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Occlusal splints for treating sleep bruxism (tooth grinding) (Review)

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TABLE OF CONTENTS

[Intervention Review]

Occlusal splints for treating sleep bruxism (tooth grinding)

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ABSTRACT

Background

Sleep bruxism is an oral activity characterised by teeth grinding or clenching during sleep. Several treatments for sleep bruxism have been proposed such as pharmacological, psychological, and dental.

Objectives

To evaluate the effectiveness of occlusal splints for the treatment of sleep bruxism with alternative interventions, placebo or no treatment.

Search methods

We searched the Cochrane Oral Health Group's Trials Register (to May 2007); the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2007, Issue 1); MEDLINE (1966 to May 2007); EMBASE (1980 to May 2007); LILACS (1982 to May 2007); Biblioteca Brasileira de Odontologia (1982 to May 2007); Dissertation, Theses and Abstracts (1981 to May 2007); and handsearched abstracts of particular importance to this review. Additional reports were identified from the reference lists of retrieved reports and from article reviews about treating sleep bruxism. There were no language restrictions.

Selection criteria

We selected randomised or quasi-randomised controlled trials (RCTs), in which splint therapy was compared concurrently to no treatment, other occlusal appliances, or any other intervention in participants with sleep bruxism.

Data collection and analysis

Data extraction was carried out independently and in duplicate. Validity assessment of the included trials was carried out at the same time as data extraction. Discrepancies were discussed and a third review author consulted. The author of the primary study was contacted when necessary.

Main results

Thirty-two potentially relevant RCTs were identified. Twenty-four trials were excluded. Five RCTs were included. Occlusal splint was compared to: palatal splint, mandibular advancement device, transcutaneous electric nerve stimulation, and no treatment. There was just one common outcome (arousal index) which was combined in a meta-analysis. No statistically significant differences between the occlusal splint and control groups were found in the meta-analyses.

Authors' conclusions

There is not sufficient evidence to state that the occlusal splint is effective for treating sleep bruxism. Indication of its use is questionable with regard to sleep outcomes, but it may be that there is some benefit with regard to tooth wear. This systematic review suggests the need for further investigation in more controlled RCTs that pay attention to method of allocation, outcome assessment, large sample size, and sufficient duration of follow up. The study design must be parallel, in order to eliminate the bias provided by studies of cross-over type. A standardisation of the outcomes of the treatment of sleep bruxism should be established in the RCTs.

PLAIN LANGUAGE SUMMARY

Occlusal splints for treating sleep bruxism (tooth grinding)

There is insufficient evidence to either support or refute the use of occlusal splints for treating patients with tooth grinding or clenching during sleep (sleep bruxism).

Sleep bruxism is characterised by several signs and symptoms. Among them abnormal tooth wear, fractured teeth, joint pain or tenderness, jaw muscle discomfort, and headaches. Treatments include odontological devices such as occlusal splints, pharmacotherapy, and psychotherapy. An occlusal splint is a removable appliance worn in the upper jaw (maxilla) or the lower jaw (mandible), with coverage of the dental surfaces. They are usually used to prevent tooth wear.

There is not enough evidence in the literature to show that occlusal splints can reduce sleep bruxism.

BACKGROUND

According to the International Classification of Sleep Disorders (ICSD-2) (AASM 2005), sleep related bruxism is an oral activity characterised by teeth grinding or clenching during sleep, it is usually associated with sleep arousals, and it is usually accompanied by sounds (Bader 2000). Sleep bruxism is characterised by several signs and symptoms. Among the signs are abnormal tooth wear, fractured teeth, tongue indentation, polygraphic observation of jaw muscle activity with audible teeth grinding sounds, masseter muscle hypertrophy, facial pain, temporomandibular joint tenderness or pain on digital palpation, reduction in salivary flow, lip or cheek biting, and burning tongue with concomitant oral habits. Symptoms include teeth grinding sounds during sleep recounted by individual's bed partner, jaw muscle discomfort with or without pain, headache, teeth hypersensitivity, stress and anxiety (AASM 2005; Okeson 1996). Severe sleep related bruxism may also result in sleep disruption which has implications not only to the patient, but also to the bed partner, because sounds caused by the teeth friction are usually quite loud, disturbing and are perceived as being unpleasant.

Bruxism has been classified into: primary (idiopatic) or secondary (iatrogenic). Primary bruxism includes clenching and sleep bruxism and is not related to any medical condition, while secondary bruxism is associated with medical conditions (e.g. neurologic, psychiatric, sleep disorders medication) that may exaggerate primary bruxism (Lavigne 2000). Bruxism can occur when awake, a semi-voluntary clenching activity of the jaw rarely associated with sounds. The presentation during sleep is significantly different from that during wakefulness, because sleep bruxism is usually associated with sleep arousals.

Sleep bruxism starts at 1 year of age, soon after the eruption of the deciduous incisors. Its prevalence in children ranges from 14% to 20% (Abe 1966; Widmalm 1995).
Frequently it appears in adolescence (Partinen 1994), with a prevalence of 13% in 18- to 29-year olds. The prevalence in adults is 8% considering the occurrence of teeth grinding during sleep at least weekly, decreasing with age, up to 3% in individuals over 60 years (Lavigne 1994; Ohayon 2001). There are no reported gender differences for sleep related bruxism (Glaros 1981; Lavigne 1994; Melis 2003). No genetic markers have been found for the transmission of this condition. However, 21% to 50% of patients who grind their teeth whilst asleep have a direct family member who ground his or her teeth in childhood (Abe 1966).

Currently the central regulation has been the focus of study in bruxism (Lobbezoo 2001 a). Several risk factors have been linked to sleep bruxism such as tobacco, drugs, alcohol, psychiatric disorders, sleep disorders, anxiety, stress (Ohayon 2001), orofacial pain, joint sound or lock at the temporomandibular.

Polysomnography is useful in the differential diagnosis of sleep bruxism, along with other disturbances: obstructive sleep apnoea, periodic leg movements, rapid eye movement (REM) sleep behaviour disorder (RBD), etc. (Lavigne 2000). A diagnosis of sleep related bruxism is given in the presence of at least four episodes per hour of sleep or 25 individual muscle bursts per hour of sleep and a minimum of two audible tooth-grinding episodes per sleep recording session in the absence of associated abnormal electroencephalogram (EEG) activity (Lavigne 1996). Polysomnographic recordings must include additional electromyogram (EMG) derivations, surface electrodes placed over bilateral masseters, temporal muscles, sometimes frontal muscles, and audio-video recordings in order to confirm the nature of the sounds (e.g. grinding, snoring) and type of movements (e.g. swallowing, myoclonus, body rocking) (Lavigne 1996). Polysomnography may be recommended to confirm the disorder or to rule out associated respiratory disturbance, RBD, night terrors, facio-mandibular, myoclonus, or epilepsy. The sensitivity of polysomnographic study in detecting severe cases of sleep related bruxism is moderate to high.

Many lines of treatment for sleep related bruxism have been proposed such as pharmacological, psychological, and dental. Pharmacological treatments include various drugs such as benzodiazepines, anticonvulsants, beta blockers, dopamine agents, antidepressants, muscular relaxants, and others. Patients with severe bruxism have been administered local injections of botulinum toxin (BTX type A) for the elimination of symptoms (Tan 2000). However, little is known about its effectiveness, pharmacological safety, and the follow up of the drug for a long period of time (Lavigne 2000). The psychological treatment is behaviour therapy based on sleep hygiene, relaxation to control stress, psychotherapy, hypnosis, and biofeedback (Lavigne 2000). Dental treatments for bruxism include occlusion adjustment, tooth surface restoration, and orthodontic treatment. These interventions are extensive and irreversible and these are not recommended in most cases (Clark 1985; Okeson 1996). Occlusal appliances such as a soft mouth guard or hard occlusal stabilization splint are reversible interventions. Soft mouth guards are usually recommended for short-term use because degradation can occur rapidly (Lavigne 2000). Occlusal splints may reduce teeth grinding, muscular activities, and myofascial pains (Dube 2004; Raphael 2003). Conversely, others have found an increase in muscle activity in 20% of hard splint users and in 50% of soft splint users (Okeson 1987). The cases presented in the literature seem to indicate a need to evaluate the use of occlusal splints for the treatment of sleep bruxism with alternative interventions.

OBJECTIVES

The purpose of this study is to evaluate the effectiveness of occlusal splints for the treatment of sleep bruxism with alternative interventions, placebo or no treatment.

METHODS

Criteria for considering studies for this review

Types of studies

We aimed to identify all randomised controlled trials (RCTs), in which occlusal splint was compared concurrently to no treatment, pharmacological interventions, any other occlusal appliances, placebo, or behaviour therapy. Trials using quasi-random methods of allocation (such as alternation, date of birth, record number) were included and subject to a sensitivity analysis.

Types of participants

All participants with sleep bruxism (tooth grinding or clenching). Children (greater than 1 year old) and adults.
Diagnostic criteria: clinical or polysomnographic or both.

Clinical diagnosis

The participant had a complaint of tooth grinding or tooth clenching during sleep and one or more of the following: abnormal tooth wear, tooth grinding sounds during sleep and jaw muscle discomfort.

Polysomnographic monitoring

Polysomnographic monitoring demonstrated both of the following: jaw muscle activity during the sleep period and absence of associated epileptic activity.

Polysomnographic diagnostic cut-off criteria: (1) more than 4 bruxism episodes per hour; (2) more than 6 bruxism bursts per episode or 25 bruxism bursts per hour of sleep or both; and (3) at least 2 episodes with grinding sounds (Lavigne 1996).

Exclusion criteria: Participants with comorbidity like movement disorders, and neurological and psychiatrical diseases.

Types of interventions

Occlusal splint compared with any of the following groups.

- Placebo.
- No treatment.
- Other types of appliances (palatal splint).
- Pharmacological interventions such as benzodiazepine, anticonvulsants, beta blockers, dopamine agents, antidepressants, botulin toxin A and B, analgesics and others.
- Behaviour therapy such as sleep hygiene, relaxation to control stress, psychotherapy, hypnosis and biofeedback.

Types of outcome measures

Primary outcome

Indexes of bruxism motor activity through masseter muscle electromyogram (EMG) associated with polysomnographic audio-video recordings: frequency of sleep bruxism episodes per hour of sleep (at least four episodes) and number of episodes with grinding noise (minimum of two).

Secondary outcomes

- Tooth wear (using an ordinal scale)
- Tooth restoration failure
- Quality of life
- Adherence
- Adverse events
- Temporomandibular joint pain (using a visual analogue scale (VAS)
- Assessment of clicking (joint sound) (yes or no)
- Assessment of jaw movement limitation
- Assessment of myofascial pain (using a VAS)
- Assessment of headaches (yes or no)
- Stress level: measures (using a validated scale)
- Mood factors (using a validated scale)
- Anxiety (using a validated scale)
- Depression (using a validated scale)
- Sleep variables: rapid eye movement (REM) sleep latency, efficiency, arousals index, stages, sleep latency, wake after sleep onset, total sleep time
- Masseteric EMG activity
- Apnoea-hypopnoea index.

Search methods for identification of studies

Studies were searched independently of language and source of information.

Electronic search

For the identification of studies included or considered for this review, detailed search strategies were developed for each database. These were based upon the search strategy developed for MEDLINE but revised appropriately for each database to take into account differences in controlled vocabulary and syntax rules.
The search strategy combined the subject search with phases 1 and 2 of the Cochrane Sensitive Search Strategy for Randomised Controlled Trials (RCTs) as published in Appendix 5b in the *Cochrane Handbook for Systematic Reviews of Interventions* 4.2.6 (updated September 2006).
The subject search used the free text terms based on the search strategy for searching MEDLINE via PubMed (*see* Appendix 1).

Databases searched

- Cochrane Oral Health Group's Trials Register (to May 2007)
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2007, Issue 1)
- MEDLINE (1966 to May 2007)
- EMBASE (1980 to May 2007)
- LILACS (1982 to May 2007)
- Dissertation, Theses and Abstracts (1981 to May 2007)
- Biblioteca Brasileira de Odontologia (1982 to May 2007).

Cross-checking references

References from original papers and abstracts, reviews, systematic reviews and meta-analyses were checked to identify any additional studies.

Personal communication

Authors of the included studies were contacted to identify further information about any relevant unpublished material.

Handsearching

Abstracts from sleep medicine meetings (American Academy of Sleep Medicine).

Data collection and analysis

Study selection

All potentially relevant articles and reports were assessed using a previously prepared inclusion criteria form. Two review authors (Cristiane Macedo (CRM), Marco Machado (MAM)) initially assessed the relevance of each article independently and in duplicate. Citation information was not masked. Disagreements were resolved by a third review author (Ademir Silva (ABS) or Gilmar Prado (GFP)). The authors of the trials were contacted for additional information, when necessary.

Data extraction

Data were extracted by two review authors (CRM, MAM) and in case of discrepancy, a third review author (ABS or GFP) was consulted for further discussion and reliability. Agreement between review authors was assessed using Kappa statistics. There was agreement between the review authors.
Data collection was undertaken according to the following criteria using specially designed data extraction forms.

- Study methods: randomisation procedure, method of allocation, blindness, design, duration.
- Participants: country of origin, sample size, age, gender, diagnosis criteria, history, setting, participants after randomisation and proportion of follow-up losses.
- Intervention: occlusal splint.
- Control: placebo, other types of appliances, drugs, behaviour therapy.
- Outcomes: primary and secondary outcomes mentioned in the section of outcome measures.

This information was used to help us assess heterogeneity and external validity of the trials.

Quality assessment

The methodological quality of included studies was assessed using the following criteria, described in the *Cochrane Handbook of Systematic Reviews of Interventions* 4.2.6.

- Randomisation: graded as adequate (A), unclear (B), inadequate (C). Adequate (A) included any one of the following methods of randomisation: computer generated or table of random numbers, drawing of lots, coin-toss, shuffling cards or throw of a dice. Inadequate method of randomisation (C) utilising any of the following: case record number, date of birth or alternate numbers were judged as inadequate (quasi-randomised studies).
- Concealment of allocation: graded as adequate (A), unclear (B), or inadequate (C). Adequate (A) methods of allocation concealment would include either central randomisation or sequentially numbered sealed opaque envelopes. This criterion was considered inadequate (C) if there was an open allocation sequence and the participants and trialists could foresee the upcoming assignment.
- Blinding of outcomes assessment: whether persons assessing the outcome of care were aware of which treatment the participant received, was graded as yes, no or unclear (detection bias).
- Handling of withdrawals and losses - was there a clear description given of the difference between the two groups of losses to follow up which was graded as yes (A), unclear (B) or no (C) (attrition bias).

Data analysis

For dichotomous outcomes, the estimate of effect of an intervention was expressed as risk ratios together with 95% confidence intervals (95% CI). For continuous outcomes, mean differences (WMD) to compare groups and standard deviations were used to summarise the data for each group. The random-effects model was used.

Data synthesis

Clinical heterogeneity was assessed by examining the types of participants, interventions and outcomes in each study. Meta-analysis was used when studies were of similar comparisons reporting comparable outcome measures in similar participants. Mean differences were combined for continuous data. Risk ratios were used for dichotomous data if meta-analysis was feasible. The significance of any discrepancies in the estimates of the treatment effects from the different trials was assessed by means of Cochran's test for heterogeneity. Inconsistency among the pooled estimates was quantified using the I^2 statistic.

Sensitivity analyses were undertaken to examine the effect of randomisation, allocation concealment and blind outcome assessment on the overall estimates of effect.
If there were an adequate number of studies, quasi-randomised studies would be analysed separately from the randomised ones in a sensitivity analysis.

In a attempt to assess publication bias, data would be plotted onto a funnel plot graph (trial effect versus trial size).

RESULTS

Description of studies

Thirty-two potentially relevant randomised controlled trials (RCTs) were identified, but just five met the inclusion criteria (Alvarez-Arenal 2002; Dube 2004; Hachmann 1999; Landry 2006; Van der Zaag 2005), one German study is waiting assessment (Ommerborn), two studies were published as abstract and as paper with full results (Dube 2004; Landry 2006) and 24 studies were excluded for the following reasons: not RCT (Hamada 1982; Holmgren 1990; Leib 2001; Mejias 1982; Nagels 2001; Ommerborn 2003; Okeson 1987; Sakaguchi 2003; Sheikholeslam 1986; Sheikholeslam 1993; Shiau 1980; Tomonaga 2005; Wang 1993; Wieselmann 1986; Wieselmann 1987 a; Wieselmann 1987 b; Wieselmann 1987 c), insufficient data presented (Harada 2006; Pierce 1988), outcome of no interest at least in one step (Fujii 2005), outcome not specified (Manns 1983), randomisation not stated (Yin 2004), and inclusion criteria not specified (Raphael 2003; Shankland 2002).

Design

Just one study was randomised inadequately (quasi-randomised) (Hachmann 1999). The other four included studies were randomised and controlled (Alvarez-Arenal 2002; Dube 2004; Landry 2006; Van der Zaag 2005). Three studies were of cross-over design (Alvarez-Arenal 2002; Dube 2004; Landry 2006) and two were parallel group studies (Hachmann 1999; Van der Zaag 2005). Blinding was attempted in all studies at least in one step. Although the occlusal splint differed in appearance from the other device (Additional Table 1), in a study (Dube 2004) participants were informed that they were to receive two active devices, and in another one (Van der Zaag 2005) neither the type of device nor expected mechanism were mentioned.

Interventions

One study compared occlusal splint with transcutaneous eletric nerve stimulation (TENS) (Alvarez-Arenal 2002); two studies compared occlusal splint with palatal splint (Dube 2004; Van der Zaag 2005) also called palatal control device (Dube 2004); one study compared occlusal splint with three configurations of the

mandibular advancement device (also called double arch device) (Additional Table 1) (Landry 2006); and one study compared occlusal splint (also called Michigan type bite plate) with no treatment (Hachmann 1999). Occlusal splint therapy consisted of a device with full coverage of the occlusal surfaces worn in the maxilla (Dube 2004; Hachmann 1999; Landry 2006; Van der Zaag 2005), or in the mandible (Alvarez-Arenal 2002). Palatal splint therapy consisted of a device with palatal coverage only (Dube 2004; Van der Zaag 2005). The mandibular advancement device which was designed to manage sleep apnoea, was used in three configurations: double arch device free without pin between arches, which allowed freedom of movement; mandibular advancement device in 25%; and 75% lower arch advancement position (Landry 2006). TENS was a low-frequency neurostimulator that generates stimuli (1 every 1.5 seconds) with a duration of 500 ms and a variable amplitude of 0 to 25mA. Among the interventions of interest across the included studies, there was a number of types of appliances as described in Additional Table 1.

Participants

One study included children (age range 3 to 5 years) (Hachmann 1999) and the other four studies analysed only adults. The majority of adults were women. In two studies the average age was 24 years (Dube 2004; Landry 2006), in one study the average age was 34.8 (Van der Zaag 2005), and the other study did not report either the average age or sex of the subgroup who grinded their teeth (Alvarez-Arenal 2002). In three studies there was polysomnographic confirmation of sleep bruxism (Dube 2004; Landry 2006; Van der Zaag 2005) and in the other two studies the diagnosis was just clinical (Alvarez-Arenal 2002; Hachmann 1999). Participants with comorbidity (temporomandibular disorders) were observed in only one study (Alvarez-Arenal 2002).

Duration

The studies were performed between 2 weeks to 2 months. Just one study (Hachmann 1999) conducted follow up for 6 months.

Outcomes

Three studies analysed sleep bruxism indexes, and sleep variables (Dube 2004; Landry 2006; Van der Zaag 2005); furthermore, two of the studies analysed which devices were preferred by participants and which of those were more comfortable during the wear (Dube 2004; Landry 2006). Just one study analysed clicks and pain in temporomandibular joints (TMJ), and headaches (Alvarez-Arenal 2002). One study evaluated the progression of wear facets (Hachmann 1999).

Risk of bias in included studies

Randomisation methods

Four studies were randomised controlled studies (Alvarez-Arenal 2002; Dube 2004; Landry 2006; Van der Zaag 2005). Only one was quasi-randomised with inadequate randomisation and concealment (C) (Hachmann 1999). The allocation concealment was adequate in three studies (A) (Dube 2004; Landry 2006; Van der Zaag 2005) and was not clear in one study (B) (Alvarez-Arenal 2002). The method to generate the randomisation sequence was appropriate in four studies (A) (Alvarez-Arenal 2002; Dube 2004; Landry 2006; Van der Zaag 2005).

Blind method

Three studies described double-blind methods (Dube 2004; Landry 2006; Van der Zaag 2005) and two studies described single-blind methods (Alvarez-Arenal 2002; Hachmann 1999).

Attrition

There were no drop outs in three studies (A) (Alvarez-Arenal 2002; Dube 2004; Hachmann 1999). There were no losses in the follow up (A) in one study (Hachmann 1999).
The authors did not report follow up in four studies (Alvarez-Arenal 2002; Dube 2004; Landry 2006; Van der Zaag 2005).

Landry 2006 reported losses (1/14) without intention-to-treat analysis.

Van der Zaag 2005 did report the number of withdrawals, but available details allowed the review authors to be sure of only two participants. On the other hand, there were two more participants whose drop-out moments were not pinpointed (whether before or after the randomisation). In both potential drop-out rates, 2/23 or 4/25, the study should be considered as of low risk of bias with regard to the attrition (B). There was no intention-to-treat analysis.

Additional considerations

All the authors of the included studies were contacted, and all of them replied (Alvarez-Arenal 2002; Dube 2004; Hachmann 1999; Landry 2006; Van der Zaag 2005).

Effects of interventions

Occlusal splint versus palatal splint (Comparison 1)

There were two studies for this comparison (Dube 2004; Van der Zaag 2005). The studies had different designs: Dube 2004 carried out a cross-over study and Van der Zaag 2005 a parallel study. There was just one common outcome (arousal index) (Outcome 1.2) which was combined in a meta-analysis.

No significant differences between intervention and control groups were found in the meta-analyses of arousal index (mean difference (WMD) 1.22 (95% confidence interval (CI) -3.61 to 6.05) P = 0.62).

Van der Zaag 2005 reported variables that could be analysed. Number of bruxism episodes per hour of sleep (Epi/h) (Outcome 01) resulted in no statistically significant differences between the groups, as expressed by its confidence interval and significance test (WMD 0.54 (95% CI -10.95 to 12.93)). No statistically significant differences between groups were found in regards to the total sleep time (Outcome 1.3) (WMD -8.60 (95% CI -96.17 to 78.97)).

In Dube 2004 no statistically significant differences between intervention and control groups were found in the episodes with grinding noise (Outcome 1.4) (WMD 0.90 (95% CI -10.19 to 11.99)). No statistically significant differences between the groups were found in the awakenings during sleep (Outcome 1.5) (WMD 0.40 (95% CI -2.51 to 3.31)). No statistically significant differences between groups were found in sleep efficiency (Outcome 1.6) (WMD -2.40 (95% CI -8.36 to 3.56)). On preference outcome all participants preferred the palatal splint, but participants rated both splints as equal in the comfort outcome (median - visual analogue scale (VAS) 100 mm) occlusal splint = 79.3, ± 4.7/100 mm; palatal splint = 77.8, 8.1/100 mm.

Occlusal splint versus transcutaneous electric nerve stimulation (TENS) (Comparison 2)

Only one study (Alvarez-Arenal 2002) in this comparison reported four variables and two of them, headaches and pain in the temporomandibular joint (TMJ), did not occur. Patients treated with splint had a lower risk of clicks in TMJ during oral opening and closing when compared to the TENS group, but without statistical significance (risk ratio (RR) 0.60 (95% CI 0.19 to 1.92)). No statistically significant differences between groups were found in the clicks in TMJ, whether opening or closing the mouth (RR 1.00 (95% CI 0.33 to 3.02)) (Alvarez-Arenal 2002).

Occlusal splint versus no treatment (Comparison 3)

Just one included study analysed the increase in the size of wear facets outcome resulting in no statistically significant difference between the groups (RR 0.20 (95% CI 0.03 to1.15)). The same results were found after the follow up of 6 months (Hachmann 1999) (Outcomes 3.1, 3.2).

Occlusal splint versus mandibular advancement device in 75% advancement (MAD max) versus mandibular advancement device in 25% advancement (MAD min) versus mandibular advancement device free (MAD free)

There was only one study that analysed this comparison. The participants preference resulted in a higher proportion of benefitted participants in the occlusal splint group (12/13) as compared to the proportion in the other groups (1/13) (Landry 2006). Results were sent by the authors: sleep bruxism episodes per hour for the MAD max (mean difference = 5.9; standard deviation (SD) = 1.68; $P < 0.001$ paired t-test); pain during the night for the MAD max and MAD min (8/13); oral dryness for MAD min (7/13); comfort (median - VAS 100 mm) occlusal splint = 79 mm, MAD free = 41 mm, MAD min = 15 mm, MAD max = 12 mm.

DISCUSSION

The objective of the present study was to evaluate the effectiveness of occlusal splints in the treatment of sleep bruxism, by means of a systematic review.

Among the studies identified in the databases, only five clinical trials satisfied the inclusion criteria and were thus selected. Non-randomised clinical trials and case series that did not satisfy the inclusion criteria for the present review were also found. The small number of clinical trials that fulfilled the criteria for inclusion in systematic reviews was probably due to two reasons: difficulties inherent to conducting randomised clinical trials; or lack of knowledge about the importance of conducting these types of studies in evaluating the effectiveness of a type of treatment.

In general, the methodological quality of the five trials included was not good. None of the studies gave a clear description of the concealment of allocation and only one study described how the allocation sequence was generated. Some inclusion criteria were not specified by the authors, and other outcomes could not be analysed because they were inappropriately described. Contact was made with the authors with the aim of clarifying possible doubts and, even after contact, only three studies were classified as A (the randomisation method was described adequately), while one study was classified as B (the randomisation method was not described) and the remaining study was classified as C (the randomisation method was described, but done inadequately). Few authors responded to the requests that were made and, unfortunately, some responses were vague and insufficient for clarifying the doubts relating to the methodological quality and the results described.

Most of the studies have a cross-over design. In contrast to parallel studies, each individual in a cross-over study receives two or more interventions in random order, and each patient acts as his own control. In this type of study, the washout period takes on great importance, because the treatment may alter the condition of interest in the subsequent phases, in which the patient systematically differs from the initial state (Elbourne 2002).

The study by Dubé 2004 was included because it was a randomised study using the chosen intervention and had the objective of determining the efficacy of the occlusal splint in comparison with a control (palatal splint) in sleep bruxism cases. However, this study presented a series of limitations, such as the fact that it was an explanatory type of study. That is, it presented a small number of participants and involved several polysomnography sessions in order to establish a baseline and the results, which is not done routinely because of the costs related to this examination. Another point is the fact that the apparatus utilised in this study (palatal splint), which was also used in the study by Van der Zaag 2005, differed from what is routinely used.

Analysis of the results from the clinical trials included in the review revealed that there were no significant differences between the group treated using an occlusal splint and those who received no treatment or were treated using a palatal splint, mandibular advancement device or transcutaneous electric nerve stimulation (TENS). The lack of significant difference between the outcomes may be due to the small number of participants included in the studies analysed. Thus, the small number of participants in the study favors the null hypothesis because insufficient statistical power was presented for verifying whether the small differences observed between the interventions were significant. On the other hand, the lack of standardisation in the analyses of the outcomes made it impossible to conduct a meta-analysis in most instances. It could only be done for the arousal index found in two studies.

The outcomes from the studies were measured in a variety of ways. Those that analysed sleep variables and the bruxism index used the polysomnography test as a tool both for diagnosing the disease and for assessing the efficacy of the treatment. Temporomandibular joint (TMJ) pain was evaluated by means of palpation and headache by means of the patient's reports. Clicks in the TMJ were evaluated by means of opening and closing the mouth. Analysis of the increased tooth wear was carried out by means of using plaster models. Finally, the comfort factor in using the device was evaluated by means of a visual analogue scale (VAS) and the patients were asked directly about their preferences regarding the devices.

Sleep outcomes

Dube 2004 and Van der Zaag 2005, compared the occlusal splint with the palatal splint for sleep variables and the sleep bruxism index. The sleep variables were sleep efficiency, total sleep duration, arousal index and awakenings index. The variables for the sleep bruxism index were assessed in two categories: number of bruxism episodes per hour (using electromyography) and episodes

with grinding noise. No statistically significant differences were found between the occlusal splints and palatal splints for any of the abovementioned outcomes. Meta-analysis was conducted only on the arousal index outcome, and the difference found for this outcome can be explained by the clinical heterogeneity of the patients between the two studies. In other words, the degree of severity of the bruxism between the participants in the two studies was probably significantly different. Another relevant point is the difference in age between the patients in these two groups: in the study by Dube 2004, the patients were much younger and this may explain the lower arousal index. Moreover, in the study by Van der Zaag 2005, the first-night effect may have occurred, in that the data were collected on the first night that the test was conducted. On the other hand, in the study by Dube 2004, this effect was minimised through adapting the patient to the laboratory on the first night and only collecting data on the second night.

The occlusal alteration produced by the occlusal splint did not provide results differing from the results using the palatal splint (which did not modify the occlusion). Thus, it can be considered that the presence or absence of occlusal protection provided by the devices did not present significant differences for the outcomes of sleep variables and sleep bruxism index. This lack of differences suggests that the effects from therapy using these devices may occur independently of the type of splint utilised. Therefore, although the two devices are different, they may have the same type of influence on oral behaviour, such as salivation and deglutition (Kato 2003). In fact, the role of occlusal interference in the aetiology of bruxism is increasingly questioned. Even though the removal of occlusal interference has been one of the mechanisms for explaining the action of the occlusal splint, Bailey 1980 demonstrated that the occlusal adjustment did not eliminate sleep bruxism. During the same period, Greene 1982 showed through epidemiological data that bruxers could not be distinguished morphologically from non-bruxers. More recently, in a case control study, Lobbezoo 2001 b did not find differences between normal subjects and bruxers for morphological and occlusal variables. The same author (Lobbezoo 2001 a) discusses that bruxism is principally regulated by a central pathophysiological mechanism that is modulated by neurotransmitters in the central nervous system (Lobbezoo 1997) and is behavioural, rather than being due to a peripheral cause such as bone morphology alterations and occlusal alterations. At present there are no reliable data that would support a role for the occlusion in bruxism.

Another mechanism proposed for explaining the action of the occlusal splint in bruxism cases is the change in muscle activity and modification in the patients' habits caused by the splint. Although some studies have correlated the use of the occlusal splint with decreased muscle activity, this effect only lasts while the treatment is utilised (Pierce 1988; Sheikholeslam 1986). The use of such splints has been proposed for preventing bruxism from damaging the periodontal zone and the teeth against the adverse effects of prolonged overload.

Pain outcomes

Alvarez-Arenal 2002 compared the occlusal splint with TENS for TMJ pain and headache outcomes, although none of these events occurred within this sample. This absence may have occurred because of the small number of participants in the study. It is worth emphasising that this study differed from the others in that the occlusal splint used was mandibular, which may have given different results. For the headache outcome, Sheikholeslam 1993 found an improvement of 82% in the chronic signs and symptoms relating to craniomandibular dysfunction in patients with sleep bruxism, following the use of the maxillary occlusal splint. Thus, improvements in TMJ pain and headache were observed. However, despite these findings, it is important to emphasise that this study was a case series without a control group. In a recent retrospective study, bruxers were compared with normal individuals and a high prevalence of headache and shoulder and neck pain was found among the bruxers (Huynh 2006). Outcomes such as morning pain, which has been reported by some patients who ground their teeth during the night (Dao 1994), were not assessed in any of the trials included in the present review. Painful processes such as morning headache, or muscle discomfort with or without pain, may interfere in daily activities and could have been measured by means of quality-of-life questionnaires.

Tooth wear outcomes

Tooth wear was only analysed by Hachmann 1999, in a quasi-randomised study among children. This was done by means of analysing the increase in the size of wear facets. In this clinical trial, there was no significant difference in occlusal wear between patients who used the occlusal splint and those who did not receive treatment, although there was a tendency towards a greater proportion of patients benefitting from the use of the splint. Out of the five patients in the treatment group, only one presented wear on the incisal face of the canine analysed in the model, and these results were also verified in the incisal wear after 6 months. Because the wear in the treatment group occurred in a single individual, the authors discussed the hypothesis that this patient may not have used the device correctly. Despite the absence of significant difference in the results, there seems to be a consensus among the professionals that, by indicating the use of occlusal splints for patients with sleep bruxism, occlusal tooth wear and soft tissue trauma are prevented (Walker 1992). This extremely important outcome was not analysed in adults, in any of the studies in the present review.

Click outcomes

Alvarez-Arenal 2002 compared the occlusal splint with TENS, in patients with and without temporomandibular dysfunction (TMD). No statistically significant difference was found for the outcome of clicks in the TMJ, either when opening or when closing the joint.

Degree of comfort outcomes

Dube 2004 compared the occlusal splint and palatal splint in relation to the degree of comfort. When the patients were asked which device type they preferred, they all said they preferred the palatal splint, rather than the occlusal splint, but when they were asked about the degree of comfort, measured using the VAS, they were evaluated as equally comfortable. 71% of the patients felt that the occlusal splint offered greater protection for their teeth. None of the patients reported a dry mouth during the night or in the morning with either of the two devices. The patients were interviewed again 1 year later. Five of the seven patients contacted were continuing to use the splints, of whom four used the occlusal splint and one preferred the palatal splint. In one other study on preferences regarding the type of device, Landry 2006 showed that

12 out of their 13 patients preferred the occlusal splint to other device (mandibular advancement device free (MAD free)).

Although the action mechanism has not yet been fully explained, splints have been widely utilised for decades, and are seen as a successful therapeutic method (Carlson 1993; Visser 1995). In the United States, it has been estimated that 1,200,000 occlusal splints are manufactured every year, for both children and adults. Since the cost per splint is 275 dollars, an estimated total of 330 million dollars per annum is spent on their production (Pierce 1995). Despite the high expenditure on these devices, no studies with any high degree of scientific reliability have been produced to justify their widespread use. The lack of reliable answers regarding the effectiveness of occlusal splints can mainly be attributed to the inadequate methodology of the studies conducted, such as the predominance of case series and case control studies, disregard for the natural course of the disease, the professional-patient relationship, and the lack of good quality randomised clinical trials with enough participants to give statistical power to the outcome analyses.

To answer the question regarding the effectiveness of the occlusal splint on tooth wear on the basis of calculating the sample size, if it is considered that 100% of cases wear tooth without treatment and 40% of cases wear tooth with treatment, and taking the statistical power to be 90% and alpha error of 5%, then at least 10 individuals would be needed in each group (treatment group and control group). Taking into consideration losses of around 20%, another four individuals would be added to each group, thus giving a total of 24 individuals.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence is insufficient for affirming that the occlusal splint is effective for treating sleep bruxism. Indication of its use is questionable with regard to the sleep outcomes, but it may be that there is some benefit with regard to tooth wear.

Implications for research

This review suggests that there is a need for more randomised controlled clinical trials that are well designed, in order to clarify whether there is any benefit from the occlusal splint in the treatment of sleep bruxism.

The method utilised in the randomisation (use of random number tables, randomisation generator, or others), and also concealment of the allocation (use of opaque sealed envelopes) must be appropriate and be described by the author. The study design must be parallel, in order to eliminate the bias provided by studies of cross-over type. Masking for evaluating the outcomes, for data analysis and, when possible, for the patient, must be implemented and described. The diagnostic criteria for sleep bruxism must be standardised in accordance with those of the American Sleep Disorders Association, as must the name to be utilised for the disease, so as to prevent possible misunderstandings regarding bruxism types. For example, the term 'nocturnal bruxism' is often used instead of 'sleep bruxism' but, obviously, people can sleep and grind their teeth both during the day and during the night. Outcomes such as tooth wear in adults, morning headache, morning fatigue, neck and shoulder pain, quality of life, tolerability of the devices, costs and patient satisfaction must be evaluated. The results must be expressed as risk ratios with 95% confidence intervals, or by means. If losses occurs, the analysis must be by intention-to-treat, and all the data must be described by the author. Attention must be paid to possible collateral effects that could appear during occlusal splint treatment. There is a need for a considerable length of follow up.

New studies could make comparisons between the occlusal splint group and other groups, such as: occlusal splint associated with transcutaneous electric nerve stimulation (TENS); occlusal splint and behavioural therapy; or occlusal splint and pharmacological intervention. Furthermore, standardisation with regard to the type of occlusal splint to be utilised must be implemented (maxillary or mandibular).

In summary, because of the limitations in the methods used in the studies included, it is recommended that future studies should include: randomised controlled studies with rigorous methodology; calculation to determine the sample size, in order to increase the power of the study for estimating the effect. It is also suggested that the guidelines produced by the CONSORT Group (CONSORT 2005) should be followed, since their use would improve the quality of trials for managing the treatment of sleep bruxism.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Alvarez-Arenal 2002

Methods	Radomised controlled cross-over study; allocation concealment unclear; blinded data collection; the order of the treatment was randomised for each participant; 1 month and a half washout period between treatments.
Participants	11 participants who grinded their teeth were diagnosed via anamnese and/or a questionnaire, clinical examination, and tooth grinding reported by partner. Among all patients, 5 presented temporomandibular disorders (TMD) at the initial evaluation.
Interventions	Group A: Occlusal splint (n = 11). They wore their splint 24 hours a day except for eating, for a 45-day period. Group B: TENS (n = 11). Each TENS session lasted 45-60 minutes and each patient underwent 15 sessions (1 every 2 days).
Outcomes	Clicks recorded in both temporomandibular joints (TMJ) during oral opening and closing; clicks recorded in both TMJ during either oral opening or closing; pain in some TMJ; headache.
Notes	The following completed data were acquired by personal communication: 1) Allocation sequence was generated by random number tables. 2) 13 clenchers clenched their teeth during the day. 3)The criteria used to identify the bruxers were dental abrade and muscle hypertrofia by clinical exam and teeth gridding reported by partner. 4) Allocation concealment was performed (the answer was unclear). Setting: Participants were recruited from the Dental School of the University of Oviedo (Spain) and from dental private clinics.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Dube 2004

Methods	Randomised controlled cross-over study; allocation concealment; patients, data extractors and data analysis were blinded; the order of the appliances was randomised for each patient.
Participants	9 young adults (4 men, 5 women), age mean of 23.7 years (SD = ± 0.9; range = 20-29 years); history of tooth grinding for at least 3 nights per week during the last 6 months reported by partner and polygraphic exam confirmed at least 4 episodes of sleep bruxism per hour of sleep and at least 2 episodes with tooth grinding sound; presence of tooth wear showed at least the degree of exposed dentine (grade 2) and/or masseter muscle hypertrophy upon voluntary clenching and/or symptons of morning orofacial jaw muscle fatigue. Were excluded from this study participants with pain, neurological or sleep disorders, and using medication, drug, or acohol. Also were excluded those who had been treated with any type of oral device in the preceding 6 months, those wearing a partial denture, missing more than 2 posterior teeth, or presenting gross malocclusion.
Interventions	Group A: Occlusal splint (n = 9). Group B: Palatal splint (n = 9). 2 weeks for each proposed intervention; after collection of polygraphic data from the first splint a second splint was given on the next morning.
Outcomes	Sleep efficiency; arousal index; awakenings/h; number of episodes with noise; preference; comfort.
Notes	The following completed data were acquired by personal communication: 1) randomisation was done with a computer generated sequence; 2) sealed opaque envelope was used to perform allocation concealment; 3) the abstract entitled 'Quantitative assessment of occlusal splint efficacy on sleep bruxism/tooth grinding: a randomized-controlled trial' is the same study as 'Quantitative polygraphic controlled study on efficacy and safety of oral splint devices in tooth-grinding subjects' with full results; 4)

Dube 2004 *(Continued)*

some data could not be obtained. Setting: Patients were recruited by referrals from clinicians and by advertisement at the Montreal University (Canada).

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Hachmann 1999

Methods	Quasi-randomised controlled study; without allocation concealment; blinded data collection; duration 2 months.
Participants	9 children, age ranging from 3 to 5 years with tooth grinding and tooth grinding sounds during sleep reported by parents, abnormal tooth wear and jaw muscle discomfort. Children with health problems were excluded from the study.
Interventions	Group A: Occlusal splint (n = 5) only at night for 2 months with adjustments weekly. Group B: No treatment (n = 4).
Outcomes	Increase in the size of wear facets (canine teeth) were analysed by visual inspection of stone models at the end of treatment and after 6 months of follow up.
Notes	The following completed data were acquired by personal communication: 1) Just allocating every alternate person. 2) All children in control group showed increase in size of wear facets at the end of treatment. 3) 1 children in treatment group showed increase in size of wear facets at the end of treatment. 4) All children in control group showed increase in size of wear facets at the end of follow up. Setting: Public day care centres, private practices and the School of Dentistry-Paediatric Dentistry outpatient clinic of the UFRGS from Brazil.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Landry 2006

Methods	Randomised controlled cross-over study; patients, data extractors and data analysis were blinded; 1 week washout period between treatments.
Participants	13 severe bruxers (9 females and 4 males), age mean of 24 years; history of tooth grinding for at least 3 nights per week and polygraphic confirmation of a minimum of 4 episodes of sleep bruxism per hour of sleep and a minimum of 2 episodes with tooth grinding sound. Participants with pain, neurological or sleep disorders, missing more than 2 posterior teeth, using medication, drug or alcohol were excluded from the study. Also were excluded those who had been treated with any type of oral device in the preceding 6 months, those wearing a dental prothesis, or presenting gross malocclusion.
Interventions	Group A: Occlusal splint (n = 13). Group B: Mandibular advancement device in 25% advancement position (n = 13). Group C: Mandibular advancement device in 75% advancement position (n = 13). Group D: Mandibular advancement device free (n = 13), 2 weeks of treatment duration.

Landry 2006 *(Continued)*

Outcomes	Sleep bruxism episodes per hour of sleep; sleep latency; number of orofacial activities; pain during the night; oral dryness; comfort; preference.
Notes	The following completed data were acquired by personal communication: 1) randomisation was done with a computer generated sequence; 2) sealed opaque envelope was used to perform allocation concealment; 3) some results are presented in results section; 4) the abstract entitled 'Effect of double arch device and occlusal splint in sleep bruxism patients' is the same study as 'Reduction of sleep bruxism using a mandibular advancement device: an experimental controlled study' with full results. Some data could not be obtained because they are reported inappropriately. Setting: Patients were recruited by advertisement at the Montreal city universities and colleges (Canada).

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Van der Zaag 2005

Methods	Controlled randomised clinical study (block randomisation); allocation concealment; patients and data extractors were blinded.
Participants	21 adults (5 men, 16 women) age mean of 34.8 years (SD = ± 12.2; range = 18-68 years); with tooth grinding sounds during sleep for at least 3 nights per week during the last 6 months reported by partner, tooth wear to at least the degree of exposed dentine (grade 2). Were excluded from this study those participants with a medical contraindication, such as epilepsy or other sleep disorder or the use of any medication with a known influence on sleep structure or SB.
Interventions	Group A: Occlusal splint (n = 11) with 4 men and 7 women with mean age of 34.2 years (SD = ± 13.1; range = 21-68 years). Group B: Palatal splint (n = 10) with 1 men and 9 women with mean age of 34.9 years (SD = ± 11.2; range = 18-55 years). They wore their splint 24 hours a day, except for eating for 4 weeks.
Outcomes	Number of bruxism episodes per hour of sleep; total sleep time; sleep efficiency; arousal index.
Notes	The following completed data were acquired by personal communication: 1) randomisation was done with a computer generated sequence; 2) sealed opaque envelope was used to perform allocation concealment. Some data could not be obtained. Setting: Participants were recruited from the Department of Oral Function, Section of Oral Kinesiology, of the Academic Centre for Dentistry in Amsterdam or the Department of Clinical Neurophysiology of the Slotervaart General Hospital in Amsterdam (Holland).

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

SD = standard deviation; TENS = transcutaneous electric nerve stimulation

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Fujii 2005	Outcome of no interest - change in occluding contact points.
Hamada 1982	Case series.
Harada 2006	Data inappropriately reported. Unsuccessful personal contact.
Holmgren 1990	Case series.
Leib 2001	Case series.
Manns 1983	Outcome not specified. Unsuccessful personal contact.
Mejias 1982	Non-randomised clinical study.
Nagels 2001	Case series.
Okeson 1987	Non-randomised clinical study.
Ommerborn 2003	Non-randomised clinical study.
Pierce 1988	Data inappropriately reported. Unsuccessful personal contact.
Raphael 2003	Inclusion criteria not specified. Unsuccessful personal contact.
Sakaguchi 2003	Non-randomised clinical study.
Shankland 2002	Inclusion criteria not specified. Unsuccessful personal contact.
Sheikholeslam 1986	Case series.
Sheikholeslam 1993	Case series.
Shiau 1980	Non-randomised clinical study.
Tomonaga 2005	Non-randomised clinical study.
Wang 1993	Non-randomised clinical study.
Wieselmann 1986	Case series.
Wieselmann 1987 a	Case series.
Wieselmann 1987 b	Case series.
Wieselmann 1987 c	Case series.
Yin 2004	Randomisation not stated. Unsuccessful personal contact.

DATA AND ANALYSES

Comparison 1. Occlusal splint versus palatal splint

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of bruxism episodes per hour of sleep (Epi/h)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2 Arousal index	2	39	Mean Difference (IV, Fixed, 95% CI)	1.22 [-3.61, 6.05]
2.1 Parallel study	1	21	Mean Difference (IV, Fixed, 95% CI)	12.90 [-5.93, 31.73]
2.2 Cross-over study	1	18	Mean Difference (IV, Fixed, 95% CI)	0.40 [-4.60, 5.40]
3 Total sleep time (min)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4 Episodes with grinding noise	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5 Awakenings/hr	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
6 Sleep efficiency (%)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

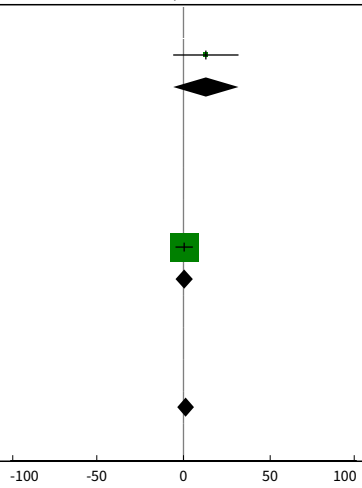
Analysis 1.1. Comparison 1 Occlusal splint versus palatal splint, Outcome 1 Number of bruxism episodes per hour of sleep (Epi/h).

Study or subgroup	Occlusal splint N	Occlusal splint Mean(SD)	Palatal splint N	Palatal splint Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Van der Zaag 2005	11	11.1 (12.2)	10	10.6 (14.5)		0%	0.54[-10.95,12.03]

Favours occlusal s. Favours palatal s.

Analysis 1.2. Comparison 1 Occlusal splint versus palatal splint, Outcome 2 Arousal index.

Study or subgroup	Occlusal splint N	Occlusal splint Mean(SD)	Palatal splint N	Palatal splint Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
1.2.1 Parallel study							
Van der Zaag 2005	11	31.2 (18.6)	10	18.3 (24.7)		6.58%	12.9[-5.93,31.73]
Subtotal ***	**11**		**10**			**6.58%**	**12.9[-5.93,31.73]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.34(P=0.18)							
1.2.2 Cross-over study							
Dube 2004	9	8 (5.7)	9	7.6 (5.1)		93.42%	0.4[-4.6,5.4]
Subtotal ***	**9**		**9**			**93.42%**	**0.4[-4.6,5.4]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.16(P=0.88)							
Total ***	**20**		**19**			**100%**	**1.22[-3.61,6.05]**
Heterogeneity: Tau^2=0; Chi^2=1.58, df=1(P=0.21); I^2=36.76%							



Favours occlusal s. Favours palatal s.

Study or subgroup	Occlusal splint N	Occlusal splint Mean(SD)	Palatal splint N	Palatal splint Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Test for overall effect: Z=0.5(P=0.62)							
Test for subgroup differences: Chi²=1.58, df=1 (P=0.21), I²=36.76%							

Favours occlusal s. -100 -50 0 50 100 Favours palatal s.

Analysis 1.3. Comparison 1 Occlusal splint versus palatal splint, Outcome 3 Total sleep time (min).

Study or subgroup	Palatal splint N	Palatal splint Mean(SD)	Oclusal splint N	Oclusal splint Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Van der Zaag 2005	10	437 (107)	11	445.6 (96.8)		0%	-8.6[-96.17,78.97]

Favours occlusal s. -100 -50 0 50 100 Favours palatal s.

Analysis 1.4. Comparison 1 Occlusal splint versus palatal splint, Outcome 4 Episodes with grinding noise.

Study or subgroup	Occlusal splint N	Occlusal splint Mean(SD)	Palatal splint N	Palatal splint Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Dube 2004	9	10.9 (11.7)	9	10 (12.3)		0%	0.9[-10.19,11.99]

Favours occlusal s. -100 -50 0 50 100 Favours palatal s.

Analysis 1.5. Comparison 1 Occlusal splint versus palatal splint, Outcome 5 Awakenings/hr.

Study or subgroup	Occlusal splint N	Occlusal splint Mean(SD)	Palatal splint N	Palatal splint Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Dube 2004	9	3.8 (3)	9	3.4 (3.3)		0%	0.4[-2.51,3.31]

Favours occlusal s. -4 -2 0 2 4 Favours palatal s.

Analysis 1.6. Comparison 1 Occlusal splint versus palatal splint, Outcome 6 Sleep efficiency (%).

Study or subgroup	Occlusal splint N	Occlusal splint Mean(SD)	Palatal splint N	Palatal splint Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Dube 2004	9	93.3 (8.1)	9	95.7 (4.2)		0%	-2.4[-8.36,3.56]

Favours palatal s. -100 -50 0 50 100 Favours occlusal s.

Comparison 2. Occusal splint and TENS

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Headaches	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2 Pain in TMJ	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

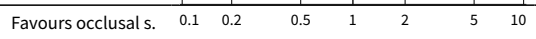
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 Clicks TMJ oral opening and closing	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4 Clicks TMJ oral opening or closing	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Analysis 2.1. Comparison 2 Occusal splint and TENS, Outcome 1 Headaches.

Study or subgroup	Occlusal splint n/N	TENS n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Alvarez-Arenal 2002	0/11	0/11			Not estimable

Analysis 2.2. Comparison 2 Occusal splint and TENS, Outcome 2 Pain in TMJ.

Study or subgroup	Occlusal splint n/N	TENS n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Alvarez-Arenal 2002	0/11	0/11			Not estimable



Analysis 2.3. Comparison 2 Occusal splint and TENS, Outcome 3 Clicks TMJ oral opening and closing.

Study or subgroup	Occlusal splint n/N	TENS n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Alvarez-Arenal 2002	3/11	5/11		0%	0.6[0.19,1.92]

Analysis 2.4. Comparison 2 Occusal splint and TENS, Outcome 4 Clicks TMJ oral opening or closing.

Study or subgroup	Occlusal splint n/N	TENS n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Alvarez-Arenal 2002	4/11	4/11		0%	1[0.33,3.02]

Comparison 3. Occlusal splint versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Increase in the size of wear facets (canine teeth)	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2 Increase in the size of wear facets (canine teeth) 6 months of follow up	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

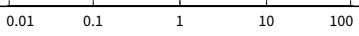
Analysis 3.1. Comparison 3 Occlusal splint versus no treatment, Outcome 1 Increase in the size of wear facets (canine teeth).

Study or subgroup	Occlusal splint n/N	No treatment n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Hachmann 1999	1/5	4/4		0%	0.28[0.07,1.15]

Favours occlusal s. Favours no treat.

Analysis 3.2. Comparison 3 Occlusal splint versus no treatment, Outcome 2 Increase in the size of wear facets (canine teeth) 6 months of follow up.

Study or subgroup	Occlusal splint n/N	No treatment n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Hachmann 1999	1/5	4/4		0%	0.28[0.07,1.15]



Favours occlusal s. Favours no treat.

ADDITIONAL TABLES

Table 1. Appliances description

Authors	Appliances
Alvarez-Arenal	Occlusal splint was a mandibular transparent thermopolymerising acrylic that was prepared via classical technique (fitting of models in a semiadjustable articulator). The occlusal surface was smooth and levelled with point form contacts, in centric relation, of the functional and non-functional antagonist cuspids of the posterior teeth. In the anterior sector of the splint the contacts of the anterior teeth were less pronounced, and the inclined planes for the canine and protrusive guides were well defined to provide immediate disocclusion of the posterior teeth during mandibular eccentric movements.
Dube	Occlusal splint was a hard acrylic U-shaped occlusal splint. Maxillary and mandibular arch impressions were made with alginate and models were cast in artificial stone. The centric tooth relation was taken with a blue wax waffle. A face bow was used to mount the models on a semiadjustable articulator. The splint was made on the maxillary models and then inserted and adjusted. The adjustment was made in centric relation with the use of a 32-µm articulation paper. Only the points corresponding to contact between the lower buccal cusp and the splint were preserved. Adjustment of lateral guidance and protrusion was done by eliminating any contact other than with the canine in lateral or incisor in anterior-posterior mandibular movements.

Table 1. Appliances description *(Continued)*

Dube	Palatal splint (can be called palatal control device) was active control made on the maxillary models and then inserted and adjusted. The device did not interfere with the occlusion in any mandibular movements and it was adjusted for maximum tooth intercuspation, and any tooth contact upon mandibular movement was eliminated.
Hachmann	Occlusal splint (called Michigan type bite plate) was a thermopolymerised colourness acrylic resin, worn in the maxilla, without palatal coverage. Maxillary and mandibular arch impressions were made with condensation silicone (Optosil -Xantopren ®) and models were cast in dental stone (Velmix ®). A face bow was used to mount the models on a semiadjustable articulator. The plate was built in wax (double layer of pink wax) being adapted over the maxillary arch teeth. The plate was1 to 3 mm in thickness, contact of all teeth in centric relation, disclusion of posterior teeth in lateral and in protusive movements, avoiding balancing side interferences through the anterior guidance.
Landry	Occlusal splint upper standard single was a classic hard acrylic resin. Dental impressions were made with irreversible hydrocolloid, and the working casts were poured with artificial stone (type III). A facebow was used to mount the models on a semiadjustable articulator. The central relation was registered with a rigid blue wax.
Landry	Mandibular advancement device free (MAD free) without pin between arches, which allowed freedom of movement.
Landry	Mandibular advancement device in 25% lower arch advancement position (MAD min).
Landry	Mandibular advancement device in 75% lower arch advancement position (MAD max).
Van der Zaag	Occlusal splint was a hard acrylic stabilisation type of splint, worn in the maxilla, with full coverage of the occlusal surfaces. It was 1 mm in thickness at the level of the first molar.
Van der Zaag	Palatal splint was hard acrylic resine with palatal coverage only.

APPENDICES

Appendix 1. MEDLINE (PubMed) search strategy

#1 bruxism*
#2 bruxist*
#3 bruxe*
#4 teeth AND grind*
#5 teeth AND clench*
#6 tooth AND grind*
#7 tooth AND clench*
#8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
#9 occlusal AND splint*
#10 splint*
#11 appliance*
#12 bite-splint*
#13 bite-plate*
#14 bite AND splint*
#15 bite AND plate*
#16 #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15
#17 #8 AND #16

WHAT'S NEW

Date	Event	Description
30 July 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Cristiane Rufino Macedo (CRM): main author of protocol, protocol development, study selection, quality assessment, data extraction and data entry, interpretation of results, writing up of review.
Marco Antonio Machado (MAM): assistance with protocol, study selection, quality assessment, data extraction and data entry.
Ademir Silva (ABS): proof-reading of drafts, to act as third party in the event of disagreement amongst review authors.
Humberto Saconato (HS): statistician.
Gilmar Prado (GFP): supervisor, co-ordinator, to act as third party in the event of disagreement amongst review authors.

DECLARATIONS OF INTEREST

None known.

INDEX TERMS

Medical Subject Headings (MeSH)

*Occlusal Splints; Randomized Controlled Trials as Topic; Sleep Bruxism [*therapy]

MeSH check words

Humans