Some issues in applied statistics in clinical restorative dental research
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Chapter 5

Replacement risk of amalgam treatment modalities:

15-year results

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Abstract

Objectives: This paper reports on the replacement risk of different treatment modalities for Class II amalgam restorations in a clinical trial of 15 years' duration.

Methods: The performance of 1117 conventional Class II amalgam restorations in a controlled, longitudinal study were analysed using logistic regression with a random component. Primary variables regarding replacement risk were the treatment modality (cavity wall treatments) and alloy (conventional versus high copper). Secondly, the operator, type of tooth and type of restoration (MO/DO versus MOD) were considered.

Results: Over 15 years, 17% of the restorations were replaced (true failures). The application of copalite varnish or silver suspension and the type of alloy did not reduce the replacement risk. Reduced risks were observed by providing a 90° cavosurface angle combined with a cavity wall finish. The operator and the type of restoration determine replacement risk to a significant extent.

Conclusions: Additional treatment modalities do not necessarily reduce replacement risks of Class II amalgam restorations within 15 years, while clinical variables affect the risk of replacement to a certain degree.
Introduction

Dentists in practice direct a great deal of time replacing restorations (Klausner, Green et al., 1987; Qvist, Qvist et al., 1990; Pink, Minden et al., 1994; Friedl, Hiller et al., 1995; Maryniuk and Kaplan, 1986). To estimate future restorative treatment needs, and consequently time and manpower planning, data on replacement rates of restorations are required. The dentist in everyday practice will be faced with amalgam restorations for several decades and the assessment of replacement risk should supply information on amalgam longevity.

Estimates of restoration longevity may be obtained from several resources. In interviews, dentists expect small amalgam restorations to survive 11 years (Maryniuk and Kaplan, 1966). Large restorations would be expected to last 6 years, on average, before replacement. Cross-sectional studies report mean survival times of about 11 years for Class II amalgam restorations (Klausner, Green et al., 1987; Pink, Minden et al., 1994) and medians of 7.5 and 10 years (Qvist, Qvist et al., 1990; Pink, Mindler et al., 1994). Long-term survival percentages also vary and were found to be 50% to 81% after some 10 years, (Robinson, 1971; Meeuwissen, van Elteren et al., 1985; resp. Bentley and Drake, 1986; Jokstad and Mjör, 1991) and 42% to 75% after 15 years of observation (Smales, Webster et al., 1991; resp. Bjertness and Sonju, 1990). Letzel, van’t Hof et al. (1989) found 88% of the restorations surviving 7 years in a clinical trial. Other trials showed 5-year failures of 5-7% and a 14-year failure of 13% (Doglia, Herr et al., 1986; Wilson, Wastell et al., 1996; Osborne, Norman et al., 1991). These findings demonstrate a large variation in longevity estimations. It is widely accepted that the performance and longevity of amalgam restorations depend on the alloy used (Doglia, Herr et al., 1986; Jokstad and Mjör, 1990). Moreover, performance is affected by several treatment variations (Mahler and Marantz, 1980; Jacobsen, 1984). For example, the application of cavity varnishes (Schwartz and Phillips, 1961; Zardiaickas, 1976; Murray, Yates et al., 1983; Manders, Garcia-Godoy et al., 1990, Ben-Amar, Cardash et al., 1993) and changes in the cavosurface angle (de Vree, Peters et al., 1984; Bryant, 1992) may influence the resistance to leakage and marginal breakdown ought to be improved. Many variables have been subjected to in vitro and in vivo studies. Few have been tested in long-term clinical trials.

In the mid-1970s a large scale clinical study was supported by the Dutch National Health Insurance to evaluate the performance and longevity of amalgam restorations. Several controlled trials with different treatment modalities were included in this study. Previous papers have reported on results of particular evaluation periods (Letzel, van’t Hof et al., 1989; Akerboom, Advokaat et al., 1993; Gruythuysen, Kreulen et al., 1996). The present paper focuses on the 15-year replacement risk of Class II amalgam restorations in
three of these trials. The modalities considered are cavity wall treatments and alloys. Treatment variables that influence the results are discussed.

Material and methods

The set-up of this study is described in more detail in earlier reports (Akerboom, Advokaat et al., 1993; Gruythuysen, Kreulen et al., 1998). In the period 1977-1978, 183 patients in need of Class II restorations were invited to join the clinical study (Gruythuysen, Kreulen et al., 1996; Akerboom, Borgmeijer et al., 1985). The mean patient age at the time of inclusion was 22.5 years (s.d. 3.8). Each patient was assigned to one of the three dentists involved and participated in one of the three trials described below. During the 15-year follow-up, these dentists provided the dental care of the patients, which included a check-up each half year. In every case bitewing radiographs were made each 5 years.

Three trials were designed to combine different treatment variables (cavosurface angle, cavity wall finish, copalite varnish (Cooley and Cooley, USA) and silver suspension (Star Dental, The Netherlands) and amalgam alloys (New True Dentalloy (S.S. White, USA), Tytin (Kerr, USA) and Cavex Non-Gamma 2 (Cavex Holland, The Netherlands)) to four treatment modalities per trial (Figure 1). The four modalities of each trial were randomly assigned to four (or eight or twelve) teeth to be treated in a 2x2 (factorial) design within a patient. This split mouth study was designed to include 120 restorations of each modality in each trial, equally divided between the operators. One modality per trial was considered to be the “standard” restorative treatment modality of that trial (Figure 1). Common features of these standards of the three trials were: no cavity wall finish and no silver suspension applied, the alloy was New True Dentalloy (NTD), and a cavosurface marginal angle (CSA) which was the result of almost parallel buccal and lingual cavity walls. In contrast to Trials 2 and 3, all preparations of Trial 1 were treated with copalite Varnish. Hence, the standard treatment of Trial 1 was comparable to the copalite/NTD modality in Trial 2. Of the alloys used, New True Dentalloy (NTD) is a low copper lathe-cut amalgam. Both Tytin and Cavex Non-Gamma 2 (CNG) are high copper amalgams, Tytin with spherical particles and CNG with a blend of spherical and lathe-cut particles.
Figure 1. Description of variables and treatment modalities of each of the three trials. The standard restorative treatment modality per trial in italics. The "unchanged" variables per trial in the boxes with dashed line.
The treatments were carried out following the steps of a written protocol with the help of a dental assistant. Class II preparations according to Rodda's design (Rodda, 1972) were made using cylindrical diamond stones. The restorations were placed using rubber dam, a calcium hydroxide lining (Dycal, Kerr, USA) and a mechanical device (Bergendahl) to condense the material. All restorations were polished. The operative procedures in Trial 1 included finished marginal walls by using a cylindrical tungsten-carbide bur (occlusal) or gingival margin trimmers (approximal), and a CSA of about 90°, provided by an inverted cone diamond stone to the depth of the enamel layer. In Trials 1 and 2 copalite was applied according to the instructions of the manufacturer. The silver suspension in Trial 3 was brushed into the cavity and dried for 30-60 seconds.

During the operative phase of the study, Trial 3 was extended by 104 non-polished restorations. As a result, 1544 restorations were included. In 15 cases large Class II restorations were provided, with cusp replacements or in need of dentine pins. To avoid additional variables, these larger restorations and the non-polished restorations of Trial 3 were excluded in the present study: 1428 Class II restorations were included. Replacement of a restoration was assessed using a standard format and the diagnosis “restoration failure” was the result of a joint decision of the three dentists (Table 1). True failures are directly related to the restoration or adjacent tooth structure. Replacements due to caries in surfaces that are not restored, or reasons of aesthetics or orthodontics, are considered false failures. Severe marginal breakdown was not used as a reason for replacement, unless in combination with one of the other three modes of true failure. Restorations that were modified during their service period were not assessed to be failures. These modifications regard refinishing of parts of the restorations and reapplication of amalgam to minor material defects (non-invasive repairs).

An earlier paper described different statistical methods for appropriateness of handling longitudinal survival data of clinical trials, based on the data of Trial 1 (Tobi, Kreulen et al., 1998). Logistic regression analysis with a random component (EGRET, 1991) yielded efficient use of data on replacement of restorations with minimal loss of information. This technique takes into account the split-mouth design, with each patient having more than one restoration. The logistic regression model assumes a baseline risk of replacement for each patient. Owing to the influence of risk factors (variables) this risk may vary. Primary variables in the analysis are the treatment modality and alloy. The variables operator, type of tooth, and type of restoration are regarded as secondary variables. If a regression model is significantly improved by adding a specific variable (using Likelihood Ratio-tests), the variable is included into the final model. The logistic regression analysis requires patients with complete follow-up.
Table 1. Format of restoration failure

<table>
<thead>
<tr>
<th>Failures</th>
<th>Reason for replacement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>True failure</td>
<td>Isthmus fracture</td>
<td>Complete fracture of the restoration between box and step, whether or not parts of the restoration in situ</td>
</tr>
<tr>
<td></td>
<td>Recurrent caries</td>
<td>Caries clinically or radiographically detected adjacent to the restoration</td>
</tr>
<tr>
<td></td>
<td>Enamel fracture</td>
<td>Fracture, or fracture lines, in the enamel adjacent to the restoration (vertical or horizontal), so that enlargement of the restoration is necessary</td>
</tr>
<tr>
<td>False failure</td>
<td>Non-related caries</td>
<td>Caries clinically or radiographically detected, not adjacent to the restoration (e.g. in the mesial surface of a tooth with a distocclusal restoration)</td>
</tr>
<tr>
<td></td>
<td>Orthodontics</td>
<td>Tooth extraction indicated by orthodontic reasons</td>
</tr>
<tr>
<td></td>
<td>Aesthetics/ health</td>
<td>Replacement of a restoration on request of the patient</td>
</tr>
</tbody>
</table>

After 15 years, 144 patients (79%) with 1141 restorations were still included in the study. The data of one patient were incomplete. Twenty false failures were observed. Table 2 shows the frequencies of some variables under study. The data of Trial 1 have been published earlier (Tobi, Kreulen et al., 1998) and are shown here for comparison. The odds for replacement of the modalities and secondary variables included in the model are compared to the standard modality of each study, using the following reference restoration: an MO/DO restoration in a premolar, made by Dentist 1 according to the standard treatment modality of the specific trial. Results are presented as odds-ratios with their 95% confidence intervals. An odds-ratio of 2, for instance, indicates that the odds for replacement of the specific modality is twice the odds for replacement of the standard treatment within 15 years. The odds for replacement can be interpreted as the risk of replacement relative to the risk of survival.
Table 2. Frequencies of variables under study

<table>
<thead>
<tr>
<th>Trial</th>
<th>Operator</th>
<th>Alloy</th>
<th>Total restorations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 2 3</td>
<td>NTD Tytin CNG</td>
<td>338 206 183 149 126 109</td>
</tr>
<tr>
<td>2</td>
<td>152 126 135</td>
<td>206 207 135 93 2 109</td>
<td>206 207 135 93 2 109</td>
</tr>
<tr>
<td>3</td>
<td>109 124 133</td>
<td>183 183 124 93 2 109</td>
<td>183 183 124 93 2 109</td>
</tr>
<tr>
<td>Total</td>
<td>357 343 417</td>
<td>727 207 183 149 126 109</td>
<td>1117</td>
</tr>
</tbody>
</table>

Table 3. Restorations under study, placed and replaced, after 15 years

<table>
<thead>
<tr>
<th>Trial</th>
<th>In Situ</th>
<th>Replaced</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>259</td>
<td>79</td>
<td>338</td>
</tr>
<tr>
<td>2</td>
<td>351</td>
<td>62</td>
<td>413</td>
</tr>
<tr>
<td>3</td>
<td>322</td>
<td>44</td>
<td>366</td>
</tr>
<tr>
<td>Total</td>
<td>932</td>
<td>185</td>
<td>1117</td>
</tr>
</tbody>
</table>

Results

The status of the restorations included are detailed in Table 3. The proportion of true failures in Trial 1 was 23%, and in the Trials 2 and 3, 15% and 12%, respectively. The reasons for replacement were combinations of isthmus fracture, recurrent caries, and/or enamel fracture in 24% of the cases, across all three trials. In 4%, pain by unclear causes led to failure. Isolated isthmus fractures, recurrent caries or enamel fractures were apparent in 28%, 22%, and 22% of the failures. During the 15-year period, 67 restorations were refinished or repaired. Of these adjusted restorations, 25% were replaced later during the study.

The results of the logistic regression analysis are described for each trial separately.
Replacement risk of treatment modalities

Trial 1 - CSA and marginal wall finish

The separate treatment variables (a 90° CSA only, or only the cavity wall finish) did not show advantages above the standard treatment (Table 4). By combining a 90° CSA and a finished cavity wall, a lower risk of replacement was obtained. Evident effects were found for operator (Dentist 2 a higher odds for replacement than Dentist 1), type of restoration (MOD a higher odds than MO and DO) and type of tooth (molars a higher odds than premolars).

Table 4. Odds-ratios and 95% confidence intervals of relevant variables with respect to replacement risk

<table>
<thead>
<tr>
<th>Trial</th>
<th>Variable</th>
<th>Odds-ratio</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Modality</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard (no 90° CSA, no wall finish)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>90° CSA vs standard</td>
<td>1.7</td>
<td>0.8 - 3.9</td>
</tr>
<tr>
<td></td>
<td>Wall finish vs standard</td>
<td>2.1</td>
<td>0.9 - 4.7</td>
</tr>
<tr>
<td></td>
<td>Combined 90 CSA and wall finish</td>
<td>0.7</td>
<td>0.3 - 1.8</td>
</tr>
<tr>
<td></td>
<td>Operator</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dentist 2 vs dentist 1</td>
<td>4.2</td>
<td>1.3 - 13.3</td>
</tr>
<tr>
<td></td>
<td>Dentist 3 vs dentist 1</td>
<td>1.1</td>
<td>0.4 - 3.2</td>
</tr>
<tr>
<td></td>
<td>MOD vs MO/DO</td>
<td>1.9</td>
<td>1.0 - 3.7</td>
</tr>
<tr>
<td></td>
<td>Molar vs premolar</td>
<td>2.1</td>
<td>1.2 - 3.8</td>
</tr>
<tr>
<td>2</td>
<td>Modality</td>
<td>1.8</td>
<td>0.9 - 3.3</td>
</tr>
<tr>
<td></td>
<td>Copalite vs no Copalite</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Operator</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dentist 2 vs dentist 1</td>
<td>0.9</td>
<td>0.3 - 2.7</td>
</tr>
<tr>
<td></td>
<td>Dentist 3 vs dentist 1</td>
<td>0.1</td>
<td>0.03 - 0.5</td>
</tr>
<tr>
<td></td>
<td>MOD vs MO/DO</td>
<td>2.7</td>
<td>1.3 - 5.7</td>
</tr>
<tr>
<td>3</td>
<td>Operator</td>
<td>1.0</td>
<td>0.4 - 2.6</td>
</tr>
<tr>
<td></td>
<td>Dentist 2 vs dentist 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dentist 3 vs dentist 1</td>
<td>0.6</td>
<td>0.2 - 1.7</td>
</tr>
<tr>
<td></td>
<td>MOD vs MO/DO</td>
<td>2.3</td>
<td>1.1 - 4.9</td>
</tr>
</tbody>
</table>
Trial 2 - copalite application and alloy

Table 4 also shows the results of the regression model regarding Trial 2. Type of tooth and alloy did not substantially influence the modelling procedure and were omitted in the final model. The use of copalite varnish tends to increase the risk of replacement (not statistically significant). The operator and the type of restoration determine replacement risk to a significant extent (p<0.05).

Trial 3 - silver suspension application and alloy

The third part of Table 4 presents the results of Trial 3. Most of the variables were not found to affect the model significantly. The incorporation of silver suspension was not found to improve significantly the fit of the model. The effect of the type of restoration is comparable to the effect in the other two trials.

Discussion

In the present study a limited number of restorations were replaced within 15 years, especially in Trials 2 and 3. This finding may be a result of, for instance, the monitoring of the patients during the 15-year period or the setting and conditions of the study. It may also be a consequence of the general experience that in research more time is spent on one single treatment than in practice (Elderton, 1976). The treatment times of the dentists involved in this study, however, seem to approximate their daily practice (Advokaat, van’t Hof et al., 1992). Although several studies have shown that recurrent caries is a highly prevalent reason for replacement, this was found to a lesser extent in this study. It might be the result of a limited caries incidence in the patients during the study period. The overall filling degree (that is the proportion restored surfaces:total surfaces) increased from 0.47 to only 0.5 in 15 years (Gruythuysen, Kreulen et al., 1996). Furthermore, the small number of restorations replaced may have reduced the statistical power to detect differences between the treatment modalities. Another source of bias might be inherent in the statistical method. Data of patients that are lost-to-follow-up are disregarded by the logistic regression analysis. Nevertheless, the high recall rate of 79% justifies the application of this statistical method.

The 15-year replacement risks of the modalities under study seemed comparable to that of each of the standard treatments of the three trials. As regards the alloys applied, a difference between NTD and Tytin or CNG was not found, which seems to be in contrast to the general opinion that conventional lathe-cut amalgams have shorter life spans than high copper amalgams (van Dijken, 1991; Smales, Webster et al., 1991). A positive interaction of CSA and cavity wall finish was found in Trial 1. It showed that the finished, 90° CSA
Replacement risk of treatment modalities

reduced the risk of replacement. However, this treatment modality is likely to be at the cost of sound tooth tissue and additional treatment time. It is reported that operators experienced difficulties in controlling the CSA and CSAs of 100-110° were most achievable (Bryant, 1992; Akerboom, Borgmeijer et al., 1985). Although the trials were similar in design, there seemed to be a difference in the overall replacement percentages among the three trials. This difference can be attributed to some factors. It might be caused by differences in the frequency distributions of secondary variables between the trials, such as the type of tooth. The ratios three:two surface restorations of the trials were similar and it, therefore, does not explain variation in replacement rates between the trials. Furthermore, it appeared that the evaluation period of Trial 1 was close to 15.5 years, while that period of Trial 3 was just about 15 years. Regarding the low replacement incidence of the study, this variation in follow-up can hardly result in the replacement differences observed. Also, a mastering period of the youngest dentist during the operative period of the study might have affected the results, although this does not provide a definite explanation. Finally, all restorations in Trial 1 were made using copalite. From Trial 2 it was concluded that copalite tends to increase the risk of replacement. This may (partly) explain the result of Trial 1.

Some studies have shown that the copalite treatment prevents marginal leakage (Schwartz and Phillips, 1961; Murray, Yates et al., 1983; Manders, Garcia-Godoy et al., 1990). On the other hand, short-term results of the copalite-treated restorations in the present longitudinal study showed more marginal fracture (Borgmeijer, Advokaat et al., 1981). More recently, several studies have reported more marginal leakage of amalgam restorations lined with copalite than for restorations lined with resin bonding (Charlton, Moore et al., 1992; Berry and Tjan, 1994), indicating an imperfect seal of copalite-treated restorations (Mazer, Rehfeld et al., 1988; Liberman, Ben-Amar et al., 1989). The silver suspension of Trial 3 should increase the retention of the amalgam restoration to tooth structure. Its function is based on sealing of the marginal gap by the reaction product of Ag-particles from the suspension and the free Hg, on one hand, and on adhesion between polycarboxylate from the suspension and the cavity wall, on the other hand (Zardiackas, 1976). A report on the 3-year data of the present trial showed that the marginal adaptation was not improved using this suspension (Charlton, Moore et al., 1992; Berry and Tjan, 1994). Based on the 15-year results, and because of their technique sensitive application (Ben-Amar, Cardash et al., 1990), both the treatments with copalite varnish and silver suspension cannot be recommended for use.

Two of the secondary variables, the operator and the type of restoration, appeared to be consistently of influence on the results. The rank ordering of the odds-ratios of the dentists varies between the three trials. In Trial 1 the
restorations made by Dentist 1 showed the least replacement risk (odds-ratios > 1.0), while in Trials 2 and 3 these restorations run highest risks (odds-ratio ≤ .0). No plausible explanation can be found for this variation. Nevertheless, it can be concluded that the operator remains an important factor in clinical research (Smales, 1991). The influence of the type of restoration was shown by the higher risk of replacement of three-surface restorations compared to that of two-surface restorations.

Marginal adaptation of restorations is often used as one of the predictors of later failure. It is difficult to distinguish between acceptable and unacceptable margins as a basis for replacement, but ranking of alloys by marginal fracture indices has been shown not to change with time (Mahler and Marantz, 1979) and also gap width has been associated with recurrent caries (Hodges, Mangum et al., 1995). Previous results of the present study regarding marginal adaptation are not in agreement with the 15-year ranking of odds for replacement. For instance, at 3 years it was found that a smooth enamel wall did not improve marginal adaptation and a 90° CSA showed less marginal breakdown compared to regular CSAs (Akerboom, Borgmeijer et al., 1981). Hence, as observed by others, the short-term marginal performance may not be an indication of long-term survival (Hamilton, Moffa et al., 1983; Söderholm, Antonson et al., 1989; Kidd and O’Hara, 1990; Smales and Webster, 1993). A real predictive parameter is still lacking.

Conclusions

Within 15 years, the risk of replacement (using odds-ratios) of Class II amalgam restorations:
1. Appears not to be reduced by: providing a 90° CSA or finishing of the cavity wall or application of copalite varnish or a silver suspension.
2. Is not statistical significantly affected by the three alloys used in this study.
3. Is higher for MOD restorations than for MO/DO restorations.
4. Is significantly affected by the operator.

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References


Chapter 5


Replacement risk of treatment modalities


