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The longevity of different restorations in primary teeth

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Background and aim. This paper reviews three published papers and adds results from a fourth study which aimed to determine which restorative material would be the best alternative(s) to amalgam (AM) in primary teeth.

Design. All studies had a practice-based design and were part of the routine treatment of children and adolescents. The clinicians were assigned which materials to use in a randomised matter in the first three studies which lasted for 7–8 years. In the fourth study conducted 4 years after the initial studies, the clinicians were free to select the restorative materials.

Results and conclusions. Resin modified glass ionomer (RMGI) and compomer (COM) restorations showed similar longevity compared with AM, whereas conventional GI restorations showed significantly shorter longevity. The studies indicated that the 'new and improved' materials based on *in vitro* tests did not always show enhanced clinical properties. In the last study, where clinicians freely selected the restorative materials they used in their practices, seven used COM, one used conventional GI materials and one used a combination of the two types of material.

Introduction

This study aimed to evaluate the success of restorative therapy in primary teeth using different restorative materials. Ideally, restorations in primary teeth should last until the teeth exfoliate, i.e., their life span is limited to about 8 years. In the early days of restorative dentistry of primary teeth, conventional dental amalgam (AM) and even copper AM was in common use. Severely cavitated primary teeth were often restored by pre-contoured steel crowns which are still in limited use in some countries. Marked variations exist in the teaching and the use of restorative materials in primary teeth[1–3].

Copper AM was in use in paediatric dentistry until about 30–40 years ago in Europe. It is a toxic material[4] and it was gradually phased out. Regular brands of dental AM were subsequently used. Nevertheless, AM has come into disrepute for a number of reasons, including poor aesthetics and concerns about the potential toxicity of mercury in the AM. Numerous studies have failed to show detrimental effects on patients, including in a recent large, well controlled prospective study by DeRouen *et al.*[5].

Presently, many materials are in use to restore primary teeth, but uncertainty exists regarding which restorative material(s) is/are optimal for the primary dentition. Many factors must be taken into consideration, including the ease of handling of the materials in practice, their physical and chemical qualities with emphasis on the longevity of the restorations, and the biologic properties of the materials. In Scandinavia and some other European countries much emphasis has been placed on potential toxic effects of AM and other restorative materials and on environmental pollution by AM. The use of AM was discontinued in 2008 as a result of the ban on the use of mercury for most restorations in primary as well as permanent teeth in some Scandinavian countries. Legislation to ban it in other countries is pending. The discontinued use of AM has largely been based on potential problems rather than on documented problems, but dentistry must face the

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problem and handle it. Aesthetic issues have also entered the discussion related to the use of restorative materials in stress bearing areas of both dentitions.

A number of tooth coloured alternatives to AM is now available as restorative materials for the primary and permanent dentitions, including conventional glass ionomer (GI), resin modified glass ionomers (RMGI), and compomers (COM) which are a polyacid-modified composite resin. These restorative materials have been evaluated in a series of randomised clinical studies in paediatric dental practice[6–8] with emphasis on the longevity of the restorations. The materials used in these studies were assigned to the clinicians in a randomised manner. These studies will be reviewed in this paper to assess which materials may be considered as the best alternative(s) to AM. Four years after the studies were completed a group of clinicians involved in the studies independently selected restorative materials they used in their paediatric practice. These restorations were followed for 5 years to assess the outcome for comparison with the results from the three original studies.

Materials and methods

The initial three studies were reviewed and the study where the clinicians freely selected which restorative material to be used, were carried out in the Danish Public Dental Health Service in municipalities where 99.9% of children and adolescents are regularly treated until the age of 16–18 years. The recall intervals for the patients were 4–16 months based on individual caries risk assessment. The caries prevalence in these municipalities has steadily been below the Danish national average. The patients included were only those in need of restorative caries treatment.

During the planning phase of the studies, the clinicians and their staff participated in meetings discussing criteria for diagnosing caries and restorations, the appropriate time for operative intervention, cavity preparation designs, the handling of the different types of materials, reasons for failure of restorations, and the use of specially designed registration forms. These meetings were followed up annually or biannually during the 10-year duration of the studies. Results from the investigations were presented and discussed these meetings. Clinical calibration exercises for diagnosing caries and evaluation of restorations were not performed.

A total of 1807 restorations were consecutively inserted in the studies during the 10-year study period of the original studies. About 4 years after these studies were completed, the last study was conducted and an additional 476 restorations were made by the same clinicians. In this final study the clinicians freely selected which material to use. The complete material included 398 AM, 406 GI, 805 RMGI, and 674 COM restorations.

The restorations were followed until exfoliation of the teeth or the time when extraction, repair or replacement was indicated. The maximum follow-up period was 7–8 years in the initial three studies and 5 years in the last sample. Most restorations were inserted as a treatment for primary caries; ranging from 83% to 88% in the different studies. All other restorations were replacements of failed restorations.

The cavity design was small conventional preparations, which were nonbevelled and not 'extended for prevention'. Rubber dam and acid etching were not employed. Most of the cavities (57%) were lined with a calcium hydroxide base material. Cavity conditioner was used by random in connection with half of the RMGI and COM restorations in the original studies and for all the COM restorations in the fourth and final study. Otherwise the restorative materials were treated according to the instructions of the manufacturer. Occlusion and articulation were checked and adjusted, but the restorations were not polished.

In the final study which lasted almost 5 years, the nine clinicians involved freely selected which restorative material to be used. The material comprised 57 GI (Ketac-Molar®; 3M ESPE, St. Paul, MN, USA) and 419 COM (Dyract AP; Jvoclar Vivadent AG, Schaan, Liechtenstein/Compoglass®; Dentsply International, York, PA, USA), mainly class II restorations. The restorations were placed in 307 consecutively treated children aged

2.6–15.3 years (median: 7.4 years). Thus, the few teeth that did not exfoliate because of the lack of a permanent successor were included in the study. Treatment of primary caries accounted for 88% and replacements for 12% of all restorations.

Statistics

The restorations were recorded as *failed* if they were repaired or replaced or if the tooth was extracted because of endodontic complications or fracture. They were recorded as *censored* in cases of exfoliation of the tooth with the restoration *in situ,* patient dropout and replacement due to primary caries, i.e., caries elsewhere on the tooth not associated with the restoration. For censored restorations, the observation period was defined as the period between the restorative treatment to mid-way between the dates when the restored tooth was last seen and the time the tooth was recorded as missing, or the patient had moved[9].

Chi-Square statistics and Kaplan–Meier survival analyses with Mantel-Cox statistics were used for comparisons of cumulative survival distributions of restorations[9]. The SPSS Data Entry System was used for computerising the data. The SPSS PC+ System[10] was used for statistical analyses (SPSS Inc., Chicago, IL, USA).

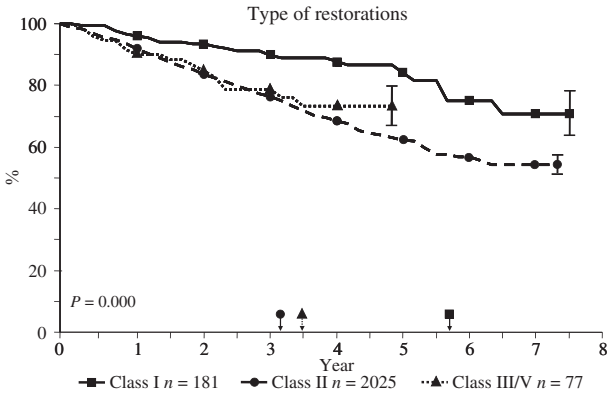

Fig. 1. Cumulative survival distributions of the 2283 class I, II, and III/V restorations in all samples. The curves are drawn as long as at least 10 restorations/surfaces remained in function. The points at which the curves cross the horizontal, quartile lines are indicated with arrows on the abscissas. Vertical bars represent standard errors.

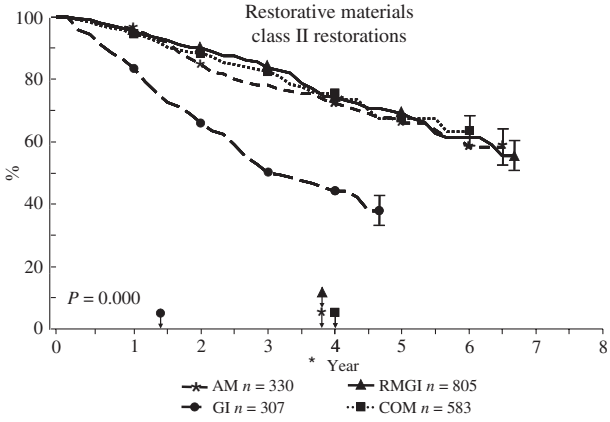

Fig. 2. Cumulative survival distributions of the class II restorations in compomer (COM), resin-modified glass ionomer (RMGI), conventional glass ionomer (GI) and amalgam (AM) in all samples. The curves are drawn as long as at least 10 restorations/surfaces remained in function. The points at which the curves cross the horizontal, quartile lines are indicated with arrows on the abscissas. Vertical bars represent standard errors.

Results

When combining the results from all studies, the greatest longevity was found for class I and the lowest for class II restorations. The 75% survival times were estimated to be 5.7 years for class I, 3.2 years for class II, and 3.5 years for class III/V restorations ($P = 0.000$) (Fig. 1).

The type of restorative material influenced the longevity. The survival distributions for RMGI and COM restorations were almost the same as that for AM and they all differed from that of GI. The 75% survival times for the predominant class II restorations were 4.0 years for COM, 3.8 years for RMGI, 3.8 years for AM, and only 1.4 years for GI ($P = 0.000$) (Fig. 2).

In the last sample where the clinicians freely selected the restorative material, the study was terminated after about 5 years with 9% GI and 14% COM restorations remaining *in situ.* These 65 restorations were all assessed as being well functioning and without apparent need for repair or replacement, although about one third showed one or more minor deficiencies. Most of the original restorations, 52%, had been in function until exfoliation of the teeth, 10% had been censored due to patient dropout, and 2% which all were COM class I restorations, had been censored

because of replacement due to primary caries on the proximal surfaces.

One third of the GI and one fifth of the COM restorations had failed mainly due to fracture of GI restorations and loss of retention as the major reason for failure of COM restorations. Endodontic complications most often occurred in teeth with GI restorations whereas clinical signs of secondary (recurrent) caries were only recorded in connection with COM restorations. Seven of the 100 failed restorations had not been replaced because of anticipated exfoliation of the teeth in the near future, 11 had been repaired, and 28 teeth with defective restorations had been extracted due to endodontic complications or fracture of tooth. The reasons for failures in the last sample reviewed have not been published and they are presented in Table 1.

The significance of 'new' versus 'old' brands of restoratives is illustrated in Fig. 3. The 75% survival time for the most frequent class II restorations were 2.0 years for GI in the 5-year study (Ketac-Molar®) versus 1.3 years for GI restorations in the initial study (Ketac-Fil®; 3M ESPE, St. Paul, MN, USA), but the improved clinical performance of the new GI brand did not continue beyond the first few years ($P = 0.41$). In contrast to these findings, the longevity of COM restorations (Dyract AP® and Compoglass®) in the 5-year study was significantly *lower* than that of the original COM restorations (Dyract®) ($P = 0.004$), and the 75% survival rate for class II restorations in Dyract AP® was only 3.3 years compared with 4.7 years for Dyract.

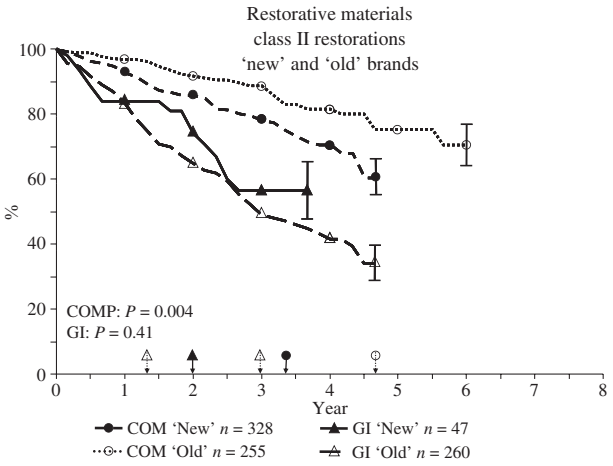

Fig. 3. Cumulative survival distributions of the class II compomer (COM) and conventional glass ionomer (GI) restorations in 'new' and 'old' brands. Only one clinician used GI 'new' in the last study. The curves are drawn as long as at least 10 restorations remained in function. The points at which the curves cross the horizontal, quartile lines are indicated with arrows on the abscissas. Vertical bars represent standard errors.

The cumulative Kaplan–Meier survival distributions for the COM-GI in the 5-year sample of restorations included all cavity types as for the AM restorations in the initial study. The 75% survival time was 3.7 years for COM-GI and 3.8 years for AM restorations ($P = 0.28$) (Fig.4).

Discussion

A number of restorative materials are in use in paediatric practice and detailed reviews are available[11–13]. Whenever comparisons are

Table 1. Reasons for re-treatments of the 19 failed GI and 81 failed COM restorations from the last study according to type of material and restoration.

	GI		COM			Sum
Reasons for re-treatment	**Class I/III/V** ***n* = 10**	**Class II** ***n* = 47**	**Class I** ***n* = 66**	**Class II** ***n* = 328**	**Class III/V** ***n* = 25**	***n* = 476**
Secondary caries			4 (6)	6 (2)	2 (8)	12 (3)
Degradation/wear	1 (10)			4 (1)		5 (1)
Fracture of restoration		8 (17)		8 (2)		16 (3)
Fracture of tooth			1 (2)	7 (2)		8 (2)
Loss of retention	1 (10)	2 (4)		32 (10)	2 (8)	37 (8)
Endodontic complication	1 (10)	6 (13)		20 (6)		27 (6)
Failures in total*	3 (30)	16 (34)	5 (8)	72 (22)*	4 (16)	100 (21)

*Five restorations failed for two reasons.
Percentages of failures in each category of restorations are given in parentheses.

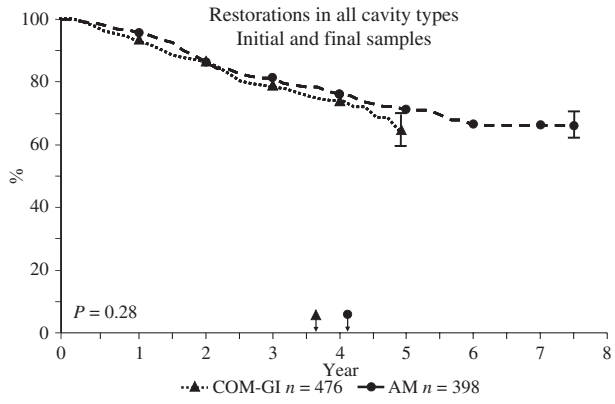

Fig. 4. Cumulative survival distributions of compomer (COM) and conventional glass ionomer (GI) restorations combined in all cavity types from the final study and of the corresponding amalgam (AM) restorations in all cavity types from the first study. The curves are drawn as long as at least 10 restorations/surfaces remained in function. The points at which the curves cross the horizontal, quartile lines are indicated with arrows on the abscissas. Vertical bars represent standard errors.

made, related to the quality and longevity of restorations, AM is frequently used as 'the gold standard'[14,15].

At the time when the last study in the present series was initiated, AM was still the most frequently used restorative material for restorations in posterior primary teeth in the Danish Public Dental Health service. Tooth coloured materials like GI, RMGI, and COM had gradually come into use in line with their development and clinical experience in using these materials, while resin based materials only have been used sporadically for anterior restorations in primary teeth[4].

The controversy over the possible and potential side effects of AM has only been of modest influence on the selection of restorative materials in Scandinavia[16,17]. Nevertheless, under the influence of largely lay groups, environmental and health authorities in many countries have placed increasing pressure on dentists and legislators to reduce the use of dental AM with the intent to protect the environment and hence the population from exposure to mercury. Presently, the use of AM for restorations in primary teeth is *de facto* banned in all Scandinavian countries. Focus on restorations in primary teeth with AM was because children *potentially* may be more vulnerable to toxic exposures[5,18].

It should be noted that none of the restorations in the final study in the series where the clinicians freely selected the restorative material were performed in AM. Seven of the nine clinicians used COM, one used GI, and one used both types of materials for routine restorations in primary teeth. The participation in the long-term projects may have had an effect on the selection of restorative materials, because the clinicians were aware of the promising, initial results from the foregoing studies and had terminated the use of AM for the primary dentition based on their experience with tooth-coloured restorative materials. They were undeterred by the somewhat complicated handling of the tooth coloured materials, such as use of cavity conditioner which is claimed to be mandatory by the manufacturers of COM and most RMGI restoratives.

Longevity of restorations is probably the most important parameter for measurement of the success of restorative therapy. Therefore, a comparison of the survival of COM-GI restorations in the fourth study with the AM restorations from the original sample provides optimal conditions of assessing the clinical effects of a post-AM era for restorative treatments in the primary dentition. Both samples consisted of consecutive restorations routinely inserted in all types of cavities by the same groups of clinicians in the same population. Therefore, it is of clinical significance that the survival distributions of the two sets of restorations were almost identical. That means that the requirements and time for re-treatment of restored teeth were unchanged from the AM to the post-AM era, although the reasons for failure differed with fracture and endodontic complication dominating for the AM restorations and loss of retention for tooth-coloured restorations.

In the initial studies, loss of retention resulted in re-treatment of 5% of the class II COM restorations performed without cavity conditioning but only 2% of those from conditioned cavities. Cavity conditioning was therefore always used together with COM in the final study; and the 10% lost class II COM restorations in this sample was

unexpected. Since the frequency of endodontic complications was also comparable to the initial data, the failure rates for the two new brands of COM restorations were significantly higher than for the old COM restorations and the survival rates significantly lower. These discouraging results are worth noting as the manufacturers steadily ensure that new versions of their products are improved compared with older versions. Nevertheless, such claims are most often based on results from laboratory tests, which are less expensive and time-consuming than clinical tests, but offer a poor reliability for the clinical situation[19].

The same dilemma was observed when comparing the longevity of class II GI restorations performed using an old and a new version of the same product in 1991 and 1999. Laboratory studies have shown enhanced mechanical properties of the new version compared with the old one[20,21]. In accordance with these results we found few early fractures among the restorations in the most recent study and a survival distribution in favour of the new version during the first 2 years after treatment. Nevertheless, due to an increased late fracture frequency of GI restorations, the curves were almost coincident, and no significant discrepancies were found between the two GI versions related to their survival distributions, i.e., it may take some years after the launching of a new material until clinical results have proved if it was an improvement or deterioration compared with earlier versions of the same material.

Another aspect of the altered restorative treatment pattern was the increased survival rates for surfaces in contact with GI, RMGI, and COM restoratives compared with surfaces in contact with AM, and that only small and insignificant differences were seen between new and old brands of GI and COM. These findings are in accordance with the conclusions in the previous studies in this project and in other comparative studies of the clinical performance of tooth coloured restorations in primary and permanent teeth[6–8, 22–26].

In 2003 the Danish Health Authorities effectuated a ban against the use of dental AM for the restoration of primary teeth. This legislation had been pending for a long time. The three randomised studies reviewed in this paper were important documentation in this context. The complete series of studies has demonstrated that tooth-coloured materials are realistic alternatives to AM showing the same or even enhanced longevity of restorations without negative consequences for the dental health of children and adolescents.

Conclusions

The comparison of results from a series of large clinical studies using different restorative materials in the treatment of primary teeth has shown that caries treatment can be successfully performed using tooth coloured restorative materials as alternatives to AM without negative consequences for the dental health of children and adolescents. An assessment of the selection of restorative materials by the clinicians, who had been involved in the long-term studies, showed that the clinicians freely selected tooth coloured restorative materials for restoration of primary teeth after the initial studies had been completed.

What this paper adds

- Involvement in clinical studies exposes clinicians to new materials and techniques and enhances clinical experience.
- Clinicians select restorative material primarily based on their own clinical experience. Enhanced experience is gained by involvement in clinical studies.

Why this paper is important to paediatric dentists

- Legislation is pending in many countries to ban the use of amalgam (AM) for restoration of primary teeth. The results presented show that alternative materials of equal quality to AM are available.
- Tooth coloured restorations are also favoured in paediatric practice.

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