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Interventions for managing root caries (Protocol)

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Interventions for managing root caries

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ABSTRACT

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

To assess the effects of interventions for:

- preventing root caries (primary prevention);
- arresting root caries (secondary prevention);
- restoring root caries lesions (tertiary prevention).

BACKGROUND

Description of the condition

Definition, aetiology, prevalence and incidence

Root caries, by definition, refers to tooth decay on the root of the tooth (Banting 2001). Root caries is not a 'new' condition

(Ettinger 1999), but has been reported as increasing in prevalence due to people living longer and maintaining their natural teeth into old age (Curzon 2004; Lamster 2016; Takahashi 2016). Gingival recession is almost certainly a prerequisite for the development of root surface caries. However, it has been reported that 10% to 20% of lesions may present subgingivally (Stamm 1990). Like coronal caries, the main aetiological factor for the initiation and development of root caries is the presence of a cariogenic biofilm and fermentable carbohydrates (mainly sugars) (Ravald 1986). When sugar penetrates a cariogenic biofilm, it is converted

to acids by bacteria. This conversion process initiates demineralisation of the root surfaces by removing calcium and phosphate ions from surface apatite crystals. For enamel, this process takes place below a pH of 5.5. Due to the lower level of mineralisation of dentine, a slight decrease in pH (to a range of 6.0 to 6.8) will induce dentine demineralisation (Bignozzi 2014). As with coronal caries, the formation of root caries is a dynamic process of demineralisation and remineralisation and caries will progress when the balance of factors favours demineralisation (Pretty 2013). Importantly, and unlike caries in enamel, coronal dentine and root caries both involve not only demineralisation but also collagen degradation (Takahashi 2016). As a result, demineralisation is approximately twice as rapid on root surfaces as on enamel (Featherstone 1994; Burgess 2002).

Although root caries can be observed in young adults, its prevalence and incidence increase with age (Griffin 2004). The prevalence of root caries in older adults is high (Curzon 2004); recent surveys have reported that around half of community-dwelling older adults had root caries' experience (Warren 2000; Splieth 2004; Imazato 2006; Du 2009). For older adults living in long-term care facilities, the oral health situation is usually worse, with very high levels of untreated root caries (Chalmers 2002; Lo 2004; Simunković 2005). A systematic review of the burden of dental caries across the world used available epidemiological evidence and identified three peaks of caries activity, at 6, 25 and 70 years of age (Kassebaum 2015). The peak at age 70 was related to the presence of root/cementum caries, representing the effect of increased tooth retention in older adults, with root surfaces exposed as a consequence of periodontal support loss. These surfaces become more susceptible to dental biofilm accumulation, and its removal is often difficult for elderly people due to limited manual dexterity (Clarkson 1995).

Risk indicators

Ritter 2010 observed that the most frequently reported indicators or predictors of root caries' incidence were root caries' prevalence at baseline, number of teeth, and plaque index. Poor biofilm control, xerostomia, coronal decay, and number of exposed root surfaces were the leading risk indicators associated with root caries in older adults living independently (Hayes 2016). Lifestyle factors such as tobacco use and alcohol consumption were also significantly associated with the occurrence of root caries lesions, mainly in people over 45 years of age (Christensen 2015). The presence of biofilm, proximity to dentures, and gingival recession were found to be important site-level risk indicators for root caries in institutionalised older adults (Tan 2014). Other identified risk indicators included frequency of carbohydrate intake, low fluoride exposure, advanced age, low socioeconomic status, reduced manual dexterity, and cognitive decline (Bignozzi 2014). These identified risk indicators may guide targeted interventions for the prevention or treatment of root caries.

Description of the intervention

Management of root caries, as in other diseases, generally comprises primary, secondary, and tertiary prevention (Whitaker 2006). Primary prevention refers to practices and procedures carried out before the onset of root caries. Secondary prevention of root caries focuses on people early in the disease process, to arrest or reverse the process. Tertiary prevention (restorative treatment) targets root caries lesions that result in complications, such as cavitation, loss of function, and pain.

Prevention of new root caries and arrest of existing root caries

Several approaches to primary and secondary prevention have been proposed. These include: control of dietary carbohydrate intake; improvement of oral hygiene (active biofilm control); antimicrobial agents; chewing gums; fluoride-containing toothpastes; fluoridated water, salt or milk; professionally-applied topical fluoride (gels, varnish, solution of silver diamine fluoride etc.); arginine-based toothpastes; amorphous calcium phosphate and casein phosphopeptide (ACP-CPP); and ozone applications. Fluoride can be delivered at a community level (as fluoridated water, milk or salt) and at an individual level (characterised by professional or self-care applications), either singly or in combination (Burgess 2002).

Restorative treatments

When the structural integrity of demineralised dentine has been lost, restorative treatment should be considered. The conventional approach of 'drilling and filling' is the treatment most commonly used for restoration of cavitated root surface caries lesions. The Atraumatic Restorative Treatment (ART) approach has been used to treat root caries lesions (Lo 2006; Da Mata 2015). Amalgam, glass ionomer cement (GIC), resin-modified glass ionomer cement (RMGIC), modified polyacid resins ('compomers'), or composite resins are frequently used to restore root caries lesions (Billings 1985; Levy 1990; Duke 1998). Sometimes, it may be necessary to consider some form of aesthetic improvement after the root caries lesion is arrested if, for example, a colour change has occurred, and restorative treatment may be offered (Mount 2016).

How the intervention might work

Prevention of new root caries or arrest of existing root caries

Theoretically, root caries is a preventable disease (Galan 1994), which can be arrested at any stage of disease development, through changes in the oral cavity environment from one that favours demineralisation of tooth tissue to one that favours remineralisation

(Lo 1998). Theoretically, remineralisation could occur during periods of change in the environmental condition prevailing in the dental biofilm covering a root caries lesion, for example a return to neutral pH, and by replenishing the calcium and phosphate content removed during demineralisation (Burgess 2002). Thus, the control and reduction of dietary carbohydrates, the modification and reduction of cariogenic dental biofilm or the application of chemical agents, such as fluoride, chlorhexidine or ACP-CPP, could inhibit demineralisation and promote remineralisation (Rodrigues 2011).

Restorative treatments

The ultimate goal for the restorative treatment of root caries is to arrest the destructive process of cavitation and to restore the tooth by replacing the affected parts of its structure so its function and appearance is maintained. The conventional restorative approach requires the use of power-driven dental rotary instruments for the removal of decayed dental tissues and cavity preparation. ART is a minimally invasive approach (Tyas 2000), involving the removal of soft, demineralised tooth tissue using only hand instruments and followed by restoration with a fluoride-releasing adhesive dental restorative material (Frencken 2014).

Why it is important to do this review

The World Health Organization (WHO) expects that the population of adults aged 60 and over will more than triple from 600 million in the year 2000 to 2 billion in 2050 (WHO 2011). This demographic change has important implications for public health. People are not only living longer but also retaining more of their natural teeth in the oral cavity, which are potentially at risk of developing caries. For the increasing older population, root caries is becoming a more significant dental problem (Banting 1980). Root caries, if left untreated, cause pain, discomfort, infection, and tooth loss, which in turn may affect chewing ability, diet, and oral health-related quality of life (Chalmers 2002).

Some clinical studies on the restorative treatment of root caries have been published. Hayes 2014 carried out a systematic review of failure rates of restorations in the management of root caries. The authors were unable to pool the included studies in a meta-analysis due to clinical heterogeneity. Additional clinical studies on restorative treatments of root caries have since been published (Gil-Montoya 2014; Da Mata 2015), which could contribute to the evidence base in this area.

Similarly, Wierichs 2015 published a systematic review on non-invasive treatment of root caries lesions. The primary outcome of this review was “incremental change”, whereby a surface with (active) root caries at baseline develops into a filled or missing surface at follow-up. There is a lack of agreement as to whether this particular definition constitutes a suitable measure of incremental change (Slade 1999). Clinically appropriate outcome measures for

measuring the effectiveness of interventions for managing root caries should be developed.

This systematic review will explore the effects of interventions for managing root caries, including prevention of new root caries, arrest of existing root caries and restorative treatment of root caries lesions. By synthesising the current evidence base, this systemic review has the potential to inform clinicians, patients and other stakeholders of evidence for methods to prevent, control and treat root caries, which in turn has the potential to significantly improve a patient's quality of life.

OBJECTIVES

To assess the effects of interventions for:

- preventing root caries (primary prevention);
- arresting root caries (secondary prevention);
- restoring root caries lesions (tertiary prevention).

METHODS

Criteria for considering studies for this review

Types of studies

We will include parallel-group randomised controlled trials (RCTs). We will not place a restriction on inclusion of studies in terms of duration of follow-up for outcome assessment. We will address variation in duration of follow-up in the analysis by grouping studies according to short-, medium- and long-term follow-up.

We will exclude studies with a cross-over design as the effects of most preventative and therapeutic interventions persist, rendering a ‘washout’ period unfeasible. We will also exclude studies of a split-mouth design due to the potential for contamination from one tooth site to another.

Types of participants

We will include adult participants (age 18 years or older), irrespective of age, sex or source of recruitment (e.g. clinic, community, nursing/residential home). We will include participants with sound exposed root surfaces in evaluations of primary prevention. Participants with initial root caries lesions at baseline will be included in evaluations of secondary prevention, and those with cavitated root caries lesions at baseline will be included in evaluations of tertiary prevention.

It is possible evaluations of primary, secondary and tertiary prevention will be made within a single trial. Where we are able to extract the data separately for the different evaluations we will include the data in the respective analyses in this review; where we are unable to extract data separately then we will present the results of the trial report narratively.

Types of interventions

We will include:

- studies directly comparing active interventions for the prevention of root caries either with another active intervention, with placebo, or with no intervention at an individual level;
- studies directly comparing active interventions for the arrest of initial root caries lesions either with another active intervention, with placebo, or with no intervention at an individual level;
- studies directly comparing one active interventions for restorative treatment with another, with no treatment, or with traditional intervention at an individual level. The active intervention may be either an innovative restorative material or technique to treat cavitated root caries lesions.

Types of outcome measures

Primary outcomes

- Prevention
 - Prevalence (proportion of adults with root caries).
 - Incidence (proportion of adults developing new root caries over a period of time).
 - Incidence density (rate per person per days of follow-up).
 - Caries increment (decayed/filled root (root-DFS) or untreated root (root DS)).
- Arrest
 - Mean numbers of root caries lesions that have been arrested at the follow-up.
 - Proportion of active root caries lesions that have been arrested at the follow-up.
 - Relief of pain or discomfort (no symptoms of pain or discomfort reported by participants).

The clinical measure for the change from active caries to arrested (inactive) caries will be measured as a change of colour, texture (softness versus hardness), or both.

- Restoration
 - Restoration failure (loss of restoration, or any need for replacement of the restoration, e.g. due to defective marginal integrity, presence of secondary caries or others) evaluated through clinical assessment.

Secondary outcomes

- Prevention
 - Adverse events.
 - Compromised aesthetics.
- Arrest
 - Adverse events.
 - Compromised aesthetics.
 - Participant satisfaction.
 - Quality of life using a validated instrument.
- Restoration
 - Adverse events.
 - Compromised aesthetics.
 - Participant satisfaction.
 - Quality of life using a validated instrument.

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, the Information Specialist will only search recent months of the Embase database. Please see the [searching page on the Cochrane Oral Health website](#) for more information. We will place no other restrictions on the language or date of publication when searching the electronic databases.

Electronic searches

Cochrane Oral Health's Information Specialist will search the following databases for relevant trials.

- Cochrane Oral Health's Trials Register;
- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Register of Studies;
- MEDLINE Ovid (from 1946 onwards);
- Embase Ovid (previous 6 months to date).

We will model subject strategies for databases on the search strategy designed for MEDLINE Ovid in [Appendix 1](#). Where appropriate, we will combine this 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, Box 6.4.c. (Lefebvre 2011)).

Searching other resources

The following trial registries will be searched:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov ([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, we will consider adverse effects described in included studies only.

Data collection and analysis

Selection of studies

Two groups of review authors (HT and LR, Group 1; TW and MV, Group 2) will independently select studies to be included from the search results, as well as selecting studies to be excluded in the review with a specified reason, identifying ongoing studies and contacting trial authors for studies that await classification because of missing information. We will resolve any disagreements through discussion, consulting a third review author to achieve consensus when necessary.

Data extraction and management

Two groups of review authors (HT and LR, Group 1; TW and MV, Group 2) will independently extract data from each included study using a specially designed and piloted data extraction form. We will resolve any disagreements through discussion, consulting a third review author to achieve consensus when necessary. We will record the following data for each included study.

- Trial registration number, design, location, number of centres, recruitment period.
- Inclusion/exclusion criteria, age and sex of participants, number randomised/analysed, any other potentially important factors (e.g. dry mouth).
- Detailed description of the intervention and comparator, including duration of administration.
- Details of all outcomes reported, including method of assessment and time(s) assessed.
- Details of sample size calculations, adverse effects, funding sources, declarations and conflicts of interest.

Assessment of risk of bias in included studies

Two review authors (HT, LR) will independently assess the risk of bias of each included study using the Cochrane's tool for assessing risk of bias (Higgins 2011). We will resolve any disagreements through discussion or by consulting a third review author to achieve consensus when necessary.

We will complete a 'Risk of bias' summary as well as a 'Risk of bias' table for each included study. For each domain of risk of bias, we will report the relevant information provided in the study publication or personal communication. We will then judge the level of risk of bias for each domain as 'high', 'low', or 'unclear'.

We will assess the following domains.

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

We will categorise the overall risk of bias of individual studies, taking into account our judgements for all domains. We will categorise studies as being at low, high, or unclear risk of bias according to the following hierarchy.

- High risk of bias (plausible bias that seriously weakens confidence in the results): if one or more domains are at high risk of bias.
- Unclear risk of bias (plausible bias that raises some doubt about the results): if one or more domains are at unclear risk of bias.
- Low risk of bias (plausible bias unlikely to seriously alter the results): if all domains are at low risk of bias.

Measures of treatment effect

For continuous outcomes (e.g. increments of root caries or the number of arrested root caries over the study period) where studies use the same outcome measures, we will use the mean values and standard deviations (SDs) reported in the studies to express the estimate of effect as mean differences (MDs) with 95% confidence intervals (CIs). Where different scales are used, we will use mean values and SDs to express the treatment effect as standardised mean differences (SMDs) with 95% CIs.

For dichotomous outcomes (e.g. incidence proportion of new root caries), we will express estimates of effects as risk ratios (RRs) with 95% CIs.

Unit of analysis issues

For parallel group trials, the trial participant will be the unit of analysis. If clustering is present (multiple sites within a participant) and this is accounted for in the analysis of the primary study, we will extract the reported effect estimate and standard error accounting for the clustering. Where clustering is present but the study has not reported the effect estimate and standard error taking account of the clustering, we will use standard Cochrane methods of calculating the effective sample size or inflating the standard error to account for the clustering (Section 9.3.1 Higgins 2011).

Dealing with missing data

Where clarification of study details is required or where the study report has data missing, we will contact study authors whenever possible. If further information is not forthcoming, we will present

the data as reported. We will use the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* to estimate missing SDs (Higgins 2011).

Assessment of heterogeneity

If a sufficient number of studies are included in any meta-analysis, we will assess clinical heterogeneity by examining the characteristics of the studies, the similarity between the types of participants, interventions, and outcomes. We will also assess statistical heterogeneity with the Chi² test, using a P value less than 0.1 to indicate statistically significant heterogeneity. We will quantify heterogeneity using the I² statistic with interpretation based on Section 9.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), where:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: represents considerable heterogeneity.

Assessment of reporting biases

If at least 10 studies are included in a meta-analysis, we will assess publication bias according to the recommendations on testing for funnel plot asymmetry (Egger 1997; Higgins 2011). If asymmetry is identified, we will explore possible sources.

Data synthesis

We will carry out meta-analyses only where there are studies of similar comparisons reporting the same outcomes. We will combine MDs (SMDs if studies use different scales) for continuous data, and RRs for dichotomous data.

Our general approach will be to use a random-effects model, given that there is evidence that heterogeneity is under-reported in meta-analysis with small numbers of studies. With this approach, the CIs for the average intervention effect will be wider than those obtained using a fixed-effect approach, leading to a more conservative interpretation. We will use an additional table to report the results from studies not suitable for inclusion in a meta-analysis. Where pooling of studies is not appropriate we will report the results in an additional table.

Subgroup analysis and investigation of heterogeneity

Where there are sufficient studies, we intend to carry out the following subgroup analyses as the prevalence, incidence and increment of root caries may vary according to these factors.

- Age.
- Sex.
- Inclusion of participants with frailty and/or cognitive impairment.
- Dry mouth.

- Receipt of radiation therapy.

Sensitivity analysis

If a sufficient number of studies are included in any meta-analysis, we will undertake sensitivity analysis to assess the robustness of the results by excluding studies with unclear or high overall risk of bias.

In meta-analyses that include several small studies and a single very large study, we will undertake a sensitivity analysis comparing the effect estimates from both the random-effects and the fixed-effect models. If these are different, we will report on both analyses within the results section.

Presentation of main results

We will produce a 'Summary of findings' table for each objective and comparison for the following outcomes, using GRADEpro (GRADEpro GDT) software (www.guidelinedevelopment.org/).

- Incidence (proportion of adults developing new root caries)
- Prevention.
 - Caries increment (root-DFS or root-DS) - Prevention.
 - Mean number of arrested root caries lesions - Arrest.
 - Proportion of arrested root caries lesions - Arrest.
 - Relief of pain or discomfort - Arrest.
 - Restoration failure - Restoration.
 - Adverse events - Prevention, Arrest, Restoration.
 - Compromised aesthetics - Prevention, Arrest, Restoration.
 - Quality of life using a validated instrument - Prevention, Arrest, Restoration.

Using GRADE methods (Arikins 2004), we will assess the quality of the body of evidence for each comparison and outcome by considering the overall risk of bias of the included studies, directness of the evidence, consistency of the results, precision of the estimates, and risk of publication bias. We will categorise the quality of each body of evidence as 'high', 'moderate', 'low', or 'very low'.

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* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE Ovid search strategy

1. “Root caries”/
2. (root\$ adj10 (cavit\$ or caries or carious or decay\$ or lesion\$ or deminerali\$ or reminerali\$)).mp.
3. ((cervical or cementum) adj2 caries).mp.
4. or/1-3

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, 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

All authors were responsible for the protocol.

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Lindsay Richards: none known.

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