The survival of Class V restorations in general dental practice. Part 2, early failure

D. A. Stewardson,[1] P. Thornley,[2] T. Bigg,[3] C. Bromage,[4] A. Browne,[5] D. Cottam,[6] D. Dalby,[7] J. Gilmour,[8] J. Horton,[9] E. Roberts,[10] L. Westoby,[11] S. Creanor[12] and T. Burke[13]

IN BRIEF

- Demonstrates the value of practice-based research to provide evidence from the 'real-life' clinical environment.
- The biggest influence on early failure of Class V restorations was the clinician who placed the restoration.
- The results suggest that good handling of restorative materials is more important than the type of material chosen.
- Some materials are less user-friendly than has been suggested.

RESEARCH

Objective To evaluate Class V restorations placed by UK general practitioners comparing those failing or surviving after two years, and to identify factors associated with early failure. **Design** Prospective longitudinal cohort multi-centre study. **Setting** UK general dental practices. **Materials & methods** Ten dentists each placed 100 Class V restorations and recorded selected clinical information at placement and recall visits. Univariate associations were assessed between recorded clinical factors and whether restorations had failed or not at two years. Multi-variable binary logistic regression was also undertaken to identify which combination of factors had a significant effect on the probability of early failure. **Results** At two years, 156 of 989 restorations had failed (15.8%), with 40 (4%) lost to follow-up. Univariate analysis showed a significant association between restoration failure and increasing patient age, payment method, the treating practitioner, non-carious cavities, cavities involving enamel and dentine, cavity preparation and restoration material. Multi-variable analysis indicated a higher probability of early failure associated with the practitioner, older patients, glass ionomer and flowable composite, bur-preparation and moisture contamination. **Conclusions** Among these practitioners, both analytic methods identified significant associations between early failure of Class V restorations and the practitioner, cavity preparation method, restoration material and patient's age.

[1]*Lecturer in Conservative Dentistry, University of Birmingham School of Dentistry, St Chads Queensway, Birmingham, B4 6NN; [2]General Dental Practitioner, Walmley Dental Practice, 1 Walmley Close, Sutton Coldfield, West Midlands, B76 1NQ; [3]General Dental Practitioner, Milton Dental Practice, Breakspeare House, Shipton Road, Milton-Under-Wychwood, Oxford, OX7 6JW; [4]General Dental Practitioner, Worcester Street Dental Centre, 68 Worcester Street, Stourbridge, West Midlands, DY8 1AY; [5]General Dental Practitioner, Evesham Place Dental Practice, 14 Evesham Place, Stratford-upon-Avon, CV37 6HT; [6]General Dental Practitioner, Cottam & Cottam Dental Surgery, 1 St Peters Road, Harbourne, Birmingham, B17 0AT; [7]General Dental Practitioner, Hagley Dental Practice, 157 Worcester Road, Hagley, Stourbridge, West Midlands, DY9 0NW; [8]General Dental Practitioner, ADP Chasetown, 27 High Street, Chasetown, Burntwood, Staffordshire, WS7 3XE; [9]General Dental Practitioner, Chelmsley Wood Primary Care Centre, 14 Crabtree Drive, Chelmsley Wood, Birmingham, B37 5BU; [10]General Dental Practitioner, Matthew Gibbons & Associates Dental Surgery, Neachells Lane, Wolverhampton, WV11 3RF; [11]General Dental Practitioner, Brighton Villa Dental Care, 7 Bath Street, Hereford, Herefordshire, HR1 2HG; [12]Lecturer in Health Statistics, School of Computing and Mathematics, University of Plymouth, Tamar Science Park, Plymouth, Devon, PL6 8BX; [13]Professor of Primary Dental Care, University of Birmingham, School of Dentistry, St Chads Queensway, Birmingham, B4 6NN
*Correspondence to: Dr Dominic A. Stewardson
Email: d.a.stewardson@bham.ac.uk; Tel: +44 (0)121 237 2812

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INTRODUCTION

General practitioners should aim to provide restorations that have a long lifespan (Fig. 1). This will limit the enlargement of cavities which often accompanies replacement, protect the pulp, promote patient satisfaction and reduce the overall cost of dental care.[1] Furthermore, it has recently been recommended that dentists should be required to bear the cost of replacing restorations which fail within three years of placement.[2] However, it has been estimated that the bulk of operative dental treatment is devoted to the replacement of restorations.[3–5] Class V restorations are less durable than other classes of restorations;[6] composite resin Class V restorations tend to fail more frequently than Class II composite restorations.[5]

To improve the longevity of restorations, clinicians should have a good understanding of why failure occurs. Many factors may influence restoration lifespan but it has been recognised that the mechanisms and causes of failure of restorations are different between failure occurring soon after placement or after a prolonged period of service.[7] Identifying the factors associated with early failure may guide practitioners towards more reliable materials and techniques and alert them to situations which demand greater skill or specific management options to ensure success.

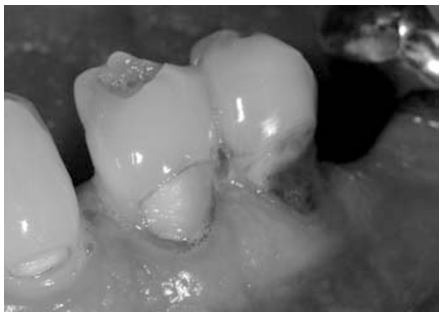

Fig. 1 Three originally non-carious cervical lesions showing total loss of one of the composite restorations

The objective of this study was to evaluate Class V restorations placed by a group of UK general practitioners, comparing those which had failed within two years of being placed with those which had not,

in order to identify which factors were associated with early failure.

MATERIALS AND METHOD

The method used to collect data has previously been described in detail.[8] Briefly, ten general dental practitioners each recorded data on 100 consecutively placed Class V restorations. Information on the patient, the tooth, cavity, occlusion and restoration material was noted and the restorations were monitored at routine recall appointments. Other studies conducted on the performance of Class V restorations frequently report on the performance of restorations after two years[9–14] and we therefore chose a duration of two years as a suitable time-point at which to conduct this comparison.

After all restorations had been in place for over two years, the information on those which had failed within two years was compared with those which had survived for over two years. Six modes of failure were to be recorded: complete loss of the restoration, partial loss, caries at the margins, fracture or loss of the tooth, discolouration or replacement with a crown. Statistical analysis of the data was carried out using the computer packages StatXact 8 (Cytel Studio Inc) and SPSS (v16. SPSS Inc, USA), with significance level set at $\alpha = 0.05$. Given the exploratory nature of the statistical analyses, no corrections were undertaken for multiple testing.

Using cross-tabulations, for each of the factors in the five data categories (patient, tooth, cavity, occlusion, restoration), univariate associations were assessed between whether failure had or had not occurred at two years and:

Patient:
- Age
- Gender
- Oral hygiene
- Payment
- Dental practitioner.

Tooth:
- Upper/lower
- Left/right.

Cavity:
- Condition: carious/non-carious
- Shape (saucer or notch)
- Size (estimated as the product of the height and the depth of the cavity)
- Position: within enamel and dentine/dentine; above, at or below the gingival margin.

Occlusion:
- Excursive contact
- Faceting
- Opposed/unopposed.

Restoration:
- Material
- Bonding agent (for composites)
- Cavity preparation: none/prophylaxis/hand instrument/bur
- Moisture contamination: none/major/minor.

The statistical significance of each of the univariate associations with two-year failure (yes/no) was assessed using the chi-squared test, with exact p-values for this test calculated when small expected values were encountered. In addition, the mean patient age (at time of placement of restoration) was compared between the failed/not failed restorations.

Where the results of these tests were statistically significant, multiple pair-wise comparisons were then performed to identify between which levels of the factor there were significant differences in failure rates. The confidence intervals for these differences between the levels were calculated using an exact method for differences in proportions and the p-values were also exact p-values from the chi-squared test for each pair-wise comparison.

Multi-variable binary logistic regression was then used to try to identify which combination of the factors had a significant effect on the probability of restoration failure by two years. A flexible modelling

Table 1 Univariate associations between two-year failure and patient factors of interest

Patient factor		Not failed (n = 793)	Failed (n = 156)	p-value
Age	Mean (sd) [range]	55.8 (14.4) [8–96]	59.2 (12.8) [20–88]	0.003
Gender	Male	83.5% (354)	16.5% (70)	0.958
	Female	83.6% (439)	16.4% (86)	
OHI	Good	84.2% (351)	15.8% (66)	0.745
	Fair	83.5% (384)	16.5% (76)	
	Poor	80.6% (58)	19.4% (14)	
Payment	NHS	82.1% (280)	17.9% (61)	0.036
	Private	86.5% (391)	13.5% (61)	
	Other	78.2% (122)	21.8% (34)	
Upper/lower	Upper	85.2% (413)	14.8% (72)	0.176
	Lower	81.9% (380)	18.1% (84)	
Right/left	Right	85.0% (403)	15.0% (71)	0.255
	Left	82.1% (390)	17.9% (85)	
Practitioner	1	82.8% (52)	17.2% (10)	<0.001
	2	88.8% (87)	11.2% (12)	
	3	81.3% (77)	18.7% (17)	
	4	90.5% (69)	9.5% (8)	
	5	71.3% (72)	28.7% (29)	
	6	89.7% (64)	10.3% (7)	
	7	73.6% (89)	26.4% (32)	
	8	83.7% (108)	16.3% (21)	
	9	92.3% (84)	7.7% (2)	
	10	85.4% (88)	14.6% (15)	

approach was adopted, with models firstly determined using both forward and backwards stepwise methods, to identify the best subset of factors. A number of possible models were examined, together with the goodness of fit of each model. In order to have reasonable numbers of restorations in all levels of each factor, some recoding of factors was required.

RESULTS

Univariate analysis

At two years, 156 out of 989 restorations had failed (16%) and 40 (4%) had been lost to follow-up. Of those which had failed, 137 (88%) had been completely lost, 7 (4%) were partially lost, 7 (4%) teeth had fractured or been removed and 5 (3%) had subsequently been crowned. The cross-tabulations of early failure against the factors of interest are shown in Tables 1 and 2. The results of the chi-squared testing showed that there was no evidence of significant differences between genders, levels of oral hygiene of the patient, upper and lower teeth, or teeth on the right or left side, in terms of the proportion of failures of restorations before two years. There was a significant association between restoration failure and the age of patients (average age of patients with failed restorations was significantly higher than patients whose restorations had not failed). There was also evidence to support a significant association between failure before two years and both the method of payment and the treating practitioner. A smaller proportion of privately funded restorations had failed at two years compared to those which had been placed within the NHS, but the largest proportion of early failures occurred among those placed under other payment schemes. Follow-up pair-wise comparisons indicated a significant difference only between the proportions of failed restorations funded by private and 'other' methods (p = 0.036).

With respect to cavity factors, there was no evidence of significant differences in the proportions of two-year failures between saucer and notch-shaped cavities, nor was failure by two years associated with either the size of the cavity or the position of the cavity relative to the gingival margin. However, a significantly smaller proportion of restorations placed in cavities which were carious before being restored failed before two years than those placed in non-carious cavities. Similarly a significantly smaller proportion of restorations within enamel and dentine only failed before two years than those involving dentine only.

Table 2 Univariate associations between two-year failure and cavity and restoration factors of interest

Restoration factor		Not failed (n = 793)	Failed (n = 156)	p-value
Cavity condition	Carious	89.5% (272)	10.5% (32)	0.001
	Non-carious	80.8% (521)	19.2% (124)	
Cavity shape	Saucer	85.0% (469)	15.0% (83)	0.169
	Notched	81.6% (324)	18.4% (73)	
Cavity size	1	89.6% (112)	10.4% (13)	0.383
	2	84.0% (242)	16.0% (46)	
	3	80.0% (8)	20.0% (2)	
	4	82.6% (284)	17.4% (60)	
	6	81.9% (113)	18.1% (25)	
	9	77.3% (34)	22.7% (10)	
Cavity position 1	In enamel and dentine	84.6% (667)	15.4% (121)	0.046
	In dentine only	78.3% (126)	21.7% (35)	
Cavity position 2	Below margin	87.5% (91)	12.5% (13)	0.483
	At margin	82.8% (480)	17.2% (100)	
	Above margin	83.8% (222)	16.2% (43)	
Excursive contact	No	83.4% (357)	16.6% (71)	0.910
	Yes	83.7% (436)	16.3% (85)	
Faceting	No	83.0% (556)	17.0% (114)	0.458
	Yes	85.0% (237)	15.0% (42)	
Opposed	No	82.4% (201)	17.6% (43)	0.562
	Yes	84.0% (592)	16.0% (113)	
Restoration material (fill type)	Amalgam	94.3% (50)	5.7% (3)	<0.001
	Glass ionomer	67.4% (60)	32.6% (29)	
	RMGI	91.4% (53)	8.6% (5)	
	Compomer	83.9% (182)	16.1% (35)	
	Composite	85.3% (330)	14.7% (57)	
	Flowable composite	81.4% (118)	18.6% (27)	
Bond type (composites)	Self-etch	88.4% (182)	11.6% (24)	0.121
	Etch and bond	83.9% (359)	16.1% (69)	
	3-step	80.9% (114)	19.1% (27)	
Cavity preparation	None	79.9% (278)	20.1% (70)	<0.001
	Prophylaxis	77.3% (150)	22.7% (44)	
	Excavator	69.2% (9)	30.8% (4)	
	Rotary/bur	90.4% (356)	9.6% (38)	
Moisture contamination	None	84.8% (573)	15.2% (103)	0.124
	Minor	80.2% (214)	19.8% (53)	
	Major	100% (6)	-	

There was no evidence of a significant association between two-year failure and any of the occlusal factors recorded. A significant difference was identified between the different materials in terms of the proportion of restorations which failed within two years. Amalgam, followed by resin-modified glass ionomer (RMGI) restorations, recorded the lowest percentage of failure at two years. Follow-up comparisons showed that the proportion of early failure was significantly greater for glass ionomer compared to all the other materials. Amalgam showed a significantly smaller proportion of early failure in comparison with glass ionomer and flowable composite restorations, but no significant differences were seen among the other materials. Separate analysis of the composite resin restorations indicated that there were no significant differences in early failure among the three bonding agent protocols (p = 0.121).

A significantly smaller proportion of cavities which had been prepared with a bur had failed by two years compared with those which had been cleaned and prepared with a hand instrument or had received no preparation. Separate cross-tabulation analysis was carried out on carious and non-carious cavities comparing preparation with a bur *vs* other preparation options. Chi-square tests showed that a significantly greater proportion of restorations which had not been prepared with a bur failed within two years compared with those which had been prepared with a bur, regardless of whether the cavities were carious (p = 0.003) or non-carious (p = 0.024). Analysing the effect of preparation with a bur among the different materials showed that there was a significant association between failure at two years and whether a bur had or had not been used to prepare the cavities only for compomer (p = 0.014) and composite restorations (p <0.001). For both of these materials, a greater proportion of restorations that had not been prepared with a bur had failed within two years compared to those where a bur had been used to prepare the cavity.

The level of moisture contamination while placing the restoration was predominantly recorded by the dentists as minor (28%) or none (71%) and there was no significant difference in the proportions of two-year failures between the restorations exposed to these different levels of moisture. Only six restorations were exposed to major contamination and all survived beyond two years. Two of these restorations were composite and the rest were different materials, but the cavity for each restoration had been prepared with a bur.

Table 3 Multi-variable logistic regression model for two-year failure, including practitioner (*reference level)

Associated factor		Adjusted odds ratio (95% CI)	p-value
Age		1.02 (1.01 to 1.04)	0.003
Moisture contamination	None*	1	0.001
	Minor/major	2.51 (1.49 to 4.24)	
Cavity preparation	None*	1	<0.001
	Prophylaxis/excavator	1.06 (0.57 to 1.98)	
	Rotary/bur	0.35 (0.21 to 0.60)	
Fill Type	Amalgam*	1	0.007
	Glass ionomer	4.77 (1.24 to 18.30)	
	RMGI	3.52 (0.62 to 20.04)	
	Compomer	3.35 (0.84 to 13.45)	
	Composite	3.03 (0.84 to 10.97)	
	Flowable composite	21.21 (3.68 to 122.17)	
Practitioner	1*	1	<0.001
	2	0.23 (0.07 to 0.74)	
	3	1.47 (0.49 to 4.37)	
	4	0.39 (0.13 to 1.16)	
	5	1.28 (0.50 to 3.28)	
	6	0.40 (0.12 to 1.35)	
	7	2.46 (0.95 to 6.39)	
	8	0.18 (0.04 to 0.80)	
	9	0.53 (0.15 to 1.81)	
	10	0.78 (0.29 to 2.07)	

Multi-variable logistic regression

After a number of possible models were examined, the best derived subsets model included: patient age – fill type – cavity preparation – moisture contamination – practitioner.

The results of fitting this model are shown in Table 3. A higher probability of restoration failure by two years was associated with:

- Older patients
- Glass ionomer and flowable composite compared to amalgam
- Preparation: prophylaxis/excavator compared to none, while preparation with rotary/bur was associated with a lower probability of failure compared to none
- Minor/major moisture contamination compared to none.

Fig. 2 A carious Class V restoration affecting a lower second premolar in a smoker with poor oral hygiene

The 95% confidence intervals for the (adjusted) odds ratios were wide, in

particular for comparisons of fill type, indicating uncertainty in the estimates.

The goodness of fit of this model was reasonable (Hosmer-Lemeshow test, p = 0.217) but the corresponding Nagelkerke R^2 value, a measure of how useful the set of explanatory variables is at predicting the response, was low (0.16), although slightly higher than other models examined.

Examination of various diagnostic plots for this best fitting model identified a small number of influential observations. Observations with high 'leverage' (ie observations which may have a disproportionately high influence on the estimated coefficients of the derived model) were removed from the dataset and the modelling rerun. This made no difference to the final derived model (Table 3), and had minimal influence on the estimates of the coefficients.

DISCUSSION

There are many inter-related factors which influence the early failure of restorations.[15] Using cross-tabulations allows the effect of a limited number of factors to be considered in isolation. For this study, such cross-tabulations suggested that, individually, factors associated with early failure were the practitioner, the restorative material, whether the cavity was carious or not and whether the cavity was prepared with a bur or not (Fig. 2). These last two factors are clearly linked and it appears from the follow-up comparisons that preparation with a bur is the principal reason that a greater proportion of restorations placed in carious cavities survived beyond two years than non-carious cavities. Among the restorative materials, amalgam and RMGI restorations performed well while conventional glass ionomer did not. Amalgam was only placed in bur-prepared cavities and its success may be linked to this factor, while regardless of the preparation method, a greater proportion of glass ionomer restorations than other restorations failed within two years.

The association of increasing age of the patient with increased proportions of early failure agrees with the findings of others and as far as the composite materials are concerned, may be the result of the increase in the amount of sclerotic dentine in Class V lesions in older patients, which resists the etching procedure needed for dentine bonding.[16–18] Although glass ionomer might be expected to bond more effectively to the increased mineral content of sclerotic dentine, it will still be subject to edge failure if the cavity is not prepared to allow the glass ionomer to be of adequate thickness at the margins to compensate for its low fracture strength.

The absence of evidence to support significant associations with some factors with early failure is also interesting. Abfraction as a result of occlusal forces has been proposed as an important aetiological process in the formation of non-carious cervical lesions.[19] However, in this study there was no evidence to support early failure of restorations being significantly associated with any of the occlusal features recorded, which lends further support to recent reviews which question the role of occlusion in the development of non-carious cervical lesions (NCCLs).[20,21] In the univariate analysis, contamination with moisture and level of oral hygiene did not appear to increase two-year failure; however the general level of moisture contamination was minor and only 10% of patients displayed poor oral hygiene. Although no significant association with moisture contamination was identified using univariate analysis, the multivariable analysis suggested that moisture contamination increased the chance of early failure, after adjusting for other important factors.

The use of two statistical approaches to analyse the data has allowed a more balanced interpretation of the results. Because the success of restorations is determined by several inter-related factors, a multivariable method may be more appropriate to the analysis of the data collected here. However, the predictive ability of the final multi-variable model was not particularly high, suggesting that there may be other important factors in predicting two-year failure of the restorations. This may be in the form of interactions between some of the collected factors but unfortunately there were insufficient data and too many potential interactions to examine for.

The multi-variable analysis agreed with some of the findings of the univariate analysis, including the importance of the effects of practitioner, preparation method, restoration material type and age of patient. From these results it can be concluded that the skills of the dentist are a major determinant of early failure of Class V restorations. Using a bur to carry out some cavity preparation is also important in improving restoration survival, at least for some materials. While it is usual to prepare the cavity with a bur where caries is present, these results suggest that for non-carious lesions, some preparation is also beneficial. This is in accord with the views of others who recommend providing some mechanical retention for composite restorations[22] and that roughening the surface is advisable to remove superficial sclerotic dentine to which current composite bonding methods are less effective.[16,23] When placing glass ionomer, preparation of the cavity margins is also necessary to allow adequate bulk for this brittle material.[24] Despite the ability of some materials to adhere to tooth tissue, it would appear advisable in practice to use a bur to prepare these lesions in some way, whichever material is selected.[24–26]

The results of our study show both some similarities to and some differences from other studies of Class V restorations conducted over two-year periods. Powell *et al.* placed 116 restorations in 25 patients to compare glass ionomer with composite restorations and with restorations where composite was placed over glass ionomer, and found that glass ionomer alone or as a base for composite restorations achieved better retention rates (97% and 100% respectively) than the composite restorations with a dentine bonding agent only (87%).[14] Folwaczny *et al.*, in a cohort of 37 patients, placed 197 restorations in carious and non-carious lesions and as replacements for existing restorations.[11] Only 151 were available for review at two years (but the number of patients returning was not reported). Of these, all the composite restorations were present, 91% of the compomer and between 90% and 94% of two RMGI materials. Onal and Pamir placed three adhesive restorative material types and realised retention rates of 100% (RMGI), 67% and 68% for two compomers and 70% for a composite.[12] Ermis restored 100 Class V abrasion/erosion lesions using four compomers and one RMGI (20 of each). Retention levels at two years were not statistically different among the materials – between 84% and 90% for the compomer and 95% for the RMGI restorations.[10] In

their study of 34 paired NCCLs, Brackett *et al.* compared the performance of compomer and RMGI restorations.[9] At two years, 32 pairs were re-examined. All the RMGI were retained and 84% of the compomer restorations. In our study, 96% of restorations were reviewed at two years, which compares well with the drop-out rate in many similar studies. There was 94% retention of the RMGI restorations, 84% for compomers and between 81% and 85% for the two types of composite restorations. The good performance of RMGIs, which exceeds that of composites, has been observed in several other studies and perhaps reflects the greater technique sensitivity and time required to bond composites to dentine. Compomers fared as well as composites in our study, whereas in other studies retention of compomer restorations was inferior to composite. As recognised by Brackett *et al.*,[9] the original application technique for compomers did not suggest that significant etching and bonding were required. This may explain the relatively poor retention rates of compomer restorations in earlier studies. The high early failure of the glass ionomer restorations recorded in this study (33%) appears to be at odds with clinical recommendations for its use in NCCLs where aesthetics is not a factor.[27] The study of Matis *et al.* is often referred to as recording a success rate of about 80% after ten years.[28] However, in that study only 18 of the original 30 patients returned for the ten year review (60%) and the survival rate of the three different glass ionomer materials used ranged from 83% down to 67%. The data from the missing patients could have indicated a much worse overall performance. Earlier clinical studies on glass ionomer use in NCCLs have reported both high[29,30] and low[31,32] failure rates. Anecdotally, glass ionomer appears to be regarded as a relatively simple material to use which adheres naturally to dentine. However, it exhibits low fracture strength and low tensile strength which results in a much lower effective bond strength than other adhesive materials.[33,34] Changes in local moisture levels impair its structure[35] and the material does not mature fully for several months, rendering it vulnerable to damage for a prolonged period.[36,37] Glass ionomer therefore demands careful handling, as has been affirmed by other workers,[29,36] and the high failure rate of glass ionomer restorations in our study may indicate that this is not fully appreciated by some practitioners.

CONCLUSIONS

Within this group of practitioners, significant associations were identified from both univariate and multi-variable analysis between failure of Class V restorations within two years and a) the practitioner who placed the restoration, b) the cavity preparation method, c) the restoration material, and d) the age of the patient. Within the restoration materials, amalgam and resin-modified glass ionomer recorded the smallest proportion of early failure while glass ionomer restorations showed the greatest.

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