

The durability of primary molar restorations: I. Observations and predictions of success of amalgams

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Abstract

The durability of amalgams in primary molars was examined retrospectively using an audit of the records of 226 pediatric dental patients attending a dental school clinic. Individual amalgam histories were followed for up to 9 years, computerized, and durability assessed in terms of amalgam replacements and length of service, using computer-appropriate definitions for failure and success. The replacement frequency of amalgams was unaffected by the child's history of exposure to systemic fluoride. Of 1898 first-placement amalgams, 73% (68% Class I; 76% Class II) were successful either to tooth exfoliation or to the end of the study; and 27% were failures requiring replacement due to restoration failure (18% "true" failures) or further extension (9% "false" failures). The highest failure rate was seen among Class II amalgams placed in children younger than 4 years. Regardless of age of child at first placement, true amalgam failures occurred within 18-24 months. In children younger than 4 years at placement, false failures combined with successful amalgams were successful for at least 48 months (mean). Use of these data allowed the statistical prediction that 75% of Class I amalgams in children younger than 4 years at placement would be successful for at least 6 years of service.

Literature Review

Despite the widespread use of amalgam, few studies have reported on the quality of such restorations in the primary dentition. This is pertinent to pediatric dentistry because many amalgams are replaced due to factors such as: newly carious surfaces; inadequate cavity preparations; inappropriate usage of dental materials; diagnostic failures; and patient cooperation. Such replacements increase both the time and cost to maintain a child's dental health.

An early study of 313 Class II amalgam failures in primary molars concluded failure of amalgam itself was responsible for significantly more marginal defects than enamel breakdown (MacRae et al., 1962). These workers

did not cite operator variables and manipulative factors as causes of failure, but suggested the need for a better restorative material or alternative methods for restoring primary teeth. A retrospective study of 150 multisurface amalgams in primary molars indicated success (i.e., no retreatment following first placement) for 11% of Class II amalgams over 33.5 months. (Braff 1975). A more recent study of 280 amalgams concluded that 75% of one-surface and 70% of two-surface amalgams in first primary molars needed replacement before the age of 8 years (Dawson et al. 1981). The average length of service for one-surface amalgams in first molars was 20.1 months and 29 months in second molars, and 22.9 months and 22.7 months, respectively, for two-surface amalgams. Neither of these studies used radiographs in assessing the reason for replacement.

This study employed a case historic approach (Gordon 1978; Lilienfeld and Lilienfeld 1980) to examine retrospectively histories of primary molar amalgams by auditing patient records over a 12-year period. The objectives were to: (1) describe the durability of primary molar amalgams; and (2) quantitate the length of their service. The single criterion of whether or not the amalgam ever required replacement was used to determine durability; this was measured using 3 outcomes: "true" failure, "false" failure, and "success" (Allan 1969). Since conditions under which an amalgam was placed with respect to patient cooperation could not be determined retrospectively, the observations were classified by the age of the child at amalgam placement.

Materials and Methods Selection Criteria

Records of 226 patients (123 males, 103 females) treated in the University of Minnesota Pediatric Dental Clinic were selected for the study based on 7 criteria.

1. The child was healthy and ambulatory. A healthy child was defined as one free of systemic disease as

determined by the recorded medical history. The child presented with no past or present medical history that would have affected either dietary patterns or caries susceptibility to the best of current knowledge.

2. The child was free of any developmental disturbances of the teeth and jaws likely to have affected either caries susceptibility or the selection of restorative materials.
3. Dental treatment at this clinic was continuous with no treatment rendered elsewhere during the study period.
4. The record appeared to be complete, accurate and legible, indicating all treatment rendered and treatment dates.
5. Each treatment series was accompanied by one pair of bite-wing radiographs and series were less than 1 year apart, unless no treatment was required.
6. The record indicated 8 primary molars present upon entry into the study (at first treatment series). Records showing missing primary molar(s) were included only if the absence was attributed to congenital absence, orthodontic extraction, serial extraction, or extraction resulting from an ectopic eruption pattern.
7. The record presented 4 or more primary molars restored with amalgam and/or fewer than 4 primary molars treated with stainless steel crowns that could be followed throughout the study. No molar was treated with an occlusal sealant.

The 226 records represented 1898 amalgams and 331 stainless steel crowns (total 2229 restorations), placed by dental students between 1970 and 1982. This paper reports the durability of amalgams; subsequent papers (in this issue) report the durability of crowns and costs associated with restorative treatment. Molar histories were taken from the records (progress notes and radiographs) by arrival condition and surfaces of treatment rendered thereafter, coded, and analyzed by the Statistical Analysis System (SAS) package program.

Fluoride History

Individual fluoride histories were verified using national and state lists of water supplies (U.S. Department of Health, Education, and Welfare; personal communication*) or by direct inquiry to water supply authorities. An optimal fluoride history was defined as the continuous consumption of optimally fluoridated water or systemic fluoride supplementation from birth until entry into and then throughout the study (Walton

and Messer 1981). A suboptimal fluoride history was defined as the continuous or intermittent consumption of suboptimally fluoridated water from birth until the time of study entry (Walton and Messer 1981). Fluoride histories were distributed as follows: optimal, 147 patients (65% of total sample); suboptimal, 72 (32%); and unknown, 7 (3%).

Restorative Technique

Amalgams were placed according to manufacturer's^a instructions in traditional cavity preparations using rubber dam and standard armamentarium (Finn 1967).

Criteria for Amalgam Failure

True amalgam failures showed evidence in the record of replacement or need for replacement, or tooth extraction (or need for extraction) in the absence of pulpal therapy (Allan 1969). False amalgam failures showed evidence in the record of replacement or need for replacement, or tooth extraction (or need for extraction), in the absence of pulpal therapy, due to the intervention of caries elsewhere in the tooth requiring replacement and extension of an otherwise satisfactory amalgam (Allan 1969).

Since amalgams were not examined clinically, a computer-appropriate definition assigned the time to failure. This was defined as the number of the months between placement of the amalgam and the last treatment series in which it was recorded as successful, plus one-half the time interval in months from the last record of success to the first treatment series in which the amalgam was recorded as a failure. This definition assumed that failure occurred at the midpoint between treatment series.

Criteria for Amalgam Success

Successful amalgams were those showing no evidence in the record of being replaced or need for replacement, or tooth extraction (Allan 1969).

The period of success was defined as the time interval in months between placement of the amalgam and the last treatment series in which it was recorded as successful. Successful amalgams included those still present and deemed successful at the end of the study.

Observation Periods

Restored molars were followed retrospectively for a mean of 5.1 ± 1.4 (SD) years (range 2-9 years) for 1 of 4 observation periods to: exfoliation; end of study; extraction; or amalgam replacement. This follow-up represented a mean of 7 ± 2 (SD) treatment series per patient (range 2-12 series). A treatment series was defined as a series of appointments initiated by an examination

* Jackson, M: Minnesota Department of Health records, 1970-1982.

^a Spherallloy (used 1970-1976) — Kerr Sybron Corp; Romulus, MI; Dispersalloy (used 1975-1982) — Johnson and Johnson Dental Products Co; East Windsor, NJ.

(including bite-wing radiographs) and planning of procedures then completed in later appointments. The mean interval between treatment series was 10.0 ± 4.6 (SD) months.

Distribution of Amalgams

Table 1 shows the distribution of amalgams, the age range of the child at first placement, and the 4 observation periods. The majority of amalgams ($N = 1035$; 54%) followed were in children ages 4-7 years; 206 amalgams (11%) had been placed in children younger than 4 years. Of particular interest were the 386 amalgams followed to tooth exfoliation, because they were judged successful from first placement to physiological tooth loss. The largest group, 957 first-placement amalgams followed to the end of the study, were successful with an unknown outcome. Failure was indicated by amalgams later replaced ($N = 518$) or the tooth extracted ($N = 37$).

Results

The data were examined for the effect of systemic fluoride on the replacement history. For all molar types and classifications of restorations, the frequency of replacements in teeth with a history of optimal fluoride exposure did not differ with statistical significance from the replacement experience of those with a history of suboptimal fluoride exposure (c^2 range 0.048-2.689; P range 0.829-0.101). Therefore, histories of restored molars from patients with and without exposure to optimal fluoride were pooled.

Table 2 shows the distribution of amalgams by outcomes. Of the 1898 amalgams studied, 18% were judged true failures ($N = 350$), 9% false failures ($N = 168$), and 73% successful ($N = 1380$). With increasing age of the child at first placement, the percentage of true failures

decreased over twofold (27, 21, and 11%), and false failures decreased sevenfold (21, 10, and 3%). Successful outcomes increased 1.5-fold with increasing age at placement (52, 68, and 86%). Regardless of age at placement, true failures occurred more frequently among Class II amalgams than among Class I amalgams. Particularly significant among Class II amalgams was the large number showing true failure (46%) and the relatively few successful (47%) among those younger than

TABLE 1. Distribution of Periods of Observation Available for 1898 Primary Molar Amalgams Placed in 226 Children

Period of Observation of Molar After First Placement of Amalgam	Distribution of Amalgam Restorations (% total amalgams)			Total Amalgams
	<4 Years ^a	4-7 Years	>7 Years	
To tooth exfoliation	20 (1)	147 (8)	219 (12)	386 (21)
To end of study ^b	65 (3)	545 (29)	347 (19)	957 (51)
To tooth extraction	8 (0.4)	21 (1)	8 (0.4)	37 (2)
To replacement of amalgam	113 (6)	321 (16)	84 (4)	518 (26)
Total amalgams	206 (11)	1035 (54)	657 (35)	1898 (100)

^a Age range of child at first placement of amalgam.

^b Amalgams still successful at end of study.

four years. False failures were more frequent among Class I than Class II amalgams; this tendency increased with the age at placement. The percentage of successful amalgams increased in both Class I and Class II categories with placement age. Among 721 first-placement Class I amalgams, 68% ($74 + 271 + 144 / 721$) were judged successful; and 76% of 1177 first placement Class II amalgams ($33 + 437 + 421 / 1177$) were judged successful.

Table 3 (next page) shows the mean times for these outcomes. Successful plus false failure amalgams were combined ($1380 + 168 = 1548$) since the latter were successful and only required replacement due to intervention of other newly carious surfaces. For the 350 true failures, the mean time to failure of Class I amalgams was similar for the 3 age groups (24.0, 21.6, 23.8 months), but Class II amalgams failed slightly sooner (18.1, 23.3, 20.9 months). The 1380 successful amalgams included the 957 still present in the mouth at the end of the study (Table 1); therefore, the mean number of months of recorded success must be considered as minimal values.

TABLE 2. Distribution of Recorded Outcomes of 1898 Amalgam Restorations With Respect to Age of Child at Restoration Placement

Recorded Outcome of Amalgams	Distribution of Recorded Outcomes (% amalgams) ^a									Total Amalgams
	<4 Years ^b			4-7 Years			>7 Years			
	Class I	Class II	Total	Class I	Class II	Total	Class I	Class II	Total	
"True" failure	24 (18)	32 (46)	56 (27)	58 (14)	161 (26)	219 (21)	13 (8)	75 (13)	75 (11)	350
"False" failure	38 (28)	5 (7)	43 (21)	85 (20)	23 (4)	108 (10)	14 (8)	3 (1)	17 (3)	168
Success	74 (54)	33 (47)	107 (52)	271 (65)	437 (70)	708 (68)	144 (84)	421 (87)	565 (86)	1380
Total Amalgams	136	70	206 (100)	414	621	1035 (100)	171	486	657 (100)	1898

^a Percentage of Class I or Class II amalgams in each age group.

^b Age range of child at first placement of amalgam.

TABLE 3. Distribution of Recorded Outcomes of Amalgam Restorations and Mean Times to Failure or Success

Recorded Outcome of Amalgams	Distribution of Recorded Outcomes (% total amalgams)						Total Amalgams
	<4 Years ^a		4-7 Years		>7 Years		
	Class I Amalgam	Class II Amalgam	Class I Amalgam	Class II Amalgam	Class I Amalgam	Class II Amalgam	
"True" failure:							
No. amalgams (% total)	24 (7)	32 (9)	58 (16)	161 (46)	13 (4)	62 (18)	350 (18)
Mo. to failure as mean ± SD	24.0 ± 16.7	18.1 ± 13.3	21.6 ± 15.8	23.3 ± 13.7	23.8 ± 17.6	20.9 ± 14.1	
Success plus "false" failure:							
No. amalgams (% total)	112 (7)	38 (2)	356 (23)	460 (30)	158 (10)	424 (28)	1548 (82)
Mo. of success as mean ± SD	48.2 ± 22.6	55.6 ± 20.0	40.1 ± 20.3	35.8 ± 20.1	43.3 ± 18.7	38.6 ± 17.9	
Total amalgams	136	70	414	621	171	486	1898 (100)

^a Age of child at first placement of amalgam.

^b Number of months of success is a minimal value since this group includes amalgams still successful at the end of the study.

In the group older than seven years, 92% of 171 Class I amalgams were successful for a mean of at least 43.3 months, and 87% of 486 Class II amalgams were successful for a mean of at least 38.6 months. In comparison, only 60% Class I (N = 356) and 74% Class II amalgams (N = 460) were successful in the 4- to 7-year group. Fewer amalgams were studied in the younger age group, resulting in 82% successful Class I amalgams (N = 112) for a mean of at least 48.2 months and 54% successful Class II amalgams (N = 38) for a mean of at least 55.6 months.

The long-term success of primary molar amalgams was explored, using the Weibull statistical distribution (Kapur and Lamberson 1977; Lee 1980). Predictions of failure were computed for 1- to 10-year periods of service (Table 4); the converse of these figures represents the predicted percentages of success. For example, using a 25% failure prediction for Class I amalgams, 75%

lower failure rate than those placed in younger children. For example, the predicted success after 5 years would be 79% Class I and 51% Class II amalgams in children younger than 4 years at placement, and 83% Class I and 70% Class II amalgams in children 4 years and older.

Discussion

This study examines retrospectively the durability of primary molar amalgams, using a case-historic approach and measurement in terms of replacements and length of service. Previously, quality assessment in restorative dentistry was limited by a lack of quantitative methods to determine success and failure of restorations. Epidemiologists now recognize the value of a case-historic elucidation of etiological factors in disease (Gordon 1978; Lilienfeld and Lilienfeld 1980). Criteria for case selection and diagnosis are held constant over time, and cases, selected retrospectively, are followed longitudinally from an earlier diagnosis to the present. This study sample was chosen from a dental school clinic in order to examine restorations under a rigorous testing situation, and followed to the present. Diverse clinical skills are expected of dental students, thus minimizing the bias possible if all amalgams were placed by a single skilled operator who may not be representative of clinicians in general.

This study appears to be the first investigation of primary molars employing computerization of amalgam histories and relying on the validity of past records. Since the amalgams were not examined clinically, as is possible in prospective studies, computer-appropriate definitions of failure and success were required for classifying outcomes and quantitating periods of service.

TABLE 4. Prediction of Failure of Class I and Class II Amalgam Restorations with Reference to Age of Child at First Placement of the Restoration

Predicted Time to Failure (years)	Percentage Prediction of Failure (95% confidence limits) ^a			
	<4 Years ^b		≥4 Years	
	Class I Amalgam	Class II Amalgam	Class I Amalgam	Class II Amalgam
1	5% (0.02, 0.09)	17% (0.12, 0.24)	4% (0.02, 0.06)	6% (0.05, 0.08)
2	9 (0.05, 0.18)	28 (0.20, 0.38)	7 (0.05, 0.12)	13 (0.11, 0.16)
3	14 (0.07, 0.25)	37 (0.26, 0.49)	11 (0.07, 0.17)	19 (0.16, 0.23)
4	18 (0.09, 0.32)	44 (0.32, 0.57)	14 (0.09, 0.21)	25 (0.21, 0.30)
5	21 (0.11, 0.38)	49 (0.37, 0.64)	17 (0.11, 0.25)	30 (0.25, 0.36)
6	25 (0.13, 0.44)	55 (0.41, 0.69)	19 (0.13, 0.29)	35 (0.29, 0.41)
7	29 (0.15, 0.49)	59 (0.45, 0.73)	22 (0.14, 0.33)	40 (0.33, 0.46)
8	32 (0.17, 0.54)	63 (0.49, 0.77)	25 (0.16, 0.37)	44 (0.37, 0.51)
9	35 (0.19, 0.58)	66 (0.52, 0.80)	27 (0.18, 0.40)	48 (0.41, 0.55)
10	38% (0.21, 0.62)	69% (0.55, 0.83)	29% (0.19, 0.43)	51% (0.44, 0.59)

^a Prediction based upon the Weibull statistical distribution with lower and upper confidence limits (Kapur and Lamberson 1977; Lee 1980).

^b Age of child at first placement of the amalgam.

of first amalgams placed in children younger than 4 years would be successful for at least 6 years of service, and 75% of such amalgams placed in children aged four years and older would be successful for at least 8 years. For both amalgam types, those in children 4 years and older at placement are predicted to show a consistently

Clearly, such definitions may not accurately represent the clinical situation for individual amalgams. However, it is significant that dentists rarely see a restoration when it has "just failed"; more typically the failure is seen on recall examination and the assumption is made that the failure occurred in the interim — since the patient was last seen, at which time the amalgam did not need replacement. Thus, selecting the midpoint between these 2 visits for designating the failure time is not unrealistic. This conservative estimate of time to failure must be recognized when comparing these results with those in the literature, which typically record failure time as coincident with amalgam replacement.

Present observations fulfill the logical expectations for length of service of primary molar amalgams. It is expected that as the age of the child at first placement of a restoration increases, there is a decrease in the need for replacement (i.e., increasing percentage of successful restorations), particularly due to false failures. As the age of the child at first placement increased, a twofold decrease in the percentage of true failures and a sevenfold decrease in false failures was seen. It is also expected that false failures occur more frequently among Class I amalgams and true failures among Class II amalgams; this was observed particularly among the children younger than 4 years. Overall, the percentage of successful amalgams increased in both categories with age of the child at placement, also supporting expectations.

Also expected is a greater number of amalgam replacements associated with false failures among patients with a history of suboptimal fluoridation (Ast et al. 1956; Backer Dirks 1974). However, the overall number of false failures was small, reflecting few amalgams replaced due to the intervention of newly carious surfaces. The history of systemic exposure to fluoride had no statistically significant effect on this replacement pattern. Since fluoride histories could not be verified, it is impossible to determine if the lack of a difference was real or only apparent. Assuming the former, the finding could be due in part to the cumulative effect of multiple sources of fluoride (other than water fluoridation or supplements) such as foods and beverages, school and home rinse programs (approximately 25% of the Minneapolis school districts maintained fluoride rinse programs during 1970-1982 [personal communication*]), office topical applications, and fluoride dentifrices (Singer and Ophaug 1979). Also, the nationally observed decline in dental caries reported by the National Caries Program (U.S. Department of Health and Human Services 1981) coincided with this audit. Previous workers studying quality of primary molar amalgams have not sorted dentitions by fluoride history.

In comparison with other reports, the present study

* Jackson, M: Minnesota Department of Health records, 1970-1982.

was biased toward selecting the records of children with amalgams in at least 4 primary molars. Possibly, these children with extensive restorative histories exhibited a higher caries index than other children and were at increased risk of further caries and amalgam replacement. These amalgams may not be representative of those in children with lower caries indices and the present findings cannot necessarily be extrapolated to dentitions with fewer than 4 restored molars.

These amalgams, placed by dental students, showed a greater experience of both success and lifespan than those cited in earlier reports where the restorations were placed by experienced clinicians. Of a total of 1177 first-placement Class I amalgams in the present study, 76% were successful, in contrast to the 11 and 30% reported, respectively, for such restorations by Braff (1975) and Dawson et al. (1981). Of a total of 721 first placement Class I amalgams in the present study, 68% were successful, in contrast to the 25% (in first molars) and 68% (in second molars) reported for Class I amalgams by Dawson et al. In the present study, the success experience was best for Class II amalgams in children older than 7 years at first placement (87%). These discrepancies in outcome could be due to differing diagnostic criteria for success and failure, or to the age of the patients at amalgam placement. The present study shows clearly that lower success rates can be expected for Class I and Class II amalgams when these are placed in children younger than 4 years. It is possible that the samples of Braff (1975) and Dawson et al. (1981) contained relatively more younger children.

The minimal periods of success reported here for Class I amalgams (48 months) and Class II amalgams (55 months) for children younger than 4 years at placement approximate the mean lifespan of 4.25 years reported for amalgams in permanent teeth of young adults (Cecil et al. 1982). The periods reported in the present study are conservative, because amalgams still successful were pooled with those requiring replacement due to intervention of caries on another surface.

The Weibull distribution uses longitudinal data to mathematically model the survival distribution of populations with increasing, decreasing, or constant risk. In this study, all amalgams served as the population at risk and the successful amalgams constituted the survival distribution. Periods of up to 10 years were selected as this is probably the longest period a restored primary molar would be present before exfoliation. Application of the predictions can be further exemplified by considering 2 hypothetical cases, in which Class I and Class II amalgams are placed in primary molars of 2 children, aged 3 and 6 years, and then followed to tooth exfoliation at age 10 (i.e., 7 and 4 years of service, respectively). Within the bounds of 95% confidence limits, the percentage failures are predicted in Table 5 (next page).

TABLE 5. Hypothetical Prediction of Failure of Amalgam Restorations of Primary Molars Based Upon the Child's Age at First Placement of Restoration

Age of Child at First Placement of Amalgam	Desired Period of Service of Amalgam ^b	Hypothetical Percentage Prediction of Amalgams That Will Fail (95% confidence limits) ^a	
		Class I Amalgam	Class II Amalgam
3 years	7 years	29 (0.15, 0.49)	59 (0.45, 0.73)
6 years	4 years	14 (0.09, 0.21)	25 (0.21, 0.30)

^a Prediction based upon the Weibull statistical distribution with lower and upper confidence limits (Kapur and Lamberson 1977; Lee 1980).

^b Assumes a 10-year period of service of the tooth, to exfoliation.

In both cases, the predicted failure of Class I amalgams is approximately half that of Class II amalgams, and the success predictions for both types of amalgams in the older child are approximately twice that of the younger child. Therefore, in a clinical population similar to that followed in the present study, a dentist could expect 86% of Class I amalgams and 75% of Class II amalgams first placed in 6 years olds to be successful for 4 years.

Computerization of patient records is expanding in both dental school clinics and private offices, allowing the recording of much clinical data. Academicians and clinicians alike are alerted to the valuable resource this provides in generating large data pools from which much information can be drawn, particularly on topics such as treatment outcomes. In an era of declining dental caries and fewer restored teeth, prospective studies evaluating the relative success of different treatment approaches will be very useful. For example, the durability data presented here on amalgam could serve as a basis for comparison in studies on new posterior restorative materials such as composites.

Conclusions

Based on a retrospective record audit of amalgams placed by dental students in primary molars, the following conclusions are drawn:

1. The age of the child at first placement of both Class I and Class II amalgams was a major factor in their replacement, but the history of systemic fluoride was not a factor.
2. Class I and Class II amalgams demonstrated low failure (18%), with failures occurring within 18-24 months of placement, and very low replacement due to intervention of newly carious surfaces (9% amalgams). The highest failure rate was seen among Class II amalgams placed in children younger than 4 years (46%).
3. Successful first-placement Class I and Class II amalgams (82%), including those where satisfactory restorations were replaced in association with extension to treat newly carious surfaces, had a mean

lifespan of at least 48 months in children younger than 4 years at first placement.

4. Statistical predictions from these data indicate 75% of Class I amalgams in children younger than 4 years at placement would be successful for at least 6 years of service, and 75% of Class I amalgams in children 4 years and older at placement would be successful for at least 8 years of service.

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Minimizing legal risks

Satisfactory answers to the questions below may help a dental office minimize the risk of legal problems.

1. Is there an established procedure for obtaining the patient's consent to treatment? A standard procedure should be used for all cases.
2. Would your patient records — charts, health questionnaires, X rays, letters, etc. — stand up under cross examination? Are they complete, legible, and accurate? Do you keep records of claims submitted to third party insurers?
3. Do you keep a written record of all referrals, consultations, and telephone conversations?
4. How safe are all your records? Are they kept locked and protected from fire? Do you keep any back-up records at a different location? How many years do you keep your office records?
5. Are all your drugs, needles, and syringes kept locked up? Do you keep copies of all prescriptions (written and verbal) attached to patients' files?
6. Is your dental equipment safe and maintained in good working order?
7. What would happen in case of an emergency? Do you have emergency equipment in the office and is it properly maintained?