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15-year evaluation of Class II amalgam restorations

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Abstract – In a clinical trial, 1544 Class II amalgam restorations were inserted. In this study 1213 restorations were evaluated after 15 years and the reasons for replacement were registered. Attention was also paid to patient drop-out and patients' variables such as gender, filling degree, type of tooth (premolar vs molar), type of restoration (MO or DO vs MOD), jaw (upper vs lower) and the patients' operator. Furthermore, replacement rates of three alloys applied in comparable circumstances (n=394) are reported. Of the restorations, 214 (17.6%) were replaced during the trial period. Factors influencing the replacement rates are gender, type of restoration and operator. Factors such as type of tooth and type of alloy seemed to have no influence on the replacement rates in this study.

Key words: dental amalgam; dental restorations; permanent; dental clinics

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Since the introduction of high-copper alloys, more than 30 years ago, minor developments have been effected in the material properties of amalgams. Due to their satisfying clinical behaviour, these alloys are still widely used in operative dentistry. It is therefore of interest to obtain perspectives in the field of clinical replacement. In the mid-70s the Dutch National Health Insurance Council and more recently the Ministry of Health Welfare and Sport (Directory-General of Health) granted research on the efficiency and efficacy of Class II amalgam restorations.

In the context of this project several randomized controlled clinical trials were performed in a cooperative project between the Catholic University of Nijmegen and the Amsterdam Academic Centre for Dentistry (ACTA). The Amsterdam part of this project consisted of three trials, in which the following variables were applied: 1. cavity wall finish and cavosurface angle; 2.cavity varnish and alloy; 3. Silver sus pension, alloy, and amalgam polish. These three trials have been continued and now have reached their 15th year of evaluation.

Longitudinal studies on restorations rarely exceed five years of observation. Such studies often have to deal with a high level of patient drop-out, which might affect the reliability of the results (1). In this study, therefore, comprehensive measures were taken to stimulate recall. This article briefly describes these measures with regard to the set-up of the study at ACTA, and discusses the results of the 15-year evaluation.

Overall failure rates and reasons of failure are described for those patients who were available for the final assessment. Data on Class II restorations show the influence of various clinical factors on restoration replacement (1-7). Accordingly, this article relates replacements to the patients' variables (gender, filling degree, type of tooth, type of restoration, jaw and the patients' operator). Replacement rates of the three alloys applied are also reported.

Material and methods

Between 1977 and 1978 a number of patients were invited to take part in this clinical study. The inclusion criteria were: 1.) between 15 and 40 years of age; 2.) good general health; 3.) needing 'standard' conservative Class II restorations, as indicated on bitewing radiographs; 4.) vital teeth; 5.) no abnormal occlusal contacts; 6.) no periodontal disease (no increased mobility); 7.) no removable dentures; 8.) willing to accept the ACTA dentist (members of the Department of the Pediatric Dentistry) as his or her regular dentist; 9.) living in, or nearby, Amsterdam; 10.) willingness for evaluation over a longer period of time (signed contract).

Using these criteria, 183 attendants of the dental school were obtained of whom 86 were men and 97 women (mean age at time of inclusion 22.5 3.8 years). Each patient participated in one of the three trials. In return for participation, patients were offered free dental care except for the laboratory costs of crowns and bridges. Patients were randomly assigned to one of the three dentists, who remained their regular dentist during this study. Initially 1544 restorations were made, four (or a multiple of four) restorations in each patient. In 15 cases, cusp replacements or parapins were necessary. Excluding these 15 restorations, 1529 restorations remained for analyses. Three dentists were involved in restoration, each carrying out about 510 restorations in about 60 patients. At the start of the research project

Table 1. The influence of the gender according to replacement rates.

	State	
Gender*	In situ	Replaced (%)
Men	431	109 (20.2)
Women	568	105 (15.6)
Total (N=1213)	999	214 (17.6)

* (Fisher's exact test, p>0.05)

the three operators had respectivily 7, 4 and 0 years experience in general practice and worked together in dental education.

Each dentist provided for the dental health of his patients and twice a year each patient was invited for a regular check-up. During the fifteen-year follow up, the next criteria for replacement were applied: ocd - *Isthmus fracture*: restoration broken by location of the isthmus. - *Enamel fracture:* cusp(s) broken and dentin exposed. - *Caries:* clinically observed by mirror and explorer and radiographically by bitewings (Observer agreement X-ray's; inter-examiner Kappa: .79 and intra-examiner Kappa: .78). - *Endo, pain, esthetics:* dependant on complains and desires of the patient.

The observers were calibrated by clinical consensus training sessions before and during the study. Marginal breakdown was only registered as a reason for failure in combination with other reasons.

The clinical trial was carried out in accordance with the FDI rules of conduct (8) and the Council on Dental Materials and Devices of the American Dental Association (9,10). Following the steps of a written protocol, the clinical procedures were carried out with the help of a dental assistant in an equal setting concerning dental equipment and instruments

Cavity preparation was performed by high speed cylindrical diamant burr and gingival margin trimmer. Caries was removed by low speed round steel bur and finally by spoon excavator. Cavities were cleaned by water spray and dried by a gentle airstream in combination with cotton pellets). All restorations were made using rubber dam, tutle matrices and cutted wooden wedges. A calcium hydroxide lining was applicated in cavities of at least 1.5 mm depth in dentine (Dycal, one layer of no more than 0.5 mm thickness). In all cases, a mechanical device (Bergendahl) was used to condense the amalgam. The three trials each required different additional operative procedures, in view of the variables of cavity wall treatment and cavosurface angle. Most patients appreciated the use of local anaesthetics. Shortly after finishing the series of restorations in the patient a baseline status was assessed that included an indication of the dental health, expressed by the filling degree of the posterior teeth (proportion filled/total surfaces).

Data handling - The 15-year overall data can be divided into patient-related and restoration-related variables. The proportion of patients dropping out and the proportion of restorations replaced within 15 years were compared mainly using Chi-square tests. For alloy replacement rates, 394 restorations were selected that were comparable with regard to the variables between the trials: they were constructed in a conventional way (cavity preparation, parallel vertical walls, and no additional cavity wall treatment). The alloys used were New True Dentalloy, Cavex Non-Gamma 2, and Tytin. Two-sided hypotheses were tested using Mann-Whitney tests and chi-square statistics, one-sided hypotheses were tested with Fisher exact tests. All analyses were performed using the statistical package BMDP.

Results

Of the 183 patients, 64 men and 80 women responded to the call for the 15-year evaluation in 1992 and 1993. With an overall positive response of 78.7%, the proportion of patients lost to follow-up is .26 in men and .18 in women (95% confidence interval for the difference in proportion lost, -.03 to .20). The number of patients lost to follow-up in the three operators did not show statistically significant differences (Pearson df=2, p=.15). The non-responders were about 14 months younger than the responders, but this age difference was not significant (Mann-Whitney, p=.16). However the mean filling degree of the non-responders rated .43 compared to .47 in the responders at the start of the study. This difference is significant (Mann-Whitney, p=.05). The filling degree of the responders after 15 years was .50. Among the responders, at baseline as well as after 15 year, the filling degree in the men did not differ significantly from the filling degree in the women (Mann-Whitney, p> 0.10)

The 144 patients who showed up after 15 years had had 1213 restorations at baseline. Of these 1213 restorations, 214 (17.6%) were replaced during the trial period. Significantly more restora-

Table 2. Distribution of the restoration after 15 yr according to type of tooth restoration and type of restoration.

	Type of restoration **			
	MO/DO		MOD	
Type of tooth*	In situ	Replaced (%)	In situ	Replaced (%)
Premolar	245	38 (13.4)	301	69 (18.6)
Molar	207	38 (15.5)	246	69 (21.9)
Total (N=1213)	452	76 (14.4)	547	138 (20.1)

*(Mantel Haenszel p>.10)
**(Fisher's exact test, p=.006)

Table 3. Replacement rates and relative risk (RR) of replacement by the three operators.

	Restorations			
Operator* (experience)	In situ	Replaced (%)	RR	95% Confidence-interval
1 (0 year)	395	55 (12.2)	1.00	
2 (7 year)	322	63 (16.4)	1.34	0.96-1.87
3 (4 year)	282	96 (25.4)	2.08	1.54-2.81
Total	999	214 (17.6)		

*(Pearson, df=2, p<.001)

Table 4. Replacement rates by type of alloy.

Type of alloy*	Restoration		
	In situ	Replaced (%)	Total
Tytin	87	17 (16.3)	104
NTD	176	22 (11.2)	198
Cavex	82	10 (10.9)	92
Total	345	49 (12.4)	394

*(Pearson, df=2, p>.10)

Table 5. Reasons for replacement.

One reason	N	%
1. Isthmus fracture	53	24.8
2. Enamel fracture	46	21.5
3. Caries	52	24.3
Combination of two reasons		
1+3	12	5.6
1+3	16	7.5
2+3	12	5.6
Combination of three reasons		
1+2+3	3	1.4
Other reasons		
endo, pain, esthetics	20	100
Total (N)	214	100

tions were replaced in men than in women (95% confidence interval for the difference in percentage replaced is .2% to 8.9%) (Table 1).

No significant difference in replacement rates could be found between the four quadrants, nor between the upper and lower jaw (Pearson, p>.10). Significantly more MOD than MO/DO restorations were replaced, 20% and 14% respectively . The replacement risk for a 3-surface restoration was between 1.08 and 1.81 times that of a 2-surface restoration. The replacement rates according to type of tooth were not significantly different (Table 2). Table 3 shows a statistically significant difference in replacement rates between the three operators. The differences in the proportion replaced restorations by type of alloy are statistically insignificant (Table 4). Reasons for replacement are given in table 5.

Discussion

After 15 years of study, the loss to follow-up is 21% (mainly because patients moved and their new address was not available). This is not a high percentage in view of the duration of the clinical trial; the literature describes losses of up to 70% after 14 years (7). It is possible that the privileged treatment terms and the shortage of dentists that existed when the study began both played a part in making the participants willing to cooperate so readily.

The applied statistical methods assume statistical independance between restorations. Because each patient has several restorations, complete independancy does not hold. This results in underestimation of the standard errors and a confidence interval that may be too small. However, since chi-square statistics are known to be robust the chance of systematic bias in results is very limited.

The fact that more women took part in the follow-up than men might be explained by the possibility that women make more time available for dental care. At any rate, epidemiological research in the Netherlands has shown that women pay more attention to their dental health than do men (11). This may well also account for the comparatively better replacement rates of amalgam restorations in women.

Study results of the replacement rates of amalgam restorations after ten years have shown strong variation. The percentage of lost restorations has been reported from 9 % to 90%, depending on the circumstances under which the restorations were originally inserted (7,12-15). In one study, analyses of amalgam restorations in recall patients showed a survival estimate of 78% after 17 years (16); however, if only one part of a MOD restoration was replaced, the restoration was separated into two parts (MO/DO) with regard to survival time, making it possible to follow the fate of the partial restoration independently of the original restoration. This criterion may have contributed to the higher survival times reported in the latter study. In all, the replacement of less than one-fifth of the original restorations in the present study may be deemed favourable.

It is generally accepted that a relationship exists between the quality of a restoration and the length of time that was spent on carrying it out, so one of the circumstances that may have influenced the replacement rates is the time given to preparation and restoration. In our study the mean total treatment time for two-surface restorations was 24 minutes and for three-surface restorations 30 minutes (17). It is doubtful whether this length of time is usually available in general practice, as various research studies on the replacement rates of amalgam restorations in general dental practice - performed during the same period - show considerably less impressive results (1,13,18).

The influence of the operator on the replacement rates of amalgam restorations has been widely reported (1,3,4,5). The present study found that the operator with the most lost restorations had 7 patients requiring 5 or more replacements, while the other two operators each had only 2 patients requiring 4 or more replacements. It is unclear whether this difference is due to an operator, a patient effect or a combination of both influences.

It was surprising that the least experienced operator had to replace the lowest number of restorations. Apparantly experience is not the sole determinator in clinical success rates.

In contrast to the findings of several other authors, the present study shows no significant difference in replacement rates between both molar types, nor of the jaw in which the restorations were situated (1,5,14).

The literature has paid little attention to the question of the size of restorations. Our study found a relation between this factor and the number of restorations requiring replacement. A Scandinavian study, though, reported no significant difference between the results of two-surface and three-surface amalgam restorations (1).

Various reports on the longevity of amalgam restorations have appeared which include special considerations of the differences between conventional and high-copper amalgams (1,3,4,7). The present study found no significant difference in replacement rates between the different amalgams employed. This result was confirmed in two of these publications (1,3). However in one of these two studies no difference was found between high-copper amalgam and the conventional amalgam employed in the present study, NTD, while it did find that high-copper amalgam was significantly better than another conventional amalgam (3). The two other publications referred to here reported reverse results (4,7). The researchers concluded that better results could be achieved with high-copper than with conventional amalgam. So, it may be asserted that the superior quali-

ties attributed to high-copper amalgams, compared to conventional amalgams, do not lead to consistently better results in clinical practice.

Conventional Dycal seems to have poor mechanical properties and shows a substantial solubility in stimulated dentinal fluid (19,20,21). It is unknown if to what extent the use of dycal has contributed to the number of restorations replaced. However, it is surprising that in spite of the frequent use of dycal the replacement rates in our study were limited.

Most publications on 'replacement rates' do not report combined causes, though in the present study this was the case in one-fifth of the cases in which restorations had to be replaced. For example, where 'isthmus fracture' and 'caries' are combined it is hard to say what is cause and what effect. An other, ten-year, study reported that it was often impossible to ascertain the exact reason for a given replacement (3).

The time and attention devoted to restorations are probably of decisive importance in clinical success, including patient factors as diet and oral hygiene. Still, it remains necessary to inquire into the various clinical factors which influence the replacement rates of amalgam restorations.

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