

Stabilisation splint therapy for temporomandibular pain dysfunction syndrome (Review)

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[Intervention Review]

Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

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ABSTRACT

Background

Pain dysfunction syndrome (PDS) is the most common temporomandibular disorder (TMD). There are many synonyms for this condition including facial arthromyalgia, TMJ dysfunction syndrome, myofascial pain dysfunction syndrome, craniomandibular dysfunction and myofascial pain dysfunction. The aetiology of PDS is multifactorial and many different therapies have been advocated.

Objectives

To establish the effectiveness of stabilisation splint therapy in reducing symptoms in patients with pain dysfunction syndrome.

Search methods

Electronic databases (including the Cochrane Oral Health Group's Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2003, Issue 2); MEDLINE (1966 to June 2001); EMBASE (1966 to June 2001)) were searched. Handsearching of relevant journals was undertaken and reference lists of included studies screened. Experts in the field were contacted to identify unpublished articles. There was no language restriction.

Selection criteria

Randomised or quasi-randomised controlled trials (RCTs), in which splint therapy was compared concurrently to no treatment, other occlusal appliances, or any other active intervention.

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 where necessary. The studies were grouped according to treatment type and duration of follow up.

Main results

Twenty potentially relevant RCTs were identified. Eight trials were excluded leaving 12 RCTs for analysis. Stabilisation splint therapy was compared to: acupuncture, bite plates, biofeedback/stress management, visual feedback, relaxation, jaw exercises, non-occluding appliance and minimal/no treatment.

There was no evidence of a statistically significant difference in the effectiveness of stabilisation splint therapy (SS) in reducing symptoms in patients with pain dysfunction syndrome compared with other active treatments. There is weak evidence to suggest that the use of SS for the treatment of PDS may be beneficial for reducing pain severity, at rest and on palpation, when compared to no treatment.

Authors' conclusions

There is insufficient evidence either for or against the use of stabilisation splint therapy for the treatment of temporomandibular pain dysfunction syndrome. This review suggests the need for further, well conducted RCTs that pay attention to method of allocation, outcome assessment, large sample size, and enough duration of follow up. A standardisation of the outcomes of the treatment of PDS should be established in the RCTs .

PLAIN LANGUAGE SUMMARY

Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Not enough evidence about whether stabilisation splints can reduce pain caused by painful temporomandibular (jaw) disorders.

Pain dysfunction syndrome (PDS) is the most common TMD (temporomandibular disorder, from the joint between the lower jaw and base of the skull). PDS is also called facial arthromyalgia, myofacial pain dysfunction syndrome and craniomandibular dysfunction. One option is a splint (a type of bite plate) at night when people otherwise may grind their teeth more. The stabilisation splint (SS) is one type, also known as the Tanner appliance, the Fox appliance, the Michigan splint or the centric relation appliance. The review found there is not enough evidence from trials to show whether or not stabilisation splints can reduce PDS.

BACKGROUND

Pain dysfunction syndrome (PDS) is the most common temporomandibular disorder (TMD). There are many synonyms for this condition including facial arthromyalgia, TMJ dysfunction syndrome, myofacial pain dysfunction syndrome, craniomandibular dysfunction and myofacial pain dysfunction (Gray 1994). In general, the term PDS is commonly used in UK while other terms such as myofacial pain, mandibular dysfunction, facial arthromyalgia, and masticatory myalgia are widely used in other countries.

The aetiology of PDS is multifactorial. Consequently, many different therapies, some conservative and reversible, others irreversible, have been advocated for patients with PDS. A number of successful treatment outcomes have been reported. Therapies may include occlusal splints, physiotherapy, relaxing appliances and pharmacological interventions.

There are various types of occlusal splints (bite plates or intra-oral appliances of variable designs used in the management of TMD) described in the literature and they have different indications and

functions. The stabilisation splint (SS) is one such type of occlusal splint and is also known as the Tanner appliance, the Fox appliance, the Michigan splint or the centric relation appliance. The stabilisation splint is a hard acrylic splint and provides a temporary and removable ideal occlusion (ideal contact between the teeth for the muscles and the temporomandibular joints) (Gray 1995). Providing an ideal occlusion by the use of splint therapy reduces abnormal muscle activity and produces 'neuromuscular balance'.

Normally, it is suggested that patients wear the splint only at night as it is mainly during the rapid eye movement period of sleep that the subjects appear to perform excessive parafunction (clenching and grinding of the teeth). The splint needs to be adjusted (rebalancing of the splint to the new position of the jaw by grinding some of its surface points, since the lower jaw will adopt a new position as a result of wearing the splint) over several visits as the masticatory muscles relax until a consistent jaw relationship is reached. The patients then should be reviewed at regular intervals. After a period of successful splint therapy (normally between

two to three months) patients can be weaned off the splint (Gray 1995).

The splint is constructed after taking impressions of the upper and lower dental arches, face bow registration and recording of centric relation. A face bow is a calliper-like device used to record the spatial relationship of the upper teeth to some anatomic reference point or points and then enable transfer of this relationship to an articulator. It orients the dental cast in the same relationship to the opening axis of the articulator as they relate to the skull.

A number of clinical studies have specifically evaluated the treatment of PDS by SS therapy and clinical success has been reported (Tsuga 1989; Gray 1991; Davies 1997). When properly adjusted, the SS delivers a good method of providing centric relation occlusion (the position of the jaw relative to the skull when the muscles are at their most relaxed and least strained position), eliminating posterior interferences (any predominant contacts between the back teeth that interfere with or hinder harmonious jaw movement), provides anterior guidance on anterior teeth (the contact between the anterior teeth without any posterior contact during jaw movements), reducing neuromuscular activity, and obtains stable occlusal relationships with uniform tooth contacts throughout the dental arch (Gray 1995). However, no systematic review of these trials (examining stabilisation splint therapy as a treatment of PDS specifically) has been published, and the true effectiveness of this splint for PDS has yet to be established.

OBJECTIVES

To determine the effectiveness of stabilisation splint therapy in reducing symptoms in patients with pain dysfunction syndrome (compared with any control group).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials, in which splint therapy is compared concurrently to no treatment, physiotherapy, relaxing appliances, pharmacological interventions, or any other occlusal appliances.

Abstracts are not considered in this study.

Types of participants

All patients with pain dysfunction syndrome (PDS) of all degrees of severity.

A diagnosis of PDS can be made if the patient exhibits more than one of the following signs and/or symptoms in any combination (Davies 1997).

- Pain on palpation of the temporomandibular joint.
- Pain on palpation of associated mandibular muscles.
- Limitation or deviation of mandibular movement (assessed by measuring the range of jaw movement - the only measurable parameter which can be objectively recorded in relation to temporomandibular disorder).
- Joint sounds and headache may or may not be a symptom, however, headache alone or joint sounds alone are not diagnostic of PDS. Joint sounds can be intermittent.

Types of interventions

Stabilisation splint (Tanner appliance, the Fox appliance, the Michigan splint or the centric relation appliance).

Any control group (no treatment, physiotherapy, pharmacological intervention, any other occlusal appliances). The results will be discussed according to treatment type.

Types of outcome measures

The outcome measures considered are improvement in pain of the temporomandibular joint, improvement in pain of associated mandibular muscles, improvement of the range of movement (normal range of movement, disappearance of joint sounds).

The response to treatment is classified as follows.

Cured - when all the symptoms and signs have disappeared.

Improved - when the symptomatology has partially disappeared.

Same - when the patient did not respond to therapy.

Worse - when the symptomatology has worsened.

Response to treatment must be assessed subjectively and clinically. Subjective assessment requires patients to have recorded their present overall state at review as being cured, improved, static, or deteriorating. Since it has been emphasised that there is a problem of discrepancies between patients' complaints and the clinical findings (Gray 1986), improvement in pain should also be confirmed clinically by palpating the muscles and the joints.

Depression, dysfunction scores, treatment credibility and quality of life have also been examined, although were not specified in the protocol.

Search methods for identification of studies

For the identification of studies included or considered for this review, detailed search strategies were developed for each database searched. These were based on the search strategy developed for MEDLINE but revised appropriately for each database to take account of differences in controlled vocabulary and syntax rules. The MEDLINE search strategy combined the subject search with phases 1 and 2 of the Cochrane Sensitive Search Strategy for Ran-

domised Controlled Trials (RCTs) (as published in Appendix 5b of the *Cochrane Reviewers' Handbook* (Clarke 2003)). The subject search used a combination of controlled vocabulary (MeSH) terms and free text terms based on the search strategy for searching MEDLINE via OVID (see Appendix 1).

Databases searched

Several electronic databases were searched in order to identify relevant trials:

Cochrane Oral Health Group's Trials Register
The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2003, Issue 2)
MEDLINE (1966 to June 2001)
EMBASE (1966 to June 2001)
Dissertations and Theses.

Language

The search attempted to identify all relevant studies irrespective of language. Every attempt was made for non-English papers to be translated.

Checking reference lists

The reference lists of all relevant trials obtained were checked, along with the reference lists of relevant review articles. In addition, reference lists from prosthetic dentistry textbooks on temporomandibular disorders and splint therapy were also checked.

Handsearching

The following journals have been identified as being important to be handsearched for this review for the period 1960 to present:

- *Journal of Prosthetic Dentistry*
- *Acta Odontologica Scandinavica*
- *Journal of American Dental Association*
- *Journal of Oral Rehabilitation*.

Where these journals were not covered by the Cochrane Oral Health Group's handsearching programme, the contact review author searched these journals. Studies pre-dating 1960 have not been searched for.

Personal contact

A comprehensive list of relevant articles along with inclusion criteria for the review was constructed and a letter was sent to the first author of each paper asking for any unpublished, relevant studies not included in the list. Copies of the same letter were sent to other experts in the field of temporomandibular disorders, or others with an interest in the area.

Data collection and analysis

Study selection

The results of the searches were screened independently and in duplicate by two review authors (Ziad Al-Ani (MZA) and Robin Gray (RG)). The full article of all studies meeting, or potentially meeting, the defined inclusion criteria were obtained for further assessment. To clarify the inclusion criteria, ten articles (including some thought to be definitely irrelevant or questionable) were used as a pilot test.

Data extraction

All relevant articles and reports were assessed independently by two review authors (MZA and RG) using a previously prepared data extraction form. The two review authors knew the names of the authors, institutions, journal of publication and results when applying both the inclusion criteria and during data extraction. After assessment of the studies, the results were compared and discussed until consensus was achieved. Disagreements were handled by discussion and by consulting a third review author (Philip Sloan (PS)). Additional information was sought from the authors when necessary. To reduce pre-formed opinions of experts in the area that can bias the assessment of the relevance of articles, one review author was not an expert in the area.

Quality assessment

Each paper included was quality assessed independently by two review authors. In the case of discrepancies, the authors of the paper were contacted for details of randomisation where necessary. Randomisation and allocation concealment method for each trial has been coded according to the criteria described in the *Cochrane Reviewers' Handbook*:

- (A) Clearly adequate: if adequate concealment reported.
- (B) Possibly adequate: if the random allocation is mentioned but the actual method used to conceal is unclear/not known.
- (C) Clearly inadequate: if inadequate concealment mentioned.
- (D) Excluded: Allocation concealment not used.

Participants and investigators cannot be blinded to splint therapy. However, it is feasible to blind the outcome assessor and all included studies were assessed for blinding of the outcome assessment (yes or no).

Completeness of the follow up (is there a clear explanation for withdrawals and drop outs in each screening group) was assessed as yes or no.

Uncertainty during the quality assessment phase was to be resolved by contacting the authors when necessary.

Data synthesis

The significance of discrepancies in the estimates of treatment effects from the different trials was assessed by inspection of a graphical display and by means of Cochran's test for heterogeneity. The Cochrane Collaboration's statistical guidelines were followed and risk ratio values calculated along with 95% confidence intervals for binary data. Weighted mean difference was used for continuous data. Meta-analysis was undertaken using a random-effects model.

The studies were grouped according to treatment type and duration of follow up. If data allowed, a sensitivity analysis was to be conducted to see how the quality of the studies affects the findings.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Twenty randomised controlled trials (RCTs) were identified as being potentially relevant. All of them were published in English. Eight trials were excluded, the reasons for which are presented in [Characteristics of excluded studies](#) (Lundh 1985; Lundh 1988; Wenneberg 1988; Lundh 1992; Linde 1995; Wright 1995; Ekbborg 1998; Pettengil 1998). Twelve RCTs fulfilled the inclusion criteria.

Apart from one study with vague descriptions of the splint used (Raustia 1986) all other studies provided some information about splint construction and adjustment to centric relation.

Comparison groups included acupuncture (Raustia 1986; Johansson 1991), biteplates (Dahlstrom 1985), biofeedback (Dahlstrom 1982; Turk 1993), visual feedback (Monteiro 1988), non-occluding splints (Rubinoff 1987; Dao 1994; Raphael 2001), relaxation/hypnorelaxation (Okeson 1983; Winocur 2002), jaw exercises (Magnusson 1999), and minimal/no treatment (Johansson 1991; Turk 1993; Dao 1994; Winocur 2002).

The study participants consisted of patients who had been referred for treatment for pain dysfunction syndrome (PDS) to a special clinic. In two studies patients were recruited through announcements published in a local journal (Rubinoff 1987; Dao 1994). The number of participants ranged from 20 (Dahlstrom 1985; Monteiro 1988) to 80 (Turk 1993) patients. The number of patients per study group was 20 or less in four studies. Five studies gave detailed criteria for inclusion and/or exclusion of patients in the study (Rubinoff 1987; Johansson 1991; Turk 1993; Dao 1994; Raphael 2001). Information about previous temporomandibular disorder (TMD) treatment was reported in only one study (Johansson 1991).

Review visits: the number of follow-up visits was standardised in both the study and control treatments in all studies included.

However, the period of treatment/follow up varied from 4 to 12 weeks across included studies.

The type of outcomes measures varied between the studies. Pain was measured using a visual analogue scale (VAS) (Johansson 1991; Dao 1994; Winocur 2002) and the Pain Severity Scale (PSS) and Muscle Palpation Index (PPI) (Turk 1993) and a pain diary (Rubinoff 1987). Two studies reported number of patients reporting pain on movement of mandible or pain on retrusion of the mandible (Raustia 1986; Magnusson 1999). Other outcomes measured included electromyographic analyses (Dahlstrom 1985), quality of life (Dao 1994), clinical dysfunction scores (Dahlstrom 1982; Johansson 1991; Magnusson 1999), depression (Turk 1993), and range in movement, sounds and locking and deviation in opening of mouth (Raustia 1986; Monteiro 1988; Winocur 2002).

Risk of bias in included studies

Randomisation and concealment procedures: None of the included studies reported on the method used to generate the randomisation sequence or allocation concealment.

Blind outcome assessment: Blind outcome assessment was clearly stated in only two trials (Dao 1994; Winocur 2002).

Drop outs: Drop outs were reported in six studies (Dahlstrom 1985; Rubinoff 1987; Turk 1993; Dao 1994; Magnusson 1999; Raphael 2001), none of which undertook a full intention to treat analysis.

Effects of interventions

Data were analysed using Review Manager (RevMan) program and the main results of the studies are presented separately for pain (TMJ, muscles and jaw movements), movement of the jaw (deviation in mouth opening, range of mouth opening, lateral movements), TMJ clicking, depression level, Helkimo dysfunction score, treatment credibility, and quality of life.

Stabilisation splint (SS) versus minimal/no treatment (Comparison I)

There is weak evidence to suggest that SS therapy may be beneficial in comparison to minimal or no treatment in terms of pain (as measured using the Pain Palpation Index (PPI), Pain Severity Scale (PSS) and a visual analogue scale (VAS) and depression (Centre for Epidemiological Studies - Depression (CES-D))).

Pain (Outcomes I.1; I.2)

In the study by Turk 1993 SS was also compared to a waiting list control group. A statistically significant lower pain score, using the

PPI, was shown in the SS patients with a WMD -3.20 (95% confidence interval (CI): -4.81, -1.59). Similarly, using PSS, a statistically significant difference in pain scores was found in favour of SS group with a WMD -1.40 (95% CI: -2.19, -0.61). A statistically significant difference was also seen when SS was compared to a minimal treatment group (Winocur 2002) in terms of change in present pain (WMD -23.53; 95% CI: -29.41, -17.65) and pain on palpation (WMD -0.77; 95% CI: -0.90, -0.64) measured using a VAS. However, no statistically significant difference was shown when SS was compared to a passive control group in terms of the number of patients showing an improvement in intensity of pain at rest (Dao 1994).

Johansson 1991 compared SS with acupuncture and a non-intervention control group. Both of the treatment groups showed a statistically significant improvement in pain post treatment compared to the non-treatment group ($P < 0.01$).

Depression (Outcome 1.3)

A statistically significant difference was shown between the same groups in terms of depression level evaluated by the CES-D (WMD -3.90; 95% CI: -6.29, -1.52) but not the Profile of Mood States (POMS) index (WMD -3.90; 95% CI: -7.74, -0.06) (Turk 1993).

SS versus non-occluding splints (Comparison 2)

There was no statistically significant difference between SS and non-occluding splints for any of the outcomes measured.

Pain (Outcomes 2.3; 2.4)

No statistically significant difference in palpation score or pain diary score was seen, however, when SS was compared with a non-occluding splint (Rubinoff 1987).

The number of painful muscles on palpation in the SS group in one study (Raphael 2001) did not differ significantly from the the number in the palatal splint group after 6 weeks of treatment.

One trial (Dao 1994) investigated improvement in unpleasantness and intensity of pain at rest and showed no statistically significant difference between the two groups with a risk ratio (RR) 0.75 (95% CI: 0.41, 1.37) and RR 1.44 (95% CI: 0.81, 2.58) for the improvement in the unpleasantness and intensity of pain respectively.

Movement (Outcome 2.1)

There was no statistically significant difference in the increase in maximal opening (mm) between groups receiving SS or a non-occluding splint (WMD 1.45; 95% CI: -1.47, 4.37) (Rubinoff 1987).

Overall improvement (Outcome 2.2)

There was no statistically significant difference in the number of participants reporting an overall improvement of symptoms between groups receiving SS or a non-occluding splint (RR 1.13; 95% CI: 0.79, 1.61) (Rubinoff 1987). Similarly, in another study comparing SS to a non-occluding splint, no statistically significant improvement was for any of the functional outcomes measured (swallowing, chewing, yawning, drinking, etc.) (Raphael 2001).

Quality of life (Outcome 2.5)

In the study by Dao 1994, quality of life was examined in terms of improvement in sleep, efficiency at work, social activities, feeling depressed, feeling anxious, and poor appetite. A statistically significant difference in favour of SS was shown for efficiency at work (RR 0.12; 95% CI: 0.02, 0.90). However, a statistically significant difference in favour of bite plates was shown for improvement when examining participants social activities and feeling of depression (RR 1.88; 95% CI: 1.07, 3.27 and RR 2.00; 95% CI: 1.07, 3.75 respectively). No other statistically significant differences were shown.

SS versus acupuncture (Comparison 3)

There was no statistically significant difference between SS and acupuncture for any of the outcomes measured, with the exception of deviation to the right on mouth opening (Raustia 1986)

Pain (Outcome 3.1)

One study (Raustia 1986) reported the number of patients with pain on palpation 3 months after treatment. There was no statistically significant difference between the two groups with a RR of 0.63 (95% CI: 0.24, 1.65) for the pain on palpation to the right side and RR 2.00 (95% CI: 0.19, 20.67) for pain on palpation to the left side. Similarly, no statistically significant difference was shown for pain on movement (retrusion), RR 0.60 (95% CI: 0.16, 2.25), or movement (opening), (RR 0.86; 95% CI: 0.34, 2.19).

One study (Johansson 1991) assessed change in severity of pain, described by a subjective symptom score (SDS). No statistically significant difference was found in the SDS when comparing SS and acupuncture groups with RR 1.50 (95% CI: 0.29, 7.73), although both groups showed a statistically significant decrease in SDS and VAS scores after treatment.

Movement (Outcomes 3.2; 3.3)

Raustia 1986 showed a statistically significant difference with regard to deviation to the right side in mouth opening movement after treatment in the SS group when compared with the acupuncture group with a RR 0.55 (95% CI: 0.35, 0.84). Interestingly, the analysis showed no significant difference between these two

groups in terms of deviation to the left side in the mouth opening movement after treatment with RR 5.00 (95% CI: 0.63, 39.79). There was no statistically significant difference between groups with regard to range of lateral movements (to the right WMD 0.80; 95% CI: -0.43, 2.03; to the left WMD 0.40; 95% CI: -0.86, 1.66) or range of mouth opening (WMD 2.60; 95% CI: -0.86, 6.06).

Clicking (Outcome 3.4)

The same study (Raustia 1986) compared the TMJ clicking in SS and acupuncture groups. No statistically significant benefit was found. The RR for TMJ clicking on the right side was 1.00 (95% CI: 0.56, 1.78) and that for the TMJ clicking on the left side was RR 0.58 (95% CI: 0.28, 1.23).

Dysfunction score

Johansson 1991 assessed the clinical signs by means of the Helkimo clinical dysfunction score. Both SS and acupuncture groups showed a statistically significant decrease in dysfunction score ($P < 0.01$) although no between group differences were found.

SS versus bite plates (Comparison 4)

Dysfunction score (Outcome 4.1)

In the trial by Dahlstrom 1985, no statistically significant difference was found in the number of patients showing a high Helkimo dysfunction score in SS and bite plates groups with a RR 0.68 (95% CI: 0.20, 2.23) at final examination (after 6 weeks of appliance treatment).

SS versus feedback (Comparison 5)

No statistically significant difference was shown between SS and feedback with regard to pain, treatment credibility, dysfunction score and movement. There is weak evidence from one study to show a statistically significant benefit in terms of depression scores in favour of biofeedback (Turk 1993).

Pain (Outcome 5.1)

One trial (Turk 1993) investigated reduction in pain severity level using pain severity scale (PSS). A comparison between biofeedback/stress management (BF/SM) and SS was undertaken. The results of this study showed that SS patients had lower pain scores for PSS. However, the difference between the two groups was not shown to be statistically significant (WMD 0.30; 95% CI: -0.48, 1.08). Similarly, no statistically significant difference was found between SS and BF/SM for the reduction in muscle severity as

evaluated by the Palpation Pain Index (PPI) (WMD 0.90; 95% CI: -0.26, 2.06).

Depression (Outcome 5.2)

In the same study (Turk 1993) a statistically significant benefit in the BF/SM group was found, when compared with the SS group, in depression level evaluated by Centre for Epidemiologic Studies-Depression (CES-D) index with a WMD 5.50 (95% CI: 1.49, 9.51). Evaluation of depression using the Profile of Mood States (POMS) index also showed a statistically significant difference between the SS and BF/SM groups with a WMD 6.50 (95% CI: 2.12, 10.88).

Treatment credibility (Outcome 5.3)

No statistically significant difference was reported in the same study (Turk 1993) regarding the increase in treatment credibility between SS and BF/SM with a WMD -0.10 (95% CI: -0.69, 0.49).

Dysfunction score (Outcome 5.4)

One trial (Dahlstrom 1982), comparing SS and biofeedback, presented data for clinical signs of dysfunction according to the Helkimo index D1. No statistically significant difference was shown with regard to the number of patients achieving a decrease in the dysfunction score, RR 1.11 (95% CI: 0.64, 1.92). Subjective rating of symptoms using a five-point scale showed a statistically significant reduction in both groups, with a median change in score from three to one in both groups. However the difference between groups was not statistically significant.

Movement

In the study by Monteiro 1988, both the SS and visual feedback groups showed statistically significant decrease in their lateral mandibular movement scores ($P < 0.01$). Data were unavailable for analysis.

SS versus jaw exercises (Comparison 6)

There were improvements in all outcomes measured for both groups at both 3 month and 6 month assessment (Magnusson 1999). A follow-up questionnaire 1 to 4 years after first clinical assessment showed a lasting treatment effect in most patients, although many patients continued to perform their jaw exercises or wear their occlusal splint. No statistically significant differences were observed between the groups at any time point.

SS versus relaxation (Comparison 7)

There is conflicting evidence with regard to the effectiveness of SS in comparison to relaxation.

Pain (Outcome 7.1)

Two trials compared SS with relaxation (Winocur 2002; Okeson 1983). Both studies assessed reduction in pain and changes in the maximal mouth opening. Okeson 1983 showed a statistically significant reduction in pain on palpation in favour of SS, however, this was not supported by the trial by Winocur 2002. Significant statistical heterogeneity was found between the two trials for reduction of pain on palpation ($P < 0.01$; $I^2 = 98.3\%$), it was therefore felt inappropriate to pool the data.

Movement (Outcome 7.2)

Similarly, for changes in maximal mouth opening, significant heterogeneity was found between the two studies both for active/comfortable opening ($P < 0.01$; $I^2 = 92.9\%$) and assisted/painful opening ($P < 0.01$; $I^2 = 94\%$). Again, it was felt inappropriate to pool the trials. Okeson 1983 found a statistically significant difference in favour of SS, but these results were not supported by Winocur 2002.

DISCUSSION

Pain dysfunction syndrome (PDS) is the most common temporomandibular disorder (TMD). The aetiology of PDS is multifactorial. Consequently many different therapies, some conservative and reversible, others irreversible, have been advocated for patient with PDS. A number of successful treatment outcomes have been reported (Tsuga 1989; Gray 1991; Davies 1997). There are various types of occlusal splints described in the literature and they have different indications and functions. The stabilisation splint (SS) is one such type of occlusal splint. The stabilisation splint

is a hard acrylic splint and provides a temporary and removable ideal occlusion. Providing an occlusion by the use of splint therapy reduces abnormal muscle activity and produces 'neuromuscular balance'.

The published literature concerning SS for PDS is considerable. However, a review of the literature shows no standardisation of outcomes of the treatment. There were studies comparing different types of treatments which did not have control group which were consequently not eligible for this review. There was little evidence of a difference in the effectiveness of stabilisation splint therapy in reducing symptoms in patients with pain dysfunction syndrome compared with other conventional treatments. However, the comparisons were based on a small number of patients with no standardisation of the outcomes measured. There is some evidence to suggest that the use of SS for the treatment of PDS may be beneficial for reducing pain severity, at rest and on palpation, when compared to no treatment.

AUTHORS' CONCLUSIONS

Implications for practice

On the basis of our analysis we conclude that the literature seems to suggest that there is insufficient evidence either for or against the use of stabilisation splint (SS) therapy over other active interventions for the treatment of temporomandibular pain dysfunction syndrome (PDS). However, there is weak evidence to suggest that the use of SS for the treatment of PDS may be beneficial for reducing pain severity, at rest and on palpation, when compared to no treatment.

Implications for research

This review suggests the need for further, well conducted randomised controlled trials (RCTs) that pay attention to the method of allocation, outcome assessment, adequate sample size, and with sufficient follow up. A standardisation of the outcomes of the treatment of PDS should be established in the RCTs.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Dahlstrom 1982

| | |
|---------------|---|
| Methods | Single-centre RCT. 6 weeks duration. |
| Participants | 30 women with mandibular dysfunction referred to Department of Stomatognathic Physiology. Mean age: 28.6 years (range 20-40 years). Mean duration of symptoms: 3.8 months (range 1-11 months). |
| Interventions | Group A: SS - full coverage occlusal mandibular splint used at night for 6 weeks (n = 15). Group B: Biofeedback - Myometer using surface electrodes placed over the masseter muscle of the most affected side for 30 mins (with a few breaks) each session. Six or less sessions in total (n = 15) |
| Outcomes | Reported symptoms (including TMJ sounds, fatigue/stiffness of the jaw, difficulty in opening mouth wide, pain on mandibular movements, pain in TMJs or masticatory muscles, locking of TMJ). Subjective rating of symptoms reported as 1 = none to 5 = very severe. Clinical dysfunction. |
| Notes | No drop outs reported. Blind outcome assessment unclear. Data taken from tables (does not match text). |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Dahlstrom 1985

| | |
|---------------|--|
| Methods | Single-centre RCT. 6 weeks duration. |
| Participants | 20 women with mandibular dysfunction, referred to Department of Stomatognathic Physiology. Mean age: 26.3 years (range 17-41 years). No statistically significant differences between the 2 groups at initial assessment |
| Interventions | Group A: SS - maxillary full-coverage, heat-cured acrylic resin splint, adjusted in mouth and worn for 6 weeks at night (n = 20). Group B: Bite plate with a frontal plateau (modified Hawley plate) made from heat-cured acrylic resin and modified in mouth. Worn for 6 weeks at night (n = 20) |
| Outcomes | Clinical and subjective evaluations were made (Helkimo dysfunction index, TMJ function, mandibular mobility and pain on movement) and electromyographic analyses undertaken (EMG) (measuring muscles activity) |

Dahlstrom 1985 (Continued)

| | | |
|-------------------------|--|--------------------|
| Notes | One woman dropped out of bite plate group due to refusal to undergo second EMG recording. Not included in analysis. Blind outcome assessment unclear. | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Dao 1994

| | | |
|-------------------------|--|--------------------|
| Methods | Single-centre RCT. 10 weeks duration. | |
| Participants | 148 patients screened following announcements in local journal and referrals from dentists. 63 met inclusion criteria with primary diagnosis of myofascial pain of jaw muscles, with no previous treatment for TMD. No statistically significant difference between female/male ratio (overall 51:10) or mean age (range 16 to 45 years) between the 3 groups at baseline | |
| Interventions | Group A: SS to be worn day and night except at meal times. Compliance assessed through questioning patients at each appointment (n = 22). Group B: Active control, consisting of U-shaped splint which did not cover or interfere with occlusion in any way. Worn as for SS group (n = 21). Group C: Passive control, consisting of SS worn for only 30mins at each appointment and retained by clinician (n = 20) | |
| Outcomes | Pain intensity and pain unpleasantness as measured on self administered VAS (100 mm) both at rest and after chewing. Quality of life was measured using a five-point scale assessing how pain affected 6 of their daily activities or states: sleep, efficiency at work, social activities, depression, anxiety and appetite. Sensory state was also measured by VAS (100 mm). During treatment, data were gathered 1, 3, 5 and 8 weeks after splint insertion | |
| Notes | Four patients dropped out or were excluded as follows: Group A: 2 - reason unstated, but data included in analysis. Group B: 1 - couldn't wear splint, not included in analysis. Group C: 1 - diagnosed as migraine, not included in analysis. Blind outcome assessment undertaken. | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Johansson 1991

| | |
|---------------|--|
| Methods | Single-centre RCT. 3 months duration. |
| Participants | 45 consecutive patients, with long-standing facial pain or headache of muscular origin, referred to the Department of Stomatognathic Physiology. No statistically significant differences between the 3 groups were found with regard to clinical variables or subjective symptoms at baseline |
| Interventions | Group A: SS - maxillary full-coverage acrylic resin occlusal splint, adjusted to stable occlusion in retruded and intercuspal position. Additional adjustments made 2 weeks later (n = 15). Group B: Acupuncture - administered by experienced dentist. Three to 7 needles used locally and 1 distally. A total of 6 sessions were conducted (n = 15). Group C: Control - examined at first visit and after 2 months only (n = 15) |
| Outcomes | Change in subjective dysfunction score (SDS) as assessed by patient (1 = no pain; 2 = mild pain; 3 = moderate pain; 4 = severe pain; 5 = very severe pain) and VAS (100 mm). Change was classified as impaired, unchanged, improved or symptom-free. Change in Helkimo clinical dysfunction score (CDS). |
| Notes | No drop outs reported. Blind outcome assessment unclear. |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Magnusson 1999

| | |
|---------------|---|
| Methods | Single-centre RCT. 6 months duration. |
| Participants | 26 patients referred to Department of Stomatognathic Physiology with TMD of muscular origin. Mean age: 34 years (range 16 to 67 years). |
| Interventions | Group A: Interocclusal appliance (n = 14). Group B: Jaw exercises (n = 12). |
| Outcomes | Impaired mandibular mobility; impaired TMJ function; TMJ pain; muscle pain; pain on movement. Each outcome assessed as none, mild or severe. In addition, clinical dysfunction and anamnestic dysfunction was scored (Helkimo). Patients also rated pain and discomfort according to a 6-graded behaviour rating scale (BRS) |
| Notes | Three patients dropped out (2 from Group A, 1 from Group B). Five further patients received additional treatment due to persistent symptoms after 3 months (3 in Group A, 2 in Group B). Blind outcome assessment unclear. |

Magnusson 1999 (Continued)

| Risk of bias | | |
|-------------------------|---------------------------|--------------------|
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Monteiro 1988

| | | |
|---------------|--|--|
| Methods | Single-centre RCT. 4 weeks duration. | |
| Participants | 20 patients with TMD with clinical signs of painful masticatory muscle disorder (myalgia) and no signs of TMJ internal derangement or arthritis. Mean age: 33.0 (=/- 9.7) years. Percentage of women: 80%. | |
| Interventions | Group A: SS - made of cold-cure acrylic resin and designed for mandibular arch (n = 10). Group B: Visual feedback - provision of image of mandibular position, 3 sessions, 1 week apart (n = 10) | |
| Outcomes | Temporomandibular dysfunction questionnaire. Right and left lateral movement accuracy. | |
| Notes | No drop outs reported. Blind outcome assessment unclear. | |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|---------------------------|--------------------|
| Allocation concealment? | Unclear | B - Unclear |

Okeson 1983

| | | |
|---------------|---|--|
| Methods | Single-centre RCT. 6 weeks duration. | |
| Participants | 24 presenting for treatment at facial pain clinic. Mean age: 29.9 years. Female/male: 21/3. | |
| Interventions | Group A: Occlusal splint. Hard acrylic resin maxillary occlusal splint (n = 12). Group B: Relaxation therapy. Each patient received a 20 minutes tape of a relaxation procedure and asked to listen to it at least once every day (n = 12) | |
| Outcomes | Pain on palpation (0 to 3, no pain to evasive action/tearing of eyes); maximum comfortable interincisal distance (mm); maximum interincisal distance (mm) | |

Okeson 1983 (Continued)

| | | |
|-------------------------|---|--------------------|
| Notes | No drop outs reported. Blind outcome assessment unclear. | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Raphael 2001

| | | |
|-------------------------|---|--------------------|
| Methods | Single-centre RCT. 6 weeks duration. | |
| Participants | 68 women meeting criteria for the myofacial subtype of TMD in which facial pain complaint was associated with localised tenderness in response to palpation at 3 or more of 20 muscle sites. Mean age (of those completing): 33.7 years (sd 10.9 years). Mean duration of pain: 5 years. | |
| Interventions | Group A: Maxillary, flat-plane, hard acrylic splint covering the hard palate (n = 35). Group B: Palatal splint, not covering the occlusal surfaces (n = 33) | |
| Outcomes | Psychological measures (including Symptom Checklist-90); widespread pain from self reporting of fibromyalgia, reports of moderate or more soreness of muscles on an SCL-90 question, and moderate or severe extracranial pain on palpation by the clinician; functional outcomes (including chewing, eating hard foods, talking, yawning, etc.); expectations for improvement | |
| Notes | Two patients from each group withdrew. One additional patient from Group A was referred to a psychiatrist for a thought disorder. Blind outcome assessment unclear. | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

Raustia 1986

| | | |
|--------------|---|--|
| Methods | Single-centre RCT. 3 months duration. | |
| Participants | 50 patients referred to the Department of Prosthodontics and Stomatognathic Physiology for diagnosis and treatment of TMJ dysfunction. No statistically significant differences between groups at baseline with regard to age (mean age Group A: 26.4 years; Group B: 27.8 years) or female/male ratio (overall 39:11) | |

Raustia 1986 (Continued)

| | |
|---------------|--|
| Interventions | Group A: Stomatognathic treatment (n = 25). Group B: Acupuncture, performed by specialist in physical medicine and rehabilitation. Puncture points chosen individually on basis of clinical interview/examination. Three sessions of at least 20 mins were undertaken (n = 25). Mean interval between initial examination and completion of treatment was approximately 6 weeks in both groups |
| Outcomes | Number of patients reporting pain on movement of mandible, pain on retrusion of the mandible. Range of movement of lateral mandibular movement to the right and to the left (mm). Range of mouth opening (mm). Deviation in mouth opening movement (number of patients). TMJ sounds and locking (number of patients). |
| Notes | Drop outs not stated. Blind outcome assessment unclear. |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Rubinoff 1987

| | |
|---------------|---|
| Methods | Single-centre RCT. 6 weeks duration. |
| Participants | 50 patients responded to newspaper notice. 30 met inclusion criteria of myofascial pain dysfunction syndrome. Mean age: 33.7 years (range 18-66 years). Women/men: 24/4. |
| Interventions | Group A: SS - designed to cover all the maxillary teeth and provide flat plane occlusion with bilateral contact of all teeth in centric relation (n = 15). Group B: Non-occluding palatal appliance (n = 11). |
| Outcomes | Pain diary (to be filled in 3 times a day). Pain on palpation (0 = no response; 1 = verbal report of discomfort; 2=verbal report of pain with facial movement such as palpebral reflex; 3 = retreat of head in anticipation of palpation along with report of considerable pain upon contact). Success rating (1 = worse; 2 = no change; 3 = slight improvement; 4 = moderate improvement; 5 = great improvement; 6 = complete improvement) |
| Notes | Two patients eliminated from study (one dropped out and one failed to complete study). Two additional patients had incomplete data at follow up. No data on these patients available. Blind outcome assessment unclear. |

Risk of bias

Rubinoff 1987 (Continued)

| Item | Authors' judgement | Description |
|-------------------------|--------------------|--------------|
| Allocation concealment? | Unclear | D - Not used |

Turk 1993

| | | |
|---------------|--|--|
| Methods | Single-centre RCT. 6 weeks duration. | |
| Participants | 80 consecutive patients referred to University TMD clinic. Mean age: 34.1 years. Percentage of women: Group A 75%; Group B 90%; Group C 80% Duration of pain: Group A 5.3 years (sd 4.7); Group B 7.1 years (sd 5.5); Group C 7.6 years (sd 7.2) | |
| Interventions | Group A: SS - full arch interocclusal appliance treatment. Flat, heat-cured acrylic resin splint. The aim of the splint was to isolate the contact relation of the teeth from the masticatory system. Patients asked to wear splint at all times for first 6 weeks of treatment (except meal times and oral hygiene). Patients seen weekly by dentist. (n = 30). Group B: Biofeedback and stress management - 6 weekly sessions by trained psychologist (n = 30). Group C: Waiting list control - patients seen for initial assessment and informed of 6 week waiting list - no intervention given during this time (n = 20). Full arch SS and biofeedback/stress management. | |
| Outcomes | Pain, evaluated with Pain Severity Scale (PSS) and muscle palpation index (PPI). Depression was evaluated with the Center for Epidemiologic Studies-Depression (CES-D) and depression scale from Profile of Mood States (POMS). Credibility of treatment was rated on 5 point scale for those in Groups A and B | |
| Notes | Two patients dropped out of Group A, reason not stated. Not included in analysis. Blind outcome assessment unclear. | |

Risk of bias

| Item | Authors' judgement | Description |
|-------------------------|--------------------|-------------|
| Allocation concealment? | Unclear | B - Unclear |

Winocur 2002

| | | |
|--------------|---|--|
| Methods | Single-centre RCT. 49 days. | |
| Participants | 40 women referred for treatment at a clinic for TMD with frequent facial pain of at least 6 months duration. Mean age: 30.3 years (range 16-49 years). | |

Winocur 2002 (Continued)

| | | |
|-------------------------|---|--------------------|
| Interventions | Group A : Full coverage, hard acrylic appliances constructed to fit the maxillary arch, adjusted to fulfill the static and dynamic rules of occlusion (n = 15). Group B: Hypnorelaxation. The purpose of the treatment was to teach the patients to perform progressive muscle relaxation and self-hypnosis to control muscular and emotional tension (n = 15). Group C: Minimal treatment. Support and advice as for other two groups but no additional active intervention (n = 10) | |
| Outcomes | Pain (VAS); mouth opening (mm); muscle sensitivity to palpation (none, mild, severe). After clinical evaluation an arithmetic mean was calculated for each masticatory muscle separately and combined); depression (0 to 4, from normal to severely depressed); somatization (0 to 4, from normal to extremely); chronic pain severity (0 to 4, from no TMD pain in the prior 6 months to 4 high disability) | |
| Notes | No drop outs reported. Blind outcome assessment undertaken. | |
| Risk of bias | | |
| Item | Authors' judgement | Description |
| Allocation concealment? | Unclear | B - Unclear |

RCT = randomised controlled trial

Characteristics of excluded studies [ordered by study ID]

| Study | Reason for exclusion |
|----------------|--|
| Ekbberg 1998 | Stabilisation splint used for treating patients with TMD of arthrogenous origin - not specifically PDS |
| Linde 1995 | Stabilisation splint used for treating patients with disc displacement without reduction - not PDS |
| Lundh 1985 | ARPS splint and flat occlusal splint used for treating patients with disc displacement - not PDS |
| Lundh 1988 | Disc-repositioning onlays and flat occlusal splints used for treating patients with disc displacement - not PDS |
| Lundh 1992 | Flat occlusal splint used for treating patients with disc displacement without reduction - not PDS |
| Pettengil 1998 | In addition to PDS, patients had disc displacement, osteoarthritis and inflammation of the TMJ |
| Wenneberg 1988 | Occlusal equilibration versus routine stomatognathic treatment (including occlusal splint) for patients with craniomandibular disorders and headaches - not specifically PDS |
| Wright 1995 | Soft splints and palliative treatment for masticatory muscle pain - no stabilisation splint therapy |

DATA AND ANALYSES

Comparison 1. Stabilisation splint (SS) versus minimal/no treatment

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|----------------|---------------------|--------------------------------------|---------------------|
| 1 Pain (3 months or less) | 2 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 1.1 Pain severity level evaluated by Pain Severity Scale | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 1.2 Muscle pain severity evaluated by muscle palpation pain scores | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 1.3 Change in present pain (VAS) | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 1.4 Change in pain on palpation | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 2 Pain (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 2.1 No improvement in intensity of pain at rest | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 3 Depression (3 months or less) | 1 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 3.1 Depression level evaluated by CES-D index | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 3.2 Depression level evaluated by POMS index | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 4 Quality of life (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4.1 No improvement in sleep | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.2 No improvement in the efficiency at work | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.3 No improvement in social activities | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.4 No improvement in feeling depressed | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.5 No improvement in feeling anxious | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.6 No improvement in poor appetite | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |

Comparison 2. Stabilisation splint (SS) versus non-occluding splint

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|----------------|---------------------|--------------------------------------|---------------------|
| 1 Movement (3 months or less) | 1 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 1.1 Increase in maximal opening (mm) | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 2 Overall improvement (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 3 Pain (3 months or less) | 2 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 3.1 Muscle pain severity evaluated by muscle palpation pain scores | 2 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 3.2 Pain diary score | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 4 Pain (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4.1 No improvement in intensity of pain at rest | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 5 Quality of life (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 5.1 No improvement in sleep | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 5.2 No improvement in the efficiency at work | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 5.3 No improvement in social activities | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 5.4 No improvement in feeling depressed | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 5.5 No improvement in feeling anxious | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 5.6 No improvement in poor appetite | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |

Comparison 3. Stabilisation splint (SS) versus acupuncture

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|----------------------------------|---------------------|
| 1 Pain (3 months or less) | 2 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 1.1 Pain on movement (opening) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 1.2 Pain on movement (retusion) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 1.3 Pain on palpation on the right side | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 1.4 Pain on palpation on the left side | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 1.5 No improvement in severity of pain | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 2 Movement (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |

| | | | | |
|--|---|--|--------------------------------------|---------------------|
| 2.1 Deviation to the right in mouth opening movement after treatment | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 2.2 Deviation to the left in mouth opening movement after treatment | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 3 Movement (3 months or less) | 1 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 3.1 Ranges in the lateral movement to the right (mm) | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 3.2 Ranges in the lateral movement to the left (mm) | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 3.3 Range of mouth opening (mm) | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 4 Clicking (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4.1 TMJ clicking on the right side | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.2 TMJ clicking on the left side | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |

Comparison 4. Stabilisation splint (SS) versus bite plates

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|----------------|---------------------|----------------------------------|---------------------|
| 1 Dysfunction score (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 1.1 High Helkimo dysfunction score | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |

Comparison 5. Stabilisation splint (SS) versus biofeedback/stress management

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|----------------|---------------------|--------------------------------------|---------------------|
| 1 Pain (3 months or less) | 1 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 1.1 Reduction in pain severity level evaluated by Pain Severity Scale | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 1.2 Reduction in muscle pain severity evaluated by muscle Palpation Pain Index | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 2 Depression (3 months or less) | 1 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 2.1 Depression level evaluated by CES-D index | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 2.2 Depression level evaluated by POMS index | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |

| | | | |
|--|---|--------------------------------------|---------------------|
| 3 Increase in treatment credibility (3 months or less) | 1 | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 4 Dysfunction score (3 months or less) | 1 | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4.1 Reduction in clinical dysfunction index | 1 | Risk Ratio (M-H, Random, 95% CI) | Not estimable |

Comparison 6. Stabilisation splint (SS) versus jaw exercises

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|----------------------------------|---------------------|
| 1 Pain (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 1.1 TMJ pain | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 1.2 Muscle pain | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 1.3 Pain on movement | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 2 Clicking (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 3 Overall improvement (3 months or less) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4 Pain (greater than 3 months) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4.1 TMJ pain | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.2 Muscle pain | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 4.3 Pain on movement | 1 | | Risk Ratio (M-H, Random, 95% CI) | Not estimable |
| 5 Clicking (greater than 3 months) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 6 Overall improvement (greater than 3 months) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |

Comparison 7. Stabilisation splint (SS) versus relaxation

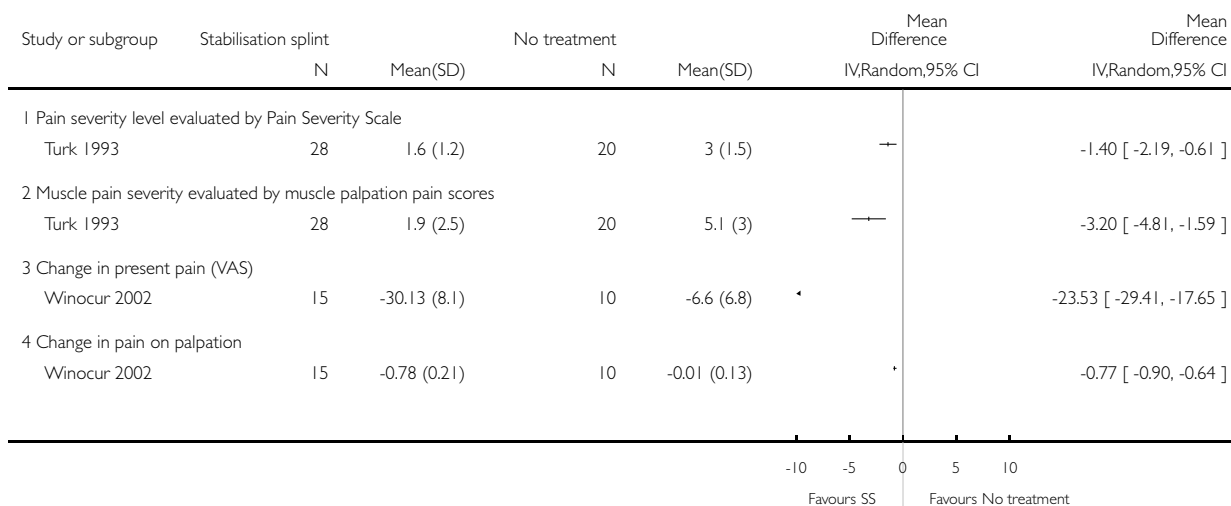
| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|--------------------------------------|---------------------|
| 1 Pain (3 months or less) | 2 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 1.1 Change in present pain (VAS) | 1 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 1.2 Change in pain on palpation | 2 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 2 Movement (3 months or less) | 2 | | Mean Difference (IV, Random, 95% CI) | Totals not selected |
| 2.1 Increase in active/comfortable maximal mouth opening (mm) | 2 | | Mean Difference (IV, Random, 95% CI) | Not estimable |
| 2.2 Increase in maximal mouth opening (mm) | 2 | | Mean Difference (IV, Random, 95% CI) | Not estimable |

Analysis 1.1. Comparison 1 Stabilisation splint (SS) versus minimal/no treatment, Outcome 1 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 1 Stabilisation splint (SS) versus minimal/no treatment

Outcome: 1 Pain (3 months or less)

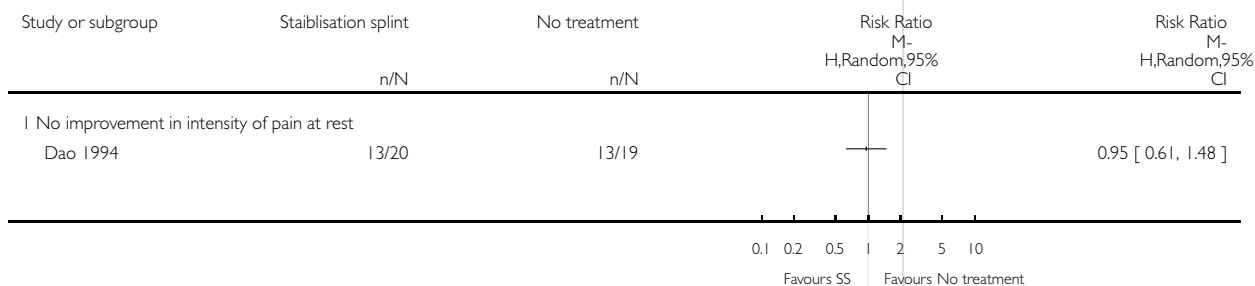


Analysis 1.2. Comparison 1 Stabilisation splint (SS) versus minimal/no treatment, Outcome 2 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 1 Stabilisation splint (SS) versus minimal/no treatment

Outcome: 2 Pain (3 months or less)

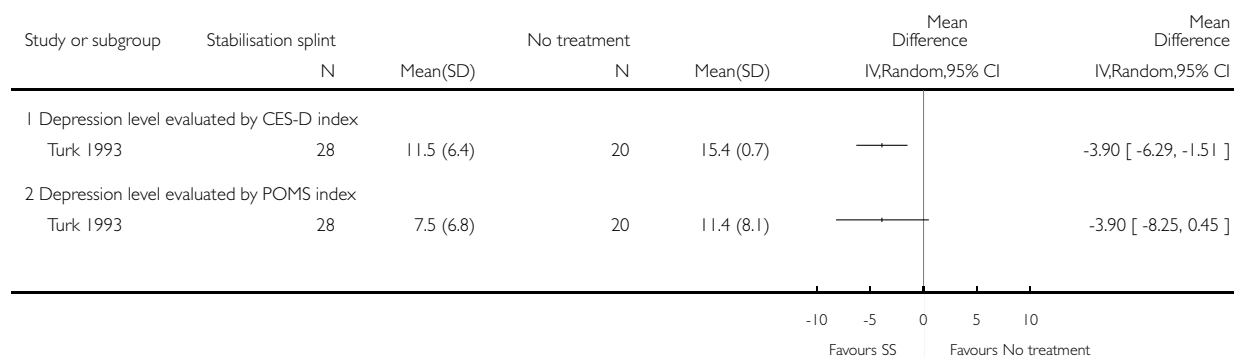


Analysis 1.3. Comparison 1 Stabilisation splint (SS) versus minimal/no treatment, Outcome 3 Depression (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 1 Stabilisation splint (SS) versus minimal/no treatment

Outcome: 3 Depression (3 months or less)

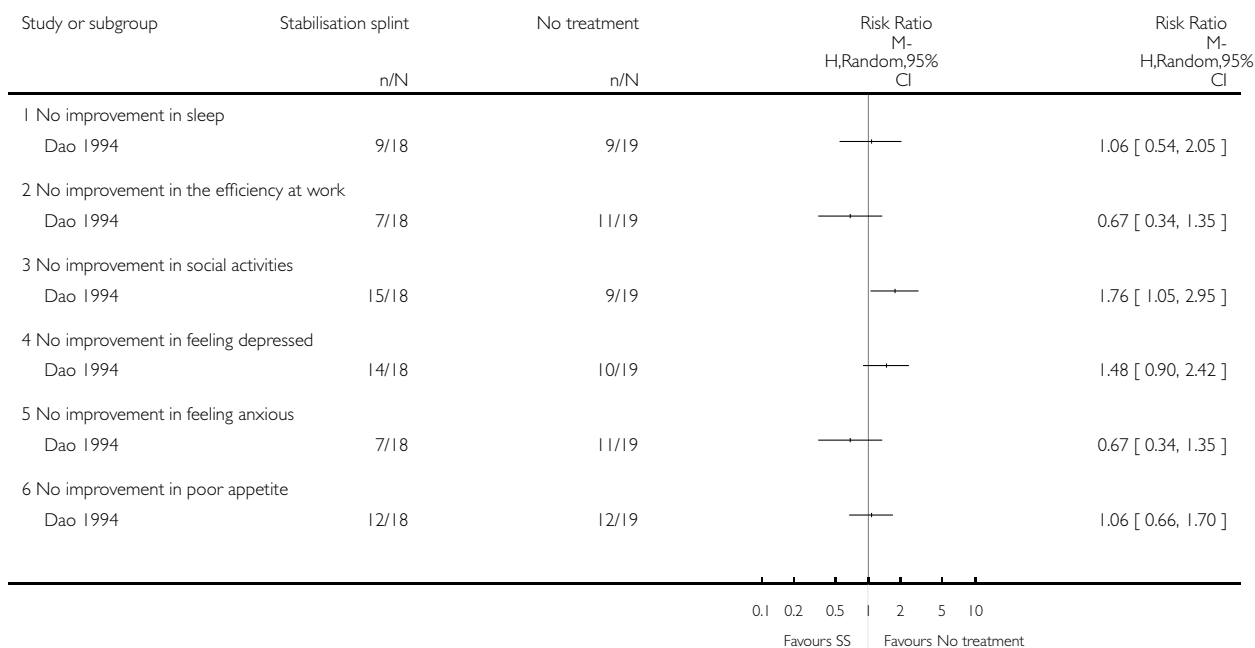


Analysis 1.4. Comparison 1 Stabilisation splint (SS) versus minimal/no treatment, Outcome 4 Quality of life (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 1 Stabilisation splint (SS) versus minimal/no treatment

Outcome: 4 Quality of life (3 months or less)

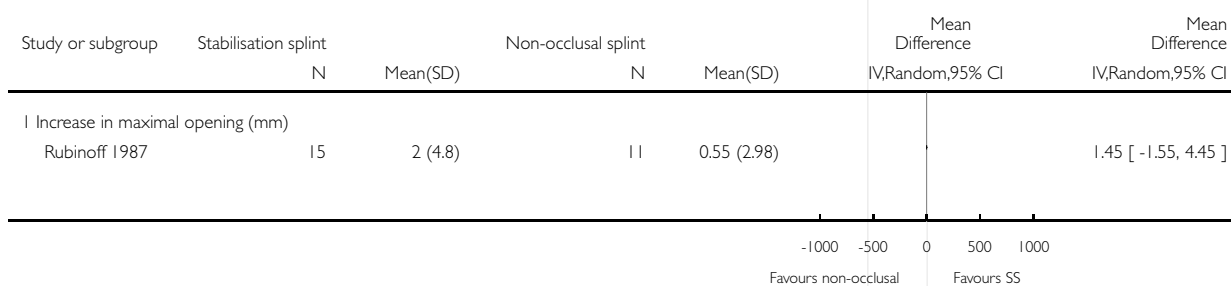


Analysis 2.1. Comparison 2 Stabilisation splint (SS) versus non-occluding splint, Outcome 1 Movement (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 2 Stabilisation splint (SS) versus non-occluding splint

Outcome: 1 Movement (3 months or less)

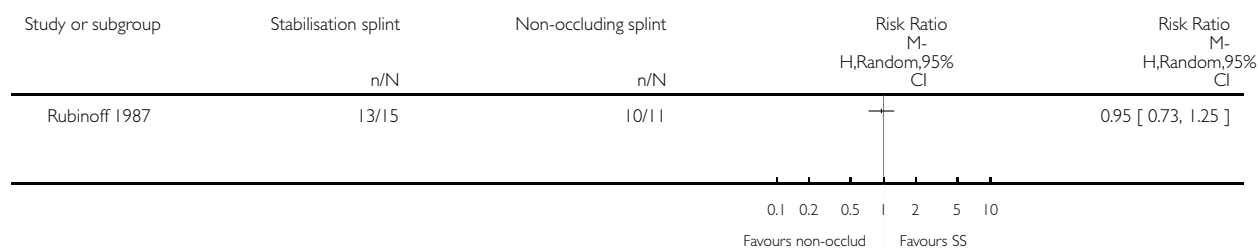


Analysis 2.2. Comparison 2 Stabilisation splint (SS) versus non-occluding splint, Outcome 2 Overall improvement (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 2 Stabilisation splint (SS) versus non-occluding splint

Outcome: 2 Overall improvement (3 months or less)

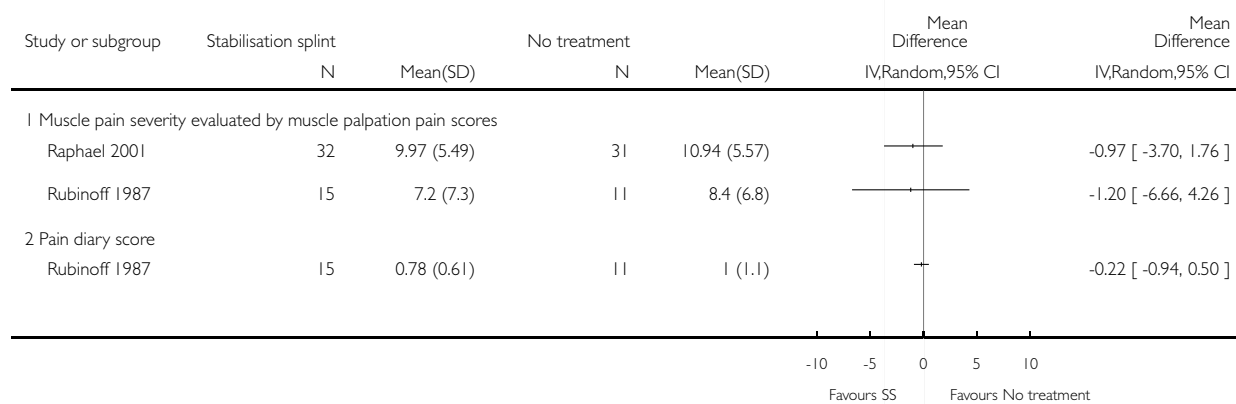


Analysis 2.3. Comparison 2 Stabilisation splint (SS) versus non-occluding splint, Outcome 3 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 2 Stabilisation splint (SS) versus non-occluding splint

Outcome: 3 Pain (3 months or less)

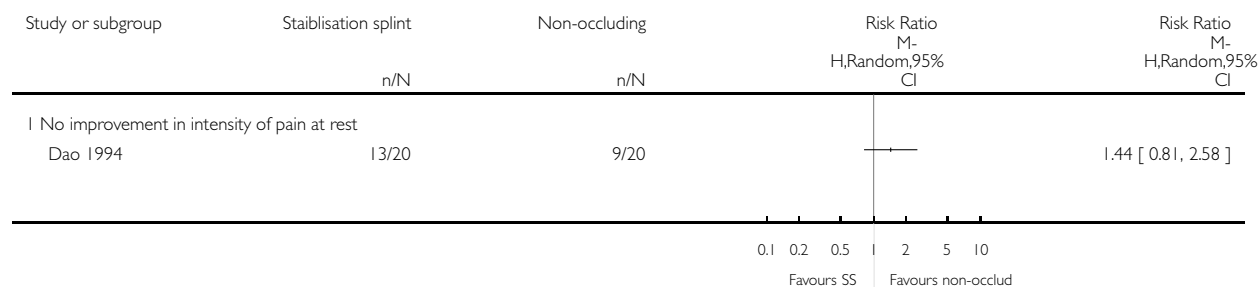


Analysis 2.4. Comparison 2 Stabilisation splint (SS) versus non-occluding splint, Outcome 4 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 2 Stabilisation splint (SS) versus non-occluding splint

Outcome: 4 Pain (3 months or less)

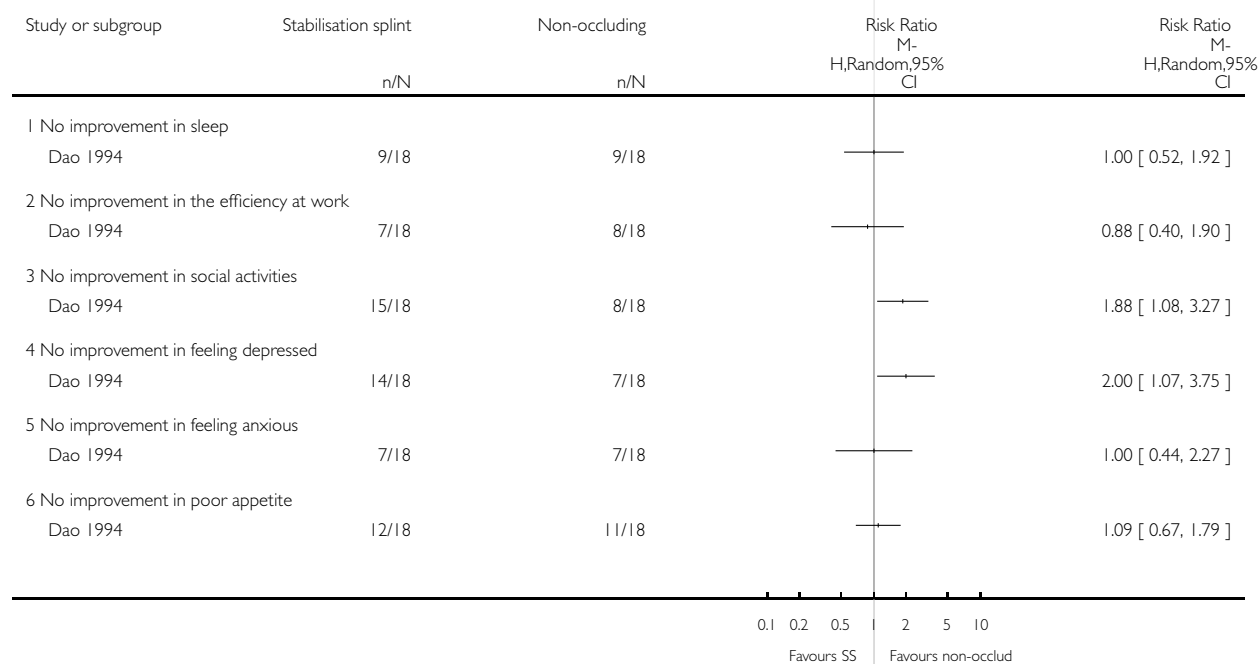


Analysis 2.5. Comparison 2 Stabilisation splint (SS) versus non-occluding splint, Outcome 5 Quality of life (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 2 Stabilisation splint (SS) versus non-occluding splint

Outcome: 5 Quality of life (3 months or less)

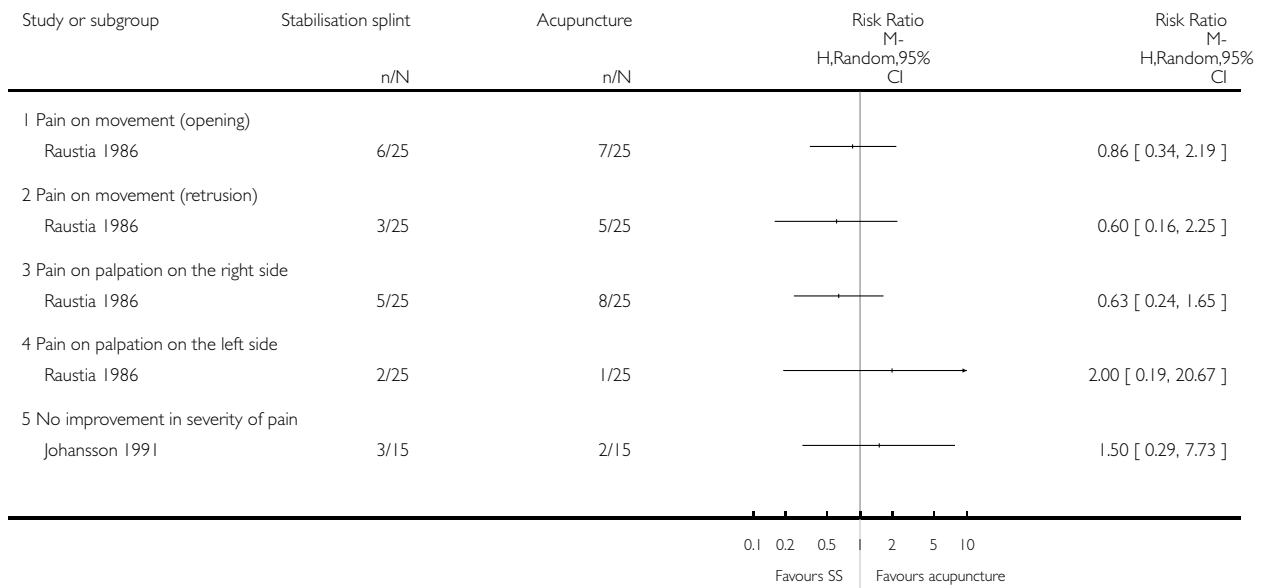


Analysis 3.1. Comparison 3 Stabilisation splint (SS) versus acupuncture, Outcome 1 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 3 Stabilisation splint (SS) versus acupuncture

Outcome: 1 Pain (3 months or less)

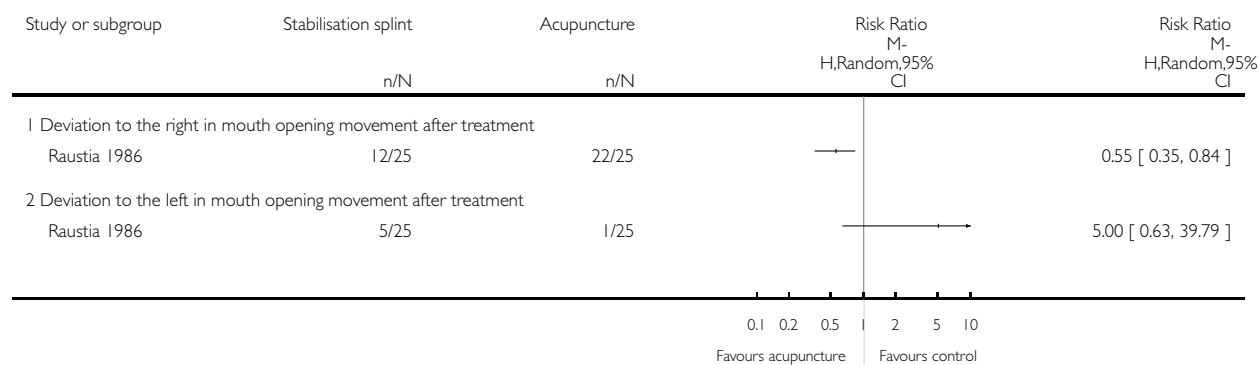


Analysis 3.2. Comparison 3 Stabilisation splint (SS) versus acupuncture, Outcome 2 Movement (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 3 Stabilisation splint (SS) versus acupuncture

Outcome: 2 Movement (3 months or less)

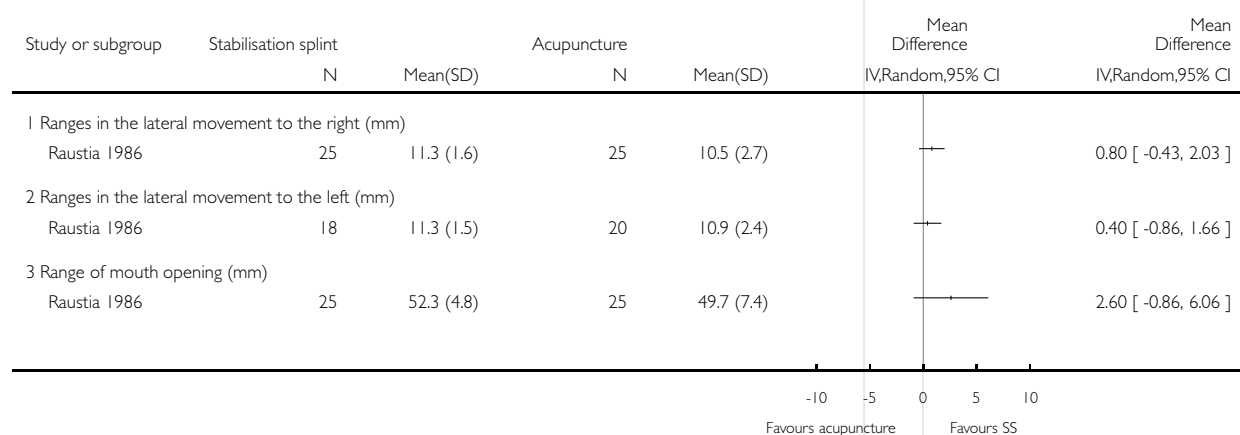


Analysis 3.3. Comparison 3 Stabilisation splint (SS) versus acupuncture, Outcome 3 Movement (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 3 Stabilisation splint (SS) versus acupuncture

Outcome: 3 Movement (3 months or less)

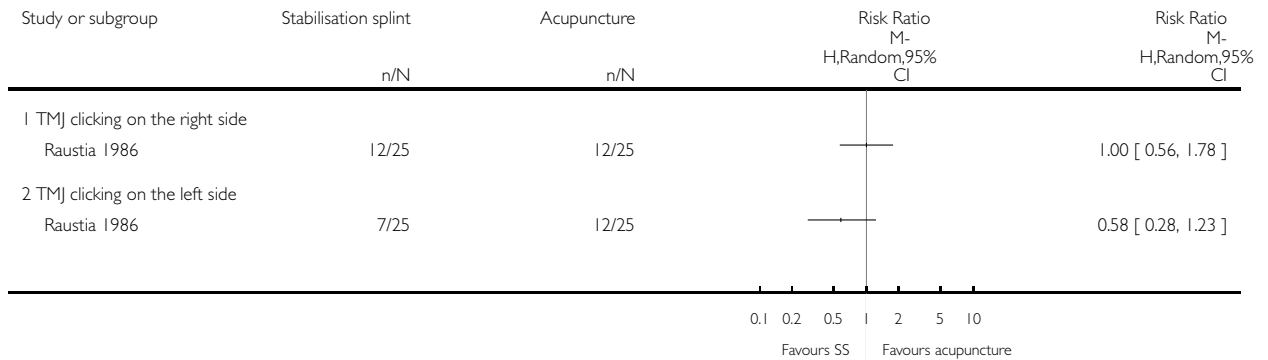


Analysis 3.4. Comparison 3 Stabilisation splint (SS) versus acupuncture, Outcome 4 Clicking (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 3 Stabilisation splint (SS) versus acupuncture

Outcome: 4 Clicking (3 months or less)

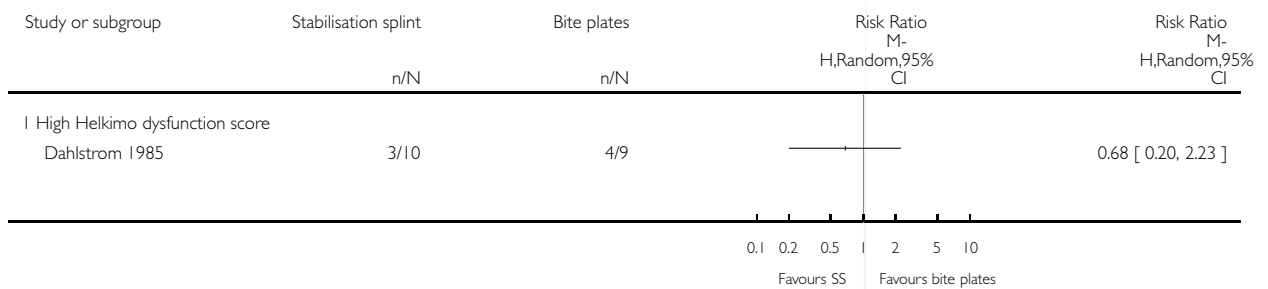


Analysis 4.1. Comparison 4 Stabilisation splint (SS) versus bite plates, Outcome 1 Dysfunction score (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 4 Stabilisation splint (SS) versus bite plates

Outcome: 1 Dysfunction score (3 months or less)

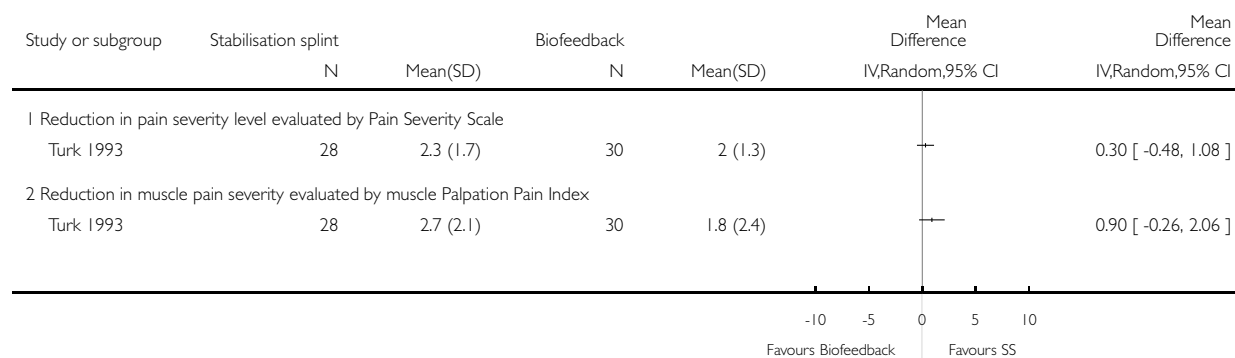


Analysis 5.1. Comparison 5 Stabilisation splint (SS) versus biofeedback/stress management, Outcome 1 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 5 Stabilisation splint (SS) versus biofeedback/stress management

Outcome: 1 Pain (3 months or less)

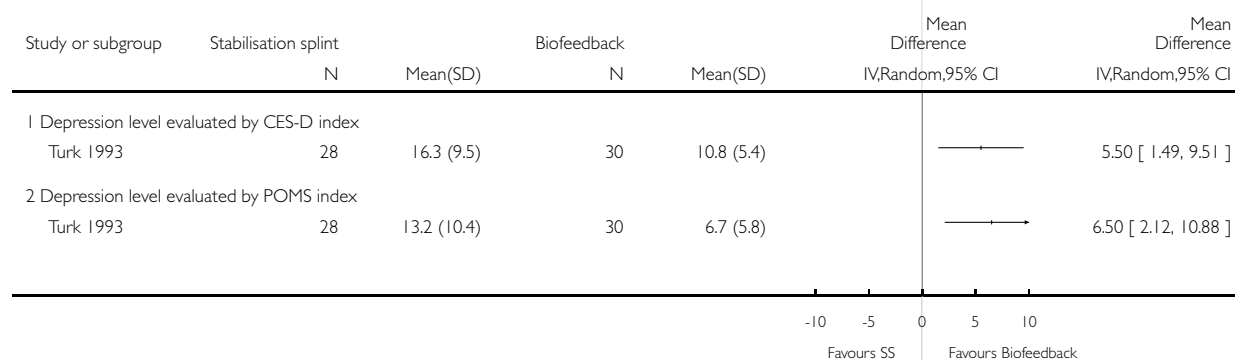


Analysis 5.2. Comparison 5 Stabilisation splint (SS) versus biofeedback/stress management, Outcome 2 Depression (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 5 Stabilisation splint (SS) versus biofeedback/stress management

Outcome: 2 Depression (3 months or less)

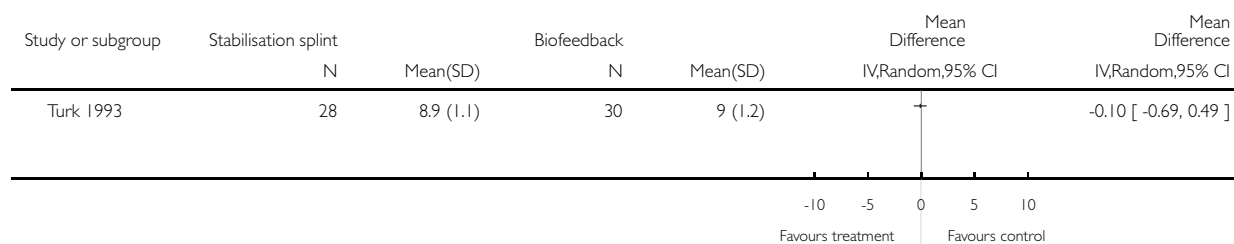


Analysis 5.3. Comparison 5 Stabilisation splint (SS) versus biofeedback/stress management, Outcome 3 Increase in treatment credibility (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 5 Stabilisation splint (SS) versus biofeedback/stress management

Outcome: 3 Increase in treatment credibility (3 months or less)

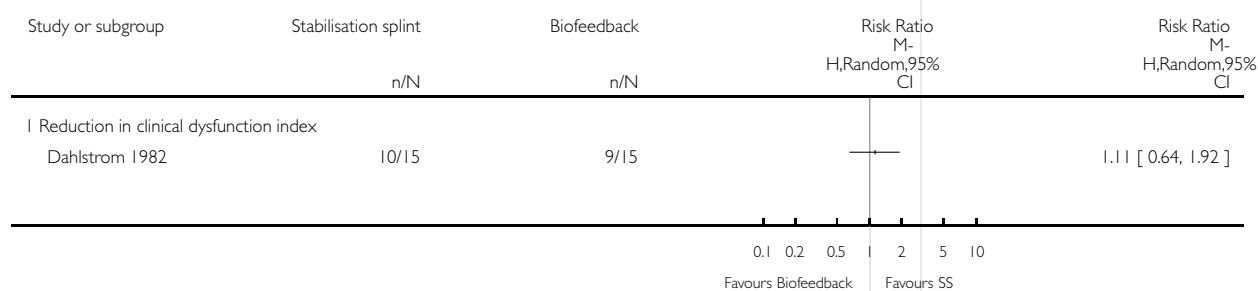


Analysis 5.4. Comparison 5 Stabilisation splint (SS) versus biofeedback/stress management, Outcome 4 Dysfunction score (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 5 Stabilisation splint (SS) versus biofeedback/stress management

Outcome: 4 Dysfunction score (3 months or less)

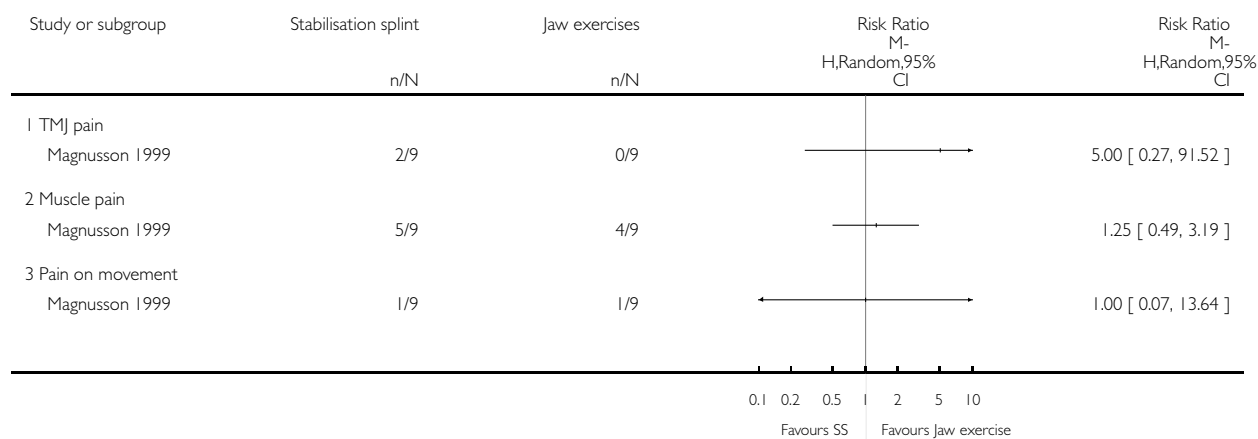


Analysis 6.1. Comparison 6 Stabilisation splint (SS) versus jaw exercises, Outcome 1 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 6 Stabilisation splint (SS) versus jaw exercises

Outcome: 1 Pain (3 months or less)

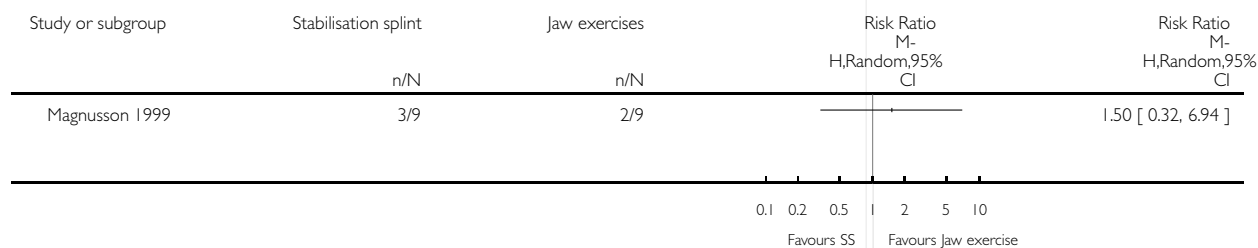


Analysis 6.2. Comparison 6 Stabilisation splint (SS) versus jaw exercises, Outcome 2 Clicking (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 6 Stabilisation splint (SS) versus jaw exercises

Outcome: 2 Clicking (3 months or less)

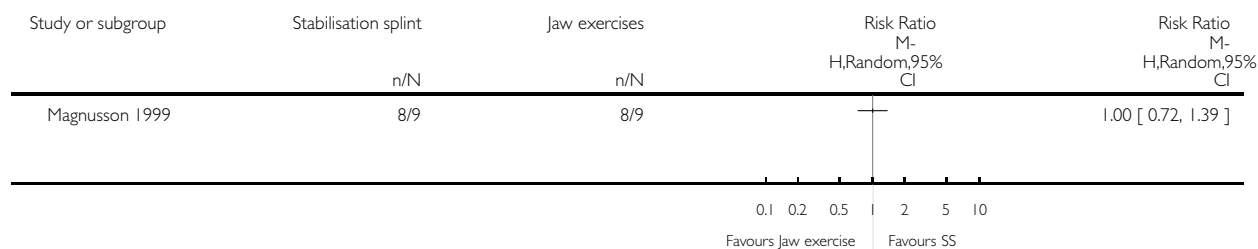


Analysis 6.3. Comparison 6 Stabilisation splint (SS) versus jaw exercises, Outcome 3 Overall improvement (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 6 Stabilisation splint (SS) versus jaw exercises

Outcome: 3 Overall improvement (3 months or less)

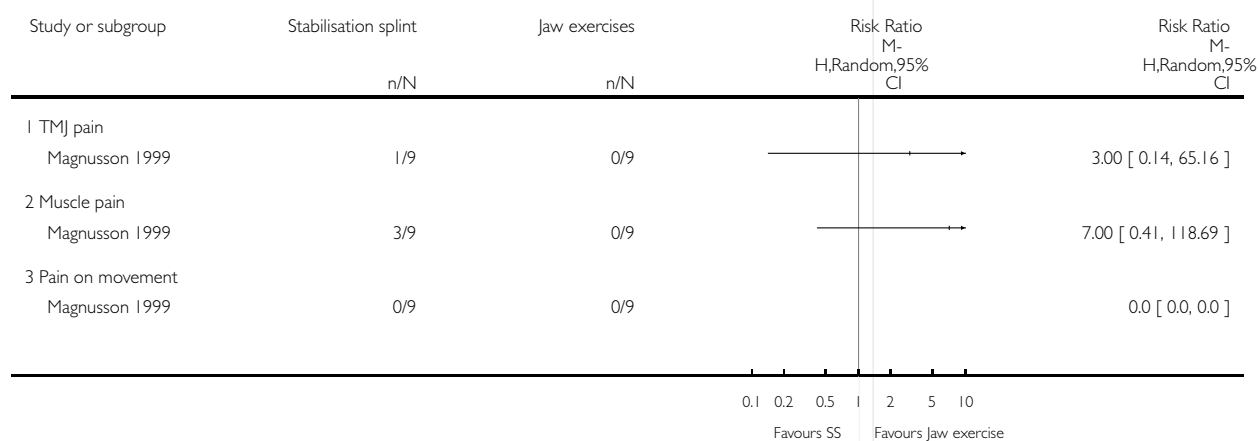


Analysis 6.4. Comparison 6 Stabilisation splint (SS) versus jaw exercises, Outcome 4 Pain (greater than 3 months).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 6 Stabilisation splint (SS) versus jaw exercises

Outcome: 4 Pain (greater than 3 months)

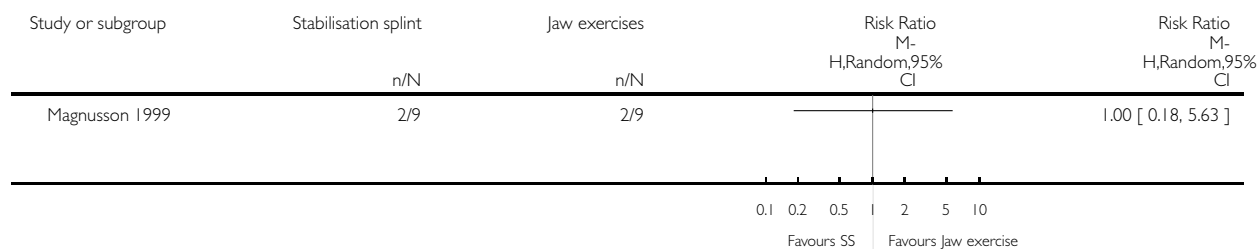


Analysis 6.5. Comparison 6 Stabilisation splint (SS) versus jaw exercises, Outcome 5 Clicking (greater than 3 months).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 6 Stabilisation splint (SS) versus jaw exercises

Outcome: 5 Clicking (greater than 3 months)

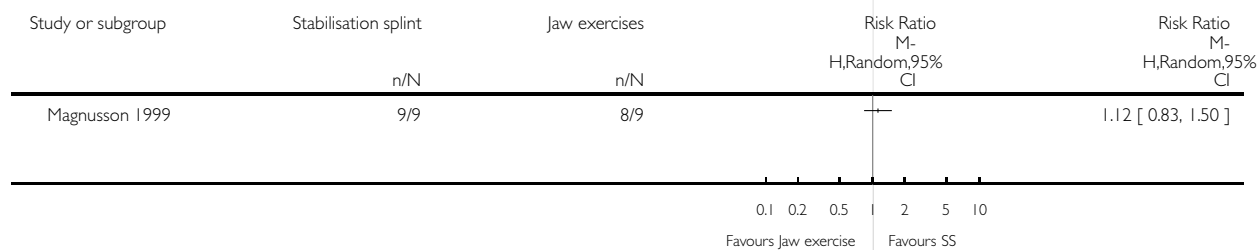


Analysis 6.6. Comparison 6 Stabilisation splint (SS) versus jaw exercises, Outcome 6 Overall improvement (greater than 3 months).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 6 Stabilisation splint (SS) versus jaw exercises

Outcome: 6 Overall improvement (greater than 3 months)

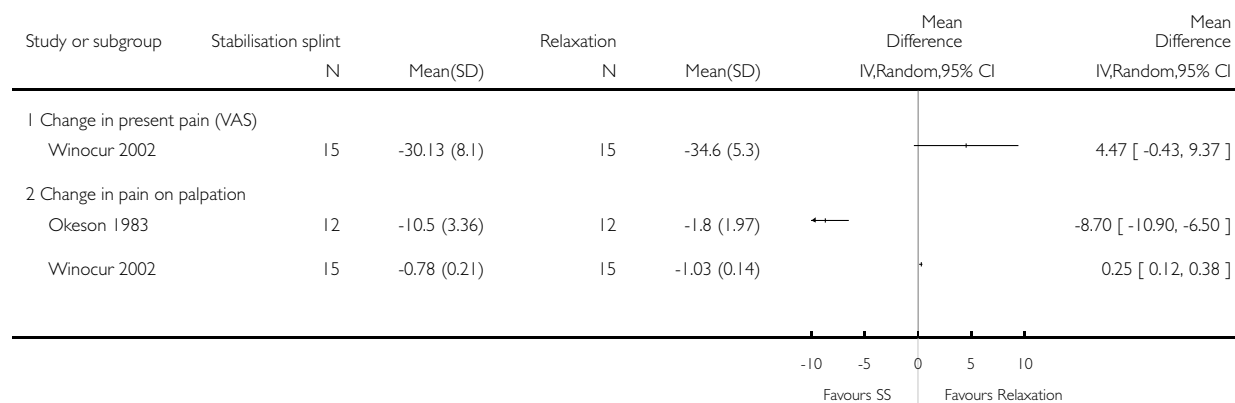


Analysis 7.1. Comparison 7 Stabilisation splint (SS) versus relaxation, Outcome 1 Pain (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 7 Stabilisation splint (SS) versus relaxation

Outcome: 1 Pain (3 months or less)

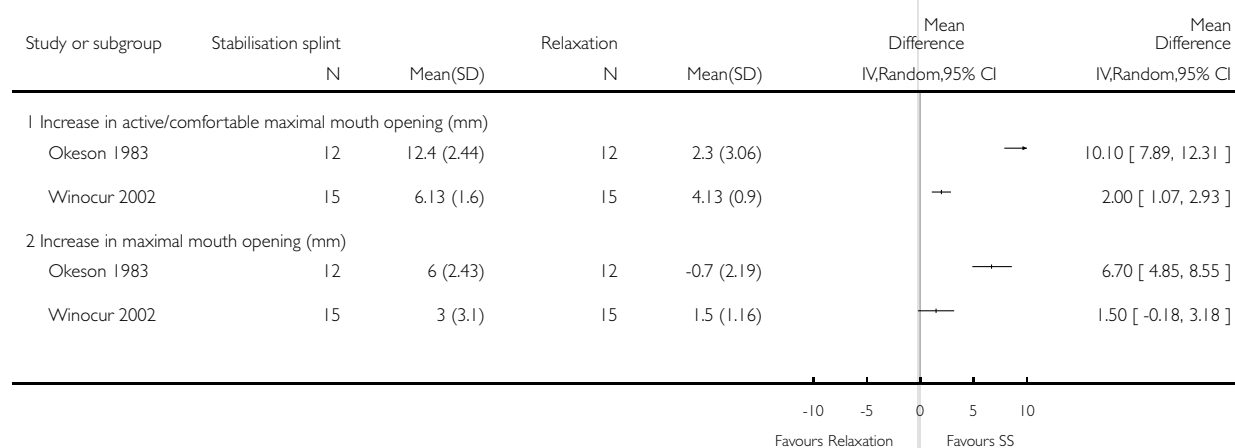


Analysis 7.2. Comparison 7 Stabilisation splint (SS) versus relaxation, Outcome 2 Movement (3 months or less).

Review: Stabilisation splint therapy for temporomandibular pain dysfunction syndrome

Comparison: 7 Stabilisation splint (SS) versus relaxation

Outcome: 2 Movement (3 months or less)



APPENDICES

Appendix I. MEDLINE (OVID) search strategy

(Controlled vocabulary is given in upper case type and free text terms in lower case).

1. exp TEMPOROMANDIBULAR JOINT DISORDERS
2. exp TEMPOROMANDIBULAR JOINT DYSFUNCTION SYNDROME
3. 'temporomandibular joint dysfunction'
4. 'pain dysfunction syndrome'
5. or/1-4
6. exp OCCLUSAL SPLINTS
7. 'occlusal splint\$'
8. 'oral splint\$'
9. 'stabilisation splint\$'
10. 'stabilization splint\$'
11. Tanner or Fox or Michigan
12. 'centric relation appliance\$'
13. 'bite plate\$'
14. or/6-13
15. 5 and 14

WHAT'S NEW

Last assessed as up-to-date: 3 November 2003.

| Date | Event | Description |
|-------------------|---------|---------------------------------|
| 16 September 2008 | Amended | Converted to new review format. |

HISTORY

Protocol first published: Issue 4, 2000

Review first published: Issue 1, 2004

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- TMD Unit, Prosthodontics, University Dental Hospital of Manchester, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Following referee comments the definition of pain dysfunction syndrome has been changed from the one originally published in the protocol.

INDEX TERMS

Medical Subject Headings (MeSH)

*Occlusal Splints; Acupuncture Therapy; Pain Measurement; Physical Therapy Modalities; Quality of Life; Randomized Controlled Trials as Topic; Relaxation Therapy; Temporomandibular Joint Dysfunction Syndrome [*therapy]

MeSH check words

Humans