Analyses of long-term clinical behavior of class-II amalgam restorations

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The purpose of the study was to estimate the influence of different clinical variables on the replacement rate of class-II amalgam restorations in permanent teeth. The study included 210 patients who had 468 restorations placed by 7 Scandinavian dentists. The observation periods varied between 7 and 10 years. At the time of the last recording 188 restorations remained intact in 88 patients, whereas 68 restorations in 53 patients had been replaced. Eighty-six patients with 212 restorations had dropped out of the study. The most prevalent criteria for replacement were secondary caries ($n = 30$) and restoration bulk fractures ($n = 24$). Chi-square analyses of the relationship between the prevalence of replacements and the clinical variables indicated effects of the operator and the patients' age and caries activity ($p < 0.001$). Similar results were observed when the functional time of the restorations was related to the clinical variables and analyzed by ANOVA and MCA analyses and by survival analyses using logrank and Wilcoxon tests ($p < 0.001$). The survival analyses using the Lee–Desu statistic D showed in addition a slight difference between the restorations in the lower premolars and upper and lower molars. There were no differences in the clinical performance between four non-gamma-2 alloys and one conventional alloy. Furthermore, no differences were noted between the survival rates of MO, DO, and MOD restorations. In a Cox regression model the strongest effects on the estimated survival rates were associated with the patients' age and caries activity covariates (global chi-square = 23.5, df = 2, $p < 0.001$), whereas the effects of the operator and the other clinical variables were insignificant. □ *Amalgam degradation; clinical study; dental materials; operative dentistry; replacement reasons; survival statistics*

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The long-term clinical behavior of dental restorations has been assessed by means of various methods. Two different approaches are available: longitudinal and cross-sectional clinical studies. Longitudinal studies rarely exceed 5 years' observation period and have an inherent problem in that patient dropout becomes a major problem with time. Consequently, many clinical studies have focused on specific clinical characteristics of the restorations in situ, such as marginal adaptation and tarnish behavior, over short observation periods, with the assumption that a relationship between such defects and the functional time of the restoration exists. However, such extrapolations are of questionable value and scientifically disputable. Cross-sectional studies include descriptions of the distribution of the ages or the morphologies of restorations in situ, or of restorations diagnosed for replacement and sometimes also combined with the criteria for replacement (Table 1). Another method used is survival analysis, when there is access to dental records that show all the treatment performed over several years. This method has also in some studies been combined with the criteria for replacement (Table 2).

In a previous report it was shown that the design and average size of the cavity preparations differ among operators, as does the frequency of discrepancies (37, 38). It has also been demonstrated that the degradation of the restoration margins was influenced by these cavity design variables (39) and by the operator (40). However, it is uncertain whether the cavity preparation or the marginal degradation could also affect the long-term clinical performance of the restorations.

The aim of the present study was therefore

Table 1. Criteria for replacement of amalgam restorations reported in cross-sectional surveys

Author (Ref.)	Country	Year	Secondary caries	Marginal integrity	Fracture: Restoration	Fracture: Tooth	Other	Clinic	Patient age, years	Class	No. of teeth: Decid.	No. of teeth: Perm
Healey & Phillips (1)	USA	1948	54	19	26		1	D. school			0	1521
Moss (2)	USA	1953	54	←	35	→	11	Military	19–27		0	1000
Allan (3)	U.K.	1969	← 68	→	4	6	22	D. school			← 201	→
Barnes (4)	USA	1973	58	←	37	→	5	Military	17–66		0	625
Richardson & Boyd (5)	Canada	1973	68	7	9	7	9	Gen. pract.	Av. 26		131	1512
Lavelle (6)	Canada	1976	54	21	24		1	Gen. pract.	20–40		0	6000
Dahl & Eriksen (7)	Norway	1978	53	← 33	→	0	14	Student		II	← 200	→
Mjör (8)	Sweden	1978	54	10	13	12	11	Gen. pract.			← 1443	→
Mjör (9)	Sweden	1979	65	8	12	10	5	Gen. pract.			← 1061	→
Rytömaa et al. (10)	Finland	1984	← 23	→	38		39	Student	Av. 20		0	73
Klausner et al (11)	USA	1985	53	13	13	11	8	Gen. pract.		All	← 2146	→
			56	12	20	9	3	Gen. pract.		II	← 1234	→
Mjör (12)	Norway	1985	72	←	28		→	Gen. pract.			50	587
Boyd & Richardson (13)	Canada	1985	50	23	9	8	10	Gen. pract.	Av. 34		183	3479
Mjör & Åsenden (14)	Norway	1986	46	28	14	7	15	Nat. H. Ser.	6–18		0	236
Qvist et al. (15)	Denmark	1986	22	14	38	6	20	Gen. pract.		II	← 1064	→
Klausner et al. (16)	USA	1987	53	17	8	13	9	Gen. pract.		All	← 2996	→
			54	18	13	10	6	Gen. pract.		II	← 1137	→
Present study	Scandinavia		44	4	35	12	4	Gen. pract.	8–71	II	0	468

Table 2. Estimated survival of amalgam restorations in permanent teeth reported in longitudinal clinical studies and in cross-sectional retrospective studies

Author (Ref.)	Country	Period	Restorations remaining (%)			Survival time (year)		Patients/ restoration, no.	Clinic	Restoration type	Operators	Method
			5 years	10 years	20 years	50%	75%					
Allan (3)	U.K.	1952–67		38				–/887	Gen. pract./mil.	Class I and II		
Allan (17)	U.K.	1954–69	55	20		5		31/93	Gen. pract			
Allan (17)	U.K.	1951–71	73	36	15	8		47/148	Gen. pract.			
Robinson (18)	U.K.	1948–71	83	55	23	11		43/145	Gen. pract.		1	*
Lavelle (6)	Canada	1953–73	80	50	10	10		400/536	Gen. pract.		3	*
Walls et al. (19)	U.K.	1971–76	57	36		6		409/1031	Dental hosp.		Students	*‡
Hunter (20)	U.K.	1949–76	70	48	30	10		113/5354	Gen. pract.		1	*‡
				74		28		113/3754	Gen. pract.		1	
Gray (21)	U.K.	–80				10		513/6731	Military		>10	
Osborne (22)	USA	1970–78				8		22/113	Dental school		1	
Crabb (23)	U.K.	1969–79	65	44		9		155/1018	Dental hosp.			
Hamilton (24)	USA	1969–79	53	30				77/209	Gen. pract.		1	*†
Elderton (25)	U.K.	1978–83	46			<5		720/1206	Dent. Estim. Board			*‡
Paterson (26)	U.K.	1967–83	67	34		8		200/2344	Nat. Health Serv.		16	*‡
Meeuwissen (27)	Holland	1958–77	70	50		10		1000/8492	Military			*‡
Milen (28)	Finland	1975–85	71	50		10		217/933	Child Nat. Dent. S.			*‡
Bentley (29)	USA	1970–85	88	72		15		70/433	Dental college		Students	*‡
Arthur (30)	USA	1965–87	92	83	70	>22		327/1198	Military			‡
Robbins (31)	USA	–88	80	54	19	11	6	171/171	Military	Complex		‡
Arthur (32)	USA	–88	91	77	52	>20	12	1211/6141	Military	Class II		‡
Moffa (33)	USA	–88				13		–/1727	Dental school	Class II		‡
Laswell (34)	USA	1977–88		84		34		47/160	Dental school		2	
Letzel (35)	Holland	1974–88	90					414/2660	Dental school	Cl. I and II	5	
Roberson (36)	USA	1983–88	98					–/1200	Dental school			‡
Present study		1979–89	89	81		>		210/468	Gen. pract.	Cl. II	7	‡

* Converted restorations and extracted teeth included as failures.
† Patient drop-out included as failures.
‡ Life-table analysis.

to identify the variables that influence the functional period of the restorations and to assess a possible relationship between these variables and the different criteria for replacement. A conjoint report will analyze the effects of the cavity preparation variables, whereas the present report will focus on other clinical variables.

Materials and methods

Seven dental practitioners from Denmark, Finland, Norway, and Sweden agreed to participate in a longitudinal clinical study. Three dentists were in private practice, two in a public health practice, and two in the school dental service. Their clinical experience varied from 15 to 30 years. Each operator randomly selected the participants for the study among their regular patients. The age of the patients varied from 8 to 71 years, with a mean age of 28 years at the start of the study. For operators 1 and 2 the mean patient ages were 12 and 16 years, and for the other operators mean patient ages varied from 36 to 40 years at the start of the study. The need for restorations could be due to primary caries or to replacements of old restorations. The operators placed 468 class-II restorations in 210 patients in their clinics between December 1979 and January 1983. One hundred and forty-seven of these were three-surface restorations, whereas the other restoration types were MO ($n = 168$), and DO restoration ($n = 153$). The number of patients and restorations per operator varied between 9 patients with 17 restorations to 52 patients with 104 restorations. The number of restorations per patient varied from 1 to 12 (Table 3). No instructions on preparation techniques were issued in advance. The cavities are therefore considered to reflect the clinical situation in everyday dental practice. Further details of the dimensions and average quality of the cavity preparations have been described (37, 38).

A conventional amalgam alloy (Revalloy, SS White Ltd., U.K.) and four non-gamma-2 precapsulated alloys (Amalcap Non gamma 2, Vivadent, Germany; Dispersalloy, Johnson & Johnson, USA; Indiloy, Shofu Dental Corp., Japan; and Tytin, SS White Ltd., U.K.) were selected for the study. Each clinician used three alloys, except one operator who used only two alloys (Table 4). The alloys were randomly assigned to the teeth to be restored. The operators were informed not to deviate from their common clinical routines and to follow the manufacturers' instructions for handling of the materials.

The patients have been recalled regularly each year for examination of their dental status, including the restorations in the present study, using the USPHS criteria. Impressions were made of the restorations at base line, after 6 months, and then annually during the first 5 years, to study the degradation of the occlusal margins.

The patients were classified into three groups on the basis of their caries activi

Table 3. The number of patients per operator and the number of restorations per patient

	No. of restorations placed in each patient									Total	
Operator	1	2	3	4	5	6	7	9	12	Patients	Restorations
Operator 1	34	15	2		1					52	75
Operator 2		4	2	2	4	1	3	1		17	78
Operator 3	3	4	2							9	17
Operator 4	25	14	4	7	1	1				52	104
Operator 5	15	13	4	3						35	65
Operator 6	17	4	7	2		1				31	60
Operator 7			6	1	3	1	2		1	14	69
Sum	94	54	27	17	9	4	5	1	1	210	468
Percentage (%)	44.8	25.8	12.9	7.1	4.3	1.9	2.4	0.5	0.5		

Table 4. Alloys used in the present study and the distribution of restorations for the seven operators

	Alloy				
	Amalcap	Dispersalloy	Indiloy	Revalloy	Tytin
Operator 1			25	28	22
Operator 2	26			28	24
Operator 3		5	6	6	
Operator 4	35	34			34
Operator 5		19	23	23	
Operator 6			24	36	
Operator 7	24	23		22	
Sum	85	81	78	143	81
Percentage (%)	18.2	17.3	16.7	30.5	17.3

The caries activity was estimated by the incidence of primary or secondary caries during the first 8 years of the trial period. Zero to 0.5 new restorations per year was defined as a low caries activity, whereas more than 2 new restorations per year suggested a high caries activity.

In case of restoration replacement, the date of loss and criterion for replacement were recorded. A seminar had been arranged before the trial to orient the operators about the indications for replacement in accordance with the USPHS criteria. The functional time was calculated as the number of months between the placement of the restoration and the time of replacement, if

Table 5. Listing of clinical variables and categorization levels of the variables in the statistics

Independent variables	Categorization level
1. Operator number	(1), (2), (3), (4), (5), (6)
2. Patient caries activity	Low: caries incidence the first 8 years = 0–0.5
	Medium: caries incidence the first 8 years = 0.5–2
	High: caries incidence the first 8 years = >2
3. Patient age	Age at time of placement:
	Alt. 1: (8) ⟶ (71),
	Alt. 2: (1) 8–18 years, (2) 18–38 years, (3) >38 years
4. Type of alloy	(1) Revalloy, (2) Amalcap, (3) Tytin, (4) Dispersalloy, (5) Indiloy
5. Restoration location	Alt. 1: 14, 15, 16, 17, 18, 24, 25, 26, 27, 28, 34, 35, 36, 37, 38, 44, 45, 46, 47, 48
	Alt. 2: (1) 14, 24, (2) 15, 25, (3) 16, 26, (4) 17, 27, 18, 28, (5) 34, 44, (6) 35, 45, (7) 36, 46, (8) 37, 47
	Alt. 3: (1) 13, 14, 15, 23, 24, 25, (2) 16, 17, 18, 26, 27, 28, (3) 34, 35, 44, 45, (4) 36, 37, 46, 47
6. Restoration type	MO, DO, MOD
7. Patient gender	(1) Female, (2) Male
8. Restoration status	(1) In situ, (2) Lost owing to patient drop-out, (3) Replaced owing to caries, (4) Replaced owing to bulk fractures, (5) Replaced owing to tooth fracture, (6) Replaced owing to margin ditch, (7) Replaced owing to other reasons.
9. Margin 0	Marginal integrity, base line, (1) Good; (2), (3), (4), (5), (6) Poor
10. Margin h	Marginal integrity after 1/2 years, (1), (2), (3), (4), (5), (6)
11. Margin 1	Marginal integrity after 1 year, (1), (2), (3), (4), (5), (6)
12. Margin 2	Marginal integrity after 2 years, (1), (2), (3), (4), (5), (6)
13. Margin 3	Marginal integrity after 3 years, (1), (2), (3), (4), (5), (6)
14. Margin 4	Marginal integrity after 4 years, (1), (2), (3), (4), (5), (6)
15. Margin 5	Marginal integrity after 5 years, (1), (2), (3), (4), (5), (6)
16. Patient	Patient number, (1) ⟶ (210)
17. Patient restoration	Restorations placed in each patient, (1) ⟶ (12)

the date was known. If the date was unknown, the time of replacement was the date of the last observation in which it was recorded as successful.

Three different statistical techniques were used to estimate the relationships between various clinical variables and the prevalence and criteria for replacement and functional time. The clinical variables and their codings are shown in Table 5. The variations in the design, size, and quality of the individual cavity preparations were not included in the present analyses and will be presented in another report. The relative influence of each variable on the functional time was estimated by analyses of variance (ANOVA), after the interaction effects of the variables were corrected by means of a multiple classification analysis of variance (MCA), with calculations of beta (39). The statistical analyses were computed using the samples of restorations that survived at the end of and those that were replaced during the observation period ($n = 188 + 68$).

The data on the functional time of the restorations were also analyzed with survival analyses. Both the product-limit method (Kaplan–Meyer) and the actuarial method (Cutler–Ederer) were applied. The equality of survival curves for different group levels of the clinical variables was tested with the generalized Wilcoxon statistics (also called the Breslow test or the Gehan test), and the logrank test (also called the generalized Savage statistic or the Mantel–Cox test) (40). Subgroup comparisons were calculated with the D statistic (41). Cox's regression model for survival data (42) was also used, to estimate the functional time while correcting for interrelationship among the clinical variables (Table 5, variables 1 to 8). In the first survival analyses random samples of only one restoration from each patient was used and compared with the results using all the restorations as a sample. No differences were noted between the survival statistics when using the individual patient or the individual restoration as the statistical unit. The individual restorations were therefore used as the statistical unit in the survival analyses.

Chi-square analyses were applied on the prevalence of the different criteria for

Table 6. Cross-tabulation of the 210 patients by the number of restorations placed in each patient and by the patient compliance in the study and occurrence of restoration replacement. The digits in parentheses show the number of replacements ($n = 68$) in each patient group

Patient compliance	Replacements	No. of restorations placed in the patient									Sum	
		1	2	3	4	5	6	7	9	12		
Dropped out	No	42	23	10	4	2	1	3	1		86	
Dropped out	Yes		5 (5)	4 (5)	5 (8)	1 (2)	1 (1)				16 (21)	102
All restorations replaced		17 (17)	2 (4)		1 (4)						20 (25)	
Remaining	Yes		4 (4)	2 (2)	2 (3)	4 (7)	2 (3)	2 (2)		1 (1)	17 (22)	
Remaining	No	35	20	11	3	2					71	88
Sum		94 (17)	54 (13)	27 (7)	15 (15)	9 (9)	4 (4)	5 (2)	1	1 (1)	210 (68)	

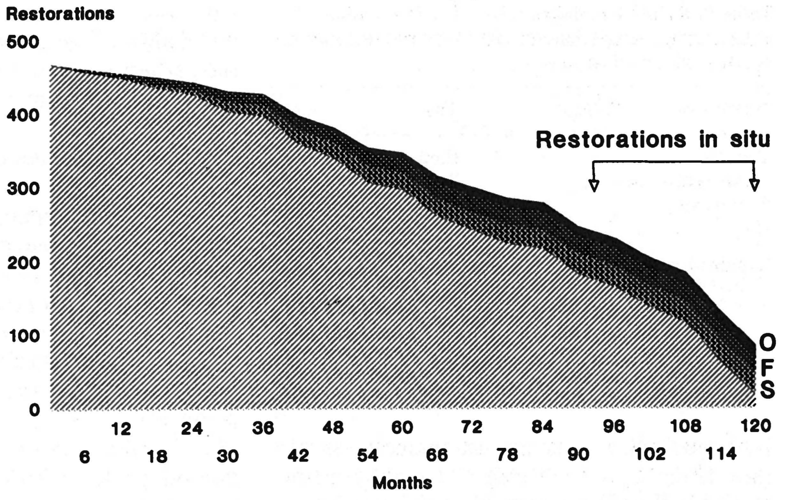

Fig. 1. The proportions of restorations remaining in the study (light shadow) and of replaced restorations (dark shadows) in relation to the age of the restorations; $n = 468$ at the start of the study. The letters represent the criteria for replacement: S = secondary caries, F = restoration bulk fractures, O = other reasons. The two arrows show the functional time of the restorations in situ at the last time of recording.

replacements at yearly intervals up to 7 years and the grouped levels of the clinical variables (Table 5, variables 1 to 8).

Results

By April 1990, 88 patients with 188 original restorations remained in the study. The observation sample as function of time is shown in Fig. 1. The main reason for the loss of restorations was the dropout of 102 patients, accounting for the loss of 212 restorations. Most of these were patients of the two operators in the school dental service (operators 1 and 2). In 53 patients 3 restorations were included in larger restorations, and 65 restorations were replaced because of caries or fractures of the restoration or the tooth. A cross-tabulation of the 210 patients by the number of placed restorations per patient, varying from 1 to 12 restorations, and by the patient compliance in the study is depicted in Table 6. The data in the table show that 16 patients who later dropped out of the study accounted for 21 of the replacements. Twenty patients had had all their restorations replaced ($n = 25$), and 17 of the patients who remained in the study had had 22 restorations replaced.

The ANOVA analysis of the functional time of the restorations as a function of various clinical variables is presented in Table 7. The operator effect was marked also after a multiple classification analysis (MCA analysis). The strong individual effects of the patients' age and caries activity on the functional time, as shown by the one-way analysis (eta), were reduced when the effects of the clinical variables were adjusted to each other (beta). The effects of the location or type of restoration, the type of alloy, and the patient gender were small. About 47% of the variance of the dependent variable—the functional period—was explained by the multivariate model of the clinical variables (Table 7).

A life table of the estimated survival pattern is given in Table 8. The analyses showed a 90% survival (SE, 1.4) at 48 months, and 81% (SE, 2.2) at 114 months. Three comparative survival analyses, using random samples with only one restoration from each patient, showed a survival pattern similar to that of the whole material (Fig. 2). The fate of the restorations in the three samples and in the whole sample was 15–16% failures, 39–40% lost due to patient drop-out, and 44–47% censored restorations.

Paired comparisons showed statistically significant differences between the survival patterns dependent on the operator, the patient age (Fig. 3), and caries activity (Fig. 4) ($p < 0.001$). The survival functions varied among the alloys, but the difference between the four non-gamma-2 alloys and the con-

Table 7. Relative strength of the effect of clinical variables on the average functional time of the restorations: MCA analysis of variance

Independent variables	Eta	Beta
Operator	0.66	0.48
Patient caries activity	0.56	0.26
Patient age	0.52	0.18
Alloy	0.12	0.08
Restoration location	0.26	0.10
Restoration type	0.17	0.08
Patient gender	0.11	0.04

$R2 = 46.7\%$.

ventional alloy was not statistically significant (Fig. 5) ($p = 0.08$). The restorations placed in the lower premolars showed longer survival than the restorations placed in the upper and lower molars ($p < 0.05$), but overall comparisons were not statistically significant. The survival function was similar for the MO, DO, and MOD restorations ($p > 0.05$) (Table 9). When the data were subjected to the Cox regression model, effects were associated with the patients' caries activity (chi-square = 18.7, $p < 0.001$) and the patients' age (chi-square = 4.6, $p < 0.001$). The effects of the operators and the other clinical variables were not statistically significant in the regression model ($p > 0.05$).

Secondary caries on the proximal surface and bulk fractures were the predominant criteria for replacement (Fig. 6). A certain relationship between the individual replacement criteria can be noted for the patients with multiple replacements, but definite conclusions are uncertain owing to the small number of observations (Table 10). The incidence of replacements and the criteria for replacement varied among the operators (Fig. 7); for example, secondary caries was diagnosed frequently by operators 1 and 2 and seldom by the other operators. Operators 2 and 4 had made 17 of the 24 restorations that fractured, besides the 4 restorations replaced owing to poor marginal integrity.

The chi-square analyses of the prevalence of the different criteria for replacement and the clinical variables identified the variables age and caries activity of the patient and the operator as the most important (Table 11).

Table 8. Actuarial life table for 468 class-II amalgam restorations

Period (months)	Restorations entering time period	Restorations not surviving	Restorations withdrawn	Estimate of cumulative proportion surviving	Standard error of proportion surviving
0–6	468	3	7	0.99	0.004
6–12	458	3	6	0.99	0.005
12–18	449	8	5	0.97	0.008
18–24	436	2	7	0.96	0.009
24–30	427	10	14	0.94	0.011
30–36	403	3	3	0.93	0.012
36–42	397	8	30	0.92	0.013
42–48	359	3	16	0.91	0.014
48–54	340	6	28	0.89	0.015
54–60	306	3	7	0.88	0.016
60–66	296	4	32	0.87	0.017
66–72	260	4	14	0.86	0.018
72–78	242	2	17	0.85	0.019
78–84	223	3	4	0.84	0.020
84–90	216	2	33	0.83	0.020
90–96	181	2	15	0.82	0.021
96–102	164	2	26	0.81	0.022
102–108	136	0	21	0.81	0.022
108–114	115	0	54	0.81	0.022
114–120	61	0	61	0.81	0.022

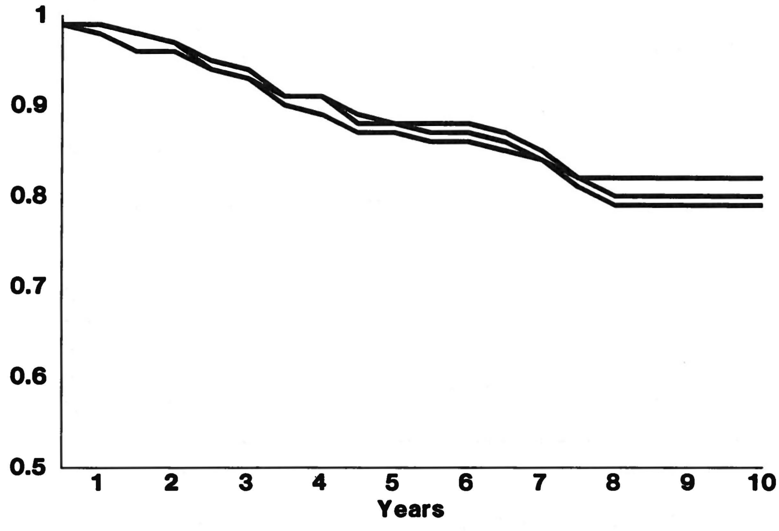

Fig. 2. The estimated survival period of class-II amalgam restorations up to 10 years on the basis of one restoration from each patient. Three samples with one randomly chosen restoration from each patient; *n* = 210.

The prevalence of secondary caries thus showed a good correlation to the general caries activity of the patient.

The four non-gamma-2 alloys and the conventional alloy did not differ in incidence of and criteria for replacements. The criteria for replacement varied slightly; for example, the 24 bulk fractures did not include the restorations made from one specific non-gamma-2 alloy (Fig. 8). The marginal integrity on the occlusal surface of the restorations that were lost during the first 5 years of the study could not be correlated to any specific criterion for replacement. However, the prevalence of restoration and tooth fractures tended to be higher in the group with more degradation (Table 12). The marginal integrity score at 5 years could not be correlated to any specific criterion for replacement of the restorations that later were replaced. On the other hand, the frequency of replacements was higher in the group with the worst marginal integrity score at 5 years, compared with the other restorations (Table 12). The

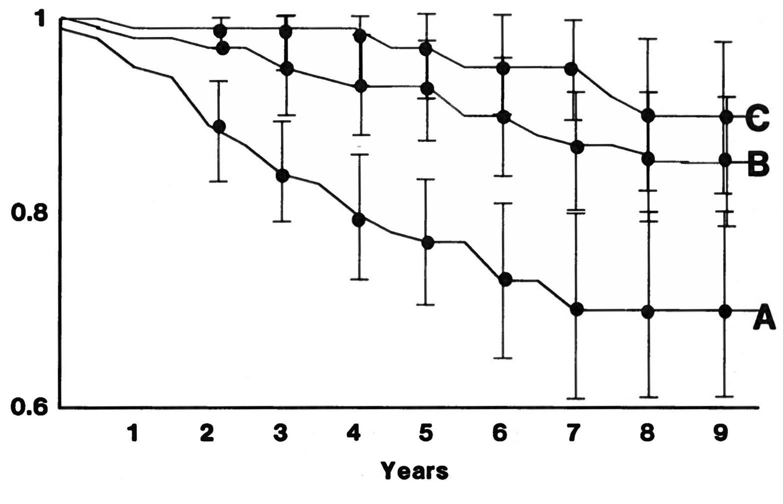

Fig. 3. The estimated survival periods of class-II amalgam restorations as a function of the patients' age. The horizontal sloping lines indicate three different age groups of patients at the time of the insertion of the restorations. A = <18 years (*n* = 181), B = 18–38 years (*n* = 214), C = >38 years (*n* = 73). The vertical lines show the 95% confidence intervals (±1.96 SE).

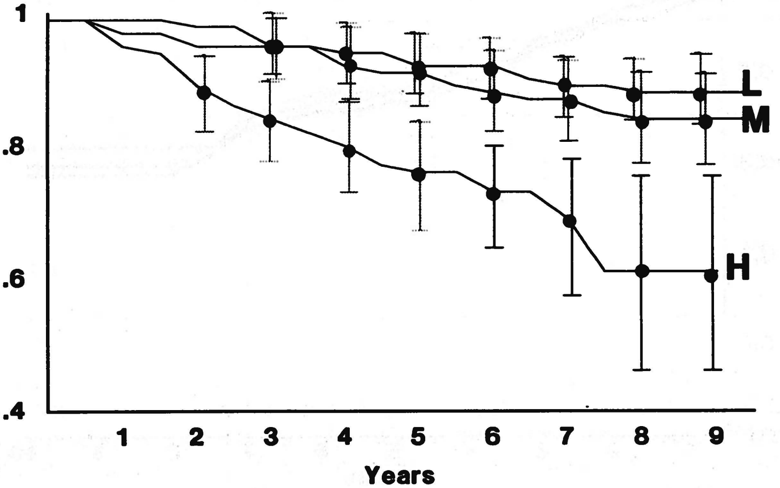

Fig. 4. The estimated survival periods of class-II amalgam restorations as a function of the patient caries activity. The horizontal sloping lines indicate three groups of patients with different caries activity throughout the 10-year trial. L = zero to 0.5 new restorations per year (low, $n = 160$), M = 0.5 to 2 new restorations per year ($n = 152$), H = more than 2 new restorations per year (high, $n = 156$). The vertical lines show the 95% confidence intervals (±1.96 SE).

seven restorations with poor marginal integrity at 5 years that were later replaced failed because of tooth fractures ($n = 2$), bulk fractures ($n = 3$), marginal fractures ($n = 1$), and secondary caries ($n = 1$).

Discussion

The reasons for replacement of restorations and, inversely, the functional times of the restorations are obviously influenced by many clinical variables. The two factors have been related to the restorative material, the technical quality of the restoration, the degree of the patient's compliance, and the styles of practice attitudes and professional values of the clinicians (43). The relative importance of each clinical variable can be measured for a group of restorations, but the validity of the conclusions from such studies is uncertain (44). When assessing individual restorations, it is also questionable whether one specific variable can be singled out as more important than the others.

Since the primary aim of the study was to assess the restoration performances in a representative sample of patients and oper-

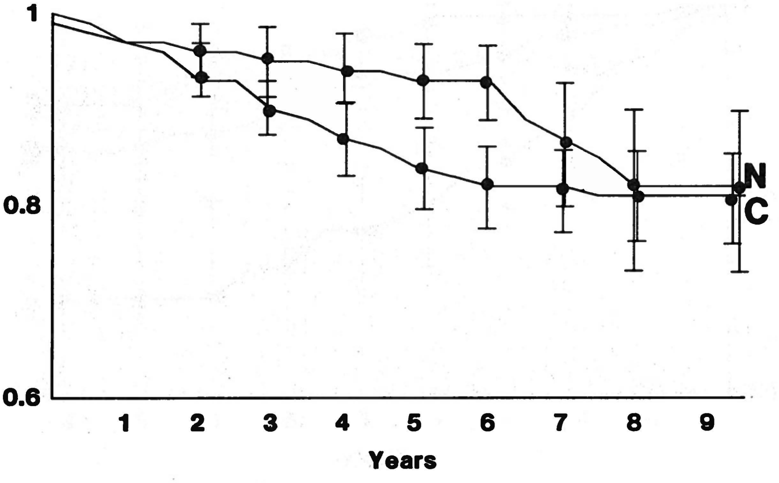

Fig. 5. The estimated survival periods of class-II amalgam restorations as a function of the type of alloy. The horizontal sloping lines indicate two types of amalgam alloy. N = non-gamma-2 alloys ($n = 325$), C = conventional alloy ($n = 143$). The vertical lines show the 95% confidence intervals (±1.96 SE).

Table 9. Paired comparisons of survival experience using the Lee–Desu statistics, the logrank (Mantel–Cox) test, and the generalized Wilcoxon (Breslow) test. DF = degrees of freedom.

		Lee–Desu		Logrank		Wilcoxon	
	DF	D	*p*	$\bar{X}$	*p*	$\bar{X}$	*p*
Operator	6	43.8	<0.001	54.2	<0.001	47.9	<0.001
Patient caries activity	2	18.7	<0.001	21.0	<0.001	22.8	<0.001
Patient age	2	23.3	<0.001	22.1	<0.001	23.7	<0.001
Alloy	4	11.6	0.02	10.3	0.03	10.3	0.03
Restoration location	3	8.7	0.03	6.4	0.09	6.3	0.09
Restoration type	2	2.6	0.28	3.1	0.21	2.5	0.28
Patient gender	1	0.5	0.46	0.8	0.36	0.5	0.47

ors, it was not possible to check the independence of each variable across the study sample. Thus, the interaction between the variables introduced limitations to the range of possible statistical tests. Three different statistical methods were, therefore, chosen to complement each other.

The selection of the patient or the individual restoration as the experimental unit for the statistical assessment has been discussed in several clinical studies (45, 46). The estimated survival time of restorations in primary molars may vary depending on whether the experimental unit is the restorations or the patients (46). The authors did, however, comment that this effect could have been caused by the inclusion of highly caries-active patients in the study sample. In the present study the statistical assessments of the three samples with one restoration from each patient did not differ from that using all the restorations as the experimental unit. The data thus suggest that estimation of cumulative survival may be performed by using restorations as the experimental units, as long as the study sample does not include patients with extremely high or low caries activity.

Until recently, various reports in the literature concluded that the median functional period of amalgam restoration varied between 5 and 8 years (Table 2). This somewhat short life span was estimated by the age distributions of replaced failed amalgam restorations in cross-sectional studies (8, 9, 15), by using statistical techniques that possibly underestimated the correct survival time in longitudinal studies (18, 23), or was based

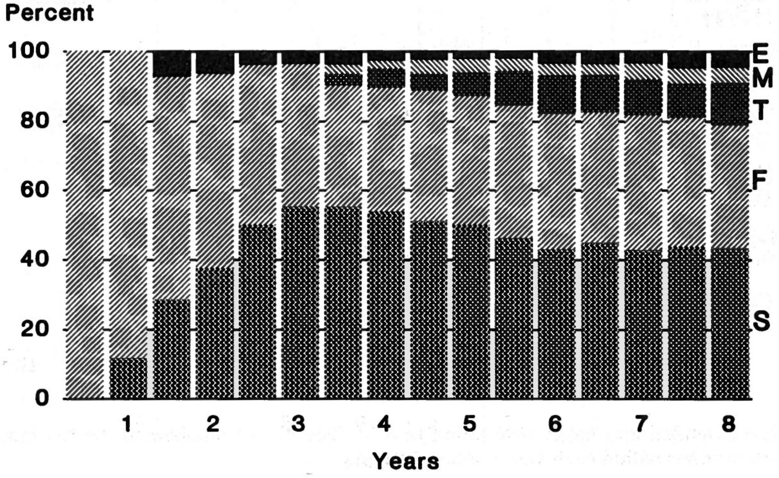

Fig. 6. Cumulative relative frequencies of the replaced restorations ($n = 68$) in accordance with the criteria for replacement and in relation to the age of the restorations. The letters represent the criteria for replacement. S = secondary caries, F = restoration bulk fractures, T = tooth fractures, M = restoration marginal fractures, E = extended into larger restoration.

Table 10. Criteria for replacement in accordance with the number of replaced restorations per patient (1 to 4). Each letter denotes one replacement. S = secondary caries, F = restoration bulk fractures, T = tooth fractures, M = restoration marginal fractures, E = included in larger restorations

Restorations replaced	Patients	Criteria for replacements
1	43	SSSSSSSSSSSSSSSSSSSSSS FFFFFFFFFFFFFFFFF MMM T E
2	7	SS SF FF TT FT SE TE
3	2	SSS TTT
4	1	SSFF
Sum	53	30*S 24*F 8*T 3*M 3*E

on survival analyses confounded with high proportions of censored data (47). The latest survival analyses show longer functional periods of amalgam restorations (29–36). The present observations also suggest that the median functional period of class-II amalgam restorations exceeds 5–8 years.

That the main criteria for replacement were secondary caries and bulk fractures, followed by tooth fractures, is in general agreement with the reasons for replacement of amalgam restorations recorded in most cross-sectional studies of amalgam restorations (Table 1). The prevalence of bulk fractures was, however, slightly higher than average. The differences in the prevalence of the replacement criteria in the present study and other studies can partially be caused by a variation in the patients' age (8, 9, 15) and in the patients' caries activity. In the cross-sectional studies the dentists were instructed to report the main reason for replacement. Bulk fractures and secondary caries are often associated, although there are no references in the literature about which precedes the other. In these clinical situations the dentist can only make qualified guesses about the main reason. Furthermore, a bulk fracture will eventually create secondary caries. The relative proportions of secondary caries and bulk fractures in a patient group will therefore depend on

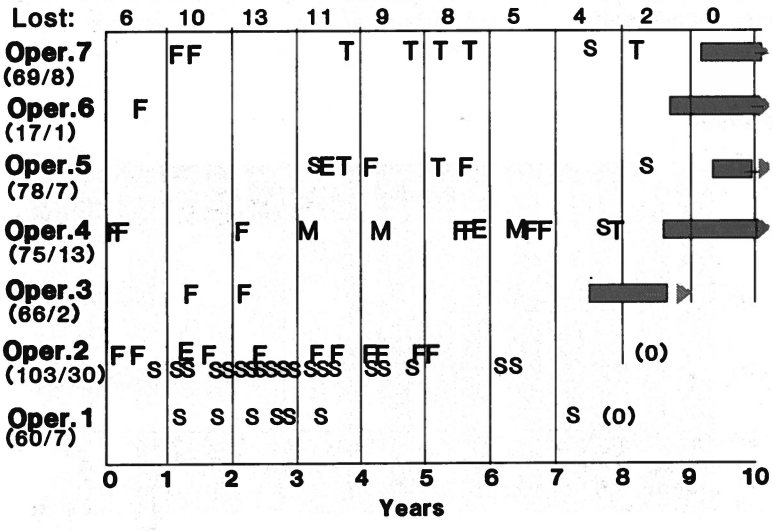

Fig. 7. Replacement incidence dependent on each operator. The numbers in parentheses show the number of restorations placed by each operator and how many have been replaced. The boxed areas represent the function period of the restorations that are still in situ. Each letter represents one replacement. S = secondary caries ($n = 30$), F = restoration bulk fracture ($n = 24$), T = tooth fracture ($n = 8$), M = margin ditch ($n = 3$), E = extended into larger restoration ($n = 3$). The line of numbers at the top indicates the number of replaced restorations within each yearly interval.

Table 11. Chi-square values for the different clinical variables and prevalence of replacement at yearly intervals up to 7 years. The number of failed restorations are cumulative values. DF = degrees of freedom

Variable	DF	Observation period in years 3	4	5	6	7
Operator	6	20.6**	31.1***	62.8***	61.3***	87.3***
Patient caries activity	2	17.1***	24.9***	37.4***	44.2***	56.9***
Patient age	2	16.2***	20.7***	34.7***	36.9***	58.3***
Alloy	4	3.7	6.5	14.4**	15.6**	13.5**
Restoration location	5	4.7	9.6	8.9	0.7	18.0**
Restoration type	2	0.5	1.1	4.5	5.1	7.7*
Patient gender	1	0.1	0.0	0.1	0.6	0.5
Failed		29	40	49	57	62
Survived		397	340	296	242	216
Total		426	380	345	299	278

Significance: $*p < 0.05$; $**p < 0.01$; $***p < 0.001$.

whether the patients seek immediate dental treatment. Thus, it is likely that the variation in frequencies of secondary caries and bulk fractures, as reported by different authors, is influenced by the dental care situation and other socioeconomic factors in the population under study. This hypothesis is also supported by the observation that the prevalence of bulk fractures is underestimated, as observed in a patient group with very low caries activity (48). Other studies have focused on the lack of inter-operator agreement on criteria for replacement (49–51) and the lack of consistency in using these criteria (52, 53). A further problem in the interpretation of the results from different clinical investigations is that the variables in the study designs are often poorly described or omitted (44). Thus, the influence on the results of factors like the intra-oral location

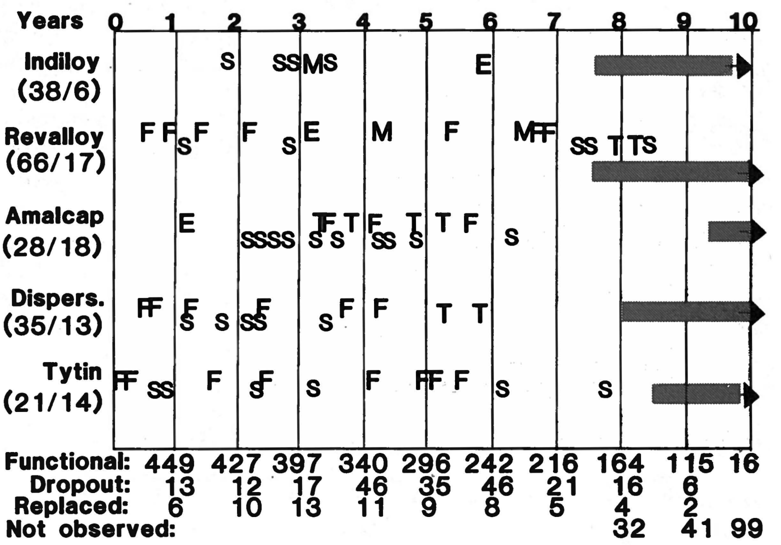

Fig. 8. Replacement incidence dependent on type of alloy. The numbers in parentheses indicate the number of restorations that are functioning at the end of the observation period and those that have been replaced. The boxed areas represent the function period of the restorations that are still in situ. Each letter represents one replacement. S = secondary caries ($n = 30$), F = restoration bulk fracture ($n = 24$), T = tooth fracture ($n = 8$). M = margin ditch ($n = 3$), E = extended into larger restoration ($n = 3$). The four lines of numbers immediately below the diagram show the restoration sample status at each yearly interval.

Table 12. The marginal scores, using a categorical scale for rating the degree of marginal degradation and prevalence of loss within each score category. The basis for the analysis: score 1 is the scoring at the last observation before the restorations were lost during the first 5 years of the study. Each letter denotes one replacement. S = secondary caries, F = restoration bulk fractures, T = tooth fractures, M = restoration marginal fractures, E = extended into larger restoration. Score 2 is the scoring after the 5-year observation period. The numbers in parentheses are the percentages of failed restorations within each score category

	Replacements during the first 5 years		Remaining at 5 years		Replacements during the 5th to 10th year		
Category	Score 1	Criteria	Score 2	%	No.	(%)	Criteria
Not scored	4	FFFF	3				
1 (Good)	1	S	1	0.1			
2	13	SSSSSSSSSSS FF	26	8.8	2	(7.7%)	SS
3	13	SSSSSSS FFFF T E	133	44.9	6	(4.5%)	SS FFF T
4	13	SSSS FFFFF TT E M	103	34.8	4	(3.9%)	S TT E
5 (Poor)	5	S FFF M	30	10.1	7	(23.3%)	S FFF TT M
	49		296		19	(6.4%)	

of the restoration, the patients' dental status, the consumption of fluorides or the use of fluoridated toothpaste, the frequency of dental visits, and other clinical factors prevent valid comparisons of the results in the different reports.

Owing to the low number of replacements in the present study, any statistically significant relationships between the clinical variables and the criteria for replacements or the functional time of the restorations could only be assessed for clinical variables exerting strong effects. The ranking of the relative importance of the clinical variables was similar for the three different statistical methods (Tables 7, 9, and 11). The patient's age and caries activity were most marked, although the measured effects were reduced when the clinical variables were adjusted for inter-relationships. The marked difference between the eta values and the beta values in the MCA analysis for the patient age and caries activity variables show that the study sample included a group of caries-susceptible children (Table 7). The significance of this observation is that the results of the chi-square analyses must be interpreted with caution (Table 11). The effects of the remaining clinical variables were small, although a weak effect could be associated with the alloy and the intra-oral location of the restoration. These observations are consistent with conclusions in other reports that are often based on clinical studies with different aims and methods (Table 13).

An association could be noted between the operator and the incidence of replacement, the criteria for replacement, and the functional period of the restorations. The variation between the operators could partly be explained by the differences between their patient groups and by the fact that the children treated in the school dental service showed a higher caries activity than the other patients. The operator effect remained also after correcting for these inter-variable effects by the MCA analyses, but to a lesser extent by the Cox regression method. Owing to the design of the study, it is not possible to conclude whether the variation is the result of a difference in the operators' assessment of the restoration quality at the time of replacement or the result of an influence on the physical properties of the amalgam per se as a function of the operators' handling (59). The latter is supported by the observation that 2 operators accounted for 17 of the 22 fractured restorations and the 3 restorations that were replaced because of poor marginal integrity, since these 2 replacement criteria can be related to physical strength properties of the alloy. An additional operator effect, indicated by the observation that seven of the eight fractured teeth had been

Table 13. Correlation between clinical variables and the functional time (FT) or criteria for replacement (RR) of amalgam restorations observed in clinical studies

	Patient		Restoration					
Auther (Ref.)	Age	Caries	Location	Class	Alloy	Operator	Effect	Study type
Robinson (18)				+			FT	Retrospective
Walls (19)	+		+	+			FT	Retrospective
Hunter (20)	+			+			RR/FT	Retrospective
Gray (21)			+	+			FT	Retrospective
Osborne (22)					+		RR/FT	Clinical
Crabb (23)			+	+			FT	Retrospective
Hamilton (24)			+		−		FT	Clinical
Elderton (25)				−			FT	Prospective
Paterson (26)	+			+			FT	Retrospective
Meeuwissen (27)			+	+			FT	Retrospective
Milen (28)	+		+	+			FT	Retrospective
Bentley (29)	+	+		+			FT	Retrospective
Arthur (30)			+				FT	Retrospective
Robbins (31)		+	−	+			FT	Clinical
Arthur (32)		+	−	+			FT	Retrospective
Moffa (33)				+	−		RR/FT	Retrospective
Laswell (34)			−				FT	Clinical
Letzel (35)		+			+	+	RR/FT	Clinical
Lemmens (48)			+		+	+	RR	Clinical
Holland (54)	+		+	+			FT	Retrospective
Levering (55)	+			+			FT	Retrospective
Drake (56)			−				FT	Retrospective
Osborne (57)					−		RR/FT	Clinical
Osborne (58)					+		RR/FT	Clinical

prepared by two of the operators, is the effect of the cavity preparation design. Further statistical inferences are, however, not possible in the present study owing to the low number of replacements.

The type of amalgam—non-gamma-2 or conventional alloys—showed similar clinical performance, in contrast to the observations of Osborne et al. (22, 58). The incidence of bulk and tooth fractures tended to correlate with the lack of marginal integrity at 5 years. Corrosion may be a common denominator for these failures, but a causal relationship between high bite forces and marginal failure has also been suggested (60), and although the number of observations is small, the results seem to support this hypothesis.

The alleged correlation between marginal discrepancies at the amalgam/tooth interface and recurrent caries is controversial (12). A relationship between poor occlusal marginal adaptation and prevalence of approximal recurrent caries has been described in one in-vitro study (61), whereas in another investigation the authors conclude that a correlation does not seem to exist (62). In two in-vivo studies an increased prevalence of secondary caries was found, although only for fillings with very poor marginal integrity—that is, analog to score 5 or 6 in the present study (63, 64). The clinical significance of poor occlusal marginal integrity was questioned after a longitudinal clinical study showed no differences in replacement frequencies due to secondary caries between a spherical alloy and a non-gamma-2 alloy (24). Later studies have also failed to identify significant correlations between the marginal integrity and the incidence of, or criteria for, replacement (33, 57) or found only weak correlations (34, 35, 48).

In the present study the marginal integrity of the occlusal surface could not be related to any specific criterion for replacement or to the functional period of the restorations. The data thus show that poor marginal integrity at 5 years is not indicative of an increased prevalence of secondary caries at later stages. On the other hand, the strong correlation with the patient caries activity during the clinical trial indicates that recurrent caries is more related to the general caries activity of the patient than to other clinical variables (64, 65). This is also consistent with Mjör's observations (12) that secondary caries rarely occur occlusally.

It is frequently stated in earlier studies that the operator error is reponsible for most of the restoration failures, either due to faulty cavity preparation or to the incorrect handling of the material (1, 2, 4, 66, 67). The data in the present study do not support this view, although it is acknowledged that the number of failures in the present study is relatively low and that this conclusion is only valid for the first 10 years of the functional period of the restorations. The results in the present study thus show that during the first 10 years after placement of class-II amalgam restorations the most prevalent cause of failure seems to be due to patient-related factors, followed by operator-related factors and material failures.

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