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Self-ligating orthodontic braces for straightening teeth (Protocol)

Smith J, Bearn DR, House K



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[Intervention Protocol]

Self-ligating orthodontic braces for straightening teeth

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To test the null hypothesis that there are no differences in treatment efficiency, occlusal outcome or patient experience between self-ligating orthodontic braces and conventionally ligated orthodontic braces.

BACKGROUND

Orthodontics is that branch of dentistry concerned with facial growth, development of the dentition and occlusion, and with the diagnosis, interception, and treatment of occlusal anomalies (Mitchell 2007). Orthodontic treatment involves the use of either fixed or removable braces to correct and straighten crooked teeth. In England and Wales between April 2002 and March 2003, claims for orthodontic treatment were made by the General Dental Services at an approximate cost of £117 million to the National Health Service (DPB 2003).

Fixed braces consist of brackets which are attached to the teeth and wires that move and guide the teeth. The wires are held in slots cut into the brackets. Conventional brackets use a loop of wire or an elastic ring - known as ligatures - to hold the wire in the slot. Brackets that have a mechanical device built into them to hold the wire instead of a ligature are known as self-ligating (Thomas 1998). Self-ligating bracket systems claim improved treatment efficiencies (3M Unitek 2006; GAC International; Ormco 2007) but the evidence to support this is weak.

Self-ligating brackets were originally designed with the intention to reduce the time needed to change wires compared with the use of wire ligatures. However, the advent of elastomeric ligatures meant that this perceived advantage was diminished.

More recently however, other advantages of a self-ligating system have been claimed with new designs for brackets. These claimed advantages are:

1. Complete and secure archwire engagement
2. Low friction between bracket and archwire
3. Less chairside assistance
4. Reduced time to change archwires
5. Reduced frequency of visits to the orthodontist to change wires
6. Promote better oral hygiene
7. Allow for better infection control.

The first two of these advantages are claimed to help reduce overall treatment duration compared with conventional bracket systems (Harradine 2003).

OBJECTIVES

To test the null hypothesis that there are no differences in treatment efficiency, occlusal outcome or patient experience between self-ligating orthodontic braces and conventionally ligated orthodontic braces.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled clinical trials which compare self-ligating braces with conventionally ligated braces.

Types of participants

Trials will be eligible for inclusion in the review if they have recruited individuals of any age receiving upper and lower fixed brace treatment. Trials including participants with cleft lip or palate or both or other craniofacial deformity/syndrome will be excluded as well as trials involving orthognathic surgery.

Types of interventions

Interventions: Fixed brace treatment in both arches with self-ligating braces.

Control: Fixed brace treatment in both arches with conventionally ligated braces.

Types of outcome measures

Primary outcome measures

- Treatment duration in time.
- Occlusal outcome as measured by a recognised occlusal index or dental arch dimensions.

Secondary outcome measures

- Number of visits during active treatment, scheduled and unscheduled.
- Quantitative pain scores following appliance placement or archwire change.
- Chairside time or time to change archwires.
- Change in incisor inclination as determined by cephalometric analysis.
- Smile aesthetics.
- Patient satisfaction.
- Rate of alignment of labial segment.
- Rate of space closure.
- Cost effectiveness.

Search methods for identification of studies

All relevant studies, irrespective of language, will be searched for. If articles are written in other languages, we will contact the authors by mail or email or ask the Cochrane Oral Health Group to translate them.

For the identification of studies included or considered for this review detailed search strategies will be developed for each database searched. These will be based on the search strategy developed for MEDLINE but revised appropriately for each database. The subject search strategy will use a combination of controlled vocabulary and free text terms based on the search strategy for MEDLINE via OVID (see Appendix 1), in conjunction with phase 1 and 2 of the Cochrane Sensitive Search Strategy for Randomised Controlled Trials (RCTs) as published in the *Cochrane Handbook for Systematic Reviews of Interventions* 4.2.6 (Higgins 2006).

Databases to be searched

The following databases will be searched:

- Cochrane Oral Health Group's Trials Register (current issue)
- Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, current issue)
- MEDLINE (1966 to present)
- EMBASE (1974 to present).

Handsearching

Handsearching of journals will be performed if this has not already been carried out as part of the Cochrane handsearching programme.

The journals that will be important to this review will be as follows:

- *American Journal of Orthodontics & Dentofacial Orthopaedics*
- *Angle Orthodontist*
- *European Journal of Orthodontics*
- *Journal of Orthodontics*
- *Australian Dental Journal*
- *Journal of Clinical Orthodontics*.

The bibliographies of the clinical trials identified will be checked for references to trials published outside the handsearched journals. Personal references will be checked by sending letters to the author(s) of each included study published to obtain information about other unpublished studies that might be eligible for inclusion. Authors may also be contacted for further information or missing data to clarify their reports.

Data collection and analysis

Study selection

Two review authors (David Bearn (DRB) and Kate House (KH)) will independently examine the title, keywords and abstract of reports identified from electronic searching for evidence of three criteria:

- A randomised or quasi-randomised clinical trial

- Involving the use of self-ligating orthodontic brackets compared with conventionally ligated orthodontic brackets
- Reporting one or more of the defined outcome measures above.

For studies appearing to meet these inclusion criteria, or for which there were insufficient data in the title and abstract to make a clear decision, the full report will be obtained.

The review authors will not be blind to author(s), institution or site of publication.

Data extraction

Data extraction forms will be designed and piloted to record the following information:

- Year of publication and country of origin
- Details of the participants including demographic characteristics and criteria for inclusion
- Details of the type of intervention (which self-ligating system and control)
- Outcomes data as listed above.

Where the data are not clear or cannot be directly extracted from the publication the authors will be contacted and further information requested.

Quality assessment

Quality assessment of the included trials will be undertaken independently and in duplicate by two review authors. Any disagreements will be resolved by discussion or further independent assessment by a third review author. Agreement will be assessed using a Kappa statistic. The following will be included in the review of methodology.

Four main quality criteria to be examined.

(1) Method of randomisation, recorded as.

(A) Yes - adequate, as described either in the text or after contacting the author.

(B) No - inadequate, as described in the text or after contacting the author.

(C) Unclear - unclear in the text and unable to contact the author.

(2) Allocation concealment, recorded as.

(A) Yes - adequate, as described either in the text or after contacting the author.

(B) No - inadequate, as described in the text or after contacting the author.

(C) Unclear - unclear in the text and unable to contact the author.

(3) Outcomes assessors blinded to intervention, recorded as.

(A) Yes - adequate, as described either in the text or after contacting the author.

(B) No - inadequate, as described in the text or after contacting the author.

(C) Unclear - unclear in the text and unable to contact the author.

(4) Completeness of follow up (was there a clear explanation for withdrawals and drop outs in each treatment group?) assessed as.

(A) None - no drop outs or withdrawals, as shown by the same number of participants in the methods and results.

(B) Yes - numbers in the methods and results were not the same and drop outs were explained.

(C) No - numbers in the methods and results were not the same and drop outs were not explained.

Other methodological criteria examined will include.

- Presence or absence of a sample size calculation.
- Comparability of groups at the start in terms of age, gender, malocclusion severity.
- Clear inclusion/exclusion criteria.
- Presence/absence of an estimate of measurement error i.e. the validity and reproducibility of the method of assessment.

Risk of bias in the included studies will be categorized according to the following.

(A) Low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria were met.

(B) Moderate risk of bias (plausible bias that raises some doubt about the results) if one or more criteria were partly met.

(C) High risk of bias (plausible bias that seriously weakens con-

fidence in the results) if one or more criteria were not met as described in the *Cochrane Handbook for Systematic Reviews of Interventions* 4.2.6 (updated September 2006) (Higgins 2006).

Data synthesis

Pooling of data and meta-analysis will only be carried out if there are sufficient similarities between studies in the types of participants, interventions and outcomes. A weighted treatment effect will be calculated and the results will be expressed as mean differences (WMD) and 95% confidence intervals (CI) for continuous outcomes and risk ratios (RR) and 95% CI for dichotomous outcomes.

Clinical heterogeneity will be assessed by examining type of intervention, type of control and appliance used, as well as operator effects in each study. Meta-analysis will only be used when studies are of similar comparisons, reporting comparable outcome measures. The significance of discrepancies in the estimates of treatment effects from the different trials will be assessed by means of Cochran's test for heterogeneity, and any heterogeneity investigated. Random-effects models will be used for all meta-analyses. Sensitivity analysis will be used based on some of the quality assessment criteria.

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Thomas 1998

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* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE (OVID) search strategy

1. RANDOMIZED CONTROLLED TRIAL.pt.
2. CONTROLLED CLINICAL TRIAL.pt.
3. RANDOMIZED CONTROLLED TRIALS.sh.
4. RANDOM ALLOCATION.sh.
5. DOUBLE BLIND METHOD.sh.
6. SINGLE BLIND METHOD.sh.
7. or/1-6
8. (ANIMALS not HUMANS).sh.
9. 7 not 8
10. CLINICAL TRIAL.pt.
11. exp CLINICAL TRIALS/
12. (clin\$ adj25 trial\$).ti,ab.
13. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
14. PLACEBOS.sh.
15. placebo\$.ti,ab.
16. random\$.ti,ab.
17. RESEARCH DESIGN.sh.
18. or/10-17
19. 18 not 8
20. 19 not 9
21. 9 or 20
22. exp ORTHODONTICS/
23. orthodontic\$.mp.
24. or/22-24
25. (Ligat\$ adj25 bracket\$).ti,ab.
26. (Self adj25 ligat\$).ti,ab.
27. or/25-26
28. 24 and 27
29. 21 and 28

WHAT'S NEW

Date	Event	Description
29 August 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 2, 2008

CONTRIBUTIONS OF AUTHORS

Jonathan Smith, lead review author, responsible for electronic database searching, co-ordinating reviewing by co-authors and preparing draft text of review.

David Bearn, assisting in protocol development, reviewing papers, data extraction, contributing to text of review.

Kate House, reviewing papers, data extraction, contributing to text of review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- School of Dentistry, The University of Manchester, UK.
- The Dental School, University of Dundee, UK.

External sources

- No sources of support supplied