

The effectiveness of Atraumatic Restorative Treatment (ART) compared to conventional treatment in restoring class II dental cavities in permanent molar and premolar teeth: a systematic review [protocol]

Protocol information

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Background

Description of the condition

Dental caries

Over the last 20 years there have been steady improvements in the oral health of children in the UK. Surveys have shown that these improvements have not been reflected in all young people, and oral health inequalities have increased (1). Moreover, dental caries in children and adults remain a public health problem in developing and many developed countries. It affects 60% to 90% of school-aged children and up to 100% of adults worldwide (2).

Furthermore, research has shown that untreated dental caries causes pain, dysfunctions in eating, chewing, sleeping, mood, attention, smiling and communication due to missing or damaged teeth, has a major impact on people's daily lives and well-being. Also, oral diseases restrict activities at school, causing millions of school hours to be lost each year throughout the world (3-6). Furthermore, research has shown that untreated dental caries affects the growth and development of children (7, 8).

Currently, dental caries shows an unequal distribution of the disease, with higher proportions of those in lower socio-economic position having the disease (9). Similarly, there are inequalities in dental care (10). Oral health care inequalities are mainly due to practice orientation (11), dependency on models of attention to oral health that requires conventional dental clinics or expensive portable equipment, and using electricity (12).

Description of the intervention

Atraumatic Restorative Treatment versus conventional restorative treatment

Traditional restorative care requires expensive equipments, while the ART approach is cheap, simpler, and cause less anxiety in children than the traditional restorative approach (13). The Atraumatic Restorative Treatment (ART) was developed in the middle of 1980s for non industrialized countries whose population are low socioeconomic status and in which there is no electricity available. The ART uses manual excavation of dental caries, which eliminates the need for anaesthesia and use of expensive equipment, and restores the cavity with high viscosity glass ionomer cement, an adhesive material that bonds to the tooth structure. Furthermore, glass ionomer cement releases fluoride leading to down regulation of demineralization of teeth, potential re-mineralization, and antibacterial effect. The ART approach reduces the overall costs of restorative care, because capital investment and maintenance costs for ART are lower than those for traditional restorative care (14).

How the intervention might work

Caries removal using hand instruments was developed for use in places where electricity and water are not readily available. Thus it was developed to allow restoration of teeth that might otherwise have been extracted. The use of hand instruments to remove caries, however, may be more conservative of tooth tissue than using a mechanical method. This could mean less trauma both directly and indirectly to the pulp resulting in fewer teeth developing pain and abscesses. The use of an adhesive restoration means that tooth need not be removed to make the cavity retentive, and the sealing properties of the material, along with fluoride release from some materials, may lead to the arrest of deep caries left in place.

The potential benefits of the ART approach has been demonstrated in a study carried out in South Africa that reported a 50% reduction in cost of restorations performed according to ART approaches compared to conventional treatment with amalgam or composite resin. Also, the introduction of the ART approach in South Africa has reduced the number of primary posterior teeth extractions by 36% in a year (14).

Why it is important to do this review

In recent years, the ART non-invasive treatment approach has been gaining wider acceptance in the dental treatment for young and uncooperative children (15). More recently Frencken and Holmgren (16) stated that the ART approach seems to be an economic and effective method for improving the oral health not only of people in developing but also of those in industrialized countries. There is some evidence in the literature that ART is effective to treat decayed teeth (17-22), but is not conclusive.

Our systematic search of the literature identified two systematic reviews (23, 24) of studies comparing the ART with conventional treatment. They have limitations including restricting the search to only one electronic data base (MEDLINE), having limited search strategies, including only English language studies, restricting the materials used for ART and conventional treatment, and not assessing the quality of included studies.

In order to assist patients, clinicians and health care funders to make decisions about whether ART is a suitable alternative to conventional treatment for the restoration of dental cavities, we need systematic reviews of high methodological quality that can summarise the data available regarding ART using GIC, RMGIC or composite compared to conventional treatment using amalgam, GIC, RMGIC or composite.

Objectives

The objective of this review is to assess the effectiveness of ART using any adhesive material to permanently restore class II cavities in permanent molars and premolars compared to restoring them using conventional means.

Our PICO is:

Problem / patients:	All patients with a class II carious cavity in a permanent molar or premolar
Intervention:	ART (see definition below)
Comparison:	Conventional treatment using partial or full (see definition below)
Outcome:	Restoration failure (see definition below)

Thus our question is: for any patient with a class II cavity in a permanent molar or premolar does ART versus conventional treatment result in a lower incidence of restoration failure?

Methods

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials that compare ART using any adhesive material to conventional treatment using amalgam or any adhesive material. Trials can be parallel group (where each patient is randomised to one type of restoration), split mouth (where one of each restoration is randomised for placement in one of two teeth in the same patient) or cluster randomized trials (where each patient is in one intervention group, which is randomised to one or other intervention).

Quasi-randomised trials, where patients are allocated using non-random allocation methods (e.g. hospital number, alternation), will be eligible for inclusion but will be subjected to sensitivity analysis owing to their higher risk of allocation bias.

Studies must report the longevity of the restorations and there should be at least 2 years follow up as we consider this to be the minimal length of time a permanent restoration ought to last.

Types of participants

Trials will involve adults or children with a class II cavity in a permanent molar or premolar that requires restoration. The trials should either concern this cavity type alone or include an identifiable subset that does.

Types of interventions

Experimental group:

This will include cases where caries was removal using hand instruments only. The chemo-mechanical removal of caries will not be included. The cavities will be restored with one of

GIC, RMGIC or composite. These are all adhesive materials and in theory would conform to the original ART protocols.

Control group:

The use of mechanical means (i.e. a handpiece with a bur) to partially or wholly remove caries. This includes gaining access through enamel with subsequent caries removal using hand instruments. The cavity will be restored with one of GIC, RMGIC, composite or amalgam.

Our rationale for including GIC and RMGIC in this group is twofold. Firstly, these materials are in theory considered suitable for long term restoration following the ART method of caries removal and should therefore be considered suitable for restoration following mechanical caries removal. Secondly, there is the possibility that the same material could be used as intervention and control in a study that seeks to compare the caries removal method alone. Such a study would be very useful to determine what part the caries removal variable plays in the overall procedure.

Types of outcome measures

Suitable outcome measures will include:

- for dichotomous data (e.g. failure or not of the restoration, loss or not of the tooth) the risk ratio or odds ratio, with confidence intervals
- for continuous data the standard mean difference with standard error
- for time to event data the hazard ration with confidence intervals

Continuous data will be dichotomised where possible when combining data. This will mean loss of power of the conclusion but will allow straight forward synthesis of trial outcomes in the form of relative risks at fixed time points - 2, 3, 4, 5 and 10 years.

Primary outcomes

The primary outcome is the failure of the restoration.

This includes: loss of filling and replaced filling (or filling needing to be replaced) due to significant material loss, tooth fracture or caries.

Secondary outcomes

Outcomes that are not long term outcomes (e.g. they occurred during or shortly after treatment) will be reported but not synthesized. These include:

- Extracted teeth

- Irreversible pulpal damage (e.g. signs and symptoms of irreversible pulpitis, abscess, catastrophic tooth fracture)
- Post-operative pain and sensitivity
- Cost-effectiveness of treatment
- Time needed to complete treatment
- Other adverse effects

We have chosen not to include other short term outcomes. This is because our review will consider only studies that have a minimum follow up of two years. As such we will have excluded short term trials that may have considered such outcomes as anxiety, patient comfort and clinician satisfaction. If we were to collect such data from the studies we include we believe this would have the potential to introduce a publication bias. Therefore, we would suggest a separate systematic review look at these outcomes.

Search methods for identification of studies

We will attempt to identify all relevant studies regardless of language or publication status (published, unpublished, in press, and in progress).

Electronic searches

The following databases and trials registers will be searched:

- OVID Medline, OVID Embase and the Cochrane Central Register of Controlled Trials (CENTRAL)
- Regional bibliographic databases LILAC, BBO and IndMed.
- Current Controlled Trials (<http://www.controlled-trials.com/>) and Clinical Trials (<http://clinicaltrials.gov/>) to identify ongoing trials that may have unpublished data
- Google Scholar and OpenSIGLE (<http://opensigle.inist.fr/> up to 2005) to identify related grey literature
- IADR conference abstracts 2001-2011 (<http://iadr.confex.com/iadr/search.epl>) and NLM Gateway (<http://gateway.nlm.nih.gov/gw/Cmd>) for conference abstracts

The search strategies for the Medline, Embase and CENTRAL searches include both keywords and MeSH terms. 'MeSH' refers to a database in which all papers have been categorised under certain headings, and if a search matches one of the headings in the MeSH database all those associated papers will be included in the search results. The keyword search retrieves all papers which contain the search term(s) in the reference. We combined both types of search to ensure an exhaustive list of publications.

Keywords and MeSH terms relating to all permanent dental restorations, ART and the materials used for this will be combined using 'OR'. Keywords and MeSH terms relating to

amalgam and caries will be combined with 'OR'. The two sets of results will be combined using 'AND' (see appendix 1).

Searching other resources

Hand searching

We have identified the following journals to hand search. ART was developed in the mid-1980s. We will therefore search from 1985 onwards. However, a number of years for these have already been searched by the Cochrane Oral Health Group – OHG (years covered are in square brackets – available at <http://us.cochrane.org/master-list>) and therefore clinical trials should be included in the CENTRAL search. We will therefore only search years not already covered by the OHG.

- International Dental Journal [OHG 1970-2001 complete, 2002-3 incomplete]
- Journal of Dental Research [OHG 1980-7, 1990-8, 2001-3 complete, remainder incomplete]
- Journal of Dentistry [OHG 1970-2001 complete, 2002-3 incomplete]
- Caries Research [OHG 1967-2003]
- Community Dentistry & Oral Epidemiology [OHG 1971-2001 complete, 2002-3 incomplete]
- Journal of Clinical Pediatric Dentistry [OHG 1996-2003 complete]

Reference lists

We will examine the reference lists of relevant trials, reviews, articles and text books in an attempt to identify any other studies or those not identified in previous searches.

Correspondence

Organisations, researchers and experts known to be involved in the field will be contacted, either by conventional or electronic mail, in an effort to trace unpublished or ongoing studies. Manufacturers will also be contacted to identify any ongoing or unpublished studies.

Data collection and analysis

Selection of studies

1. Reports retrieved from the various searches will be merged in Endnote and duplicates removed using automated and manual means.
2. The total will be screened by a trained screener using titles and abstracts to remove articles that have no relevance at all to glass ionomers or ART.

3. The articles left will be screened by two reviewers (DH) and (AB) for reports of clinical trials that could potential meet our inclusion criteria using the titles and abstracts.
4. Full copies of these reports will be obtained and, using predefined eligibility criteria and a custom sheet, the two reviewers will identify studies that should be included for data extraction and further analysis.

Data extraction and management

Data from all included studies will be extracted independently by two review authors (DH and AB) using a pilot-tested data extraction form. Extracted data will be entered separately by each of two review authors into a specially designed data extraction sheet. Data will only be included if there is an independently reached consensus. Disagreements will be resolved by a third review author (WM) until consensus is obtained. All trial authors will be contacted for clarification or missing information. Data will be excluded until further clarification is available or if agreement cannot be reached.

Papers in languages not known by the review authors will be data extracted with help from appropriate translators.

Studies with duplicate publications will be treated as a single source of data.

Review authors will not be blinded to the names of the authors, institutions, journal of publication or results of the studies. The level of agreement (Kappa) between review authors will be calculated.

Items that will be extracted are:

- Study 1st author and year of publication
- The reference for the article
- The language it is written in
- Contact details for the relevant author
- Study design:
 - RCT or Q-RCT
 - Parallel, split mouth or cluster randomised.
- Risk of Bias assessment
 - Sequence generation method
 - Blinding
 - Outcome data
 - Allocation concealment
 - Other concerns regarding bias
 - Overall risk of bias

- Participants
 - Total participants in the study
 - Total with class II cavities in permanent teeth
 - Diagnostic criteria for caries
 - Mean age and SD
 - %male
 - %female
 - Country(ies) in which study was conducted
 - Sociodemographic details
 - The clinician type (dentist, DCP, student, other healthcare worker)
 - Average DMFT score
- Interventions
 - ART:
 - material used – High, Medium or Low density GIC, RMGIC, Compomer, Carbomer, or composite
 - Whether LA was used
 - Conventional
 - Material used – amalgam, High, Medium or Low density GIC, RMGIC, Compomer, Carbomer, or composite
 - Whether LA was used
- Outcomes
 - Time point:
 - when data collected
 - Whether this time point was the same as that prespecified in the protocol
 - Whether the protocol time points are reported
 - Definition of outcome with criteria (e.g. failure of restoration: criteria = any thing that meant dentist felt need to replace)
 - Unit of measurement (e.g. failed / not failed)
 - If a scale, the upper and lower limits
- Results
 - Dichotomous data
 - Data will be entered into a 2 x 2 table (e.g. failure +/- as rows, ART / conventional as columns)
 - Continuous and ordinal data
 - Mean and standard deviation for ART and conventional treatment will be entered into a table, and the total number of participants for each entered.
- Miscellaneous
 - Funding sources
 - Key conclusions of study authors

- Miscellaneous comments from study authors
- References to other relevant studies
- Miscellaneous comments by review authors

Individual patient data will not be used.

Assessment of risk of bias in included studies

Selection, performance, detection, attrition, reporting and other biases will be assessed using the Cochrane 'risk of bias' tool. This involves making a judgement of 'yes / no / unclear' for each of 6 questions:

- Was sequence generation adequate?
- Was allocation concealment adequate?
- Was blinding of personnel and patients adequate?
 - We do not anticipate this being possible in most studies due to the use of mechanical means of caries removal being so different in feeling from the hand removal, and of the difference in colour of amalgam and the adhesive materials.
- Was blinding of the assessor(s) adequate?
 - As above but where the same materials is used the assessor could be blinded.
- Was incomplete outcome data dealt with adequately?
- Was selective outcome reporting dealt with adequately?
- Was the trial free of other sources of bias?

The data will be summarised in a 'risk of bias' summary figure.

Measures of treatment effect

The effect measure of choice for dichotomous data will be risk ratio (RR) and for continuous data the mean difference (MD).

Where data has not been presented in this way it will, where possible, be converted.

Unit of analysis issues

In the parallel group studies the unit of analysis will be the patient. In split mouth studies, it will be the tooth. For cluster randomised trials the unit of analysis will be the group.

Dealing with missing data

Where data is missing attempts will be made to contact the authors to see if they are available. If we are unable to retrieve the data sensitivity analysis will be conducted to see the effect on the meta-analysis conclusion using three scenarios: 1) assume the worst case

and that all missing data are due to failure of the restoration 2) assume the best case and that all missing data are intact restorations 3) assume that proportionally the same number of restorations failed / survived as in the non-missing data.

Assessment of heterogeneity

Statistical heterogeneity will be assessed formally using the Chi² test using P=0.10 as the upper limit for statistical heterogeneity. The Forrest Plot of included trials will give a visual indication of statistical heterogeneity by demonstrating the degree of overlap of confidence intervals. Where overlap is not present, heterogeneity is greater than where overlap is significant.

The I² test will be used to assess inconsistency between studies and the following thresholds used to interpret the result:

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

Clinical heterogeneity is likely between the composite, GIC and RMGIC groups in the experimental arm, and the amalgam and composite, GIC and RMGIC groups in the control arm. The effect of this on a summary statistic will be tested by sensitivity analysis. Studies with a particular material will be removed sequentially to assess the impact.

We might expect there to be a difference in the outcome dependent on the operator. This will be explored using sensitivity analysis.

Methodological heterogeneity is likely between parallel and split mouth study designs and cluster trials. There is also likely to be heterogeneity between randomised and quasi-randomised trials as the latter is more likely to result in allocation bias. It is anticipated that heterogeneity will also arise from differences in study quality including loss to follow up. The effect of different study types will be assessed using sensitivity analysis as described above.

Assessment of reporting biases

A funnel plot will be used to assess the risk of publication bias on included trials. The plot is a scatter plot of the effect size of the study on the horizontal axis and the standard error of the intervention effect (a measure of the size of the study) on the vertical axis. Asymmetry of the plot, particularly the absence of smaller studies on one side of the plot or the other would suggest publication bias.

Data synthesis

Where statistical heterogeneity is low, the summary results from the studies will be combined using the fixed-effects method. Where there is moderate heterogeneity it will be combined with the random-effects method. Where the Chi^2 and I^2 tests suggest moderate to high heterogeneity, or where the studies are considered too clinically or methodologically heterogeneous, the results will not be combined.

Subgroup analysis and investigation of heterogeneity

Whilst we could do this for the different materials used, the analysis would be likely to be between-group rather than within-group. This weakens the analysis.

Likewise, whilst it could be tempting to subgroup based on DMFT(S) or similar, without individual patient data our analysis would be between studies as we would be dependent on the average score. The risk of other study characteristics confounding the result means making conclusions about the relative impact of DMFT(S) weak.

Sensitivity analysis

Sensitivity analysis will be conducted where:

- different materials are used for either of the interventions
- randomisation and quasi-randomisation have been used in different studies
- different clinical operators have been used between studies
- where baseline measures of caries experience are very high or very low
- studies are judged to be at moderate or high risk of bias

Reporting

The review will be reported as per the PRISMA guidelines. Where for some reason an item cannot be completed, an explanation will be given for why this is so in the interest of improving transparency of reporting. The flow diagram will be used to show the process of deciding which trials to include in the review.

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