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[Intervention Protocol]

Self-ligating brackets versus conventional pre-adjusted edgewise brackets for treating malocclusion

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effectiveness and efficiency of self-ligating brackets versus conventional pre-adjusted edgewise brackets for the treatment of malocclusion.

BACKGROUND

Description of the condition

Malocclusion can be defined as a deviation from a normal bite (Andrews 1972). It can have a negative impact on quality of life and may be associated with aesthetic and functional problems (Dimberg 2015). Malocclusion can be corrected using a number of orthodontic appliances, which can be either removable or fixed in nature. Fixed orthodontic appliances use brackets and arch wires to move teeth and correct the underlying malocclusion. Malocclusion occurs in the majority of racial groups, with only 35% of adults having well-aligned lower incisors and about 20% of the population having deviations from the ideal bite relationship (Proffit 1998). The term 'malocclusion' refers to a number of possible conditions. The most common are: upper protrusion

(overjet), spacing or crowding problems, misplaced midline, open bite, deep overbite, underbite, crossbite and rotations.

Description of the intervention

Conventional orthodontic brackets (Figure 1) use ways to tie in the wires (e.g. stainless steel ligature wires (Tidy 1989) or elastomeric rings (Dowling 1998)) to hold the arch wire within the bracket slot. In contrast, self-ligating brackets use a slide or clip to maintain the arch wire in the slot (Voudouris 1997). Self-ligation was introduced in 1935 (Stolzenberg 1935), however it is only more recently that there has been a renewed interest in the use of self-ligating brackets. Self-ligating brackets can be divided into two main categories, active and passive, according to their mechanisms of closure and interaction with the arch wire. Active self-ligating brackets (Figure 2) have a spring clip that stores en-

ergy pressing against the arch wire for rotation and torque control in larger dimension arch wires. In-Ovation (GAC International Inc., Central Islip, New York, USA), SPEED (Strite Industries Ltd., Cambridge, Ontario, Canada), and Time (Adenta GmbH, Gliching/Munich, Germany) are examples of active self-ligating brackets. Conversely, passive self-ligating brackets (Figure 3) usually have a slide that can be closed without exerting an active force on the arch wire. Damon (Ormco, Glendora, California, USA) and SmartClip (3M Unitek, Monrovia, California, USA) are two popular brands of passive design.

Figure 1. Edgewise (conventional) bracket.



Figure 2. Active self-ligating bracket.



Figure 3. Passive self-ligating bracket.



How the intervention might work

The standard edgewise appliance is designed to move teeth to their desired location using brackets in conjunction with a series of arch wires. Pre-adjusted edgewise brackets have an inbuilt tip, torque, angulation and in/out prescription into each individual bracket. Once bands and brackets are cemented and bonded in their ideal position, the arch wire is ligated into the bracket slots. Evidence from laboratory-based studies indicates that the rate of tooth movement may be affected by friction between arch wire and tube or bracket slot (Ehsani 2009).

It has been proposed that self-ligation may have an influence on the efficiency of orthodontic alignment and sliding mechanics (Damon 1998). This assertion relates to the absence of steel or elastomeric ligatures that increase friction. It has also been claimed that passive designs are associated with less friction than active self-ligating brackets (Kim 2008). It has been postulated that this reduced friction may translate into a requirement for lower force levels to produce tooth movement (Berger 1990). Self-ligating brackets are proposed to induce more physiologically harmonious tooth movement without interrupting the periodontal vascular supply (Damon 1998). Therefore, the potential for alveolar bone generation, greater amounts of expansion, less proclination of anterior teeth, better anchorage conservation, less patient discomfort (Berger 2008) and less need for extractions have variously been attributed to these designs. Other proposed advantages include fewer treatment visits, reduced overall treatment time, improved aesthetics and oral hygiene (Forsberg 1991), and full and secure ligation (Turnbull 2007).

However, it has been recognised that self-ligating brackets have disadvantages including higher cost, possible breakage of the clip or the slide, higher profile related to the complicated mechanical design, which may potentially impair control, may risk occlusal

interferences, and may result in lip discomfort, and difficulty in finishing due to incomplete expression of the arch wires (Chen 2010). Furthermore, it has also been reported that using self-ligating brackets resulted in no significant differences in long-term stability compared to pre-adjusted edgewise brackets (Yu 2014).

Why it is important to do this review

While several advantages of self-ligating over conventional brackets have been proposed, many of these are lacking in supporting evidence. In particular, *in vitro* and retrospective studies have reported significant advantages of self-ligating over conventional brackets (Damon 1998), while results from prospective clinical studies have often been less positive in relation to treatment time and number of visits required for orthodontic treatment (Ong 2010).

Despite a growing number of randomised controlled trials, there has been no Cochrane systematic review to summarise the effects of treatment of malocclusion using self-ligating brackets and to provide evidence to guide clinical practice. Given the wide range of advantages claimed in relation to self-ligation, and the powerful marketing to clinicians and patients making, perhaps, unsubstantiated claims, a comprehensive review to ascertain the effectiveness of treatment with self-ligating brackets compared with conventional brackets is necessary.

OBJECTIVES

To assess the effectiveness and efficiency of self-ligating brackets versus conventional pre-adjusted edgewise brackets for the treatment of malocclusion.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials. We will include both parallel-group and split-mouth studies. No minimum time of follow-up will be required.

Types of participants

Participants in the permanent dentition treated with full arch (single arch or both upper and lower arches), fixed orthodontic appliances. We will include participants of all ages and both genders. Subjects with cleft lip and palate or any other known or suspected craniofacial syndrome will be excluded.

Types of interventions

Active or passive self-ligating brackets versus pre-adjusted edgewise (conventional) brackets.

Studies where participants had previous orthodontic treatment, combined orthodontic-surgical treatment or correction of molar relationships will be considered ineligible.

Types of outcome measures

Primary outcomes

- Occlusal outcome judged using a validated index or scale (e.g. Peer Assessment Rating) and measured at the end of active treatment.
- Treatment duration. Measured subsequent to each phase of orthodontic treatment and at the end of active treatment.
- Subjective pain experience. Subsequent to changing wires.

Secondary outcomes

- Arch dimensional changes (intercanine widths, intermolar widths, arch depth) measured at the end of alignment (working arch wire passive).
- Stability of treatment (at a minimum of 6 months).
- Participant satisfaction.
- Cost-effectiveness.
- Bracket failure rate over the course of treatment.
- Chair-side time.
- Adverse events including root resorption and periodontal effects over the course of treatment.

Search methods for identification of studies

Cochrane Oral Health's Information Specialist will conduct systematic searches for randomised controlled trials and controlled clinical trials. Due to the Cochrane Embase Project to identify all clinical trials on the database and add them to CENTRAL, only recent months of the Embase database will be searched. Please see the [searching page on the Cochrane Oral Health website](#) for more information. No other restrictions will be placed on the language or date of publication when searching the electronic databases.

Electronic searches

We will search the following databases for relevant trials:

- Cochrane Oral Health's Trials Register;
- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;
- MEDLINE Ovid (from 1946 onwards);
- Embase Ovid (previous six months to date).

The subject strategies for databases will be modelled on the search strategy designed for MEDLINE Ovid in [Appendix 1](#). Where appropriate, these will be combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0, Chapter 6, Box 6.4.b. (Lefebvre 2011)).

Searching other resources

We will search the following trials registries:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (<http://clinicaltrials.gov/>);
- World Health Organization International Clinical Trials Registry Platform (<apps.who.int/trialsearch>).

We will check the bibliographies of included studies and any relevant systematic reviews identified for further references to relevant trials.

We will not perform a separate search for adverse effects of interventions used for the treatment of malocclusion. We will consider adverse effects described in included studies only.

We may contact original authors for clarification and further data if trial reports are unclear.

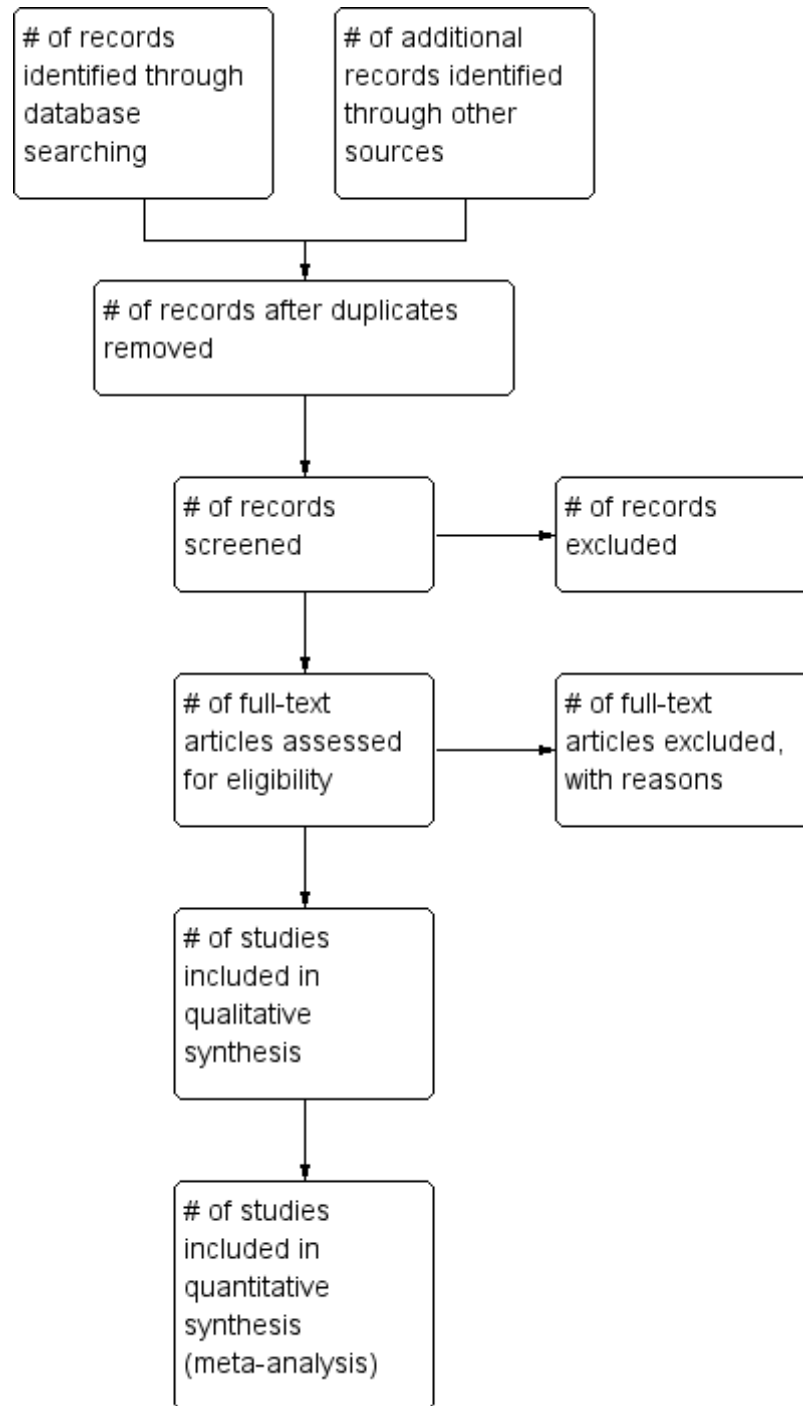
We will include published and unpublished studies.

Data collection and analysis

Selection of studies

Two review authors will independently assess the titles and abstracts of studies resulting from the search. We will obtain full copies of all potentially relevant publications, those appearing to meet the inclusion criteria, and those for which there are insufficient data in the title and abstract to make a definitive decision. Two review authors will assess the full-text papers independently and resolve disagreement relating to eligibility of included studies through discussion with a third review author. From this group, we will record those studies not meeting the inclusion criteria in the 'Characteristics of excluded studies' section of the review and report the reason for exclusion in the 'Characteristics of excluded studies' table. The whole process of study inclusion is illustrated in [Figure 4](#).

Figure 4. Study flow diagram illustrating the process of study inclusion.



Data extraction and management

We will design and pilot a data extraction form recording year of publication and country of origin, and details of the participants including demographic characteristics and selection criteria.

We will enter study details into the 'Characteristics of included studies' tables in RevMan 5.3 (RevMan 2014). Two review authors will extract data independently. We will resolve any disagreements through discussion, consulting a third review author to achieve consensus when necessary.

We will also extract the following details if reported.

- Trial methods: (a) method of allocation; (b) conduct of sample size calculation; (c) masking of participants, trialists and outcome assessors; (d) exclusion of participants after randomisation and proportion and reasons for loss to follow-up.
- Participants: (a) study setting; (b) sample size; (c) age; (d) gender; (e) inclusion and exclusion criteria.
- Intervention: (a) type; (b) materials and techniques used; (c) time of follow-up.
- Control: (a) type; (b) materials and techniques used; (c) time of follow-up.
- Outcomes: (a) primary and secondary outcomes mentioned in the 'Types of outcome measures' section of this review.

We will record sources of funding, if stated.

We will use the characteristics of the included studies to assess the heterogeneity and the external validity of any included trials. We will collate multiple reports of the same study. We will extract estimates of 2 x 2 tables (dichotomous data), mean and standard deviations from effect estimates, confidence intervals, etc. In case of multi-arm studies, the results will be extracted for each intervention arm and we will include these studies as pair-wise comparisons.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in section 8.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion or by involving a third assessor.

We will assess the following domains as 'low', 'unclear' or 'high' risk of bias.

- Sequence generation (selection bias).
- Allocation concealment (selection bias).
- Blinding of participants and personnel (performance bias).
- Blinding of outcome assessment (detection bias).
- Incomplete outcome data (attrition bias).
- Selective outcome reporting (reporting bias).
- Other bias.

We will report these assessments in a 'Risk of bias' table for each included study and we will provide supporting judgements for each assessment.

We will provide summary assessments of the risk of bias for each important outcome (across domains) within and across studies (following Table 8.7.a in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011)):

- low risk of bias (plausible bias unlikely to seriously alter the results) if all domains were assessed as at low risk of bias;
- unclear risk of bias (plausible bias that raises some doubt about the results) if one or more domains were assessed as at unclear risk of bias; or
- high risk of bias (plausible bias that seriously weakens confidence in the results) if one or more domains were assessed as at high risk of bias.

Measures of treatment effect

For continuous data, we will use the mean difference (MD) if studies all report the outcome using the same scale and the standardised mean difference to combine studies that measure the same outcome but using different scales, with 95% confidence intervals (CIs). For dichotomous data, we will present results as summary risk ratio with 95% CIs as measures of the treatment effect.

Unit of analysis issues

The participant will be the unit of analysis. Where cluster-randomised trials are included, we will undertake data analysis at the same level as the randomisation, or at the individual level accounting for the clustering. In so doing we will follow the advice provided in section 9.3.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Dealing with missing data

In studies where data are unclear or missing we will contact the principal investigators. If missing data are unavailable we will follow the advice given in Section 16.1.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Assessment of heterogeneity

We will assess clinical heterogeneity by examining the variability in the participants, interventions and outcomes. We will assess statistical heterogeneity using a Chi² test where a P value of < 0.1 indicates statistically significant heterogeneity. The I² statistic will be used to assess the degree of heterogeneity.

We will use the following guide for interpretation of the I^2 as given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011):

- 0% to 40%: implied slight heterogeneity;
- 30% to 60%: moderate heterogeneity;
- 50% to 90%: substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

If there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by Egger 1997, and for dichotomous outcomes we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using Review Manager software following guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If there are studies of similar comparisons reporting the same outcomes, we will use the random-effects model to pool the results in a meta-analysis. We will provide supporting judgements for each assessment.

Subgroup analysis and investigation of heterogeneity

If a sufficient number of studies are included and we identify moderate, substantial or considerable heterogeneity (see 'Assessment of heterogeneity') we plan to carry out the following subgroup analyses according to type of self-ligating bracket (active or passive) for the following outcomes.

- Occlusal outcome judged using a validated index or scale (e.g. Peer Assessment Rating).
- Treatment duration.

- Subjective pain experience.

We plan to conduct the prespecified subgroup analyses classifying whole trials by interaction tests.

Sensitivity analysis

We plan to carry out sensitivity analyses to assess the robustness of our review results. This would involve repeating the analyses in accordance with study limitations.

Summarising findings and assessing the quality of the evidence

We will create a 'Summary of findings' table for the main comparison and the primary outcomes. This will include occlusal outcome measured at the end of active treatment, treatment duration measured subsequent to each phase of orthodontic treatment and at the end of active treatment, and subjective pain experience measured subsequent to changing wires.

We will use the GRADE system (GRADE 2004), and the GRADEproGDT software (GRADEproGDT 2014) to create the table. We will categorise the quality of each body of evidence as high, moderate, low, or very low. The evidence can be downgraded from 'high quality' by one level for serious, or by two levels for very serious limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, and imprecision of effect estimates or potential publication bias.

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* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE Ovid search strategy

1. exp Orthodontics/
2. orthodontic\$.mp.
3. exp Malocclusion/
4. (malocclu\$ or crossbite\$ or "cross bite\$" or deepbite\$ or "deep bite\$" or overjet\$ or "over jet\$" or overbite\$ or "over bite\$" or underbite\$ or "under bite\$" or prognathism or "Angle Class" or openbite\$ or "open bite\$" or apertognathia or nonocclu\$).mp.
5. ((tooth or teeth) adj5 crowd\$).mp.
6. or/1-5
7. (self adj25 ligat\$).mp.
8. (In-Ovation or SPEED or Damon or SmartClip).ti,ab.
9. (Time and Adenta).mp
10. or/7-9
11. 6 and 10

The above subject search will be linked with the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0, Chapter 6, Box 6.4.b. (Lefebvre 2011)).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

CONTRIBUTIONS OF AUTHORS

Protocol.

- Review planning and protocol writing: Noha Abbas (NA) and Mais Sadek (MS).
- Revision of the protocol draft: Padhraig Fleming (PF) and Ama Johal (AJ).
- Expert opinion and supervision of protocol writing: Ashraf Nabhan (AN).

Review.

- Identification of studies: NA, MS, PF, AJ.
- Data extraction: NA, MS.
- Assessment of risk of bias: NA, MS.
- Data input and analysis: AN.
- Draft the review: NA, MS.
- Revise review draft: PF, AJ.
- Methodological expertise: AN.

DECLARATIONS OF INTEREST

Ashraf Nabhan: none known.

Noha Abbas: none known.

Mais Sadek: none known.

Padhraig Fleming: the author is the principal investigator of randomised controlled trials concerning self-ligating brackets. If those studies are eligible, other review authors will evaluate them for inclusion and assess the risk of bias. The author has no financial conflict of interest as the study is self-funded.

Ama Johal: the author is a co-author of randomised controlled trials concerning self-ligating brackets. If those studies are eligible, other review authors will evaluate them for inclusion and assess the risk of bias. The author has no financial conflict of interest as the study is self-funded.

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Internal sources

- No sources of support supplied

External sources

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- Cochrane Oral Health Global Alliance, Other.

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