Absence of carious lesions at margins of glass-ionomer and amalgam restorations: a meta-analysis

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ABSTRACT. ***Aim*** *To report on the absence of carious lesions at margins of glass ionomer cement (GIC) and amalgam restorations.* ***Methods*** *Six Anglophone and 1 Lusophone databases were searched for articles up to 5 January 2008. Inclusion criteria for articles were: (i) titles/abstracts relevant to topic; (ii) published in English, Portuguese or Spanish language; (iii) reporting on a randomised control trial. Exclusion criteria were: (i) insufficient random allocation of study subjects (ii) operator and subject not blinded, where appropriate; (iii) not all entered subjects accounted for at trial conclusion; (iv) subjects of both groups not followed up the same way. Articles were accepted only if they complied with all the criteria. Ten articles complied with the inclusion criteria and were selected for review. From these 4 were rejected and 6 articles reporting on 8 separate studies accepted. Due to aspects of heterogeneity, studies were sub-grouped before meta-analysis.* ***Results*** *Significantly less carious lesions were observed on single-surface GIC restorations in permanent teeth after 6 years as compared to restorations with amalgam (OR 2.64 - CI 95% 1.39 – 5.03, p= 0.003). No studies investigating multiple-surface restorations on permanent teeth were identified. Studies investigating carious lesions at margins of restorations in primary teeth showed no difference between both materials after 3 and 8 years.* ***Conclusions*** *Carious lesions at margins of single-surface GIC restorations are less common than with amalgam fillings after 6 years in permanent teeth. No difference was observed in primary teeth. More trials are needed in order to confirm these results.*

Key words: *Glass ionomer cement; Amalgam; Caries; Meta-analysis.*

Introduction

Carious lesions associated with the margins of tooth restorations have previously been defined as recurrent or secondary caries [Mjör, 2005]. In recent years it has been suggested that placing a filling does not cure caries and that the "recurrence" of lesions on restoration margins results from neglecting to treat caries as disease before placing a restoration [White and Eakle, 2000]. Part of the treatment of caries is to encourage remineralisation in the cavity walls [Tyas et al., 2000]. Ten Cate and van Duinen [1995] have shown, in-situ, a hyper-remineralisation effect in demineralised tooth tissues bordering glass ionomer cement (GIC) type restorations. In contrast, tissues bordering amalgam showed further extensive demineralisation. The significant remineralisation potential of GIC has been ascribed to the release of fluoride ions, facilitated by a hydrophilic environment [Asmussen et al., 2002]. In addition, the release of strontium by GIC and its diffusion into demineralised tooth tissue, thus further aiding remineralisation, has been observed [Ngo et al., 2006]. Several trials have compared the clinical success rates of GIC and amalgam restorations in vivo [Taifour et al., 2002; Rahimtoola and van Amerongen, 2002; Taifour et al., 2003; Mandari et al., 2003; Qvist et al., 2006; Frencken et al., 2007]. During these trials marginal integrity, anatomic form, material loss at surface and carious lesions at the restoration margins were assessed. Qvist et al. [1990] established that carious lesions were the main cause of failures of amalgam restorations in permanent teeth. In contrast, it has been suggested that carious lesions are rarely the cause of GIC restoration failures [Mjör, 2005].

So far no meta-analysis has been conducted to this topic. One narrative review, lacking a systematic methodology for literature search and article inclusion- and exclusion criteria, concluded that the effect of fluoride release of materials, such as GIC,

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remains clinically unproven [Wiegand et al., 2007]. In addition, one systematic review was unable to identify conclusive evidence for or against a treatment effect of secondary caries inhibition by GIC [Randall and Wilson, 1999]. This systematic review was of qualitative nature and did not include a meta-analysis.

The aim of this meta-analysis was to report on the combined results of trials comparing the absence of carious lesions at margins of GIC and amalgam restorations. The objectives were to determine absence of carious lesions in single and multiple-surface restorations (GIC versus amalgam) in: (a) permanent teeth and (b) primary teeth.

Materials and methods

Data collection

Six Anglophone databases: Biomed Central, Cochrane Library, Directory Of Open Access Journals, PubMed, Science-Direct, Research Findings Electronic Register (ReFeR) and one Lusophone database: Literatura Latino-Americana e Caribenha em Ciências da Saúde (LILACS) were systematically searched for articles reporting on clinical trials up to 5 January 2008. Articles were selected for review from the search results on the basis of their compliance with the inclusion criteria:

1 titles/abstracts relevant to topic;
2 published in English, Portuguese or Spanish;
3 reporting on a randomised or quasi-randomised control trial.

Where only a relevant title without a listed abstract was available, a full copy of the article was assessed for inclusion.

Article review

Only articles, that complied with the inclusion criteria were reviewed further. Articles were reviewed independently by 6 reviewers for compliance with the exclusion criteria shown in Table 1 [Sutherland, 2001]. Disagreements were resolved by discussion and consensus. Articles were accepted for meta-analysis only if they complied with all the criteria. Where several articles had reported on the same trial, the article covering the longest period in accordance with the exclusion criteria was accepted. If one article reported more than one outcome, these were analysed as separate trials.

1. Insufficient random allocation of study subjects
2. Operator and subject not blinded, where appropriate
3. Not all entered subjects accounted for at the end of the trial
4. Subjects of both, study and control group, not followed up the same way

TABLE 1 - *Exclusion criteria for trials.*

Data extraction from accepted trials

The outcome measure of this meta-analysis was the absence of carious lesions at the margin of restorations. Two reviewers (VY and SM) independently extracted data from the accepted articles, using a pilot-tested data-extraction form that included information contained in Table 2. Where possible, missing data were calculated from information given in the text or tables of included trials, in order to complete a 2x2 table used to enter per-trial data for meta analyses. In addition, authors of articles were contacted in order to obtain missing information. Disagreements between reviewers during data extraction were resolved through discussion and consensus. It was anticipated that some of the studies eligible for inclusion would be split-mouth in design (quasi-randomised trials). The split-mouth study design is commonly used in dentistry to test interventions and has the advantage of enabling an individual to serve as both subject and control. In this study design one or more pairs of teeth (e.g. primary molars) form the unit of randomisation. These pairs are, strictly speaking, not independent and should be analysed as "paired data" on a per-child basis. However, as in a similar review [Ahovuo-Saloranta et al., 2004], in order to prevent exclusion of data, split-mouth trials were included and the pairs were analysed independently.

Quality of studies

The quality assessment of the accepted trials was undertaken independently by two reviewers (VY and SM). Trials not included in this review were used to pilot the process. Subsequently quality assessment rating scored by both reviewers was derived by consensus within the review group. Four main quality criteria were examined:

1. Generation of randomisation sequence (allocation), recorded as:
   a. Adequate - e.g. computer-generated random numbers, table of random numbers;
   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. 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 (clear explanation for

Trial	Country	Study design	Age (years)	N. Restorations		Dentition	Cavity type	Follow-up period
				GIC	Amalgam			
Frencken et al. [2007]	Syria	Parallel group	13.8	487	403	Permanent	Single-surface	6.3 years
Mandari et al. [2003]	Tanzania	Split-mouth	11	164	177	Permanent	Single-surface	6 years
Taifour et al. [2002 (Study 1)]	Syria	Parallel group	6-7	441	326	Primary	Single-surface	3 years
Taifour et al. [2002 (Study 2)]				610	425		Multiple-surface	3 years
Östlund et al. [1992]	Sweden	Parallel group	4-6	25	25	Primary	Multiple-surface	3 years
Welbury et al. [1991]	U.K.	Split-mouth	No information	99	99	Primary	Single/ Multiple surface	22.7-26.3 months
Qvist et al. [2004 (Study 1)]	Denmark	Parallel group	2.8. - 13.5	131	87	Primary	Single-surface	8 years
Qvist et al. [2004 (Study 2)]	Denmark	Parallel group	2.8. - 13.5	384	456	Primary	Multiple-surface	8 years

TABLE 2 - *Some characteristics of trials comparing caries on margins of GIC and amalgam restorations.*

withdrawals and loss-to-follow-up in each treatment group) assessed as:

a. Yes, drop outs less than 30%;
b. Yes, drop outs more than 30%;
c. No explanation.

Statistical Analysis

The incidence of caries was treated as a dichotomous outcome. The results of trials were pooled for meta-analysis based on their clinical homogeneity. A fixed effects model in RevMan Version 4.2 statistical software by The Nordic Cochrane Centre, The Cochrane Collaboration (Copenhagen; 2003) was used. Trials were considered to be clinically homogeneous if they did not differ in type of dentition (primary or permanent), cavity type (single of multiple surfaces) and years of follow-up period.

Differences in treatment groups were computed on the basis of odds ratios (OR) with 95% confidence intervals (CI). χ^2 and degree of freedom (df) were used in assessing statistical heterogeneity, which was assumed at $p<0.10$ following Cochrane guidelines [The Cochrane Collaboration, 2002]. Studies were assigned a Mantel-Haenszel weight directly proportionate to their sample size.

Results

Only articles published in the English language were identified during the literature search. From the initial search results, 10 articles complied with the inclusion criteria and were selected for further review. From these, 4 articles were excluded: 2 articles [Mjör and Jokstad, 1993; Phantumvanit et al., 1996] did not report how subjects were allocated to either the study or the control group; 1 article reported on 4 treatment and restoration groups: amalgam restoration after hand-excavation; GIC restoration after hand-excavation; amalgam restoration after drilling; GIC restoration after drilling. However, this article did not report on the number of carious teeth for each group and was thus excluded [Rahimtoola and van Amerongen, 2002]. One further article was an older report [Taifour et al., 2003] of the same trial [Frencken et al., 2007].

Six articles reporting on 8 separate studies were accepted [Welbury et al., 1991; Östlund et al., 1992; Taifour et al., 2002; Mandari et al., 2003; Qvist et al., 2004; Frencken et al., 2007]. The main characteristics of the accepted studies are described in Table 2.

Table 3 provides information about quality aspects assessed for these studies. Details about loss-to-follow-up were reported in all accepted studies. Treatment allocation was rated A (Adequate) in one study [Welbury et al., 1991], B (Unclear) in three [Östlund et al., 1992; Taifour et al., 2002; Frencken et al., 2007] and C (Inadequate) in the remaining two [Welbury et al., 1991; Qvist et al., 2004].

Absence of carious lesions in single- and multiple-surface restorations (GIC versus amalgam) in permanent teeth

Data from two studies [Mandari et al., 2003; Frencken et al., 2007] were used to investigate this objective. Figure 1 shows that margins of single-surface GIC restorations in permanent teeth had significantly less carious lesions ($p = 0.003$) after 6 years than did similar teeth restored with amalgam (OR = 2.64; CI 95% 1.39 – 5.03). No trials covering multiple-surface restorations in permanent teeth were identified.

Study	Random.	Allocation	Alloc. Conceal.	Blinding	Drop-outs
Frencken et al. [2007]	Randomised	B - Unclear (By use of gender-stratified class list)	B - Unclear	D - Not possible	A 84/681 (12.3%) pat.
Mandari et al. [2003]	Quasi-randomised	C- Inadequate (By toss of a coin)	B - Unclear	D- Not Possible	A 38/152 (25%) pat.
Taifour et al. [2002] 1; 2	Randomised	B - Unclear (By use of a class list)	B - Unclear	D- Not Possible	A 185/835 (22.1%) restorations
Östlund et al. [1992]	Randomised	B - Unclear	B - Unclear	D- Not Possible	C No explanation
Welbury et al. [1991]	Quasi-randomised	A - By use of random permuted block design	B - Unclear	D- Not Possible	A 12/88 (13.6%) pat.
Qvist et al. [2004] 1; 2	Randomised	C - Alteration	B - Unclear	D- Not Possible	A (7%) restorations

TABLE 3 - *Quality assessment of accepted studies.*

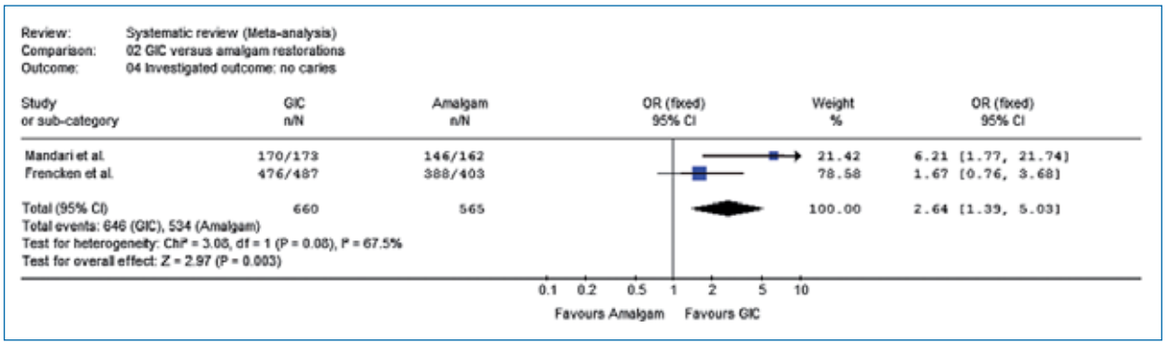

FIG. 1 - *Caries on margins of single-surface GIC and amalgam restorations on permanent teeth after 6 years. Odd ratios (OR) and 95% confidence intervals (CI) per study and combined.*
CI = confidence interval; OR = odds ratio N= total number of restorations; n = number of restorations with caries absent

Absence of carious lesions in single- and multiple-surface restorations (GIC versus amalgam) in primary teeth

Information on carious lesions in multiple-surface GIC and amalgam restorations 3 years after placement are shown in Figure 2. The difference between the numbers of carious lesions of both materials was not statistically significant (p = 0.10). This implies that both materials were equally effective in terms of their caries-preventive effects.

When data from the 8-year follow-up study by Qvist et al. [2004 (Study 2)] were added to the meta-analysis, the result, however, favoured GIC (OR = 2.35; CI 95% 1.18 – 4.71) and was statistically significant (p = 0.02).

For single-surface restorations in primary teeth, the

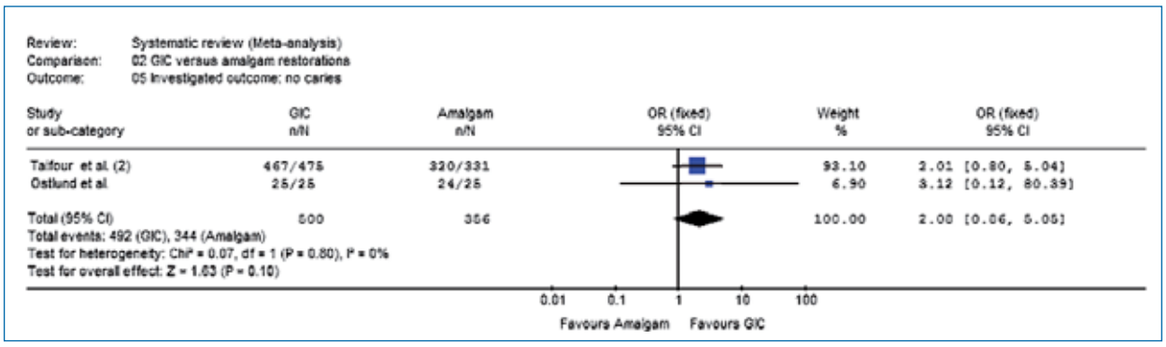

FIG. 2 - *Caries on margins of multiple-surface GIC and amalgam restorations on primary teeth after 3 years. Odds ratios (OR) and 95% confidence intervals (CI) per study and combined.*
CI = confidence interval OR = odds ratio N= total number of restorations n = number of restorations with caries absent

data from the studies by Taifour et al. [2002 (Study 1)] and Qvist et al. [2004 (Study 1)] were pooled, even though the follow-up periods were 3 and 8 years respectively. The results showed no statistically significant difference (p = 0.24) between both materials (OR = 1.78; CI 95% 0.67 – 4.72) and need to be considered with caution, since these studies did not comply with the criteria for homogeneity. On an individual basis, the study by Taifour et al. [2002 (Study 1)] showed an odds ratio of 2.88 (CI 95% 0.88 – 9.44) and the study by Qvist et al. [2004 (Study 1)] 0.39 (CI 95% 0.04 – 3.82). A further study by Welbury et al. [1991] showed no statistically significant difference (p = 0.33) between GIC and amalgam after 22.7 – 26.3 months (OR = 1.64; CI 95% 0.61 – 4.43) in primary teeth.

Discussion

This meta-analysis investigated the absence of carious lesions at margins of GIC restorations in comparison to amalgam restorations. A general lack of randomised control trials complying with all criteria was identified. Despite the systematic literature search in 7 databases and 3 different languages, only 6 articles, reporting on 8 separate studies, were accepted. Moreover, clinical heterogeneity between the studies meant that even fewer trials could be pooled together for meta-analyses. The studies were grouped according to type of dentition, cavity type and follow-up period (Table 2). The decision to sub-group the studies into these categories was justified by the consideration that survival rates of restorations in primary teeth, as well as for large cavities, are lower than in permanent teeth and small cavities, and that restoration survival is associated with the time factor [van't Hof et al., 2006]. It has to be noted that appraisal for clinical heterogeneity between studies did not include assessment of differences in the types of caries removal applied before GIC restorations were placed or in the types of GIC material used. Hand-excavation of infected dentine, following the Atraumatic Restorative Treatment (ART) approach, was used in 3 studies [Taifour et al., 2002 (Study 1); Taifour et al., 2002 (Study 2); Frencken et al., 2007]. In one study hand-excavation was aided by use of chemo-mechanical agents [Mandari et al., 2003] and 2 studies did not specify how caries was removed for GIC restorations [Welbury et al.,1991; Östlund et al.,1992]. Caries removal by hand-excavation has been reported to remove soft infected dentine, but not the harder, demineralised affected dentine [Tyas et al., 2000]. Thus, hand-excavation could be assumed to result in greater susceptibility to recurrent caries than caries removal by drilling, where more affected tooth material is generally removed. However, contrary to such an assumption, all studies [Taifour et al., 2002 (Study 1); Taifour et al.,2002 (Study 2); Frencken et al., 2007] in which hand-excavation was applied showed less caries on GIC restoration margins than were found on margins of amalgam restorations placed after drilling. Low-strength GIC material was used in 5 studies [Welbury et al.,1991; Östlund et al.,1992; Mandari et al., 2003; Qvist et al., 2004 (Study 1); Qvist et al., 2004 (Study 2)] and high- strength GIC in the others [Taifour et al., 2002 (Study 1); Taifour et al., 2002 (Study 2); Frencken et al., 2007]. It has been suggested that both types of GIC material show distinctly different physical characteristics [Frencken et al., 2004]. However, these characteristics are more likely to impact on the marginal integrity, anatomic form and material loss at the surface of GIC restorations.

The results of the meta-analysis indicate that carious lesions are less observed on the margins of GIC, than amalgam restorations in single-surface restorations of permanent teeth. It is thought that the continued fluoride release from the GIC material is protective, and hence the tooth may remain caries-free even in the presence of a marginal defect. In the case of amalgam, the protective effect is purely mechanical and the tooth is at higher caries risk. The combined odds ratio for single-surface restorations in permanent teeth, of 2.64 (CI 95% 1.39 – 5.03), suggests that teeth restored with GIC are more than twice as likely to remain free of carious lesions as those filled with amalgam (Fig. 1).

In the primary dentition, the results for multiple-surface restorations after 3 years (Fig. 2), as well as the results of the study by Qvist et al. [2004 (Study 2)] after 8 years, suggests that none of the materials is superior. The results of the 2 studies investigating carious lesions at margins of single-surface restorations in primary teeth [Taifour et al., 2002 (Study 1), Qvist et al., 2004 (Study 1)], as well as the study by Welbury et al. [1991], do also show no difference. The reason for this is unclear. It can be assumed that factors such as the larger restoration surface, as well as the greater difficulties involved in placing restorations in children than in adults may outweigh any caries-preventive properties of GIC in comparison to amalgam. In addition, none of the accepted studies reported on fluoride exposure of subjects. It can be assumed that if subjects were exposed to external fluoride sources that this may have increased caries resistance of teeth restored with amalgam, thus confounded the caries-preventive effect of GIC as suggested by Hara et al. [2006].

Conclusion

Despite the limitations of this meta-analysis, due to the low number of randomised control trials, it can be concluded that absence of carious lesions at margins of single-surface GIC restorations is higher than on

amalgam fillings of permanent teeth after 6 years. This result is in line with in-situ and in-vitro observations of the characteristics of GIC [Wesenberg and Hals, 1980; Tsanidis and Koulourides, 1992; ten Cate and van Duinen, 1995; Tam et al., 1997; Knight et al., 2007; Takeuti et al., 2007]. Results for both multiple- and single-surface restorations in primary teeth show no difference between both materials. More clinical trials are needed in order to confirm these findings.

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