

## IN BRIEF

- Partial caries removal in primary teeth, lining with BCC and restoration with GIC showed poor durability over a 2-year period.
- Such restorations, however, demonstrated no significant progression in the carious process.
- Partial caries removal and restoration with GIC demonstrated comparable durability with and effectiveness as, complete caries removal and restoration over a 2-year period.
- Further research is required on partial caries removal and the use of cariostatic materials.

# Partial caries removal and cariostatic materials in carious primary molar teeth: a randomised controlled clinical trial

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**Objective** To determine the durability and effectiveness of a black copper cement (BCC) and a conventional glass ionomer cement (GIC) when used to restore primary molars following partial caries removal (PCR) and to compare these results with conventional cavity preparation and restoration.

**Design** Split-mouth randomised controlled clinical trial.

**Setting** Department of Paediatric Dentistry, Dundee Dental Hospital, Dundee, 1998–1999.

**Subjects** Patients with previously unrestored, matched carious cavities in non-pulpally involved primary molars.

**Interventions** Three treatment groups: (1) Partial caries removal followed by lining with BCC and restoration with GIC (PCR:BCC); (2) Partial caries removal and restoration with GIC alone (PCR:GIC), and (3) Complete caries removal and conventional restoration (CR). Restoration durability and effectiveness was assessed both clinically and radiographically over 24 months.

**Main outcome measures** Median survival time (MST) of restorations.

**Results** Forty-four patients (F: 31; M: 13), mean age 6.8 years (range: 3.7–9.5), had 120 restorations placed (PCR:GIC: 43; CR: 41; PCR:BCC: 36). Eighty-six molars (29 patients) (PCR:GIC: 30; CR: 29; PCR:BCC: 27) were reviewed at 24 months. The median survival times (MST) with 25% and 75% quartiles in parenthesis were as follows: PCR:BCC, MST = 24 months (6, 24); PCR:GIC, MST = 24 months (24, 24) and CR, MST = 24 months (24, 24). The MST for PCR:BCC restorations was significantly less than for PCR:GIC and CR restorations ( $W = 1163.5$ ,  $P = 0.028$  and  $W = 1081.0$ ,  $P = 0.004$  respectively).

**Conclusion** There were no differences in the proportions of restorations lost between restoration types, although PCR:BCC restorations did have significantly more abscess/sinus formation over the 24-month study period.

## INTRODUCTION

Despite recent dental publications expressing concern about the necessity for restorative care of carious lesions in primary molars,<sup>1,2</sup> currently accepted best practice for the management of such lesions involves complete caries removal followed by placement of a plastic restoration. These include amalgam, composite and glass ionomer, all of which perform best in small, one- and two-surface restorations.<sup>3–5</sup> Alternatively, a preformed metal crown (PMC), which is suitable for multi-surface lesions, extensive caries or where pulpal treatment has been performed.<sup>6</sup> All of these methods are effective, particularly when used in specialist practice<sup>4</sup> and dental hospitals.<sup>3</sup>

Conventional restorative treatment techniques, however, are not popular with general dental practitioners (GDPs) in primary care, where over 90% of child dental care is provided; one survey found that less than 9% of cavities in primary teeth in five-year-olds are being restored.<sup>7</sup> Anxiety about such conventional dental treatment amongst child patients, however, is a well-recognised problem, particularly fear of the 'dental drill'.<sup>8</sup> As such, by the age of five years, 16% of Scottish children have had at least one dental extraction.<sup>7</sup> With this background, there is clearly a need to find an alternative method of managing carious primary teeth that is acceptable to patients, parents and dental practitioners.

Fortunately, the requirements for the management of caries in the primary dentition are different from those in the permanent dentition, since primary teeth are only temporary and as such, a restoration is required to function for only a finite time. Previous authors have suggested that some adhesive materials are capable of fulfilling this requirement<sup>3,9</sup> and indeed, the use of adhesive materials results in a less destructive cavity preparation, often without the use of local anaesthesia. In addition, a smaller restoration is often sufficient, requiring a reduced treatment time. Some adhesive materials have also been investigated in relation to isolating or sealing the carious process from the oral environment following incomplete caries removal, with variable results. Some studies have demonstrated a non-detectable number of microorganisms following caries isolation,<sup>10</sup> some a minimal number<sup>11</sup> with others showing substantial numbers of microorganisms in some of the teeth studied.<sup>12</sup> This variability is most likely due to differences in methodology and initial lesion sizes. Furthermore, sealing in dental caries has been shown to cause little or no change

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in lesion depth, as long as the sealant remains intact;<sup>13</sup> with an incomplete seal, the caries activity can increase.<sup>14</sup>

Some of the restorative materials used to seal the caries process from the oral environment are themselves reported to have cariostatic properties, ensuring reductions in the remaining microorganisms and inducing structural changes in the dentine, leading to lesion arrest. Fissure sealants, composite resins, glass ionomer cements (GICs) and resin-modified glass ionomer cements (RM-GICs) have been investigated in this respect, with studies indicating that caries-inducing microorganisms left under restorations and sealants show both reduced viability and density over time. These cariostatic effects are frequently attributed to the component ions of the respective restorative materials.<sup>12,15</sup>

Copper phosphate cements may also be suitable candidates for caries isolation, although published work is limited, with previous literature being both out-dated and often based on anecdotal reports. A number of early reports, however, suggested that copper cements are bactericidal<sup>16</sup> and it has been postulated that this effect is due to copper ion release. Copper ions are known to have a proven anti-bacterial and hence anti-plaque effect, both *in vitro* on selected oral bacteria<sup>17</sup> and *in vivo*,<sup>18</sup> as well as anti-caries activity in animal models.<sup>19</sup> Given this background, the aims of this clinical trial were to determine the durability and effectiveness following partial caries removal of a copper phosphate cement, Black Copper Cement® (PD, Vevey, Switzerland) compared with a conventional glass ionomer, Chemfil Superior® (Dentsply De-Trey De-Dent, Konstanz, Germany). The resulting restoration success of each was compared with conventional cavity preparation, involving complete caries removal and restoration.

## MATERIALS AND METHODS

Patients attending the Department of Paediatric Dentistry at Dundee Dental Hospital for routine dental care were assessed for inclusion in the study if they required at least one pair of restorations in their primary molar teeth. Molars were suitable for trial inclusion providing that the carious teeth were in different quadrants and that all molars were asymptomatic, with neither clinical nor radiographic evidence of the lesions having reached the pulp of the tooth. Only previously unrestored cavities were suitable for trial inclusion. A patient information sheet was provided and a consent form was obtained from every child recruited and his/her parent or legal guardian. Caries diagnosis was by clinical examination, supplemented by standardised bitewing radiographs, taken using film holders. The cavity pairs were matched according to tooth type (first primary molar or second primary molar); cavity type (occlusal or approximal) and cavity depth (less than or more than half-way through dentine). The study was approved by the Tayside Committee on Medical Research Ethics.

Molar pairs were randomly assigned (computer-generated random numbers in sealed opaque envelopes) to one of three restorative treatment groups and treated by four staff dentists as part of a split mouth clinical trial. Both restorations of a pair were completed on the same day and all patients were given the option of local anaesthetic after allocation of the teeth to the experimental groups. Isolation was achieved with cotton wool rolls and saliva ejector. The treatment groups were as follows:

### *Group one: PCR:BCC vs PCR:GIC*

Instrumentation was limited to gaining access to the dental caries, removal of gross soft caries only and the preparation of a cavity, sufficient to allow an adequate bulk of restorative material to be placed (ie at least 3 mm). For non-cavitated lesions (ie caries into dentine without surface cavitation), access to the carious dentine was made using a small, round, high-speed diamond to penetrate through the enamel layer, followed by minimal use of the slow speed handpiece to make the cavity retentive. No other instrumen-

tation was undertaken (ie partial caries removal (PCR)). For occlusal cavities, the cavity was lined with a thin mix of Black Copper Cement® (BCC) (powder: liquid ratio 1:2) and restored with a conventional glass ionomer cement, Chemfil Superior® (GIC), prepared according to the manufacturers' instructions. The restoration was then covered with petroleum jelly. This was termed a PCR:BCC restoration. The matching cavity was prepared in the same way and restored with GIC and then covered in petroleum jelly: this was termed a PCR:GIC restoration. The occlusion was checked and any excess removed with a sharp excavator and the restoration was covered in petroleum jelly. For approximal cavities, a cellulose acetate matrix was placed prior to restoration, and restored as for occlusal restorations.

### *Group two: PCR:BCC vs CR*

For one molar of each pair, cavity preparation was as above, followed by a PCR:BCC restoration. The other cavity of the molar pair was prepared in a conventional manner with removal of all carious dentine, followed by a restoration of the operator's choice; usually either a conventional glass ionomer cement or an amalgam restoration; where an amalgam restoration was placed, the cavity was also made mechanically retentive. This was termed a conventional restoration (CR).

### *Group three: PCR:GIC vs CR*

Cavity preparation was as for group two, with the minimal intervention cavity receiving a PCR:GIC restoration and the CR preparation cavity restored with a material of the operator's choice.

## Post-operative assessment

Direct evaluation of the restorations at recall was accomplished by one investigator (JF). Restorations were assessed clinically at 6-monthly intervals for 24 months (ie censor date). For validation, a random sample of restorations was re-assessed by a clinical staff member at review appointments for inter-examiner reproducibility. To determine intra-examiner reproducibility, a random sample of restorations were re-assessed by JF, at least 1 week but less than 2 weeks after the initial recall appointment. Standardised bitewing radiographs were taken at baseline and subsequently at 12 and 24-month recall appointments. Radiographs were assessed blind. They were mounted against a dark background and with the aid of a light-box, viewed with an ×2 magnifier, with an integrated 1 mm graticule. A distinct point was identified on sequential radiographs for each patient and the incremental change in lesion size assessed between baseline, 12 and 24 months. Inter-examiner reliability was determined by re-assessment of a random sample of radiographs by another trained practitioner. In addition, intra-examiner reproducibility was determined by re-assessment of a random sample of radiographs at least 1 week but less than 2 weeks after the initial viewing.

## Data analysis

The results were analysed using Kaplan-Meier survival analysis techniques in Number Cruncher Statistical Systems (NCSS, Utah, USA), allowing accurate comparison of the restoration types during the whole of the follow-up period, rather than at specific time intervals. The significance of any differences between survival curves was determined with Log Rank tests over the whole of their length.<sup>20</sup> Survival data for the different restoration types were rejected as being normally distributed (Kolmogorov-Smirnov Test) and hence, median survival times (MST) were calculated and compared with Mann-Whitney *U* tests. Due to relatively small sample sizes (due mainly to poor patient re-attendance), it was not possible to make inter-pair comparisons between different restoration types and as such, following statistical advice, data within each treatment group were combined and differences assessed by chi-

squared ( $\chi^2$ ) analysis. From the bitewing radiograph data, differences between the incremental changes in lesion size were also assessed by  $\chi^2$  analyses (comparing the proportions either increasing, decreasing or showing no change).

## RESULTS

At completion of the trial, 44 patients (F: 31; M: 13) had been recruited; the mean age at presentation was 6.8 (range: 3.7-9.5) years. Between January 1998 and January 1999, 60 pairs of restorations were placed (PCR:GIC: 43; CR: 41; PCR:BCC: 36). Forty-three molar pairs (29 patients) (PCR:GIC: 30; CR: 29; PCR:BCC: 27) were reviewed at the end of the study period and all molar pairs had censor-date bitewing radiographs available. Six molars were withdrawn from the trial due to restoration failure and abscess formation; after consideration of their prognosis, these teeth were subsequently extracted. Two molars had exfoliated at censor date and the remaining 13 molar pairs (8 patients) were lost to follow-up.

A total of 31 restorations of those reviewed failed over the 24-month follow-up period. Thirty-one molars had suffered restoration loss and of these, 29 had active caries in the base of the cavity; the remaining two teeth had suffered partial restoration loss (Fig. 1). Nine teeth demonstrated either abscess or sinus formation and of these, three molars received pulp canal therapy and extra-coronal restoration and were withdrawn from the trial. The remaining six molars were extracted.

Restoration survival was analysed according to: (a) tooth type (first or second molar), (b) cavity type and (c) restoration type. Concerning both tooth type and cavity type, there were no significant differences between either first and second primary molars (range:  $P = 0.078$  to  $0.602$ ) or between Class I and Class II cavity types (range:  $P = 0.060$  to  $0.088$ ) in relation to restoration failure. As such, data for different molar and cavity types were combined and analysed according to the different restoration types placed.

Of the 31 restorations lost, 23.3% were PCR:GIC restorations, 22.0% were CR restorations and 33.4% were PCR:BCC restorations. Over the 24-month experimental period, there were no differences in the proportions of restorations lost between restoration types, although PCR:BCC restorations did have significantly more abscess/sinus formation, the majority of which occurred within the first 6 months (Fig. 2). In addition, significantly greater numbers of both PCR:GIC and PCR:BCC restorations were lost within the first 6 months than CR restorations. These restoration failures were represented in the cumulative survival curves for overall failure for PCR:GIC, CR and PCR:BCC type restorations (Fig. 3), with a statistically-significant deviation of the PCR:BCC curve from the others (ie showing its poor performance overall). The poor performance of the PCR:BCC restorations was confirmed by comparing the median survival times (MST) for the different restorations. The MST times



Fig. 1 A molar restored with PCR:BCC demonstrating partial restoration loss



Fig. 2 A PCR:BCC restoration demonstrating sinus formation, seen in 16% of such restorations by 24 months

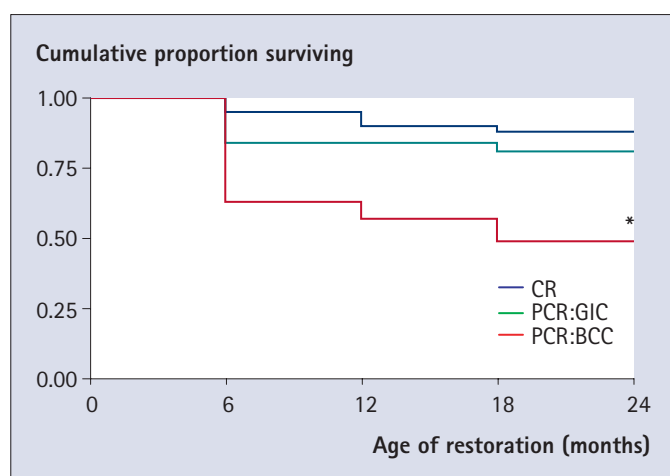


Fig. 3 Cumulative survival curves for overall failure for PCR:GIC, CR and PCR:BCC restorations. \*The survival curve for PCR:BCC restorations was significantly different from the curves for PCR:GIC restorations ( $\chi^2 = 7.80$ ,  $P = 0.005$ , 1 d.o.f.) and for CR restorations ( $\chi^2 = 12.74$ ,  $P = 0.001$ , 1 d.o.f.)

with 25% and 75% quartiles in parenthesis were as follows: PCR:GIC, MST = 24 months (24, 24); CR, MST = 24 months (24, 24); PCR:BCC, MST = 24 months (6, 24). The MST for PCR:BCC restorations was significantly less than for PCR:GIC ( $W = 1,163.5$ ,  $P = 0.028$ ) and CR ( $W = 1,081.0$ ,  $P = 0.0037$ ) restorations.

Sixty and 42 bitewing radiographs were available at baseline and 24-months respectively. Only three radiographs (3% of the total) were discarded from the analysis due to overlapping surfaces, making the detection of dentine radiolucencies indistinct. By the censor date, greater proportions of lesions had decreased in size, although these values were still less than those recorded as either increasing or not changing in size. Between the treatment groups, there were no significant differences between the proportions increasing, decreasing or remaining the same size, with the exception of significantly more CR restorations increasing in size compared with PCR:BCC. Within each treatment group, there were no significant differences between the proportions increasing and not changing for PCR:GIC and PCR:BCC restorations, whereas significantly more CR restorations increased than showed no change. Significantly fewer restorations of all treatment groups decreased in size than either increased or stayed the same (Fig. 4).

## DISCUSSION

Overall, more restorations were lost in first primary molars than second primary molars; 35.3% and 24.0% respectively, although this difference was not statistically significant. Other studies have found that the mean survival time of restorations in second primary molars was significantly greater than in first primary molars,

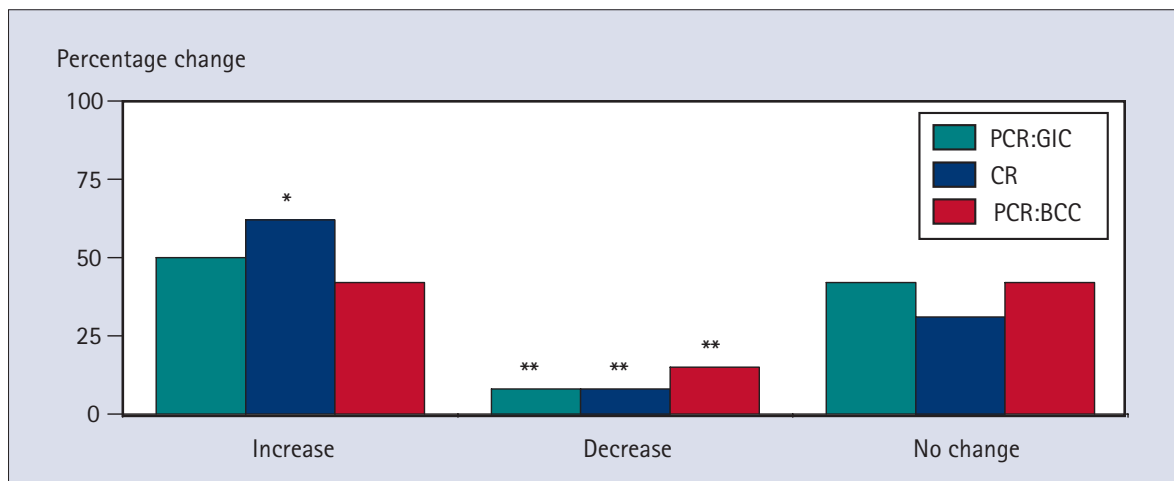


Fig. 4 Percentage increase, decrease and no change in lesion progression for PCR:GIC, CR and PCR:BCC restorations at 0-24m. \*Significantly more lesions increased in size from PCR:BCC restorations than either of the other two restorations ( $\chi^2 = 5.29$ ,  $P = 0.046$ , 1 d.o.f.). \*\*For all restoration types, significantly fewer lesions decreased in size than either increased or showed no change (PCR:GIC,  $\chi^2 = 17.50$ ,  $P = 0.001$ , 1 d.o.f.; CR,  $\chi^2 = 24.47$ ,  $P = 0.001$ , 1 d.o.f.; PCR:BCC,  $\chi^2 = 6.72$ ,  $P = 0.001$ , 1 d.o.f.). Inter-examiner reliability,  $k = 0.82$  and intra-examiner reproducibility,  $k = 0.86$ .

irrespective of the age of the patient or the type of restoration.<sup>21</sup> A further study also found that restorations lasted longer in second primary molars, although only for Class I restorations.<sup>22</sup> Other studies, however, have demonstrated no significant difference in survival rates between first and second primary molars.<sup>4,23</sup>

In relation to cavity type, by the censor date, 49.9% and 62.3% of Class I and Class II restorations had been lost respectively, with the majority being lost within 6 months of placement. There was no significant difference, however, between the reasons for failure of Class I and Class II restoration types over the entire 24-month period. One longitudinal study of 1,024 amalgam restorations placed in primary molars also found no significant difference between the survival rates of Class I and Class II restorations.<sup>4</sup> In contrast, other workers investigating the longevity of amalgam restorations in primary molars, found that Class I restorations survived longer than Class II amalgam restorations.<sup>21</sup> Finally, in a more recent study, over 500 primary molar pairs were restored using 'Dispersalloy' amalgam and Ketac-fil glass ionomer; three-year results indicated a higher failure rate amongst Class II restorations.<sup>24</sup>

In relation to restoration type, over the 24-month experimental period, there were no differences in the proportions of restorations lost between restoration types, although PCR:BCC restorations appeared to be associated with higher rates of sinus/abscess formation, the majority of which occurred within the first six months; this factor clearly needs further investigation and clarification. Early studies suggested that continued leaching of phosphoric acid from the set copper cement, may lead to pulpal irritation.<sup>25</sup> In addition, significantly greater numbers of PCR:GIC and PCR:BCC restorations than CR restorations were lost within the first 6 months, associated with higher levels of active caries. The poor performance of BCC may be accounted for by the fact that BCC is inherently very soluble<sup>26</sup> and hence, might be expected to create a relatively 'leaky' seal, undermining the overlying GIC restoration leading to PCR:BCC restoration failure. These restoration failures were represented in the cumulative survival curves for overall failure for PCR:CS, CR and PCR:BCC type restorations, highlighting the poor overall performance of PCR:BCC restorations, which was confirmed by comparing the MST data for the different restorations types. The MST of the restorations in this study should be interpreted in the light of the fact that a large proportion of restorations were 'censored', surviving intact until the end of the trial, resulting in the MST being an under-estimation. Hence, prediction of actual

longevity was not possible. The high durability of the PCR:GIC restorations was achieved with minimal cavity preparation without the use of local anaesthesia. Coupled with the fact that the mean age of the children in the present study was 6 years and 8 months, then a restoration surviving for 2 years can be argued as clinically acceptable, since primary teeth exfoliate with a maximum normal life of 8 to 9 years.

Of the bitewing radiographs taken at baseline and 24-months, only 30% were discarded from the analysis due to overlapping surfaces. Due to the anatomical curvature of the dental arch, a proportion of posterior approximal surfaces will inevitably appear as overlapped on a bitewing radiograph<sup>27</sup> and whilst previous authors have highlighted that exclusion of such overlapped surfaces will inevitably lead to the loss of valuable data,<sup>28</sup> it was considered that such a small percentage would not impact on the trial results. Over the study period, the majority of the lesions either increased or showed no change, with only a small number decreasing in depth. The only significant difference within the treatment groups was that for CR restorations, significantly more lesions increased in depth, probably due to initial cavity preparation with removal of carious, soft and probably sound dentine, particularly for amalgam restorations to render the cavity retentive. There were no significant differences between the treatment groups.

With regard to lesion depth, isolation of the carious process from the oral environment using a cariostatic material has been shown to lead to a reduction of increasing lesion depth but not always to a complete arrest of the caries process.<sup>10,29,30</sup> Furthermore, in a 2-year serial radiographic assessment, in which 113 permanent posterior teeth with occlusal caries were sealed with resin sealant, caries regressed in sealed teeth with early caries.<sup>31</sup> An earlier radiographic study suggested that the depth of the lesion at baseline may be important, with caries which penetrated less than one quarter of the way through dentine and which was subsequently sealed showing no progression and in some cases, lesion depth regression.<sup>30</sup> Several authors have mentioned the quality of the sealant as an important condition of lesion arrest<sup>13,32</sup> and in cases of an incomplete seal, caries activity will increase.<sup>14</sup>

Caution, however, must be exercised in relation to results that relate to apparent lesion regression in the light of the known errors and variability associated with visual radiographic examination.<sup>33</sup> Another very significant factor concerns the level of standardisation achieved in reproducing the relationship and distances between tooth, film and x-ray source, since changes in angulation can cause

apparent changes in radiolucency size. The use of film-holding, beam-aiming devices (which were used in this study) has been advocated previously to minimise such variables.<sup>34</sup> Further problems relate to the variability in scoring radiographs of occlusal caries, whilst with approximal carious lesions it is possible to achieve relatively higher inter- and intra-examiner correlations.<sup>35</sup>

## CONCLUSION

Partial caries removal, followed by lining with BCC and restoration with GIC demonstrated greater abscess/sinus formation than either conventional restoration or partial caries removal and restoration with GIC. Partial caries removal and GIC restoration demonstrated comparable durability with and effectiveness as, conventional restorations over the 24-month study period.

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