

# Oral splints in the management of nociceptive pain and migraines: A scoping review

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**Abstract.** Temporomandibular disorders (TMDs) are characterized by numerous pain manifestations. Their treatment often involves the use of an oral splint. Recent research has found a relationship between migraines, nociceptive pain and TMDs. The aim of the present study was to perform a scoping review of studies in order to evaluate the effectiveness of the various types of oral splint in the treatment of migraine or nociceptive pain. Publications were retrieved from seven databases (PubMed, Web of Science, EMBASE, Scopus, ProQuest, SpringerLink and Ovid). Out of the 15 included publications, three studies were before and after studies, with no control group, whereas the other twelve studies were clinical trials, among which two publications were crossover studies. A clear, single distinction of pain was difficult to describe. Therefore, numerous publications focused on a combination of various types of pains, including myofascial, temporomandibular joint, headaches and migraine-like symptoms, all of which mimicked TMD pain. Overall, six studies used the stabilization splint (SS), three explored the comparison between the SS and the nociceptive trigeminal inhibition splint (NTIS) and two the NTIS. The majority of publications reported a positive outcome of splint therapy. Regarding the type of oral splint usage, the most commonly used one was the SS, followed by the NTIS. The definition and assessment of pain were heterogeneous in the identified articles. The findings of the current study showed that occlusal splints may help with pain management, and that effective treatment of TMD-related pain at an early stage can enhance the quality of life of patients.

## Introduction

Migraines are considered to be one of the most distressing disorders, especially in chronic cases. Moreover, patients frequently utilize excessive amounts of drugs in order to treat these intense headaches (1). The International Classification of Headache Disorders (3rd edition) diagnoses a migraine as a primary headache, whereas a headache that is attributed to temporomandibular disorders (TMDs) is considered to be a secondary one (2). Migraines can cause facial or dental pain, which demonstrates the trigeminal-vascular systems role, as well as the roles of inflammatory or pathological processes in the facial area that may trigger or aggravate migraines (3).

Preconscious nociceptive mechanisms are unconscious, whereas pain is a conscious subjective assessment of an organism's physical harm (4). Nociceptive pain is caused by the stimulation of nociceptive trigeminal receptors and the exposure of these receptors may result in neurogenic pain (5).

The gold standard for diagnosing TMD is based on the Diagnostic Criteria for TMD for clinical and research applications (6,7). Accordingly, the systematic classification of TMD comprises of temporomandibular joint (TMJ) disorders (including joint pain, joint disorders, joint diseases, fractures and congenital/developmental disorders), masticatory muscle disorders (including muscle pain, contracture, hypertrophy, neoplasm, movement disorders and masticatory muscle pain attributed to systemic/central pain disorders), headaches and craniofacial structures (6).

TMD can trigger headaches, as well as exacerbate existing primary headaches, and also contributes to the chronicity of migraines (8). A standardized therapeutic approach to treat TMDs has not yet been established due to the wide range of symptoms and a complex etiology (9). Oral splints (10), along with other treatment possibilities, have been proposed, such as drugs (11), self-care (12), exercise therapy (13,14), acupuncture (15), physiotherapy (16), photo-biomodulation (17), laser therapy (18) and surgery (19,20).

Oral splints are a reversible, non-invasive treatment for temporomandibular dysfunction; however, their clinical effectiveness is still unknown (21). Numerous types of oral appliances have previously been described, including stabilization splints (SSs), anterior repositioning appliances, bite planes and hard or soft splints (22).

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The role of oral splints in the treatment of nociceptive pain or migraines is still unclear.

Manriquez *et al* (23), in a systematic review and meta-analysis, demonstrated that SSs induces a reduction of headache intensity or frequency in patients with TMD headache comorbidity. However, the evidence quality in this study was low, with only nine studies being analyzed in the qualitative synthesis and five studies in the quantitative synthesis (meta-analysis). However, the authors reported no significant difference in the use of partial hard or soft splints or full arch splint use (23). A recent review investigating the effects of a SSs on headaches in patients with TMDs, revealed that even though SS therapy reduced headache intensity and frequency, the evidence quality was inadequate due to the high bias risk and small sample size, which indicated that there is a need for more research (23).

To the best of our knowledge this is the first scoping review which investigated both therapeutic approaches, stabilization splints and nociceptive trigeminal inhibition splints, with regards to nociceptive pain and migraines.

## Materials and methods

**Protocol and registration.** The present review was performed according to the procedures proposed by the Joanna Briggs Institute Methods Manual for scoping reviews (24). The findings were reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews (25). The Open Science Framework platform (identification no. Y86QX) was used to register the study protocol prospectively on 30th May 2022 (<https://osf.io/y86qx>).

**Eligibility criteria.** Peer-reviewed journal studies that were written in the English language, without a time limit of publication, that addressed nociceptive pain or migraine and oral splints and engaged human participants, were included in the present review. Moreover, studies were included if they were peer-reviewed original studies, including nociceptive pain and migraine patients, and were focused on oral splints.

The exclusion criteria included, systematic reviews, literature and scoping reviews, meta-analyses, letters to the editor, comments, communications, case reports, conference abstracts, practice guidelines, editorials and articles written in languages other than English.

**Information sources and the search strategy.** Searches were performed without time restrictions using seven electronic databases directed in the English language in May 2022. The search strategy was drafted by a specialist in TMDs with over 10 years of experience and was adapted to other databases. The following terms were searched: ‘nociceptive pain’, ‘migraine’, ‘migraine disorders’, ‘migraineous’, ‘oral splint’, ‘oral splints’. The research strategy was constructed using the Patient, Intervention, Comparison, Outcome (PICO) framework: P-subjects with nociceptive pain or migraine; I-oral splint; C-controls without an oral splint; and O-oral splint effect.

This comprehensive search was performed using the following databases: PubMed, Web of Science, Embase, Scopus, ProQuest, SpringerLink and Ovid, to find original

articles using the following keywords, ‘nociceptive pain’, ‘migraine’ and ‘oral splint’. The last search was conducted on 30th May 2022.

**Screening.** The study selection was performed using the Rayyan online platform (26), a web tool (<https://www.rayyan.ai/>) to assist in working on systematic reviews and scoping reviews. The publications were examined by two researchers who assessed the titles and abstracts for relevance and the presence of the eligibility criteria. The full text of the retrieved articles was assessed. The publications were classified into the following three groups: i) Included; ii) excluded; and iii) maybe. In the case of any possible disagreements, or articles that were put in the maybe group, a consensus was reached by discussion and differences in opinion were settled via a debate.

**Data collection and analysis.** Two reviewers participated in creating a data-charting template to establish which parameters to extract. A data extraction form was created using Microsoft Excel (Microsoft Office 2019®; Microsoft Corporation) software (27). The data collected and recorded included author and year of publication, country, study population, type of oral splint and effect of oral splint on pain or migraine. A descriptive analysis of the data was performed and the data were recorded independently by two researchers and subsequently confirmed.

**Critical appraisal of individual sources of evidence.** The methodological quality of the eligible studies included in the present review was rated using the quality assessment tools (questionnaires that help to assess the methodological quality of articles) provided by the National Heart Lung and Blood Institute (28).

## Results

**Selection of sources of evidence.** The performed search within seven databases [PubMed (n=21), EMBASE (n=22), Scopus (n=6), Web of Science (n=21), SpringerLink (n=18), ProQuest (n=13), Ovid (n=13)] yielded 114 publications in total. After removing duplicates, a total number of 92 publications were considered. The remaining publications were screened for eligibility, eliminating studies that had a study design specified in the exclusion criteria (n=57), background articles (n=10), irrelevant articles (n=2) and duplicate records, which were removed manually (n=3); this led to 18 articles being retrieved. Out of the identified articles, two articles could not be retrieved. The 16 full texts of the relevant publications were acquired and reviewed according to the inclusion and exclusion criteria. One paper was excluded since the outcome was not reported. A final list of 15 publications was collated.

**Characteristics of the studies and synthesis of results.** The characteristics of the included studies are presented in Table I, including the country, study type, study population, main complaint, type of oral splint used, method of assessment and treatment effect.

All included publications were published in the last 15 years and came from a variety of sources, including one from Austria (29), four from Brazil (30-33), one from

Table I. Study characteristics.

First author/s, year	Country	Study type	Study population and splint wearing time	Main complaint	Oral splint type	Method of assessment	Oral splint effect	(Refs.)
Aksakalli <i>et al</i> , 2015	Turkey	CT	40 patients with TMD (34 women and 6 men; mean age, 31 years). Group 1, 20 subjects with SS And 20 subjects with NTIS for 3 months.	Clenching/grinding, pain in the TMJ, earache.	SS, NTIS	Fonseca questionnaire, OHQoL-UK and VAS	Both splints reduced the patients' pain and the patient experienced an improved quality of life following treatment.	(42)
Amin <i>et al</i> , 2016	India	RCT	45 patients with MMP. Group 1, 15 subjects with hard splints; group 2, 15 subjects with soft splints; group 3, 15 subjects with liquid splints for 3 months.	Myofascial pain dysfunction syndrome.	SSs, including hard splints, soft splints and liquid splint	Subjective pain, Mod-SSI objective pain, muscle palpation	Significant reduction in pain for all three groups at the end of 3 months. Hard splints proved to be very effective over a shorter period of time, followed by liquid splints and finally soft splints.	(36)
Baad-Hansen <i>et al</i> , 2007	Denmark	Blinded randomized CO	10 patients (3 men and 7 women; age, 23-39 years). Each splint was used for 2 weeks.	Painful muscles upon clinical palpation, TMD characteristic pain intensity. Tooth-grinding during Sleep and muscle soreness on awakening.	SS, NTIS	RDC/TMD, VAS	Reduced EMG activity of the masseter muscles during treatment with the NTIS, which was not associated with a short term reduction in TMD signs or symptoms (pain).	(34)
Blumenfeld and Boyd, 2022	USA	Single-blinded placebo-controlled CO	19 patients with chronic migraine. 2 months wearing time: 30 days of the placebo splint and 30 days the NTL splint	The severity of pain and the adverse impact that headaches had on the quality of life.	NTIS placebo device	HIT-6 score	The improvement produced by the NTIS suggested that patients with chronic migraines may have nocturnal jaw clenching as a contributing factor.	(41)
Conti <i>et al</i> , 2012	Brazil	Blinded, CS	51 patients with MMP. Group 1, 21 subjects-with SS and counselling; group 2, 16 subjects with NTIS and counselling; group 3, 14 subjects with no splint but with counselling and self-care. Duration, 2 weeks, 6 weeks and 3 months, respectively.	Pain of masticatory muscles	SS, NTIS, counselling/self-care	RDC/TMD, VAS, PPT	Behavioral changes are effective in the management of pain in patients with masticatory muscle pain. Moreover, the simultaneous use of occlusal devices produces an earlier improvement.	(30)

Table I. Continued.

First author/s, year	Country	Study type	Study population and splint wearing time	Main complaint	Oral splint type	Method of assessment	Oral splint effect	(Refs.)
Conti <i>et al</i> , 2015	Brazil	Blinded, controlled RCT	33 patients. Group 1, 12 subjects with DDR and arthralgia, ARC and counselling; group 2, 12 patients with NTIS and counselling; group 3, 9 control patients with counselling. Duration, 2 weeks, 6 weeks and 3 months, respectively.	TMJ pain.	ARS, NTIS	RDC/TMD, VAS, PPT	Significant decrease in pain intensity in all groups. Patients wearing occlusal devices accompanied by counselling and behavioral changes reported faster significant improvements. This demonstrated the importance of the intraoral device in the management of TMJ pain. NTIS may be used in patients with TMD, TMJ and muscular pain, headaches or migraines.	(31)
Costa <i>et al</i> , 2016	Brazil	CT	Adults with MMP. Group 1, 17 patients with TMD-attributed headaches; group 2, 17 patients without TMD-attributed Headaches; both groups had SS and counselling. 5 months.	TMD attributed headaches and masticatory myofascial pain	SS	RDC/TMD, VAS, PPT	Reduction in facial pain intensity in TMD-attributed headaches in patients with MMP. This study changed the pattern for muscle pain improvement. The presence of a headache was demonstrated to modify muscle pain patterns in MMP subjects.	(32)
Didier <i>et al</i> , 2017	Italy	CT	88 patients with MOH and 49 patients with PIFP. 6, 12 months.	Neuromuscular component of patients suffering from chronic craniofacial pain.	Acrylic resin device	VAS, MIDAS questionnaire	Significant decrease in pain intensity (VAS). Significant decrease of the Migraine Disability Assessment Test, after treatment with an occlusal device.	(38)
Hasanoglu Erbasar <i>et al</i> , 2017	Turkey	RCT	40 patients. Group 1, 20 patients with guidance, assurance and counselling behavioral changes; group 2, 20 patients with an NTIS. 3 and 6 weeks.	Myofascial pain.	NTIS	RDC/TMD	Reduction in pain levels and improvement of jaw function. However, the integration of an NTIS into the therapy protocol did not provide any additional benefits in relieving symptoms of myofascial pain.	(43)

Table I. Continued.

First author/s, year	Country	Study type	Study population and splint wearing time	Main complaint	Oral splint type	Method of assessment	Oral splint effect	(Refs.)
Haggiag <i>et al</i> , 2017	Brazil	CT	74 patients (56 female, 18 male) with chronic migraine headaches. 6, 12 months.	Chronic migraine headaches, masticatory myofascial pain and awake bruxism.	Posterior occlusal device and an intraoral device called 'DIVA®'	Standard patient chart, Oral Behaviors Checklist, EMG recordings	Reduction in overall pain, including headaches.	(33)
La Mantia <i>et al</i> , 2018	Italy	RCT	60 patients. Group 1, 30 patients with treatment; group 2, 30 control patients.	Sleep bruxism and jaw muscle discomfort	SS	EMG, MIDAS	Short-term use of occlusal splint therapy was effective in reducing both bruxism activity and migraine related discomfort.	(39)
Mortazavi <i>et al</i> , 2010	Iran	R chart review (CS)	138 patients (26 males and 112 females).	Early TMD/TMJ pain.	SS	Chart review study	Overall, 64% of the patients were completely relieved of signs and symptoms and 22% were moderately relieved. Patients with pain and clicking had a better response to treatment.	(37)
Rampello <i>et al</i> , 2013	Italy	CT	50 patients. Group 1, 25 patients with splints; group 2, control patients. 3 months.	Muscle pain, TMJ pain, headaches or migraines.	'UNIRA' splint	VAS	Resolution or improvement of symptoms. Muscular pain, migraine and cervical pain improved in group 1.	(40)
Saha <i>et al</i> , 2019	Germany	RCT	60 patients. Group 1, 30 patients with SS and standard care; group 2, 30 patients, with usual care alone (no particular therapy).	Headache symptoms in patients with migraines and/or tension-type headaches.	SS	VAS	Day and night occlusal splint therapy, in addition to standard care, was not superior to standard care alone in patients with chronic headache and comorbid TMD.	(35)
Schmid-Schwab <i>et al</i> , 2009	Austria	R	97 patients. Group 1, 37 patients with splints; group 2-29 patient with exercise therapy; group 3, 31 patients with splints and exercise therapy. 18±12 weeks for exercise or splint therapy, 29±15 weeks	Muscle pain, TMJ pain, headache pain during chewing and pain during mouth opening.	SS	VAS	Significantly improved muscle pain upon palpation in all groups. A significant reduction of pain was found in all groups. Mouth opening exhibited the most marked improvement seen for the patients in the group with a combination of splint therapy and exercise therapy.	(29)

Table I. Continued.

First author/s, year	Country	Study type	Study population and splint wearing time	Main complaint	Oral splint type	Method of assessment	Oral splint effect	(Refs.)
for patients receiving a combination of both therapies.								
CT, clinical trial; CO, crossover; RCT, randomized clinical trial; R, retrospective; TMD, temporomandibular disorder; TMJ, temporomandibular joint; SS, stabilization splint; NTIS, nociceptive trigeminal inhibition splint; ARS, anterior repositioning splint; OHQoL, oral health-related quality of life; VAS, visual analog scale; Mod-SSI, Modified Symptom Severity Index; EMG, electromyographic; RDC/TMD, research diagnostic criteria for temporomandibular disorders; MMP, masticatory myofascial pain; DDR, disc displacement with reduction; HIT-6, Headache Impact Test questionnaire; PPT, pressure pain threshold; MOH, medication overuse headache; PIFP, persistent idiopathic facial pain; MIDAS, migraine disability score.								

Denmark (34), one from Germany (35), one from India (36), one from Iran (37), three from Italy (38-40), one from the USA (41) and two from Turkey (42,43). The continental distribution of these publications was similar across America (33.33%), Asia (26.66%) and Europe (40%). Three studies were before and after studies (studies that made repeated observations on one group, before and after an intervention), with no control group (33,37,42), whereas the other 12 studies were clinical trials, among which two publications were crossover studies (each subject in the study received both treatments, but the order of receiving it was randomized) (34,41).

A clear, single distinction of pain was difficult to describe and therefore numerous publications focused on a combination of nociceptive pains, such as myofascial, TMJ pain, headaches and migraine-like symptoms, all of which mimicked TMD pain. Myofascial pain (29,30,33,34,36,40,43) and TMJ pain (29,31,34,37,40,42) were investigated in a number of studies. Pain assessment was usually assessed using questionnaires, like the Fonseca questionnaire (42) and a visual analog scale was cited by numerous studies (29-32,34,35,38,40,42). The migraine disability score was applied in two studies (38,39). The Headache Impact Test questionnaire was used by Blumenfeld and Boyd (41).

Regarding the type of oral splints used, numerous publications reported the use of SSs, including Amin *et al* (36), Costa *et al* (32), La Mantia *et al* (39), Mortazavi *et al* (37), Saha *et al* (35) and Schmid-Schwab *et al* (29). The nociceptive trigeminal inhibition splint (NTIS) was used by Blumenfeld and Boyd (41), who compared it to a placebo device and Hasanoglu Erbasar *et al* (43). Comparisons between the SS and the NTIS were reported in numerous studies (30,34,42). Haggiag *et al* (33) introduced an innovative splint, the 'posterior occlusal intraoral device named 'DIVA®', whereas Rampello *et al* (40) described a special, particularized splint called 'UNIRA'.

The reported outcomes of splint therapy varied. A number of studies (60%) reported a positive outcome for splint therapy, including Aksakalli *et al* (42), Amin *et al* (36), Blumenfeld and Boyd (41), Conti *et al* (30,31), Costa *et al* (32), Didier *et al* (38), Haggiag *et al* (33) and Mortazavi *et al* (37). Aksakalli *et al* (42) demonstrated that splint therapy decreased TMD complaints, improved the movements of the mandible in patients with TMD and reduced overall pain in patients with both SSs and NTISs. Amin *et al* (36) suggested that practitioners should consider using occlusal splints as a therapeutic option when treating patients with myofascial pain dysfunction, which demonstrated that the splints reduced pain symptoms. Blumenfeld and Boyd (41) demonstrated that patients with chronic migraines may experience nighttime jaw clenching, which may be a potential cause; however, an improvement of these symptoms was observed in patients using NTISs. Conti *et al* (30) reported that behavioral adjustments are helpful in pain management and that the simultaneous use of oral devices appears to lead to an earlier improvement. Furthermore, Conti *et al* (31), demonstrated that oral appliances are efficient in the management of disc displacement with pain reduction, in association with behavioral therapy. Costa *et al* (32) reported an early improvement of symptoms in patients with masticatory myofascial pain, wearing a SS. Didier *et al* (38) demonstrated that occlusal devices are effective and well-tolerated in the treatment of headaches and persistent idiopathic facial

Table II. National Heart Lung and Blood Institute quality assessment tool for before-after (pre-post) studies with no control group.

Criteria	Aksakalli <i>et al</i> (42)	Haggiag <i>et al</i> (33)	Mortazavi <i>et al</i> (37)
1. Was the study question or objective clearly stated?	Yes	Yes	No
2. Were eligibility/selection criteria for the study population prespecified and clearly described?	Yes	Yes	Yes
3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?	CD	Yes	CD
4. Were all eligible participants that met the prespecified entry criteria enrolled?	NR	Yes	CD
5. Was the sample size sufficiently large to provide confidence in the findings?	No	NR	NR
6. Was the test/service/intervention clearly described and delivered consistently across the study population?	NR	Yes	Yes
7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?	Yes	Yes	NR
8. Were the people assessing the outcomes blinded to the participants' exposures/interventions?	No	No	NR
9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?	Yes	Yes	NR
10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided P-values for the pre-to-post changes?	Yes	CD	CD
11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?	No	Yes	NR
12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?	NA	NA	NA
Quality rating	Poor	Fair	Poor

CD, cannot determine; NA, not applicable; NR, not reported.

pain. Haggiag *et al* (33) reported that an intraoral device could aid in the reduction of pain in subjects suffering from chronic migraine headaches. Moreover, Mortazavi *et al* (37) demonstrated that oral splints were effective in >80% of the enrolled subjects in the treatment of TMDs, in a study that had a follow-up period of 1-9 years.

However, Baad-Hansen *et al* (34) reported that splints did not reduce pain in a short period of time, whereas Saha *et al* (35) demonstrated that the splint was not superior to standard care in pain reduction (drugs, including non-steroidal anti-inflammatory drugs, opioids, corticosteroids and muscle relaxants.). Hasanoglu Erbasar *et al* (43) reported that the NTIS, along with behavioral changes, guidance and counseling, did not add additional relief benefits to patients suffering from TMD myofascial pain.

**Critical appraisal within sources of evidence.** The risk of bias assessment in individual studies was assessed. The quality

assessment of the included studies demonstrated a fair quality for eight studies and a good one for two studies, whereas only five studies were assessed as poor (Tables II and III).

## Discussion

The connection between migraines, headaches, nociceptive pain and TMDs has preoccupied researchers for a long period of time. Furthermore, there is still debate on the role of oral splints in the treatment of associated pain. In the present review, 15 studies addressing the role of occlusal splints in the management of nociceptive pain or migraine, published between 2007-2022, were identified. The results indicated that there is still a scarcity of studies primarily focused on the influence of oral splints on nociceptive pain or migraines. Moreover, the type of splint varies between studies, and studies should focus on the same type of splints to improve outcome and symptom relief.

Table III. National Heart Lung and Blood Institute quality assessment of controlled intervention studies.

Criteria	Amin <i>et al</i> (38)	Baad- Hansen <i>et al</i> (34)	Blumenfeld and Boyd (41)	Conti <i>et al</i> (30)	Conti <i>et al</i> (31)	Costa <i>et al</i> (32)	Didier <i>et al</i> (38)	Hasanoglu Erbasar <i>et al</i> (43)	La Mantia <i>et al</i> (39)	Rampello <i>et al</i> (40)	Saha <i>et al</i> (35)	Schmid- Schwap <i>et al</i> (29)
1. Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT?	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes	No
2. Was the method of randomization adequate (i.e., use of randomly generated assignment)?	CD	NA	NR	NR	NR	No	NR	NR	Yes	NR	Yes	No
3. Was the treatment allocation concealed (so that assignments could not be predicted)?	NR	Yes	NR	NR	NR	No	NR	NR	Yes	NR	Yes	No
4. Were study participants and providers blinded to treatment treatment group assignment?	NR	Yes	NA <sup>a</sup>	Yes	Yes	Yes	NR	NR	NR	No	NR	NR
5. Were the people assessing the outcomes blinded to the participants' group assignments?	NR	Yes	No	Yes	Yes	Yes	NR	NR	NR	No	NR	NR
6. Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?	Yes	Yes	No	No	No	Yes	NR	Yes	NR	NR	No	NR



[illegible]

Table III. Continued.

Criteria	Amin <i>et al</i> (38)	Baad- Hansen <i>et al</i> (34)	Blumenfeld and Boyd (41)	Conti <i>et al</i> (30)	Conti <i>et al</i> (31)	Costa <i>et al</i> (32)	Didier <i>et al</i> (38)	Hasanoglu Erbasar <i>et al</i> (43)	La Mantia <i>et al</i> (39)	Rampello <i>et al</i> (40)	Saha <i>et al</i> (35)	Schmid- Schwap <i>et al</i> (29)
14. Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to- treat analysis?	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Quality rating	Fair	Good	Fair	Poor	Fair	Fair	Poor	Good	Fair	Fair	Fair	Poor
CD, cannot determine; NA, not applicable; NR, not reported. <sup>a</sup> just the participants were blinded.												

Primary headache disorders, particularly migraines, are closely linked to TMD, as they exhibit similar dentofacial pain characteristics (44). A relationship between painful TMD and headaches has previously been reported (45). It has also been demonstrated that managing craniofacial pain using an oral splint and physical therapy in patients with TMDs and migraines significantly improves migraines, neck pain and head and neck posture (46). However, these effects, are not as noticeable in patients who have migraines before the onset of TMD (46).

Greene and Menchel (47) previously debated several controversies related to splint therapy, including full coverage vs. partial coverage, how oral appliances affect TMJ loading and how oral appliances work to relieve TMJ pain. Wiens (48) reported that patients with TMD can benefit from SSs as a reversible treatment. Kuzmanovic Pficer *et al* (49) reported that SSs have a positive effect on pain reduction and pain intensity in muscular disorders, as well as a decrease in muscle tenderness and result in improvements in mouth opening. Vrbanović and Alajbeg (50) demonstrated that SSs were effective in treating patients with chronic TMDs compared with placebo splints. The SS, constructed in centric relation out of hard acrylic or polycarbonate material, is one of the most frequently used types of splint. It causes minimal changes to the relationship between the maxilla and the mandible and therefore has the fewest adverse effects in comparison to irreversible treatment (such as occlusal adjustment, orthodontics or fixed prosthetic procedures) (51).

Al-Moraissi *et al* (52), when studying the hierarchy of different treatments for myogenous TMDs, found that manual therapy, along with counseling and occlusal devices, were considered effective treatments. Almozni *et al* (53) investigated the long-term adherence of patients to occlusal splints and reported that those with mild to major pain reduction had higher adherence rates compared with those with no or complete pain relief. Moreover, Garstka *et al* (54) demonstrated that physical manifestations of TMDs are on the rise amongst individuals and posture disturbances and associated functional disorders are associated. Consequently, the diagnosis and medical therapy of patients with TMD ought to be comprehensive.

A recent study reported that the influence of occlusal splints on muscle strength is yet unknown, with no consensus on whether occlusal splints can be used as synergists, these results indicated the need for further research (55). Moreover, occlusal splints have been demonstrated to improve postural balance in patients suffering from TMD (56). Ferrillo *et al* (57), when analyzing the effects of occlusal splints on the spinal posture in subjects with TMDs, reported that occlusal splints have positive effects, which indicated their use as a non-invasive method in treating patients. Noguchi *et al* (10) also demonstrated efficient results for patients with myofascial pain and local myalgia using SSs. Honnef *et al* (58), in a systematic review investigating the effects of SSs on the signs and symptoms of TMDs, reported that the effect of the SS on the signs and symptoms of TMDs of muscle origin could not be determined. In spite of its extended benefits, the use of occlusal devices regarding their type, wearing time and splint type (full coverage splint or partial coverage splint), still need to be taught. Krief *et al* (59) also reported that a higher level of practitioner education is

needed as well as an improvement in the homogeneity of treatment procedures. Cruz *et al* (44) demonstrated that by determining the onset sequence of concomitant diseases related to TMD, the impact of TMD therapy on clinical alterations of its comorbidity, such as migraines and cervical dysfunction, might be identified. This study also reported that SS therapy improves the symptoms of migraines and TMD-related craniofacial and cervical discomfort.

Taking into consideration the fact that occlusal splints produce reversible changes to the occlusion, the extension limits of the splint must be considered as well as its thickness. It has previously been reported that splints with a thickness of 2 and 4 mm are both effective in the treatment of muscle disorders (60), as well as 3 mm in thickness (61). Kostrzewa-Janicka *et al* (62) determined that the thickness of the SS should be individualized for each patient according to the vertical jaw separation and skeletal morphology (62). A specific vertical dimension of the splint is difficult to generalize due to the individual characteristics of the occlusion. The design of the splint is determined by the therapeutic goals, whereas the underlying mechanisms behind the treatment success are still unknown (47).

After assessing the efficiency of the SS integrated with a digital occlusal analysis device in the therapy of TMD with myofascial pain, Li *et al* (63) discovered that the guided occlusal adaptation of the splint using digital technology can achieve an enhancement of the curative implications and outcome of patients suffering from this condition.

SSs has been proven to be superior to NTISs (64). However, Oh *et al* (65) demonstrated that in subjects with TMDs and an SS, the onset of an anterior open bite can be induced. Moreover, Stapelmann and Turp (66) reported negative side effects related to teeth and occlusions; therefore, careful management of patients receiving these devices is mandatory. Dalewski *et al* (67), when studying the occlusal splint vs. the NTIS in subjects with bruxism, by means of using surface electromyography, reported that neither splint type had any influence on the muscles.

Over a long period of time, the side effects of a partial coverage splint should be considered, and side effects, if present, need to be managed adequately. NTISs have been proven to be efficient in the treatment of TMD muscle disorders (68), as well as migraine and tension headaches (69). However, being only partial coverage splints, NTISs have been shown to cause side effects, including unwanted changes in the occlusion (64). When compared to the Michigan splint, the NTIS is more efficient in reducing jaw muscle activity during sleep in patients with bruxism (70).

Of the publications investigated in the present study, according to the quality assessment, eight studies were fair, five were poor and two were good. The studies that were included clearly advocate study of the relationship between the oral splint and nociceptive pain and migraine to improve a patients' quality of life.

There are certain limitations to the present scoping review. The literature only contains a small number of papers on the relevant topic. A few of the reviewed papers used a before and after design and were therefore subject to several possible biases, including the attribution of the effect to the intervention, confounding bias and difficulty in sustaining causality. A

number of the clinical trials were not randomized and suffered from a lack of controlling confounding bias. However, the main limitation was the quality of the reviewed papers. Regarding the controlled trials, there were problems in the reporting of the randomization method and allocation concealment, followed by a lack of blinding and an unequal percentage of subjects lost during follow-up. There was also a high heterogeneity between the splint types and methods of outcome assessment that made it challenging to perform meta-analyses. Finally, the studies were performed on a limited number of subjects.

The strength of the present review relies on the overview of splint therapy for nociceptive pain and migraines since the etiology and clinical manifestations are so broad. It brings together different types of occlusal splints, which are aimed at pain relief in patients with migraine-like headaches and TMDs. Furthermore, the search strategy used in the present study was complex and extensive, being performed in seven databases.

The present study demonstrated that the definition and assessment of nociceptive pain and migraine was heterogeneous in the identified articles. A number of the studies (60%) reported a positive outcome for splint therapy. The most frequently used oral splint was a SS, followed by NTIS. Due to the complexity of nociceptive pain and migraines associated with TMJ dysfunction, the diagnosis and treatment should be comprehensive. Along with medication, physiotherapy, counselling, cognitive adjustments and splint therapy can be effective in the overall outcome of patients with migraine or nociceptive pain. The present study demonstrated that occlusal splints may assist in pain reduction and the early and feasible treatment of TMD-related pain will improve a patient's quality of life. A specialist in TMDs, along with a neurologist, a psychiatrist, a psychologist, a physiotherapist and a dentist, should be involved in the treatment of nociceptive pain and migraines. Therefore, nociceptive pain and migraine should be identified as early as possible and treated by a multidisciplinary team, using a multifaceted approach, including oral splints, to diminish pain and improve the well-being of new patients as well as individuals with chronic conditions. To establish a clear relationship between oral splint therapy and migraines or nociceptive pain, more randomized controlled trials with a proper methodology and a systematic review are warranted.

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## Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Authors' contributions

OA came up with the idea. OA, SB and MH devised the methodology. MH, SB and CD validated the data. OA and DCL performed the formal analysis. OA, CD and MH contributed

to the investigation. OA and DCL performed data curation. OA and DCL prepared the original draft. OA, DCL, MH, CD and SB contributed to writing of the article, its review and editing. OA and DCL performed the visualization. CD and SB supervised the project. OA administered the project. MH and CD confirm the authenticity of all the raw data. All authors read and approved the final manuscript.

### Ethics approval and consent to participate

Not applicable.

### Patient consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

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