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Innes, Nicola; Ricketts, David; Evans, Dafydd J. P.

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Preformed metal crowns for decayed primary molar teeth

Nicola P T Innes¹, David Ricketts², Dafydd J P Evans¹

¹Unit of Dental and Oral Health, Dundee Dental Hospital and School, Dundee, UK. ²Restorative Dentistry, Dundee Dental Hospital and School, Dundee, UK

Contact address: Nicola P T Innes, Unit of Dental and Oral Health, Dundee Dental School, Park Place, Dundee, Tayside, DD1 4HN, UK. n.p.innes@dundee.ac.uk.

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ABSTRACT

Background

Preformed metal crowns (PMCs) are recommended by the British Society of Paediatric Dentistry (BSPD) for restoring badly broken down primary molar teeth. However, few dental practitioners adopt this technique in clinical practice, citing cost and clinical difficulty as reasons for this. Whilst there is a subjective impression by clinical academics that PMCs provide a more durable restoration than filling materials, there appears to be little evidence within the literature to support this.

Objectives

The primary aim of this systematic review was to compare clinical outcomes for primary molar teeth restored using PMCs compared to those restored with filling materials.

Search methods

The literature was searched using: the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2005, Issue 3); MEDLINE (1966 to August 2005); EMBASE (1980 to August 2005); System for Information on Grey Literature in Europe (SIGLE) (1976 to August 2005). Relevant publications’ reference lists were reviewed for relevant articles. The most recent search was carried out on 24 August 2005.

Selection criteria

Randomised controlled trials (RCTs) that assessed the effectiveness of PMCs compared with filling materials or where there had been no treatment in children with untreated tooth decay in one or more primary molar teeth.

Data collection and analysis

Two review authors independently assessed the title and abstracts for each article from the search results to decide whether it was likely to be relevant. Full papers were obtained for relevant articles and all three review authors studied these.

Main results

Forty-seven records were retrieved by the search strategies of which some were duplicates. Of these, 14 studies were scrutinised. No studies met the inclusion criteria and six studies were excluded from the review as they were either retrospective in design or reported as prospective outcomes but not randomised. No data were available for extraction and analysis and therefore, no conclusion could be made as to whether PMCs were more successful than filling materials for restoring primary molar teeth.
Authors’ conclusions

No RCTs were available for appraisal. Whilst this technique is recommended by the BSPD for use in clinical practice, the evidence to support this is not strong, consisting mainly of case reports and uncontrolled studies. It is important that the absence of evidence for PMCs is not misinterpreted as evidence for their lack of efficacy.

There is a strong need for prospective RCTs comparing PMCs and fillings for managing decayed primary molar teeth. The lower levels of evidence that have been produced, however, have strength in that the clinical outcomes are consistently in favour of PMCs, despite many of the studies placing PMCs on the most damaged of the pair of teeth being analysed.

Plain Language Summary

Preformed metal crowns for managing decayed primary molar teeth in children

Management of decay in primary molar teeth conventionally involves removal of decayed tooth and placement of a preformed metal crown (also known as a stainless steel crown) to completely cover the tooth or placement of a filling (a soft material which is placed in the hole and hardened) to restore the tooth. Preformed metal crowns are recommended by specialists in children’s dentistry for the management of these teeth when they are affected by moderate to advanced tooth decay. We were unable to find any high quality research evidence either for or against this recommendation. No randomised control trials were found which compared removal of decay followed by placement of a preformed metal crown with removal of decay followed by placement of a filling material or no treatment.

However, there is some evidence from clinical studies of poor to medium quality that preformed metal crowns may last longer than fillings for these teeth. Confirmation of this will require well controlled clinical trials.

Background

Dental decay in children’s teeth is a significant public health problem, affecting 60% to 90% of school children in industrialised countries (WHO Report 2003).

In Scotland, the National Dental Inspection Programme (NDIP 2003) showed that over half of 5-year old children had decayed primary teeth, with the average number of decayed teeth in these children being five. Untreated decay in primary teeth may lead to pain, abscess formation and possible loss of teeth, and 15% of the 5-year olds in this sample had already had at least one tooth extracted. This large burden of treatment need has implications both for individual patients, and on a public health agenda basis.

Currently accepted best practice is to treat dental decay in primary teeth by removing all the decayed tissue, before restoring the tooth with a filling material. However, this process can leave the tooth structurally weak, both through loss of decayed tissue and through unavoidable loss of sound tissue necessary to gain access to the decay to allow its removal. Re-establishing the original form of primary molar teeth with a filling material can cause problems, particularly with multi-surface cavities, where the increased occlusal loading that these larger fillings are subjected to, often leads to premature restoration failure. In view of this, current guidelines recommend placing a preformed metal crown (PMC) over primary molar teeth affected with moderate to severe dental caries involving two or more surfaces, in order to provide a more durable restoration than simply placing a filling (Fayle 2001).

Fitting a PMC can be more demanding both of clinical skill and child co-operation than placing a filling. In addition, there are considerable variations in opinion as to when to place PMCs and when a filling would be more clinically appropriate (Pair 2004; Tran 2003). In a prescribed case scenario (Blinkhorn 2003) investigating which restoration dentists would place on a decayed primary molar tooth, 88% of USA dentists would place a PMC compared to 4% of UK respondents. In fact, PMCs are not popular amongst UK dentists, and made up only 0.7% of restorations placed in children in the year 2001/2002 (Scottish Dental Practice Board figures). It has been reported that primary care dental practitioners do not routinely use PMCs as part of their daily practice (Roshan 2003). Other studies report similar findings and that there is knowledge of recommendation of their use by the British Society of Paediatric Dentistry (BSPD). Some of the barriers to their use cited are a reflection of the poor National
To date, there has only been one systematic review comparing the durability of PMCs with filling materials (Randall 2002). This review supported the increased efficacy of PMCs compared with amalgam restorations in primary molars. However, the review was criticised by Ismail and Sohn (Ismail 2002), who suggested that a significant problem was that it comprised 10 studies with differing designs and inclusion criteria. No analysis for heterogeneity of the data was carried out, and a fixed-effect analysis model was used. When the data were checked for the level of heterogeneity, this was found to be significant, and the authors argued that the data would have been more accurately analysed in a random-effects model. When the authors carried out this analysis, they found less of a difference between the improved performance of PMCs compared with fillings. This review also focused on comparing PMCs to amalgam fillings. However, this material is being used less in primary teeth with the advent of more aesthetic, adhesive materials and it would be more appropriate now to compare the performance of PMCs with these newer and more commonly used materials.

Dental caries has a significant impact on the lives of children and there is a clear need to base the effective management of the disease on the best available evidence. Current guidelines encourage the use of PMCs and this Cochrane review will review the clinical outcome of PMCs compared with currently used filling materials.

**OBJECTIVES**

1. To evaluate the clinical outcome of primary teeth restored with preformed metal crowns (PMCs) compared with those restored with conventional filling materials such as amalgam, composite, glass ionomer, resin modified glass ionomer, and compomers.

2. To determine whether the extent of decay has an effect on the clinical outcome of primary teeth restored with PMCs compared with those restored with conventional filling materials.

3. To report any adverse effects associated with PMCs or conventional fillings such as periodontal (gum) problems, temporomandibular joint dysfunction syndrome (TMD), phobia as a result of undergoing restorative treatment and alteration in age at exfoliation. We recognise that these side effects may not be well reported in studies where an assessment of efficacy was the main outcome.

The following null hypothesis was tested.

There is no difference in the clinical outcomes for primary molar teeth restored with PMCs when compared to those where conventional fillings have been placed.

**METHODS**

**Criteria for considering studies for this review**

**Types of studies**

Randomised controlled trials (RCTs) that assess the effectiveness of preformed metal crowns (PMCs) compared with conventional fillings or where there has been no treatment.

**Exclusion criteria.**

Studies investigating filling materials not currently advocated for the restoration of primary teeth were excluded e.g. cermets, temporary restorative materials.

PMCs are not routinely used in the restoration of permanent teeth, therefore where studies present data for permanent and primary teeth, only the results from primary teeth were included. Where these data could not be separated, studies were excluded.

**Types of participants**

Children who had untreated tooth decay in one or more primary molar teeth. Where possible, the caries risk status of the participants was recorded.

**Types of interventions**

Caries removal followed by placement of a preformed metal crown in one tooth compared with caries removal followed by placement of a filling material or no treatment.

**Types of outcome measures**

The main outcome measures for children and carers were long-term freedom from the main symptom of dental decay - pain.

Primary outcome measures:

- freedom from clinical or radiographic signs or symptoms of pulp pathology including pain/pulp infection/discharging sinus/swelling;
- time until filling or crown needs to be replaced or requires further intervention;
- proportion of filled or crowned teeth retained until appropriate age of shedding.

Other measures of success recorded and analysed:

- absence of clinical or radiographic evidence of secondary caries;
- other clinical signs of pathology (fracture of tooth or filling, wear of crown, inflammation of gingival (gum) tissue);
- patient satisfaction;
- costs to patient and provider;
- adverse events.
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. The MEDLINE search strategy was combined with phases 1 & 2 of the Cochrane Sensitive Search Strategy for Randomised Controlled Trials (RCTs) as published in Appendix 5b.2 of the Cochrane Handbook for Systematic Reviews of Interventions 4.2.5 (updated May 2005) (Higgins 2005) and amended by the Cochrane Oral Health Group to include research design terms particular to oral health trials. See Appendix 1.

Databases searched

- The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2005, Issue 3)
- MEDLINE (1966 to August 2005)
- EMBASE (1980 to August 2005)

Language

The search attempted to identify all relevant studies irrespective of language. Efforts were made to translate all non-English articles via the Cochrane Oral Health Group.

Reference list searching

The reference lists of review articles, and standard clinical textbooks were checked for additional studies. The reference lists of included studies was also checked for additional studies.

Handsearching

The following journals were identified as being important to be handsearched for this review:

British Dental Journal
International Journal of Paediatric Dentistry.
Both journals were covered by the Cochrane worldwide handsearching programme (www.cochrane.org).

Unpublished studies

Requests for information about unpublished studies/studies published in the ‘grey literature’ were sent to relevant companies, relevant investigators and relevant professional organisations.

Data collection and analysis

The titles and abstracts of all reports identified by the search strategy were scanned independently and in duplicate by two review authors (Nicola Innes (NI) and David Ricketts (DR)). For studies that appeared to meet the inclusion criteria but where there was insufficient information in the title and abstract to be certain, the full report was obtained and assessed independently by these two review authors to establish whether the study met the inclusion criteria. Disagreements were resolved by discussion. For any disagreements that could not be resolved, the third review author (Dafydd Evans (DE)) was consulted. All studies meeting the inclusion criteria were to undergo validity assessment and data were to be extracted. Studies excluded at this or subsequent stages were entered in the Characteristics of excluded studies table, with the reasons for exclusion recorded.

Data extraction

Data were extracted by two review authors independently and in duplicate using specially designed data extraction forms. The data extraction forms were piloted on several papers and modified as required before use. The data to be extracted included:

- Citation details: including year of publication, country of origin, setting and source of funding.
- Details of participants: including demographic characteristics.
- Details of intervention: including type and method of restoration.
- Details of outcomes reported: including method of assessment.
- Quality issues.

Authors were contacted for clarification and missing information. Data were excluded until further clarification was available. In cases of disagreement, a third review author (DE) was consulted to resolve the issue.

Quality assessment

The quality assessment of the included trials was to be undertaken independently and in duplicate by two of the review authors based on the information given in the articles.

Four main quality criteria were to be examined:

1. Generation of randomisation sequence, recorded as.
   (A) Adequate - e.g. computer generated random numbers, table of random numbers, drawing lots, coin tossing, shuffling of cards, throwing dice.
   (B) Unclear.
   (C) Inadequate - e.g. case record number, date of birth, date of administration, alternation.

2. Allocation concealment, recorded as.
   (A) Adequate - e.g. prior numbered or coded drug containers prepared by an independent pharmacy, central randomisation, sequentially numbered sealed opaque envelopes.
   (B) Unclear.
(C) Inadequate - e.g. open allocation schedule, unsealed or non-opaque envelopes.
(3) Blind outcome assessment, recorded as.
  (A) Yes.
  (B) Unclear.
  (C) No.
  (D) Not used/possible.
(4) Completeness of follow up (is there a clear explanation for withdrawals and drop outs in each treatment group?) assessed as.
  (A) Yes, drop outs less than 10%.
  (B) Yes, drop outs more than 10%.
  (C) No explanation.
As there were no included studies, agreement for the quality criteria between assessors was not assessed.
After taking into account the additional information provided by the authors of the trials, studies were to be grouped into the following categories.
  (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 all criteria were at least partly met.
  (C) High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria were not met as described in Section 6.7 of the Cochrane Handbook for Systematic Reviews of Interventions 4.2.5.
In addition to the above quality criteria, the presentation of a sample size calculation was to be recorded.

Data synthesis
It was planned that for dichotomous data, the estimate of effect of an intervention would be expressed as risk ratios, together with 95% confidence intervals using a random-effects model. In addition, the number needed to treat (NNT) would be calculated. For continuous outcomes, mean differences and 95% confidence intervals would be used to summarise the data for each group. Clinical heterogeneity would be assessed by examining the types of participants (e.g. age), interventions (e.g. method of restoration) and outcomes (e.g. pain relief) in each study. Only if there were studies of similar comparisons reporting the same outcome measures would meta-analysis be attempted. The significance of any discrepancies in the estimates of the treatment effects from the different trials would be assessed by means of Cochran's test for heterogeneity.
Sensitivity analyses would be undertaken to examine the effect of randomisation, allocation concealment and blind outcome assessment on the overall estimates of effect. In addition, the effect of including unpublished literature on the review's findings would also be examined if data allowed.
Where possible, subgroup analyses would be performed on trials involving different types of interventions, different age groups, types of service delivery and types of funding.

However, as no studies met the inclusion criteria, no data were able to be extracted and therefore, no analyses were carried out.

RESULTS

Description of studies
See: Characteristics of excluded studies.

Included studies
None.

Excluded studies
Six studies were found that compared preformed metal crowns (PMCs) with conventional restorations (Braff 1975; Einwag 1996; Eriksson 1988; Farooq 2000; Holan 2002; Roberts 2005). However, none of these studies met the inclusion criteria, namely, prospective randomised control clinical trials. In five studies PMCs were compared with amalgam restorations (Braff 1975; Einwag 1996; Eriksson 1988; Farooq 2000; Holan 2002) and in the sixth study, with resin modified glass ionomer (Roberts 2005). However, four studies were retrospective in design (Braff 1975; Einwag 1996; Farooq 2000; Holan 2002) and one study was unclear as to whether it was a prospective or retrospective analysis (Eriksson 1988). Roberts' prospective analysis (Roberts 2005), reported outcomes of different restorations placed in a private practice. Treatment was dictated by the clinical presentation of the tooth in question and not based on random allocation, making true comparisons of outcomes between restoration types not possible. The retrospective studies were also not randomised, nor was the study by Eriksson (Eriksson 1988) which included dissimilar lesions in control and experimental groups, with the PMC being placed on the tooth with the most extensive carious lesion.
Two studies investigated the success rates of restoration type placed over teeth that had undergone formocresol pulpotomy (Farooq 2000; Holan 2002).

Risk of bias in included studies
No studies met the inclusion criteria as they were either retrospective in design or reported as prospective outcomes but not randomised; treatment being based on extent of lesion, with the most severe lesion receiving the preformed metal crowns (PMCs).
Effects of interventions
As no studies met the inclusion criteria, no data were available for extraction and analysis.

DISCUSSION
The gold standard of evidence about effectiveness on which to base a particular practice is a systematic review of multiple randomised control clinical trials (RCTs) (Butani 2005). At present, however, this level of evidence is only available for a very small proportion of regular dental treatments currently offered to patients on a daily basis. What evidence there is must be appraised and made use of as we work towards obtaining the gold standard evidence. Although in this systematic review there were no studies meeting the inclusion criteria, it is interesting to note that in the following excluded studies (where allocation method was reported), there was a general bias towards placing preformed metal crowns (PMCs) on teeth with more extensive caries (Eriksson 1988; Roberts 2005) or where there was less remaining tooth structure (Holan 2002), yet despite this, all but the study by Roberts (Roberts 2005) reported greater success rates for the crowned teeth.

In Randall’s systematic review of the literature (Randall 2002) comparing PMCs with amalgam, it was noted that, despite the heterogeneity of the 10 studies looked at, there was a positive outcome in all studies in favour of the PMC compared with amalgam restorations. However, there were no RCTs available for inclusion in the review and the potential for bias must be taken into consideration. There is evidence that general dental practitioners’ (GDPs) reluctance to use PMCs as part of their routine treatment may be related more to such factors as perceived difficulties in placing PMCs, and funding issues (Maggs-Rapport 2000; Threlfall 2005) rather than doubts as to whether PMCs are an effective restoration. It is important that the absence of evidence for PMCs is not misinterpreted as evidence for their lack of efficacy.

AUTHORS’ CONCLUSIONS
Implications for practice
No randomised controlled trials (RCTs) were available for appraisal. Whilst this technique is recommended by the British Society of Paediatric Dentistry (BSPD) for use in clinical practice, the evidence to support this is not strong, consisting mainly of case reports and uncontrolled studies. The lower levels of evidence that have been produced, however, have some strength in that the clinical outcomes are consistently in favour of preformed metal crowns (PMCs), despite many of the studies placing PMCs on the most damaged of the pair of teeth being analysed. It is important that the absence of evidence for PMCs is not misinterpreted as evidence for their lack of efficacy.

Implications for research
There are no prospective RCTs or high quality prospective controlled clinical trials (CCTs) comparing outcomes for PMCs with plastic restorations in carious primary teeth. There is a strong need for prospective RCTs comparing PMCs and fillings for managing decayed primary molar teeth.

ACKNOWLEDGEMENTS
The review authors would like to thank Sylvia Bickley for her assistance with searching, the peer reviewers who commented on this review as part of the pre-publication process and Jan Clarkson for insight into the implications of the methodological inadequacies of some of the clinical trials.

REFERENCES

References to studies excluded from this review

Braff 1975  {published data only}

Einwag 1996  {published data only}

Eriksson 1988  {published data only}

Farooq 2000  {published data only}

Holan 2002  {published data only}

Roberts 2005  {published data only}
Roberts JF, Attari N, Sherriff M. The survival of resin

Additional references

Blinkhorn 2003

Butani 2005

Fayle 2001

Higgins 2005

Ismail 2002
Ismail AI, Sohn W. Evidence suggests more favourable outcomes with preformed metal crowns than amalgam restorations in primary molars. Evidence-Based Dentistry 2002;3(1):10.

Maggs-Rapport 2000

NDIP 2003

Pair 2004

Randall 2002

Roshan 2003

Threlfall 2005

Tran 2003

WHO Report 2003

* Indicates the major publication for the study
### Characteristics of Excluded Studies

#### (Ordered by Study ID)

<table>
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<th>Study</th>
<th>Reason for Exclusion</th>
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| Braff 1975  | Retrospective  
Not randomised  
Went on to limit within selected group of 131 PMCs (on basis of treating dentist and failure to fulfil follow-up criteria) leaving only 76 PMCs with presented data |
| Einwag 1996 | Retrospective  
Not randomised  
Selected group of patients initially and only 66 out of 106 traced for follow up                                                                 |
| Eriksson 1988 | Unclear whether retrospective or prospective  
Not randomised - PMC placed on tooth in worst condition                                         |
| Farooq 2000 | Retrospective  
Not randomised                                                                                                                                     |
| Holan 2002  | Retrospective  
Not randomised  
Primary outcome related to success of pulpotomy treatment related to restoration rather than success of restoration itself |
| Roberts 2005 | Although prospective, treatment dictated by clinical status of tooth; no randomisation                                                              |

PMCs = preformed metal crowns
DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

(Controlled vocabulary terms (MeSH) are presented in uppercase text, free text terms in lowercase.)
1 CROWNS (single term MeSH)
2 crown$
3 ((1 or 2) and ("preformed metal$" or "pre-formed metal$" or "stainless steel" or "nickel chromium crown$" or "NiCr crown$"))
4 TOOTH DECIDUOUS (explode all trees MeSH)
5 ((deciduous or primary or milk or first or baby or natal) and (teeth or tooth or dentition))
6 (4 or 5)
7 (3 and 6)

WHAT'S NEW

Last assessed as up-to-date: 13 November 2006.

<table>
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<tr>
<th>Date</th>
<th>Event</th>
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<td>1 August 2008</td>
<td>Amended</td>
<td>Converted to new review format.</td>
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HISTORY

Protocol first published: Issue 4, 2005
Review first published: Issue 1, 2007

CONTRIBUTIONS OF AUTHORS

The review was conceived and co-ordinated by Nicola Innes (NI). All review authors (NI, David Ricketts (DR) and Dafydd Evans (DE)) participated in protocol writing, developing the search strategy and the screening of search results and retrieved papers. DR and NI screened retrieved papers against inclusion criteria and appraised their quality with DE being consulted where necessary. All review authors contributed to writing and revising the review.
DECLARATIONS OF INTEREST

Whilst there is no conflict of interest with regard to one of the review authors (David Ricketts (DR)), two of the review authors (Nicola Innes (NI) and Dafydd Evans (DE)) have received partial sponsorship in 2000, from 3M/ESPE, for a clinical trial investigating the use of preformed metal crowns to seal caries into primary molar teeth using a different technique (the Hall technique) to that investigated in this review.

NOTES

Controlled clinical trials (CCTs) were not considered for this review. This should not have been included in the 'Types of studies' in the protocol or in the selection criteria in the abstract. All the searches, with the exception of MEDLINE, searched the subject only with no restriction to study design. Only the MEDLINE search was linked to a study design filter and this would have included both randomised controlled trials (RCTs) and CCTs. This approach was taken in order to reduce the chance of missing any RCTs and it was appropriate that the search strategy included this but inappropriate for it to be included as an inclusion criteria for types of studies. CCTs have been removed from the final review and noted as an amendment.

INDEX TERMS

Medical Subject Headings (MeSH)

*Crowns; Dental Caries [*surgery]; Molar; Tooth, Deciduous [*surgery]

MeSH check words

Child; Humans