria	Exclusion criteria	Groups	n	Study duration
Truelove *et al.* [91]	Clinic patients, Department of Oral Medicine, University of Washington, Seattle (USA)	• RDC/TMD diagnosis of myofascial pain		(1) Stabilization appliance (use: not reported) (2) Soft appliance (use: not reported) (3) Conservative treatment without a appliance	(1) 65 (2) 55 (3) 48	12 months
Huggins *et al.* [44]	"	"		"	(1) 47 (2) 38 (3) 33	"
van der Glas *et al.* [98]	Clinic patients, University Medical Center Utrecht (Netherlands)	• At least two months of myogenous TMD complaints • Between 18 and 65 years old		• Patients without occlusal interferences: (1) Maxillary appliance (use: evening and night) (2) Physical therapy • Patients with pronounced occlusal interferences: (1) Maxillary appliance (use: evening and night), followed by (not earlier than 6 weeks later) occlusal adjustment (combination therapy) (2) Occlusal adjustment	*(average)* (1) 35 (2) 36 (1) 25 (2) 22	*(average)* 1 year 24 weeks 1 year 16 weeks 1 year 27 weeks 1 year 18 weeks
Ekberg *et al.* [28]	Patients referred for (and requesting) TMD treatment to the Department of Stomatognathic Physiology, Faculty of Odontology, Malmö University (Sweden)	• Diagnosis of myofascial pain with or without limited opening, according to the RDC/TMD • Self-assessed myofascial pain of at least 40 mm on a 100-mm VAS	• TMJ pain • Previous TMD treatment • Complete dentures • History of psychiatric disorders • Symptoms related to disease in other components of the stomatognathic system	(1) Maxillary stabilization appliance (use: not reported) (2) Non-occluding palatal appliance (= active control)	(1) 30 (2) 30	10 weeks
Sakuma *et al.* [84]	Clinic patients, Aichigakuin University Dental Hospital (Japan)	• Masticatory muscle pain		(1) Stabilization appliance (use: not reported) (2) Non-occluding palatal appliance	(1) 20 (2) 20	12 weeks

TMJ temporomandibular joint, *MPD* myofascial pain dysfunction, *TMD* temporomandibular disorders, *CMD* craniomandibular disorders, *RDC/TMD* Research Diagnostic Criteria for Temporomandibular Disorders [22], *CDI* Clinical Dysfunction Index [38], *VAS* visual analog scale, *(?)* not explicitly reported in the paper

Table 3 Characteristics of studies in which stabilization appliance therapy in patients with masticatory muscle pain was investigated

Study	Outcome variables for treatment success	Improvement of signs	Improvement of symptoms	Authors' conclusion	Reviewers' comments
Rubinoff *et al.* [80]	*Signs* - Maximum interincisal distance - Mandibular deviation - Joint sounds - Tenderness on muscle palpation - Tenderness on TMJ palpation *Symptoms* - Pain intensity (pain diary) - Subjective symptom improvement (treatment success)	*Within-treatment-groups pre-post-improvement* • Statistically significant for stabilization group only: joint sounds, palpation *Between-groups post-treatment differences* • No statistically significant differences between the groups	*Within-treatment-groups pre-post-improvement* • Statistically significant for both groups: pain intensity *Specific symptoms* Symptom improvement (= moderate, great, or complete) *Treatment groups* (1) 87% (13/15) (2) 77% (10/13) *Between-groups post-treatment differences* • No statistically significant differences between the groups	Average pain intensity on a scale from 0 to 5 (0 "no pain at all"; 5 "most intense pain ever experienced") after treatment: stabilization appliance group 0,73; non-occluding appliance group 0,98. "In summary, none of the measures showed significant differences in treatment effectiveness between the groups that received the occluding splint and the group that received the nonoccluding splint." "...both conventional and non-occluding appliances seem to relieve symptoms equally."	• Randomization of patients. • Blinded evaluation: clinical examiner unaware of patient group affiliation. • Small sample size. • Significantly lower pretreatment pain levels in the stabilization appliance group at the beginning of the study: average pain intensity on a scale from 0 to 5: stabilization appliance group 1,27 (n=15); non-occluding appliance group 2,07 (n=11). [cf. 61]
Siegert & Gundlach [86]	*Signs* - Muscle palpation - CDI *Symptoms* - Masticatory muscle pain	*Within-treatment-groups pre-post-improvement* • Symptom improvement ("treatment success") in both treatment groups *Between-groups post-treatment differences* • Statistically greater symptom improvement in the stabilization appliance group (1) than in the anterior appliance group (2) *Treatment groups* (1) 92% (11/12) (2) 42% (5/12)		"In spite of the small number of patients the statistical evaluation of the results showed stabilizing appliances to be significantly ($p<0.03$) superior to relaxing appliances in the treatment of myofacial [*sic*] pain."	• Randomization of patients. • No blinded evaluation. • Small sample size. • Significantly lower pretreatment CDI score (points and categories) in the anterior appliance group at the beginning of the study.

Table 3 (continued)

Study	Outcome variables for treatment success	Improvement of signs	Improvement of symptoms	Authors' conclusion	Reviewers' comments
Johansson *et al.* [47]	*Signs* - Mandibular mobility - Pain during mandibular movement - Mandibular deviation - Joint sounds - Tenderness on muscle palpation - Tenderness on TMJ palpation - Occlusal condition - CDI [38] *Symptoms* - Subjective dysfunction - Pain intensity - Subjective symptom improvement	*Within-treatment-groups pre-post-improvement* • Statistically significant in both treatment groups: CDI, tenderness to muscle palpation *Between-groups post-treatment differences* • Statistically not significant between treatment groups • Statistically significant improvement in both treatment groups vs. no treatment: CDI	*Within-treatment-groups pre-post-improvement* • Statistically significant in both treatment groups *Between-groups post-treatment differences* • Statistically not significant between treatment groups • Statistically significant improvement in both treatment groups vs. no treatment *Specific Symptom:* Subjective dysfunction *Treatment groups* (1) 86% (2) 90% (3) < 15%	"The two examined treatment modalities have quite different ways of influencing the stomatognathic system..., but with practically the same success rate as measured by the subjective and clinical variables."	• Randomization of patients. • No blinded evaluation.
Dao *et al.* [17]	*Symptoms* - Pain intensity at rest and after chewing on wax - Pain unpleasantness at rest and after chewing on wax - Quality of life	*– not recorded –*	*Within-treatment-groups pre-post-improvement* • Statistically significant in all treatment groups for all 5 outcome variables *Between-groups post-treatment differences* • No statistically significant differences found	"There were no significant treatment effects... for any of the variables under study. However, there was a general reduction in the pain ratings during treatment and an improvement in the quality of life." "This study casts doubt on the therapeutic value of oral appliances."	• Randomization of patients. • Blinded evaluation.

Table 3 (continued)

Study	Outcome variables for treatment success	Improvement of signs	Improvement of symptoms	Authors' conclusion	Reviewers' comments
Cane *et al.* [7]	*Signs (for masticatory muscles)* - Presence of masticatory muscle pain and tension on palpation of the muscle belly and its insertion	*Within-treatment-groups pre-post-improvement* • Reduction in the splint group only (5/18), not in the control group (0/15). Odds ratio: 11.5 (95% confidence interval: 0.6-231.0) *Between-groups post-treatment differences* • Statistically (marginally) significant differences	*– not recorded –*		• Randomization of patients. • No blinded evaluation. • All patients suffered from cervical problems. • The outcome of this study does not add much to answer our question.
Truelove *et al.* [91] / Huggins *et al.* [44]	*Signs* - Muscle and TMJ palpation - Joint sounds - Maximum jaw opening *Symptoms* - Pain level - TMJ sounds - Eating difficulty - Tinnitus - Clenching/bruxism - Jaw locking/catching	*Within-treatment-groups pre-post-improvement* • Statistically significant in the treatment groups *Between-groups post-treatment differences* • No statistically significant differences	*Within-treatment-groups pre-post-improvement* • Statistically significant in the treatment groups *Between-groups post-treatment differences* • No statistically significant differences	"These data suggest that treatments using lower cost alternatives... to hard appliances provide levels of pain control and symptom reduction equivalent to more costly appliance therapy even over an extended period of time." "These data indicate that for the long term clinical outcomes examined, neither the more costly [flat plane hard acrylic] appliance nor the less expensive [soft vinyl athletic mouthguard] is superior to non-appliance therapy."	Only meeting abstract available. • Randomization of patients. • No blinded evaluation (?)

Table 3 (continued)

Study	Outcome variables for treatment success	Improvement of signs	Improvement of symptoms	Authors' conclusion	Reviewers' comments
van der Glas *et al.* [98]	*Signs* Pain intensity during - mandibular movements - traction of the TMJs - palpation of the masticatory muscles and TMJs - clenching in centric occlusion and in eccentric mandibular position *Symptoms* - Pain intensity - Pain frequency - Masticatory muscle stiffness/tiredness - Limited jaw opening - Neck and shoulder pain - Pain in front of the ear - Headache - TMJ sounds	*Within-treatment-groups pre-post-improvement* • Statistically significant in the treatment groups *Between-groups post-treatment differences* • No significant differences between the therapies	*Within-treatment-groups pre-post-improvement* • Statistically significant in the treatment groups *Between-groups post-treatment differences* • No significant differences between the therapies	(a) Patients with low level myogenous TMD signs and symptoms: "Counseling [...] will most likely eliminate any further need for treatment [...].". (b) In more severe cases: "physiotherapy might be preferred as a starting option". Advantages as compared to appliance therapy: 1. similar efficacy; 2. shorter treatment duration; 3. lower costs. (c) In patients with pronounced occlusal interferences: occlusal adjustment. Advantages as compared to appliance therapy: 1. similar therapy efficacy; 2. shorter treatment duration; 3. lower costs.	• Randomization of patients. • Blinded evaluation.

Table 3 (continued)

Study	Outcome variables for treatment success	Improvement of signs	Improvement of symptoms	Authors' conclusion	Reviewers' comments
Ekberg *et al.* [28]	*Signs* - Mandibular mobility - Pain during non-guided mandibular movements - Masticatory muscle and TMJ tenderness on palpation - CDI [38] *Symptoms* - Pain duration, frequency, intensity - Pain at rest and during mandibular movements - Improvement of overall subjective symptoms	*Within-treatment-groups pre-post-improvement* • Statistically significant in the stabilization appliance group only *Between-groups post-treatment differences* • Maximum jaw opening, masticatory muscle tenderness, CDI: statistically significant decrease in the appliance group as compared to the control group	*Within-treatment-groups pre-post-improvement* • Statistically significant in both groups, but more pronounced in the stabilization appliance group *Between-groups post-treatment differences* • Pain frequency and intensity, pain during mandibular movements, improvement of overall subjective symptoms: statistically significant decrease in the appliance group as compared to the control group	"the stabilization appliance can be recommended as a short-term treatment modality for TMD of mainly myogenous origin."	• Randomization of patients. • Blinded evaluation. • High pre-treatment pain intensity.
Sakuma *et al.* [84]	*Signs* - Maximum jaw opening *Symptoms* - Pain level	*Between-groups post-treatment differences* • Statistically significant	*Between-groups post-treatment differences* • Statistically significant	"It is suggested that in patients with masticatory muscle pain, stabilization splints can be an effective therapy." *[Authors' translation from the original article]*	Only meeting abstract available. • Randomization of patients. • No blinded evaluation (?)

TMJ temporomandibular joint, *MPD* myofascial pain dysfunction, *CDI* Clinical Dysfunction Index [38], *(?)* not explicitly reported in the paper

Table 4 Assessment of the quality of the studies by using the quality score proposed by Jadad et al. [46]

Study	Study described as randomized?	Method described *and* appropriate?	Study described as (double) blind?	Method described *and* appropriate / inappropriate?	Description of withdrawals / dropouts?	Jadad score
Rubinoff *et al.* [80]	Yes	Not described	Yes	Yes	Yes (n=4)	4
Siegert & Gundlach [86]	Yes	Yes	No	–	Yes (n=2)	3
Johansson *et al.* [47]	Yes	Not described	Yes	–	Yes (n=0)	3
Dao *et al.* [17]	Yes	Not described	Yes	Yes	Yes (n=2)	4
Cane *et al.* [7]	Yes	Not described	No	–	No withdrawal or dropout in the muscle group	2
Truelove *et al.* [91] / Huggins *et al.* [44]	Yes	Not described	No	–	No	1
van der Glas *et al.* [98]	Yes	Not described	Yes	No	No withdrawal or dropout	3
Ekberg *et al.* [28]	Yes	Yes	Yes	Yes	No withdrawal or dropout	5
Sakuma *et al.* [84]	Yes	Not described	No	–	No	1

stabilization splint. In two other studies of somewhat lower reporting quality and validity as compared to the trial by Ekberg et al. [28] (see Discussion), no statistically significant difference could be found between the two types of appliances [17, 80].

3. A stabilization appliance does not appear to yield a better clinical outcome than a soft splint [44, 91].
4. There is some evidence from one study with a small number of patients that with a (mandibular) stabilization appliance a statistically significant greater symptom improvement can be achieved than with an anteriorly occluding maxillary splint ("relaxing appliance") [86].
5. Evidence is missing that treatment with a stabilization appliance leads to a statistically significant greater improvement of signs and symptoms than body acupuncture [47], physical therapy [98] and occlusal adjustment [98].

Discussion

The present investigation has focused on the effect of hard acrylic stabilization splints on pain located in the masticatory muscles. Our review is the first one that has looked specifically into this question. The available data indicate—at different levels of scientific evidence—that a hard acrylic stabilization splint does not yield a better clinical outcome than a non-occluding palatal appliance, a soft splint, or conservative treatment without a splint such as physical therapy and acupuncture. In the only controlled clinical study in which stabilization splints were compared with a partial-coverage anterior splint—a Sved appliance [88]—, there was a trend for greater symptom improvement in the stabilization splint group. This finding should be interpreted with caution, however, because the sample size was small [86]. In one study [98], occlusal adjustment was carried out. In a recently published systematic review, Koh and Robinson [51] came to the conclusion that there is an absence of evidence that this invasive procedure is an effective therapeutic measure. Therefore, the systematic selective adjustment of the occlusal surface of teeth is not recommended [31, 51, 93].

Within the hierarchy of scientific evidence, systematic reviews are considered to have the highest quality level. These types of publication are carried out to answer one or more focused clinical questions about a topic related to health care [50]. In systematic reviews, it is not always possible to quantitatively combine the data from the identified studies (meta-analysis) [24]. Among other reasons, this may be due to the lack of reported original data or to methodological differences applied in the trials. In that case, a qualitative rather than a quantitative systematic review is carried out [49].

Kalso et al. [49] have noted that the strength of evidence lies in the quality of controlled trials: "Systematic reviews can only be as convincing as the quality of the controlled trials allows." The 13 pertinent publications to answer our clinical question represent nine (mostly short-term) RCTs of varying reporting quality and validity. We have included the meeting abstracts of the RCT by Huggins/Truelove et al. [44, 91] and Sakuma et al. [84], although these reports have not yet been substantiated by more detailed articles in peer-reviewed journals. Of the 13 publications, three [17, 47, 80] were considered in the qualitative systematic reviews on occlusal splints published by Forssell et al. in 1999 [31], Kreiner et al. in 2001 [52], and Al-Ani et al. in 2004 [2], respectively.

We had to exclude a great number of articles. The reasons for exclusion were:

1. Study participants were not randomized (e.g., [8, 33, 36, 74]). Randomization is the most important proce-

dure to avoid selection bias [48]. In general, non-randomized studies overestimate treatment effects [9].
2. Patients with masticatory muscle pain *and* TMJ pain were included in a trial / no clear distinction was made between muscle pain and TMJ pain (e.g., [8, 15, 16, 18, 20, 32, 35, 40, 41, 55, 56, 57, 60, 70, 73, 74, 77, 92, 94, 101]). (Nonetheless, inclusion of the results gained in these studies would *not* have altered the conclusions of the present review.)
3. The effect of stabilization splints was evaluated in patients with TMJ pain (e.g., [25, 26, 27]) or TMJ disk displacement (e.g., [54, 59]).
4. The effect of splint therapy on the accuracy of mandibular movements of patients with masticatory muscle pain was studied (e.g., [64]).
5. The effect of soft occlusal splints on masticatory muscle pain was investigated [102].
6. Multiple simultaneous treatments were carried out (e.g., [14, 37, 39, 69, 78]).
7. No control group was used (e.g., [4, 8, 36, 100]). Without controls, it cannot be excluded that unspecific effects, e.g., spontaneous remission, natural course of the symptoms, regression to the mean, the placebo effect, the Hawthorne effect, biased (favorable) patient's answers, and accompanying therapeutic measures [95], may have been responsible for observed differences among groups.

When appraising articles on clinical studies in a qualitative systematic review, vote counting (determination of the number of articles showing that an intervention works or does not work) should be avoided [49]. Instead, more weight should be given to publications of (a) high reporting quality (i.e., Jadad score 3 to 5) and (b) high validity [49].

In our review, reporting quality of RCTs was assessed with the help of the Jadad score (range: 0–5). Among the many checklists, scales, and indexes that have been suggested for the evaluation of the (reporting) quality of randomized trials, the Jadad score was developed using standard scale development techniques [46]. Since it is the only known validated scale [6], it has been widely used by clinical researchers. Nonetheless, some critical voices have been raised lately alluding to the fact that the Jadad scale gives more weight to the quality of reporting than to actual methodological quality [49]. In addition, recent reports have pointed out that the inter-rater reliability of the Jadad score may be low [6, 12]. We have striven to avoid this latter problem by independent assessments of the identified articles and discussion between the two reviewers in case of inconsistencies of the scoring results. As Kalso et al. [49] point out, writing a qualitative systematic review requires at least two authors—it "is not a lonely (wo)man's affair."

Six of the nine studies considered had a Jadad scale score of 3 or more. In contrast, three studies had an unacceptably low reporting quality of 1 or 2. It has been shown that studies with a Jadad score of 2 or less tend to give an overoptimistic picture of the real treatment effect than studies with a higher score (e.g., [29]).

There are indications that the reporting quality of a published article does not always correlate with the actual methodological quality of the trial [45]. Deficits in reporting about the results of RCTs have been mentioned by authors in dentistry [65, 87] as well as in medicine [1, 6, 19, 34, 45, 75]. For example, only 25.4% of the articles of RCTs published in the journal *Intensive Care Medicine* up to the year 2000 had a Jadad score of 3 or more [53]. In our review, there is reason to believe that the methodological quality of the studies by Huggins/Truelove [44, 91] and Sakuma et al. [84], which were awarded 1 point, respectively, is much better than the actual Jadad score suggests.

As far as the assessment of the second quality factor—high validity—is concerned, two important criteria are a sufficient baseline pain intensity [66] and an adequate number of patients in each group [67]. In the identified trials, recruiting of study participants took place by either resorting to patients seeking care at or being referred to an orofacial pain care center, or by placing announcements in local print media [17, 80]. It should be taken into consideration, however, that patients seeking TMD treatment by referrals are probably different from individuals recruited by a notice in a local newspaper or journal [28]: Rubinoff et al. [80] argued in the critical discussion of their study published in 1987 that the latter patients "may have been biased toward milder conditions that were tolerable to the patient until prompted by a media notice." This assumption appears to be correct. When the baseline pain intensities of the three studies published in peer-reviewed journals in which a stabilization appliance were compared with a non-occluding appliance are analyzed, the following can be observed:

a. In the trial by Rubinoff et al. [80], the majority of the study participants had low pain before the start of the study. All patients were recruited by a newspaper notice.
b. In the investigation by Dao et al. [17], pre-treatment pain intensities were about 40 mm, which is equivalent to moderate pain [13], on a visual analog scale (VAS). Part of the participants were recruited through announcements published in local journals; the other part were referred by dentists.
c. In the study by Ekberg et al. [28], the pain intensity prior to the start of the study was between moderate and very severe. All patients were referred for and requested treatment.

Hence, differences in the recruitment of patients may be one reason for different pre-treatment pain levels and the different results achieved in the three studies. The three trials also differ considerably with regard to the included number of patients (cf. Table 2). The result from this comparison is that two studies with an acceptable reporting quality and a moderate validity [17, 80] found no difference between a stabilization appliance and a non-

occluding appliance. These results differ from the recent study by Ekberg et al. [28] with both strong evidence and a strong validity supporting the efficacy of the Michigan splint compared with a palatal appliance.

Only two trials—those conducted by the Huggins/Truelove group [44, 91] and by van der Glas et al. [98], respectively—had an observation period of at least 1 year. In three studies [28, 47, 86], Helkimo's CDI [38] was used. However, the validity of this index has been shown to be doubtful [99].

Our search has also demonstrated the inconsistencies that exist among different authors with regard to the diagnosis "muscle pain" (Table 2). This variability is reflected in the number of diagnostic systems that have been proposed over the past decades for classifying the different subsets of TMDs (c.f. [71]). It was not before 1992 that biologically plausible classifications with specific diagnostic categories became available [22, 89]. As a result, comparisons among the studies identified in this search are difficult to make, and pooling of data is impossible. As far as the evaluation of trials carried out in the 1970s and 1980s is concerned (c.f. [8, 36, 80]), study participants diagnosed with "myofascial pain dysfunction syndrome" are not necessarily patients suffering from myalgia only. Although masticatory muscle pain is a symptom encountered in most, albeit not all of these patients, symptoms such as limited mandibular opening, TMJ sounds, and deviation on jaw opening may be present. Only one of these older articles allowed an explicit assessment of the symptom "muscular pain" [8].

Furthermore, our investigation questions the strategy of relying exclusively on Medline when looking for evidence. Of the 13 pertinent articles, seven were identified by the Ovid Medline search. Conversely, the meeting abstracts found by handsearching were not listed in any of the consulted electronic databases. Hence, as our search demonstrated, important study results may be missed if one relies on Medline as the sole information source [1, 21, 97]. Besides, limitation of the search to the English language, as it is often seen in reviews, may lead to different conclusions (English language bias) [23, 63].

Another point that can be made is that keywords are likely to change depending on the prevailing thinking in the field. For example, whereas "temporomandibular disorders" is a term that was agreed upon by most clinicians in the early 1990s [62], Medline lists articles about this topic under the medical subject heading "Temporomandibular Joint Dysfunction Syndrome."

Conclusions

The dearth of adequate clinical studies that are available to answer our clinical question mirrors the lack of hard data in an important and frequent scenario in clinical dentistry. We found this result astonishing because full-coverage heat-cured (or self-curing) acrylic resin occlusal splints have been in use since the 1960s [76], and these devices have been recommended by many clinicians around the world for the management of patients with TMDs, including masticatory muscle pain [68]. Generally, the wealth of anecdotal reports and uncontrolled clinical observations tend to give a much more optimistic picture about the presumed effects of the stabilization splint therapy.

Due to the limited number of available studies, our clinical question can only be answered tentatively: based on the currently best available evidence it appears that most patients with masticatory muscle pain are helped by the incorporation of a stabilization splint. Nevertheless, evidence is equivocal that improvement of pain symptoms after incorporation of an intraoral appliance is caused by a specific effect of the splint [17, 28, 80]. In addition, there is not enough data about the long-term efficacy and effectiveness of these widely used therapeutic tools. It should be noted that a scarcity of prospective randomized controlled trials with high power does not discredit the concept or the applicability of EBM, because EBM is based on the *best available* evidence. However, by pointing out deficits in the quantity and quality of the evidence, EBM highlights the empirical nature of current management and emphasizes the need for more focused clinical research in dentistry.

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