The influence of restorative material on the survival rate of restorations in primary molars

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Abstract

The survival rates of restorations in primary molars were calculated after a retrospective examination of patients' dental records from a study population of 1,065 children. A random sample of 128 records showing information for 604 dental restorations was examined, coded, and analyzed by the life table method of survival analysis. The order of the survival rate of restorations from higher to lower success was preformed crowns, amalgam, composite resin, and glass ionomer restorations. A highly statistically significant difference (P = 0.0001) was found among the survival success rates of different material restorations. For preformed crowns and amalgam restorations, the median survival time was more than 5 years. The 5-year survival estimate for preformed crowns was 68% and for amalgam restorations was 60%. For composite resin the median survival time was 32 months and the 4-year survival estimate was 40%. For glass ionomer restorations, the median survival time was 12 months and the 4-year survival estimate was 5%. (Pediatr Dent 16:282–88, 1994)

Introduction

The recent introduction of glass ionomer cements, composite resins for posterior teeth, and high copper amalgam alloys creates a difficult dilemma for the dentist regarding the best choice of a restorative material. The choice of the best restorative material becomes even more difficult as the desired survival period for a restoration ideally coincides with the time of primary tooth exfoliation, a maximum of 8 to 9 years.

The literature reports that preformed crowns achieve a better success rate than multisurfaced amalgam restorations in studies of dental records from private pediatric dental practices,[1-3] a hospital,[4] and a university dental clinic.[5, 22]

The increasing demand for esthetics coupled with concern about mercury has led to the development of composite resins for the posterior teeth. Composite resins have been reported to achieve either similar success rate as amalgam restorations[6, 7] or inferior success rate.[8-11] Amalgam restorations were superior in anatomic form (wear),[6-8] but composite resins achieved better[7] or similar margin adaptation[6] and the same percentage of secondary caries.[6, 7]

Recently, glass ionomer (GI) cement has been suggested as a suitable material for primary tooth restoration,[12] but very few controlled clinical studies have tested this suggestion. A review of the literature shows a wide variety of approaches to the study of success rate and longevity of restorations. However, no one study has compared the performance of all types of restorations placed by a variety of operators. This study examined the survival rates of primary molar restorations placed by dentists and dental students in the pediatric dental clinic at the University of Leeds, England.

Methods and materials

The study plan had four steps: data (restorations) selection, data processing, control, and data analysis.

Study population

The study population consisted of 1,065 children who were registered as new patients at the Department of Child Dental Health, Leeds Dental Hospital, during the 4-year period January 1, 1985, to December 31, 1988. Subjects were between 3 and 10 years old, and attended the dental hospital at least once during the 2-year period February 1, 1989, to January 31, 1991.

Sample selection

The study sample was selected in two steps. First, one-third (355 records) of the study population was selected randomly, then the final sample was created from the initial sample patients' records that fulfilled the criteria for inclusion in the study.

A multistage, stratified, random sampling technique was used.[13, 14] In the first stage the patients' records were stratified in eight strata according to age (in years) when they registered in the hospital. Next, each age group was further stratified into four second-level strata according to the patients' registration year in hospital. Finally, one-third of the patients' records in each of the 32 final strata (8 x 4 = 32) were selected randomly, using an alphabetical list of patients' surnames.

Each patient's record from the initial sample of 355 was scrutinized on the basis of the following inclusion and exclusion criteria:

1. Dental treatment performed during the 68-month period January 1, 1985, to August 31, 1990, was continuous in the Leeds Dental Hospital, with no treatment rendered elsewhere.

2. The patient was healthy and free of systemic disease or any developmental disturbances of the teeth and jaws that would have affected dietary patterns, caries susceptibility, or the selection of restorative materials to the best of current knowledge.
3. The patient's record was legible, accurate, and complete.
4. One or more definitive restorations were performed in the primary molars in an ambulatory setting.
5. A complete charting at the first visit, and adequate documentation — either narrative or by charting or radiographic history — was available to determine the caries index (dmft status) at the first visit, the treatment dates, the reason for treatment, the tooth treated, the number of surfaces involved, the restorative material that was used, and the operator's name.

Data coding

Each record had two parts; the demographic data and the narrative treatment notes. The dentition charting was present, indicating the decayed, missing and filled teeth, as completed at the first appointment and at most of the review visits. The patient's demographic variables were: gender, date of birth (month and year), registration year in the hospital, and hospital identification number. The restoration variables were:

- Caries index (dmft) at the patient's first appointment
- Patient's cooperation level during the restorative procedure
- Restorative material
- Tooth identification code (FDI)
- Number of tooth surfaces that were restored
- Operator's group
- Number of restorations replaced
- Insertion date of the restoration (month and year)
- Fate of the restoration
- Date of fate of the restoration (month and year)
- Identification code of the restoration
- Use of rubber dam
- Administration of local anesthetic.

The findings from the dentition charting and the oral and radiographic examination (orthopantomogram or bite-wings) at the first patient's visit in hospital were used to measure the sum of decayed, missing, and filled primary teeth (dmft). A tooth was reported missing if it was missing prematurely and the patient's record indicated that the tooth had been extracted due to caries.

Restorative materials

The restorative materials, used in the study period were:

1. Preformed crowns (ion Ni-Chro,® 3M; St. Paul, MN), cemented with zinc polycarboxylate cement (Poly-F Plus,® De Trey/Dentsply; Weybridge, Surrey, UK)
2. Amalgam (Tytin,® Kerr Manufacturing Co.; MI)
3. Composite resin (Occlusin,® ICI Pharmaceuticals; Macclesfield, Cheshire, UK)
4. Glass ionomer (Chemfill II,® Dentsply; Weybridge, Surrey, UK).

Operator's group

The teaching staff, the hospital staff, the postgraduate students, and the undergraduate students working in the child dental health department in the study period placed the restorations.

Fate of the restoration

Each restoration could have one of three possible fates: failed, withdrawn, or censored.

A restoration was failed if it was partially or completely lost; repaired; replaced due to caries in the restored area, mechanical failure, pulp pathology that appeared to stem from the defective restoration, or an unknown reason; extracted due to caries; or subsequently diagnosed as carious.

A restoration was withdrawn if:

- The patient was lost to followup within four months of the last date of the study (censor date August 31, 1990)
- The patient stopped receiving treatment at the Leeds Dental Hospital, or an interval between visits exceeded 12 months
- The restored tooth was exfoliated and in the last visit before the exfoliation the restoration was intact
- The restoration was repaired due to caries in a different surface of the tooth
- The restoration was repaired or the restored tooth was extracted due to pulp pathology, that did not appear to stem from the defective restoration (i.e. an intact stainless steel crown over an unsuccessful pulpotomy)
- The restored tooth was extracted for orthodontic reasons, but it was otherwise healthy.

A censored restoration indicated that it survived intact until the censor date (August 31, 1990) and the patient had attended the hospital continuously.

Restorative technique

The restorative materials were placed according to manufacturer's instructions in traditional cavities or crown preparations using standard armamentarium.[15] The departmental policy was use of rubber dam and local anesthesia whenever possible. From the records, it was estimated that local anesthesia was used on 90% of the restorations and rubber dam on 60%.

Control of the data processing

Although no attempt was made to evaluate the quality of the restorations placed by the teaching or the hospital staff, the placement of restorations by the students (undergraduate and postgraduate) was supervised by a member of the teaching staff. The guidelines on recording information in the treatment sheets were

defined by the Head of Child Dental Health Department, Professor MEJ Curzon. Control over the quality and quantity of the information recorded by the student operator (undergraduate or postgraduate) was performed by the member of staff who supervised the clinic during the treatment.

The recorded values (data) were expected to be in a certain type and in a certain range, according the variable that they described. A program,[16] based on a statistical software package (CMS SAS, release 5.18, SAS Institute Inc.; Cary, NC) was developed to detect any abnormal values or values outside a certain range for every variable in the study. The detected error value was corrected, by comparison with the original one on the patient's record.

For every 50 coded data sheets that had been transferred to the computer, two patient record cards, randomly selected, were entered into the data processing step twice. The new coded data sheets were compared with the original ones to determine the investigator's reproducibility during the processing step.

Data analysis

Estimating survival time of the restoration

The survival time of a restoration was an estimate of the number of months between the placement of the restoration and when it was terminated. The termination date was estimated from the fate of the restoration using the life table method of analysis. Each restoration was compared, in turn, with subsequent treatments of the tooth, until one of the three previously described fates (failed, withdrawn, or censored) could be attributed. If the first subsequent treatment of the tooth did not cause a fate to be decided, it was compared with the next subsequent treatment, until a fate was attributed. Following the above procedure, the termination date was the date of failure, or an unknown date later than the date when the restoration was last seen intact if the fate was withdrawn or censored. The survival time of the "unknown termination date" restoration was calculated using the life table method based upon the last time when the restoration was seen intact, and upon all the available data concerning restorations that have been seen intact at least for defined periods.

Statistical analysis was carried out using a statistical[17] software package CMS SAS in the Leeds University mainframe computer. Descriptive statistics were incorporated to present the study sample characteristics. Survival analysis by the life table method[18] was involved to obtain descriptive graphs of the observed outcome in each restorative material group, which were compared with each other visually. A median survival time (MST), a *P*-value, and survival estimates of the restorations at three, four, or five years were estimated to check if the observed differences between the groups were plausibly just chance. The logrank test, which places more weight upon the later survival times, and the Wilcoxon's test, which places more weight on early survival times, were used. These tests compared the difference between the whole of the survival curves.

Table. Restoration characteristics

Material	*Frequency*	*%*	*Operator*	*Frequency*	*%*
SSC•	183	30%	Hospital Staff	62	10%
Amalgam	198	32	Pg Student	298	49
Composite	173	28	Teach. Staff	80	13
Glass ionomer	50	8%	Ug Student	164	27%
Fate	*Frequency*	*%*	*Patient's Age*	*Frequency*	*%*
Failed	210	34%	3–5 years	312	51%
Withdrawn	281	46%	6–8 years	264	43%
Censored	113	18%	9–10 years	28	4%
dmft	*Frequency*	*%*	*Patient's Cooperation*	*Frequency*	*%*
Low (< 3)	48	7%	Not available	398	65%
Medium (4–7)	289	47%	Negative	8	1%
High (> 7)	267	44%	Fair	39	6%
			Positive	72	11%
			Excellent	87	14%
Replacement	*Frequency*	*%*	*Restored Surface*	*Frequency*	*%*
New	510	84%	One surface	165	27%
First replacement	81	13	Two surfaces	249	41
Second replacement	10	1	Three surfaces	7	1
Third replacement	3	0.5%	Full cover	183	30%
Tooth Type	*Frequency*	*%*	*Sex*	*Frequency*	*%*
First molar	257	42%	Female	311	51%
Second molar	347	57%	Male	293	48%

• SSC = preformed crowns.

Results

Records from 128 patients with data on 604 restorations fulfilled the criteria to be included in the final sample. The frequency and the percentage frequency characteristics of the restorations are presented in the table. The most frequently used material was amalgam at 32%, whereas GI was the least used material at 8%. Almost half of the study restorations were placed by postgraduate students and more than two-thirds of the total restorations were placed by students. Sixty-five percent of the restorations were classified as either withdrawn or censored. The termination date was known in 34% of the failed restorations.

Each restorative material group was stratified further according to the fate that was attributed to the restorations in the group (Fig 1). A higher frequency of failed fate restorations was observed in the GI and composite resin group, whereas a higher frequency of withdrawn fate restorations was observed in the SSC (preformed crown) and amalgam group. More than half of the restorations, 51%, were placed in the 3- to 5-year-old group, whereas only 4% of the restorations were placed in the 9- to 10-year-old group. Five different levels of cooperation during restoration placement were recorded: negative, fair, positive, excellent, and not applicable when no information regarding the patient's cooperation during restoration was found in the patient's record. For the majority of restorations, no information about cooperation during the restoration was found. Cooperation was listed as negative in only eight cases of the 604 restorations. The majority of the known cooperation level restorations, 77%, were of the excellent and positive group. Approximately 92% of the restorations had been placed in patients with a caries index value more than three. The two-surfaces filling was the most frequent type of restoration, 41%, whereas only seven fillings restored three surfaces in seven teeth. The majority of the restorations, 57%, were placed in second primary molars. First-time placed restorations were the most frequent type of replacement (84%). The patients were distributed about equally according to gender.

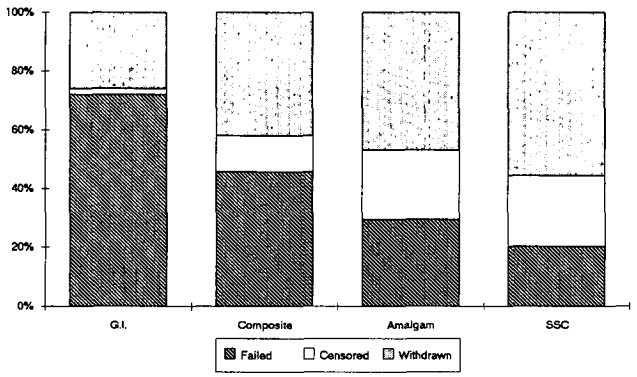

Fig 1. Percentage fate of restorations distribution by restorative material group. SSC = Preformed crowns; GI = Glass ionomer.

Survival estimates of the restorations by restorative material

The descriptive survival curves of the observed outcome in each group of variables were compared with each other visually (Fig 2), and median survival times (MST) with survival estimates of the restorations at three, four, or five years were estimated.[18] The *P*-value was estimated when the logrank and Wilcoxon's tests compared the differences between the whole of the survival curves. A *P*-value < 0.05 was accepted as indicating significant difference between the survival curves. SSC (preformed crowns) had the highest restoration survival rate followed by amalgam, composite, and glass ionomer (GI) restorations. As the examined restorations were followed up over time, the difference between the survival success rates increased. For both statistical tests, the observed differences in the survival curves were highly significant (P = 0.0001). For SSC and amalgam restorations, the MST was more than 5 years and the 5-year survival estimate values were approximately 68% for SSC and 60% for

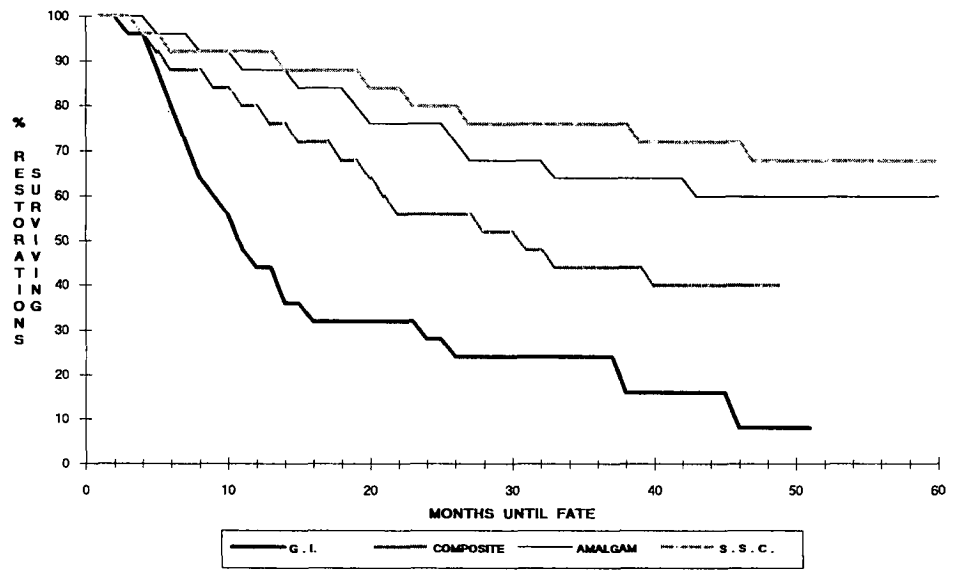

Fig 2. Survival rates of restorations by restorative material. SSC = Preformed crowns; GI = Glass ionomer. (P = 0.0001 by Logrank and Wilcoxon statistical tests).

amalgam. The MST was 32 months for composite and 12 months for GI; the 4-year survival estimates were 40% for composite and 5% for GI.

Investigator's reproducibility

Twenty-five randomly selected patient records were entered in the data processing step twice to determine the investigator's reproducibility during the processing step. This revealed a total of 142 restorations. Eighteen different values were recorded from each restoration. The 142 restorations yielded a total of 2,556 values for the investigator to reproduce. The investigator's reproducibility percentage was 99.21%.

Discussion

Survival analysis of the restorations by restorative material

The main finding of this study was that the order of the survival rate of the restorations, from the higher success to the lower success, with regard to the restorative materials used, was: SSC, amalgam, composite, and GI restorations. Both logrank and Wilcoxon's tests indicated that the observed differences were highly significant ($P = 0.0001$). The difference in survival rate success was small in the first year of the study, but it increased as the restorations were followed up for longer periods. The 4-year survival estimate of the GI restorations was only 5%, when almost 40% of the composite, 60% of the amalgam, and 68% of the SSC restorations survived.

Types of dental restoration longevity studies

Four different types of longevity studies (literature survey, laboratory, practice experience, and clinical studies) have been undertaken in an attempt to estimate the survival rate of dental restorations and to identify factors that could have influenced survival rates. Clinical studies give the most valid impression of the survival rate of dental restorations, because they examine restorations that have functioned in the patients' mouths.

Short-term follow-up studies appear in the dental literature frequently. Nevertheless, the assumption of a relationship between specific restoration defects and the functional time of the restoration, the ideal clinical conditions, and the short-term followup of these studies have been criticized.[19-21] As Maryniuk[19] concluded, this type of study establishes the higher limit of restorative materials success. Cross-sectional studies on the other hand, focus only on the ages of the failed restorations — the intact restorations do not have the opportunity to fail due to study design — and establish the lower limit of a restorative material's success. The most accurate estimate of a restorative material's survival rate can be derived from the longitudinal prospective controlled clinical studies. However, due to the complexity and length of the study organization of these studies, a retrospective longitudinal study has been accepted as the best alternative design. Retrospective studies' limitations are variables such as clinical conditions at the time of treatment, quality of the restoration, operator's technical skill, patient's hygiene, and dietary habits that cannot be controlled.

In a long-term clinical study, a number of cases may be lost to followup (withdrawn), or sometimes the critical event — failure of the restoration — may not happen during the study period (censored). A statistical method that will take account of such cases is necessary in any longitudinal study. The life table method of survival analysis incorporates those cases, achieving a smaller sample variation and statistically more reliable results.

The study population

In a retrospective study, the population characteristics and the method of sample selection are very important to decrease uncontrolled variables and establish sample homogeneity. The computerized organization of the patients' records in the Leeds Dental Hospital was suitable to achieve these goals. A program was developed to identify any patients, 3 to 10 years old, who registered as new patients in the 4-year period, January 1, 1985, to December 31, 1988, and who attended the Dental Hospital at least once in the 2-year period February 1, 1989, to January 31, 1991. The restorative material, restorative techniques, fate, and the patients' age variables were controlled. The restorative techniques and the quality control of the restorations were constant as the head of the department, the teaching staff, and the teaching methods of restorations were constant.

The censored and withdrawn restorations were decreased, as all the patients of the study had attended the hospital at least twice. The initial appointment occurred in the 4-year period and further appointment occurred in the remaining 2 years of the study period, for the computer to identify the patients' cards. Restorations placed after the December 31, 1988, were not examined, so the censored restorations' fate was even more decreased. In addition, since the upper age limit of patients included in the study was 10 years old, the fate of the censored type of restorations — due to exfoliation of the restored tooth in a short period — was kept low.

The sample selection

A multistage, stratified, random sampling technique was used to ensure that the sample was representative of the study population. To reduce the sampling error below that for a single random sample, the variables age and year of registration were used to stratify the patient population. By sampling within the strata (age, year of registration) and then combining the results according to each stratum contribution to the total population, the sample selection was completely free of the variability between the strata group, however great.[14]

Furthermore, since the patients' age is a significant factor, it was desirable to keep this variable uniformly distributed in the sample. In a similar way, the registration year variable was distributed uniformly in the sample in an attempt to include an equal number of restorations for each year (1985–1989) of the study period. Also, this sampling method avoided a major possible contribution of the last years' (1987–1988) restorations, which could have created a large amount of censored fate restorations. Control over some variables (e.g., patients' age and year of registration, the decreased amount of withdrawn and censored data, and the reduction of the necessary time for the study) were the reasons for the present sampling method. The final sample was 128 patients' records, showing data on 604 restorations. Although this size was derived from a sampling procedure on the study population, it still compares satisfactorily with the population size of other studies. It is larger than Braff's[1] population size of 39 patients with 226 restorations, and Dawson et al.'s[4] study of 114 patients with 113 restorations, and it is smaller than Wong and Day's[23] 345 patients with 1,510 restorations, and Roberts and Sherriff's[3] study of 1,697 primary teeth restorations.

GI restorations

The poor performance of the GI restorations likely isn't due to underestimation of the life table method of analysis, since the percentage of censored and withdrawn GI restorations (28%) was smaller than the censored and withdrawn restorations with composite (54.33%), amalgam (70.70%), and SSC (79.78%). The GI material used in the pediatric dental clinic during the study period is mixed manually, so one possible explanation of the poor performance could be the inadequate mixing ratio of the powder/liquid. This is supported by a recent investigation by Billington[24] who reported that the mean powder/liquid ratio mixing of this material was 5.0:1 compared with the manufacturer's recommended ratio 6.8:1. When the GI material was tested at the mean ratio used in practice, the compressive and the diametrical strengths were about half the values found at the manufacturer's recommended ratio. Only three controlled clinical studies have been performed to test appropriate suggestions for GI use.

When Fuks[28] compared the clinical performance of a GI material in Class II restorations in primary molars with control amalgam restorations, she reported an extremely high failure rate — only nine of 101 initially placed GI restorations met all quality criteria — at the one-year examination. Although, this high failure rate rendered the comparison with amalgam meaningless, it is worthwhile to mention that 90% of the amalgam controls in 3 years time met all the evaluation criteria.

When the GI restorations were compared with lathe-cut amalgam restorations after 2 years, no significant differences in overall failure rate were reported in the Newcastle study.[25] Nevertheless, it was evident that the GI restorations underwent greater loss of anatomical form than amalgams. When Welbury[26] added 65 pairs of restorations to the previous study and reported the results after following up the total of 119 pairs for 5 years, he reported that the GI restorations had worse survival time than amalgam. The reported difference between the GI and the amalgam median survival times was 8 months in the Welbury study,[27] compared with more than 4 years in the present study.

Some factors that could have attributed to the higher success of the GI restorations in the Welbury study[26] may include fewer operators, placement in older children, use of encapsulated material, an optimally fluoridated study site, and comparison with conventional rather than high-copper alloy.[26]

Composite restorations

The composite restorations' survival rate was better than GI but worse than amalgam and SSC restorations. The patients' young age in this study — predominantly 3- to 5-year-old children — might have contributed to the increased failure rate. Tooth isolation is very important in composite restorations, and is sometimes difficult to achieve if the patient is very young. If the patient is very young or uncooperative, this could lead to a poor quality composite restoration. The majority (99) of the composite restorations in this study were Class II, compared with 70 Class I composite restorations, so an explanation of some of the failures could be the high incidence of marginal leakage around the Class II restorations. Fuks[29] reported that when 13 exfoliated primary molars were assessed according to the degree of marginal leakage around Class II composite restorations, only one had no evidence of dye penetration, but the majority of the other restorations showed mild to moderate or severe penetration.

Salama and Liwen[30] suggest an explanation for the failures of composite restorations in primary teeth. They found that the dentin bonding agents achieved significantly lower bond strengths in primary teeth than in permanent teeth.

The only longitudinal study in the literature using life table analysis that examined composite restorations in primary teeth was done by Varpio.[9] No control amalgam restorations were used in the study, but the 5-year survival rate (38%) and the median survival time (40.8 months) can be compared with our study's 4-year survival rate (40%) and median survival time (32 months).

Amalgam and SSC restorations

In the first seven to eight months, amalgam had fewer failures than SSC restorations. After this period and until the end of the study, SSC restorations were superior to amalgam restorations. The early low survival rate of SSC restorations could be explained by cementation failure. Once the SSC cementing is successful, the survival expectation of the restoration is

better than an amalgam restoration. The literature supports that the SSC has a more successful survival rate than amalgam restorations.[1, 3–5, 22]

The results of this study can only be compared with Roberts and Sherriff,[3] who used a similar method of analysis. They reported a 5-year survival estimate for the SSC of 92–94% and for the amalgam restorations of 66–73%.[3] In this study, the 5-year survival estimate for the SSC was 68% and for the amalgam, 60%. The higher success in Roberts and Sherriff's[3] study could be explained by Roberts' greater familiarity with treating children — he is a specialist pediatric dentist with many years of experience — or that he judged his own work. Also, the lower caries incidence in London, where the Roberts and Sherriff study[3] was carried out, compared with the caries incidence in the Yorkshire region, may explain part of the difference between the two studies.

Although our study cannot estimate accurately the absolute survival time of each restorative material group, because of the limitations of a retrospective design and the amount of subjects lost over time, it still satisfactorily compares the relative success and survival rate of each material in time.

Conclusions

1. The order of survival rate of the restorations, from the higher to the lower success, was preformed crowns, amalgam, composite resin, and glass ionomer restorations.
2. The difference between the survival success rate increased with time.
3. The MST for preformed crowns and amalgam was more than 5 years. The 5-year survival estimate for preformed crowns was 68% and for amalgam was 60%. The MST for composite was 32 months and the 4-year survival rate was 40%. For GI, the MST was 12 months and the 4-year survival rate was 5%.

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