Eight-year study on conventional glass ionomer and amalgam restorations in primary teeth

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The aim of this randomized clinical study was to compare the longevity and the cariostatic effects of conventional glass ionomer and amalgam restorations in primary teeth placed in everyday practice in the Danish Public Dental Health Service. All restorations inserted during a 7-month period by 14 clinicians in 2 municipalities were included in the study. The sample consisted of 515 conventional glass ionomer restorations and 543 amalgam restorations in 666 children aged between 2.8 and 13.5 years. The restorations were in contact with 592 unrestored surfaces in primary and permanent teeth. The study was terminated after 8 years, with 2% of the restorations in function and 7% patient dropouts. Fifty percent of the teeth restored with glass ionomer and 63% of those with amalgam were exfoliated with the restoration in situ, while 42% of the glass ionomer and 20% of the amalgam restorations had been repaired or replaced. Fracture of restoration, endodontic complication, and loss of retention were the major reasons for failure. The 50% survival time for glass ionomer restorations in all cavity types was 42 months, while the median survival time for amalgam restorations could not be estimated but exceeded 7.8 years ($P < 0.001$). Progression of caries lesions on tooth surfaces adjacent to amalgam restorations required operative treatment on 30% of the teeth, while only on 16% of teeth adjacent to glass ionomer restorations. The 75% survival time was 40 months for surfaces in contact with glass ionomer compared to 25 months for surfaces in contact with amalgam ($P = 0.005$). Multivariate analyses were performed in order to assess the influence of a number of factors on the longevity of restorations, occurrence of prevalent failures, and caries treatment of surfaces in contact with the restorations. Owing to the high frequency of failures of the conventional glass ionomer restorations, it was concluded that they are not an appropriate, universal alternative to amalgam for restorations in primary teeth, although they reduce caries progression and the need for operative treatment of adjacent surfaces. □ *Clinical trials; cariostatic effects; dental amalgam; dental restorations; glass ionomer cements; long-term behaviour; pedodontics*

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The present study was initiated in 1991 in light of the first official recommendation from the Danish Environmental Protection Agency to reduce the use of mercury in Denmark (1). As in most other countries in the industrialized part of the world, amalgam was at that time used as the major restorative material in deciduous teeth and in almost all class I and class II restorations in posterior teeth. In the primary dentition, composite resin materials and conventional glass ionomer were only used for class V restorations and the few class III restorations in anterior teeth (2, 3). The choice of restorative materials in Denmark during the late 1980s reflected the results from studies on the clinical quality and durability of composite resin, conventional glass ionomer, and amalgam restorations (4–6). These studies had turned out in favor of amalgam with a higher failure rate for both composite resin and glass ionomer restorations. However, there was a strong belief in the cariostatic potential of conventional glass ionomer and these materials were considered to be the best alternative to amalgam for the restoration of deciduous teeth (7–9). Few, and mostly short-term comparative studies of the outcome of restorative treatments in the primary dentition were available (4–6). The prospective studies were of restorations made under optimal conditions, by a few especially skilled clinicians on selected groups of patients according to the criteria for the 'controlled clinical trial', where the clinical procedures are controlled and standardized as much as possible. The results from these studies could not therefore be used as a basis to estimate the consequences of a possible Danish ban on amalgam for restorations in the primary dentition.

As a consequence, the present study was initiated to provide a realistic basis for the selection of conventional glass ionomer and amalgam for restorative treatment of primary teeth within the Danish Public Dental Health Service. It focused on 1) the requirements for additional treatment of the restored teeth before exfoliation and 2) the need for operative caries treatment of adjacent teeth with approximal surfaces in contact with the restorations in the two materials.

The 3-year results of the study indicated that conventional glass ionomer was not an appropriate alternative to amalgam for restorations in primary teeth; especially not for class II typed restorations, which comprised the major

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part of all fillings in the primary dentition in Denmark. The glass ionomer restorations showed many fractures and a short longevity. However, they decreased caries progression on adjacent approximal surfaces compared to amalgam restorations although not the need for operative treatment of the surfaces (10).

One-third of the restorations and one-fourth of the adjacent surfaces remained under observation after the first 3 years. It was therefore decided to follow the remaining restorations until the shedding of the teeth for further assessment of the clinical behavior of the two materials. After an observation period of 8 years, all the teeth treated had exfoliated, except for a few with well-functioning restorations. This article, therefore, describes the final 8-year comparison of the longevity and potential cariostatic effects of conventional glass ionomer and amalgam restorations in primary teeth. Based on these results an estimate will be made of some of the consequences of a shift from amalgam to glass ionomer restorative materials in routine, everyday practice settings.

Materials and methods

The study was carried out at the Public Dental Health Service (PDHS) in the municipalities of Værløse and Hillerød in Denmark, where 99.9% of all children and adolescents are regularly treated up to the age of 16 years. For several years now the treatment strategies in the two municipalities have been based on individual needs with recall intervals between 4 and 16 months depending on caries risk assessments. The caries prevalence in the municipalities has steadily been below the national average (11). However, it must be pointed out that the population being studied only included the children in need of treatment of active caries.

Information about the programmed systematic use of restorative materials was given to children and adolescents treated within the PDHS as well as their parents, and the study was approved by the Danish Data Protection Agency. The 14 clinicians and staff members in the PDHS participated in discussions concerning clinical assessment of caries and restorations, appropriate time for operative interventions, cavity preparation designs, handling of the glass ionomer and amalgam materials, reasons for failure of restorations, and the use of specially designed registration forms. These discussions were continued at biannual or annual meetings, where results from the study were presented. The clinical teams in this study, therefore adhered to the requirements for participation in controlled clinical trials (12), but direct calibrations of criteria for diagnosing caries and assessment of restorations were not performed.

Restorations

The restorative materials chosen for the study were the encapsulated, conventional glass ionomer Ketac-Fil (GIC) (ESPE, Seefeld/Oberbay, Germany, batch no. 013H25), and the encapsulated amalgam (AM) Dispersalloy (Johnson & Johnson, New Brunswick, NJ, USA, batch nos J836, 1K837, and 2A864). The materials were handled in accordance with the manufacturer's instructions. They were used alternately for 1 week each for 7 months in 1991/92. In this way a randomized study design was obtained, except for 30 anterior restorations where only the glass ionomer was used. The few restorations made with another material than the scheduled one were excluded from the study. A total of 515 restorations were made in GIC, and 543 in AM in the primary teeth in 666 consecutively treated children aged 2.8 to 13.5 years (median age 7.6 years). Treatments of primary caries lesions accounted for 86% of the treatments and replacements for 14%.

Originally, the study consisted of 15% class I restorations, 79% class II, and 5% class III/V restorations. The cavities were prepared as small, non-bevelled, conventional cavities. They were not 'extended for prevention', but the width and depth were aimed to be at least 1½ mm at the isthmus and in stress-bearing areas, and 1 mm in other areas for both restorative materials. It was not recorded whether a proxitector was used during the cavity preparation, but rubber dam, acid etching, conditioners or bonding agents were never used. Most of the cavities (84%) were lined with Dycal (De Trey Dentsply, Konstanz, Germany, batch nos. 910807 and 910815). Eleven percent of the teeth had been endodontically treated prior to the restorative treatment.

The surfaces of the GIC restorations were coated with light-curing Ketac-Glaze or petroleum jelly under the initial hardening, and after adjusting the morphology. The AM restorations were burnished, carved, and smoothed with pellets of cotton wool. Occlusion and articulation were checked, but neither the GIC nor the AM restorations were polished. The restorations were followed until exfoliation of the tooth or to the time when extraction, repair, or replacement was indicated.

Adjacent surfaces

The restorations were in contact with 592 unrestored, approximal surfaces in 485 primary and 107 permanent teeth. The surfaces were assessed as being clinically sound, with arrested caries, or with active caries lesions with or without cavitation according to general criteria for the Danish PDHS (13). The approximal assessments were made after preparation of the cavities and at each recall until failure of the restoration, exfoliation/extraction of the restored tooth or the adjacent tooth, or until operative treatment of the adjacent surface was deemed necessary.

Statistical analyses

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, replacement due to primary caries, and patient dropout. The adjacent surfaces were recorded as *failed* if operative caries treatment was required or else they were considered as *censored*. For censored restorations and surfaces, the observation period was defined as the period between the restorative treatment to midway between the dates when the restored/adjacent tooth was last seen, and the time the tooth was recorded as missing, or the patient had moved (14).

Chi-square statistics, sign test and Kaplan-Meier survival analysis with Mantel-Cox statistics were used for bivariate comparisons of the two types of restorations, including cumulative survival distributions of restorations and adjacent surfaces (14). The Cox proportional hazards model, which is particularly suitable for analysis of survival data that contain censored observations, was applied to assess the multivariate influence of various categorical and continuous predictor variables on the survival of restorations and unrestored surfaces in contact with the restorations (Table 1). The variables were removed from the model by backward stepwise elimination. Removal testing was based on the likelihood-ratio statistic based on conditional parameter estimates and a removal probability >0.05. Interactions between the restorative material and significant variables were added to the reduced model and were eliminated by the same procedure. Regression parameter estimates with corresponding standard errors and risk ratios were estimated for significant variables in the final models (14). The general results for the restorations were supplemented by specific analyses of variables of significance for each of the most frequent reasons for re-treatments. A P value of <0.05 was considered statistically significant. The SPSS Data Entry System (SPSS Inc.) was used for computing the data. The SPSS PC+ Advanced Statistics version 5.0 (SPSS Inc.) and the SAS/STAT user's guide version 6 (SAS Institute Inc.) were used for statistical analyses.

Table 1. Multivariate analyses of continuous and categorical predictor variables included in the Cox proportional hazards model for survival of restorations and adjacent surfaces

Predictor variables	Levels of categorical variables
Restorations and adjacent surfaces	
Restorative material	Glass ionomer—Amalgam
Age of patient	Continuous variable, years
Caries experience, 5 years	Positive—Negative—Unknown
Jaw	Upper—Lower
Treatment problem	Yes—No
Clinician	C_1—C_{14}
Restorations	
Type	Class I—Class II—Class III/V
Tooth	1st Molar—2nd Molar—Others
Surface	Mesial—Distal—Others
Initial restoration	Yes—No
Base material	Yes—No
Endodontic treatment	Yes—No
Adjacent surfaces	
Adjacent surface	Mesial—Distal
Adjacent tooth	Primary—Permanent
Baseline status	Sound—Arrested caries – Active caries ÷ cavitation – Active caries + cavitation

Results

Restorations

There was a rapid decrease in the number of restorations remaining under observation for both materials. Only half were in function after 2 years, one-third after 3 years, a fifth after 4 years, and 10% after 5 years. The decrease became fairly independent of the percentages of failed restorations, indicating that it reflected the natural shedding of restored primary teeth. The median observation period for all restored teeth was 1.8 years for GIC and 2.3 years for AM restored teeth. The ultimate ratio of censored to failed restorations was 1.4–1 for GIC and 3.9–1 for AM ($P < 0.001$) (Fig. 1).

Two percent of the restorations (5 GIC, 21 AM) remained in function when the study was terminated and were assessed as being well functioning without need for repair or replacement before exfoliation of the teeth. The majority of the 69% censored restorations remained in function until exfoliation of the teeth, but 7% were censored due to patient dropout and 3% when they were replaced due to treatment of primary caries. Most of the 31% failed restorations had been replaced, but 10 restorations had been repaired and 17 defective restorations were not replaced because of anticipated exfoliation in the near future. Seven percent of the restored teeth were extracted due to endodontic complications or fracture of tooth.

The percentages of re-treatments of class I and class II restorations were approximately the same and twice that for class III/V restorations with both materials. However, nearly half of all re-treatments of class I restored teeth were caused by approximal caries lesions (13 GIC, 14 AM)

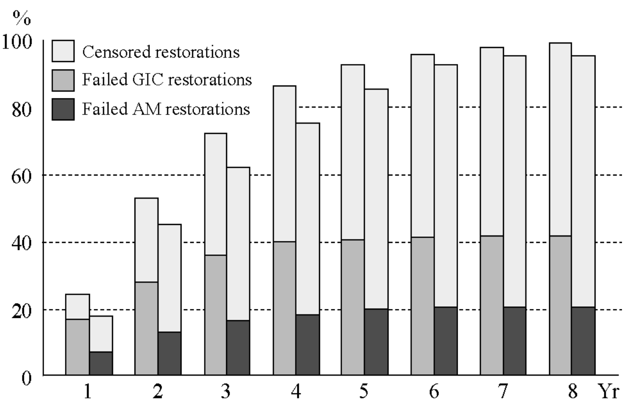

Fig. 1. Cumulative annual percentages of censored and failed glass ionomer (GIC) and amalgam (AM) restorations.

Table 2. Reasons for re-treatments of the 327 failed conventional glass ionomer (GIC) and amalgam (AM) restorations according to type of restoration and restorative material. Percentages of failed restorations are given in parentheses

	Class I		Class II		Class III/V		All types of restorations	
Reasons for re-treatment	GIC *n* = 87	AM *n* = 73	GIC *n* = 384	AM *n* = 456	GIC *n* = 44	AM *n* = 14	GIC *n* = 515	AM *n* = 543
Secondary caries	3 (3)	1 (1)	4 (1)	13 (3)	–	1 (7)	7 (1)	15 (3)
Degradation/wear	5 (6)	–	4 (1)	6 (1)	–	–	9 (2)	6 (1)
Fracture of restoration	7 (8)	–	111 (29)	31 (7)	1 (2)	–	119 (23)	31 (6)
Fracture of tooth	1 (1)	1 (1)	–	3 (1)	–	–	1 (0)	4 (1)
Loss of retention	12 (14)	2 (3)	30 (8)	20 (4)	6 (14)	–	48 (9)	22 (4)
Endodontic complication	3 (3)	4 (5)	34 (9)	40 (9)	4 (9)	1 (7)	41 (8)	45 (8)
Failures in all*	28 (32)	7 (10)	177 (46)	102 (22)	11 (25)	2 (14)	216 (42)	111 (20)

* Nine (2) GIC and 12 (2) AM restorations failed for two reasons.

and only half were caused by true failures of the fillings (28 GIC, 7 AM). Primary caries resulted in a few replacements of two-surfaced class II restorations (2 GIC, 3 AM).

The clinical diagnosis 'secondary caries' for lesions at the margin of restorations resulted in few re-treatments (7 GIC, 15 AM), and the frequency was independent of the restorative material. Similarly, failures due to degradation and wear, fracture of tooth, and endodontic complications occurred independently of restorative material, while bulk fracture and loss of retention occurred most frequently for GIC restorations ($P < 0.001$). Bulk fracture was by far the most frequent reason for replacement of class II GIC restorations, followed by endodontic complication and loss of retention. Endodontic complications and fractures including a few tooth fractures were the major types of failure of class II AM restorations (Table 2).

The low numbers of class III/V restorations as well as the few total failures call for caution when interpreting the results for these types of restorations. Yet, loss of retention was the most common reason for failure of such GIC restorations (Table 2).

The overall median time from treatment to *failure* was 1.3 years for GIC and 1.6 years for AM restored teeth. The median ages of the failed restorations varied between 1 and 2 years irrespective of restorative material and reason for failure. The only exceptions were the 17 GIC restorations, which failed due to secondary caries, degradation/wear, and fracture of tooth with median ages of 3–4 years (Fig. 2).

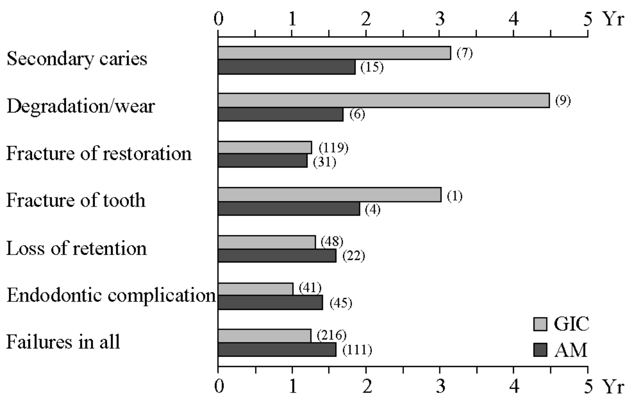

Fig. 2. Median survival time of the 216 *failed* glass ionomer (GIC) and the 111 *failed* amalgam (AM) restorations according to reason for failure. The numbers of failed restorations are given in parentheses.

The cumulative Kaplan-Meier survival distributions of classes I, II, and III/V GIC and AM restorations with corresponding standard errors are depicted graphically in Figs 3 and 4. The type of restorations influenced the survival distributions with the shortest longevity for class II restorations in both materials. The median survival time for GIC restorations in all cavity types was 42 months while 3 out of every 4 AM restorations were still in function at that time, provided the tooth had not exfoliated. The 50% level for all types of amalgam restorations could not be estimated but exceeded 7.8 years ($P < 0.001$).

Adjacent surfaces

Caries lesion progression occurred in 37% of the 309

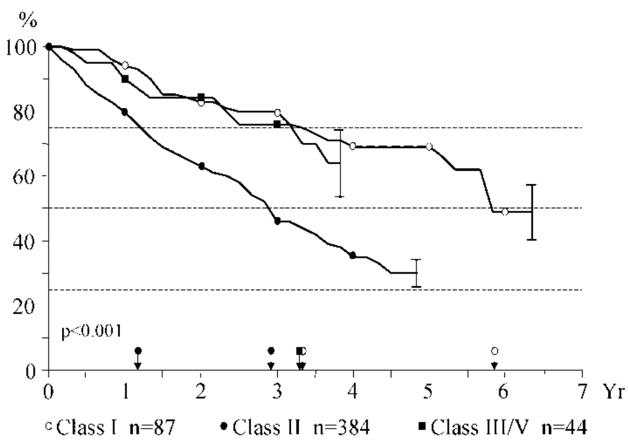

Fig. 3. Cumulative survival distributions of the 87 class I, 384 class II, and 44 class III/V glass ionomer restorations. The curves are drawn as long as at least 10 restorations remain in function. The points at which the curves cross the horizontal, quartile lines are indicated with arrows on the abscissas. Vertical bars represent standard errors.

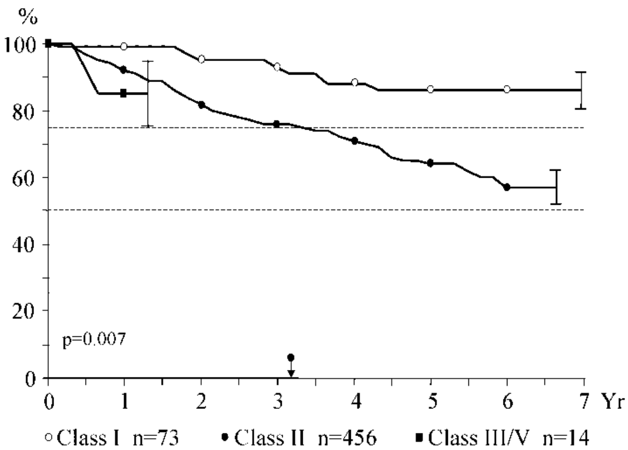

Fig. 4. Cumulative survival distributions of the 73 class I, 456 class II, and 14 class III/V amalgam restorations. The curves are drawn as long as at least 10 restorations remain in function. The points at which the curves cross the horizontal, quartile lines are indicated with arrows on the abscissas. Vertical bars represent standard errors.

surfaces in contact with AM versus 19% of the 283 surfaces in contact with GIC. An unchanged caries status was recorded for 40% and 55% of the corresponding surfaces, and regression of caries lesions from an active to an inactive, or even a sound status, was assessed in one-fourth of the surfaces in contact with both materials.

Progression of caries lesions resulted in operative treatment of 94 (30%) of the surfaces adjacent to AM and 45 (16%) surfaces adjacent to GIC restorations. The 139 operative treated surfaces included 8 mesial surfaces on first permanent molars. The survival analyses showed a 75% survival time of 25 months and a median survival time of 50 months for surfaces in contact with AM. The

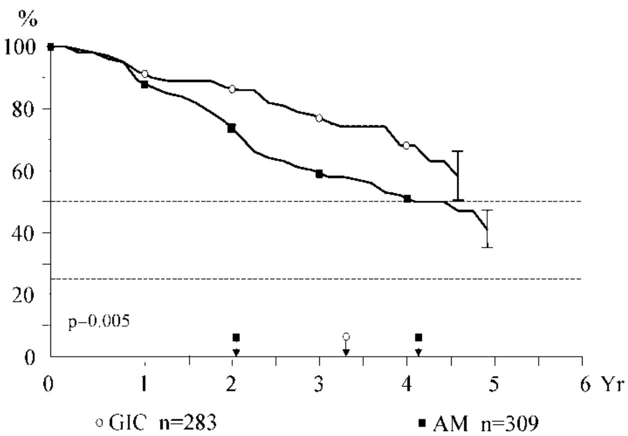

Fig. 5. Cumulative survival distributions of the 283 unrestored surfaces adjacent to glass ionomer restorations and the 309 surfaces adjacent to amalgam restorations. The curves are drawn as long as at least 10 restorations remain in function. The points at which the curves cross the horizontal, quartile lines are indicated with arrows on the abscissas. Vertical bars represent standard errors.

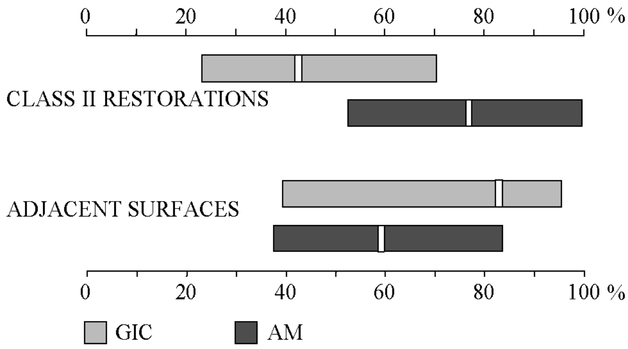

Fig. 6. Median values and ranges for the 3-year cumulative survival proportion of class II restorations and unrestored adjacent surfaces for 11 of the clinicians with at least 15 restorations of each material.

75% survival time for surfaces in contact with GIC was 40 months, while the 50% level was not reached but exceeded 56 months ($P = 0.005$) (Fig. 5).

Fig. 6 illustrates the variation in the 3-year results obtained by 11 of the 14 clinicians who had completed at least 15 class II restorations of each material. The ranges were about 45% for class II restorations of both materials and for surfaces in contact with AM and 55% for surfaces in contact with GIC. However, the intra-individual 3-year survival results for the 11 clinicians were in favor of AM as restorative material for all 11 clinicians ($P = 0.001$). On the other hand they were in favor of GIC as contact material for 9 of the 11 clinicians while 1 clinician got the same results and 1 the highest 3-year survival probability for adjacent surfaces in contact with AM ($P = 0.02$).

Multivariate analysis

Table 3 summarizes the results of the general, multivariate survival analysis for restorations. The risk ratio is the relative hazard for a level or unit change in the corresponding variate. For example, 0.35 is the risk of failure of an AM restoration relative to that of a GIC restoration, and 0.90 is the risk of failure of a restoration made in a child at the age of 'a + 1 years' relative to a child aged 'a years'. Other significant variables in the general model were the type of restoration with the shortest survival for class II restorations and the longest for class III/V restorations; endodontic treatment of the restored tooth; technical or psychological treatment problems; and the clinician. In addition, there were significant interactions between the restorative material and the clinician, and between the restorative material and the age of the child.

Further specific analyses of variables of significance for the various types of failures showed that the odds of fracture of a class II restoration were approximately 10–1 that of a class I or class III/V restoration. The restorative material and the age of the child resulted in approximately the same risk ratios in the specific model for fracture as in

Table 3. Variables and interactions (×) of significance for survival of restorations with corresponding degrees of freedom (DF), test probability, parameter estimate, standard error, and risk ratio

Variables–interactions	DF	Test probability	Parameter estimate	Standard error	Risk ratio
Restorative material	1	<0.001			
Glass ionomer			–	–	1
Amalgam			−1.04	0.12	0.35
Type of restoration	2	<0.001			
Class I			−1.05	0.19	0.35
Class II			–	–	1
Class III/V			−0.95	0.30	0.39
Age of patient, years	1	0.002	−0.099	0.031	0.90
Endodontic treatment	1	<0.001			
Yes			0.83	0.17	2.29
No			–	–	1
Treatment problems	1	0.002			
Yes			0.54	0.18	1.72
No			–	–	1
Clinician	13	<0.001	–	–	–
Restorative material × Age of patient	1	0.035	–	–	–
Restorative material × Clinician	27	0.008	–	–	–

the general model, and the interaction between restorative material and clinician was also reflected in the final model for fracture of restorations. The analysis for loss of retention showed that the rate was influenced by treatment problems, risk ratio 2.25, and the restorative material, risk ratio 2.66 for GIC relative to AM. The odds for endodontic complications were approximately 11–1 for an endodontically treated tooth compared to a tooth with untreated pulp. Also the type of restoration influenced the occurrence of endodontic complications (class III/V ≥class II ≥class I) together with the age of the child where the risk ratio corresponded to that in the general model.

The variables of significance for survival of the adjacent surfaces are listed in Table 4. These included the restorative material, risk ratio 0.61 for GIC relative to AM; the age of the child; the jaw; and the clinician. Finally, the baseline caries status of the adjacent surfaces had a significant influence on the need for operative treatment with an increased risk for carious surfaces compared with sound surfaces.

Discussion

The main goal of the present study was to assess the cost implication of a ban on the use of amalgam, with conventional glass ionomer as the alternative to amalgam as the dominant restorative material in primary teeth. Longevity of restorations is a major component in such assessments (15). Owing to the short median longevity of GIC compared to AM restorations, the cost for the dental health care system must be taken into consideration. The long-term assessment of restorations in primary teeth should be viewed in a perspective of maximum 10 years, while that on permanent teeth must be assessed on at least a 60-year term (15). On condition that the cost of inserting

Table 4. Variables of significance for survival of adjacent surfaces with corresponding degrees of freedom (DF), test probability, parameter estimate, standard error and risk ratio

Variables	DF	Test probability	Parameter estimate	Standard error	Risk ratio
Restorative material	1	0.01			
Glass ionomer			−0.49	0.19	0.62
Amalgam			–	–	1
Baseline caries status	3	<0.001			
Sound			–	–	1
Inactive caries lesion			1.22	0.47	3.40
Active caries − cavitation			0.73	0.21	2.09
Active caries + cavitation			1.72	0.48	5.59
Dentition	1	0.029			
Primary			–	–	1
Permanent			−0.74	0.37	0.87
Jaw	1	<0.001			
Upper			0.73	0.18	2.07
Lower			–	–	1
Clinician	13	0.001	–	–	–

the two types of restorative materials is the same, longevity of restorations will be the decisive factor.

As the study should provide a realistic basis for the selection of conventional glass ionomer and amalgam for restorative treatment of primary teeth, all 1058 restorations were included in the survival analyses. The estimates of the longevity of the restorations/adjacent surfaces obtained in this way are more reliable but probably a little shorter than would have been the case if only the first restoration performed in each of the 666 children had been included in the analyses. Normally, the dentist who had made a restoration also assessed the need for repair or replacement at later recalls. This may affect the longevity, too, and is not considered an ideal situation in clinical research. However, it reflects daily clinical practise and strengthens the generalization of the results.

The 3½ years longevity of GIC restorations in the present study is in conformity with the results from most other longitudinal studies on primary teeth (16–21) and longer than that reported in a recent cross-sectional survey on failed restorations (22). The low rate of primary and secondary caries in the present population may influence this difference, but the variety in study design, longitudinal versus cross-sectional studies, may be the most important factor.

The main reason for failure of class II GIC restorations was fracture of restoration, which concurs with most other studies in primary teeth and 5-year data on similar restorations in permanent teeth (23). This mode of failure indicates inadequate physical properties of GIC as a restorative material for stress-bearing restorations.

The median longevity of amalgam restorations in the present study could not be estimated, but it exceeded 7.8 years. Based on longevity alone, a theoretical 2-fold increase in cost of restorative treatment of primary teeth may therefore be projected if amalgam is banned and conventional glass ionomers are used instead. However, restorations in primary teeth are usually needed to serve for only 5–6 years with a median of less than 2.5 years in the present population. Based on the frequencies of failed restorations in the two materials, the actual increased cost can therefore be estimated at minimum 20% in the present population.

It should also be noted that the need for restorative treatment of primary teeth is probably increasing in Denmark (24). Thus, the need for monitoring the effects, including the cost implications, is recommended. In Sweden and Finland the change from amalgam to glass ionomer materials was made without cost analysis (8, 9, 25). The present results do not support such a change without some means by which to absorb the additional cost. Furthermore, many replacements provoke endodontic complications and increase the risk of iatrogenic damage to adjacent surfaces and associated caries progression. In addition, it should be kept in mind that health authorities on a worldwide basis confirm that dental amalgam restorations are safe and effective (25–27).

The frequent replacement of GIC restorations increases the risk of iatrogenic damaging on adjacent tooth surfaces associated with replacement of restorations. This effect is difficult to assess, but it is important to keep in mind that it often affects the permanent first molar (28). Accordingly, Mejare et al. (29) have pointed out that the caries risk of the mesial surface of a first molar is greater if the adjacent primary tooth has been restored.

The negative effect of the iatrogenic damage is counteracted by the caries preventive effect of relatively short-lived glass ionomer restorations on adjacent tooth surfaces. This is especially important with respect to the prevention of caries on adjacent permanent teeth. The effect on adjacent teeth is considered an important parameter in the total assessment of the outcome of restorative treatments. The inconsistency in results as a function of observation period was particularly noticeable with regard to the development of caries on adjacent teeth; the reasons are likely due to the fact that it takes time for caries lesions to progress. One-year data gave no difference in the development of caries lesions on adjacent teeth, and not until after 3 years of observation was this finding ascertained (10).

The cariostatic effect of restorative treatment was evaluated as the power to prevent 1) secondary caries on the restored tooth, 2) primary caries on unrestored surfaces on the same tooth, and 3) primary lesions on adjacent tooth surfaces. The assessment of the caries status of the adjacent surfaces was made by clinical inspection that was seldom supplied by bitewing radiographs. This is the current procedure in Denmark. It definitely makes it difficult to separate between cavitated and non-cavitated lesions at recall examinations. However, despite uncertainty in the diagnosis, the restorations in the adjacent surfaces caused by caries progression were a reality and the reduced need for operative caries treatment of adjacent tooth surfaces to GIC restorations is an important finding. This observation was conclusively demonstrated after the 8 years' observation period. It has beneficial implications for dental health as well as economic consequences. Thus, the cariostatic effect of glass ionomer compared to amalgam could be estimated to reduce the cost by about 8% in the present population, based on the performed treatments of adjacent surfaces.

The lack of effect on the development of secondary caries by conventional glass ionomers confirms the results from practice-based studies (22, 30). However, in the present material secondary caries lesions were diagnosed in less than 2% of the restored teeth and the caries incidence in the population was generally low. It must also be kept in mind that the clinicians involved in the study were specially trained for the types of studies reported on in the present paper.

The present 8-year results on longevity of restorations and cariostatic effect on adjacent teeth confirm those from the 3-year data (10). This finding indicates that 3-year observation periods may be satisfactory for clinical studies of restorations in deciduous teeth. However, data from 1–3-year observations will not provide a complete picture with regard to the reasons for failures or survival of the restorations or the adjacent surfaces. Furthermore, different reasons for failures of restorations require an observation period up to 4 years because the various reasons for failures are time dependent to some extent. After 4 years the reasons for failures remained constant, as did the results of the survival analyses. Based on the present data, it may therefore be concluded that 4 years are the optimal and maximum required observation time for studies on restorations in primary teeth.

The multivariate analyses added detailed information related to variables and their interactions with regard to the survival of the restorations, the major types of failures, and the fate of tooth surfaces in contact with the GIC and AM restorations. These analyses singled out factors that have previously been shown to have an impact on the final outcome of restorative treatments in primary teeth, including the restorative material, class of restoration, and age of the patient (16–21, 31–34). In agreement with common clinical experience they also stressed the importance of the pulp condition (35) and treatment problems. Such cases are often excluded from clinical trials, just as endodontic complications are not considered true failures. The influence of the individual restoration on adjacent teeth has also been neglected. The analyses for survival of adjacent surfaces are therefore of special interest and they have thrown light on the much debated cariostatic action of conventional glass ionomer (30, 36–38). The results also confirmed that a sound surface has a lower risk of developing caries in need of operative treatment than an already carious surface (39).

Thus, the multivariate analyses added dimensions to the study that may be otherwise missed. In accordance with previous observations they also concluded that the individual clinician plays a significant role in the quality of restorative treatment in the primary and the permanent dentition, and that reliable evaluations of different treatment strategies therefore have to be based on results obtained by a number of clinicians (39–43), although for comparing the success of different materials studies with only one or a few operators can also be useful.

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