Longevity of conventional and bonded (sealed) amalgam restorations in a private general dental practice

IN BRIEF

- Bonding dental amalgams conferred no significant benefit upon restoration longevity compared to placing such restorations conventionally.
- From 1,000 days onward the decline in restoration survival accelerated for the bonded amalgams.
- The lack of any obvious benefit upon longevity and greater cost of bonded amalgam restorations challenges the wisdom of their routine provision.

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Objective To compare and contrast the longevity of conventionally placed dental amalgam restorations with those placed using bonding techniques. **Design** Retrospective survival analysis (Kaplan Meier) of dental amalgam restorations placed by a single operator in a private general dental practice. **Subjects and methods** The records relating to dental amalgam restorations placed between 1 August 1996 and 31 July 2006 were sourced. The details of these were placed into a database that permitted flexible interrogation. Survival data on conventionally placed amalgams (C) and those bonded with either Panavia Ex (PE) or Rely X ARC (RX) were exported into a statistical package to permit survival analysis by the method of Kaplan and Meier. **Results** The number of restorations available for analysis were C = 3,854, PE = 51 and RX = 1,797. Percentage survival at one year was C = 96.29, PE = 95.65, and RX = 97.58. Percentage survival at five years was C = 86.21, PE = 76.35 and RX = 82.59. A Log Rank test demonstrated no statistically significant difference (p >0.05) in survival between the restoration types. Amalgam restorations bonded with PE or RX exhibited an acceleration of failure rate around 1,000 days post-placement. Further survival analyses of the method of restoration *versus* type of restored teeth (molar/premolar) and cavity preparation (Class I/II) showed no significant difference in the survival curves in respect of type of restored tooth. In the comparison of Class I and II cavities, the survival curves for the restorations differed significantly (p <0.0001), however when the curves for the Class I restorations alone were compared, no significant difference was found (p = 0.2634). This was also the case for the Class II restorations (p = 0.2260). **Conclusions** Within the limitations of the study, bonding amalgams, compared to placing them conventionally, afforded no significant benefit upon restoration longevity. This, coupled with the emerging trend of an accelerating decline in longevity of bonded amalgams from 1,000 days onwards and with the greater cost, challenges the justification for routine bonding of amalgams.

INTRODUCTION

Dental amalgam is a mixture of a silver alloy with mercury.[1] Traditional amalgam alloys suffered from a lack of strength, exhibited flow and creep and were susceptible to corrosion due to the presence of the γ2, tin-mercury phase.[2] Furthermore, amalgam on its own does not bond to tooth structure and cannot provide a complete seal or be retained in the tooth without some form of mechanical retention such as under-cuts.[3] More recently, attempts have been made to reduce or even eliminate the γ2 phase by increasing the copper content in the alloy to above 13%.[4] This modification of the setting reaction has resulted in some important changes in the properties of the amalgam, namely a higher compressive strength, a more rapid set to full strength, a reduction in creep and a reduced susceptibility to corrosion.[2] This latter point, although a benefit of the newer alloys, can work against the clinician as the corrosion products produced by the γ2 phase in traditional amalgams blocked up the marginal gap at the tooth material interface and decreased microleakage.[5,6] The application of an adhesive material between the tooth and the amalgam at restoration placement theoretically overcomes this problem by creating a better seal between restoration and tooth. It may also improve the retention of the material if the adhesive material bonds to both tooth and dental amalgam. This has the potential to culminate in a restoration of enhanced durability.

Over the years, many materials have been employed to plug the amalgam/tooth interface. These have included zinc phosphate cement,[7] copal varnish[8] and carboxylate cement.[9] Since the mid-1980s, for this purpose, resin composite adhesives which bond to metal have become the materials of choice[10,11] as their bonding potential has been thought to offer considerable advantages. Resin-based composite cements that set by either a chemical (anaerobic) reaction[3] or dual cure[12] have been

mainly employed in contemporary clinical practice, though resin-modified glass polyalkenoate (ionomer) cements have also been used with some success.[13-15]

The technique of *in situ* bonding of amalgam, if realised, offers many benefits. Firstly, reduced microleakage[16-18] offers the potential to decrease post-operative sensitivity,[19] pulpal inflammation[20] and reduce the incidence of recurrent caries.[21] It has also been reported to provide additional retention for the restoration.[22] If bonding was universally applied and successful, precious tooth tissue could be conserved rather than sacrificed to provide mechanical retention and resistance form. In addition, a bonded restoration has been shown to increase the fracture resistance of the tooth and render it more able to resist flexural forces.[23] In the case of teeth exhibiting fractured cusp syndrome, this property can be harnessed to great effect to alleviate or eliminate its symptoms.[24,25] Much of the clinical research on amalgam restorations has been conducted in the university or dental hospital setting. This has been criticised as non-representative of what happens in the setting of dental practice, where most treatment is delivered.[26]

In relation to conventional amalgam restorations, there is not only much variability in their reported lifespan but also in the statistic used to convey this. Of those reporting median survival rates, restoration longevity is between 5.5 to 12.8 years.[27-29] Another approach adopted by others[30] is to report the proportion of restorations surviving at a defined time interval. At 14 to 15 years post-placement, this is 72.8% for simple and 76% for complex amalgams. A comprehensive retrospective literature review[31] concluded that 50% of conventionally placed amalgams last eight to ten years. Others, upon reviewing Class I and II stress bearing amalgams placed in longitudinal, controlled clinical studies and retrospective cross-sectional studies, report annual failure rates of 0% to 7%.[32]

A very recent study retrospectively evaluated the longevity of Class I and II conventionally placed amalgam restorations placed in a general practice. From patient records, data showing longevity and reasons for failure of Class I and II amalgams between the years 1990 and 1997 was collated and evaluated. This yielded 912 amalgam restorations for analysis, of which 502 were placed by one operator and 410 by another. One hundred and eighty-two amalgams failed during the period of follow up. The main reasons for failure were caries (34%), endodontic treatment required (12%) and fracture of the tooth (13%). Life tables calculated from the data revealed a survival of 89.6% at five years and 79.2% for conventionally placed amalgam restorations at ten years. Cox-regression analysis showed a significant effect on the amount of restored surfaces on the survival of the restorations but no significant effect of operator, material or the combination of material and operator was found.[33]

In contrast to the extensive literature available for conventional amalgams, there is a scarcity of clinical studies that relate to the longevity and long-term clinical performance of bonded amalgams. Those which have been published are only of a short duration. One double blind study, conducted over a 42 month period, reported that amalgams which were bonded and those which were placed using copal varnish were free of secondary caries and rated clinically acceptable.[34] Another study prospectively assessed the failure, marginal fracture and marginal staining behavior of 366 Permite C amalgam restorations placed in the posterior permanent teeth of 190 adult patients. These had been lined with one of five dentine bonding resins (Scotchbond 2, Panavia Ex, Amalgambond, Amalgambond Plus, Geristore) and a polyamide cavity varnish (Barrier). Over a five year follow-up period there were five restoration failures (1.4%), usually from tooth fracture, involving Class II preparations in molar teeth.[35] This study was undertaken in general dental practice.

As can be seen, there is clearly a need for further evaluation of the bonded amalgam restoration. The present work therefore sought to compare the clinical durability of conventional and bonded amalgams placed in the setting of general dental practice, the null hypothesis being that there is no statistically significant difference in restoration longevity between the placement techniques.

MATERIALS AND METHOD

The present study is a retrospective study of all silver amalgam restorations placed in Class I and II cavities in permanent teeth between 1 August 1996 and 31 July 2006 by one operator (the lead author) in a private general dental practice in Aberdeen, Scotland. Written correspondence with the Tayside and Grampian Ethics Committees in 2003 before the study commenced established that ethical approval was not required as the study was a retrospective audit of case records.

Restoration placement

Placement of the restoration followed best practice at the time the restoration was provided. Initially, this did not utilise adhesive technology (from 1996 to approximately 2000) but in later years (from 2000 onwards) there was a trend towards more adhesive restorations being placed than conventional amalgams, as a consequence of the lead author's attendance at postgraduate courses.

In all cases the procedure for placement was that local anaesthesia was administered if clinically indicated, recommended or requested by the patient. The cavity was prepared by the use of an air rotor handpiece (W&H Dentalwerk GmbH, Bürmoos, Austria) using a Diatech diamond fissure bur (Coltène Whaledent, Altstätten, Switzerland) to access the caries or to remove a previous restoration. Any caries present was then removed using a stainless steel round bur (UnoDent, CM8 3TZ, England) in a slow speed handpiece (W&H), the bur size depending on the size of the lesion to be excised. When the cavity was considered ready for restoration, a lining was placed if clinically indicated and the material noted. A Siqveland matrix band (Dentsply Ash, Weybridge, England) was placed around the tooth in the case of a Class II cavity. Those restorations that were bonded in place utilised one of two bonding agents: (a) Panavia Ex (Kuraray, Okayama, Japan) or (b) Rely X ARC (3M ESPE, Seefeld, Germany). The clinical technique employed for these agents was:

(a) Panavia Ex – the etching gel supplied with the Panavia Ex kit was applied to the cavity walls and floor using a Microbrush (UnoDent) and

allowed to remain *in situ* for 30 s to etch the cavity in accordance with manufacturer's instructions. This was washed using the 3 in 1 syringe for 60 s and the cavity dried with air from the 3 in 1 syringe for 10 s. Panavia Ex, having been hand mixed as per the manufacturer's instructions, was then applied sparingly with a Microbrush to the cavity walls and floor

(b) Rely X ARC – 37% phosphoric acid etching gel (3M ESPE) was applied to the cavity walls and floor using a Microbrush (UnoDent) and was allowed to remain *in situ* for 15 s to etch the cavity. This was washed using the 3 in 1 syringe for 10s and the cavity dried with air from the 3 in 1 syringe for 2 s. Care was taken not to desiccate the tooth surface. 3M™ Single Bond Adhesive (3M ESPE) was applied to the dentine in two coats with a Microbrush and dried gently using the 3 in 1 syringe for 5 s. This was then cured for 20 s using an Optilux 501 highspeed halogen curing light (SDS Kerr, Danbury, CT, USA). Rely X ARC having been mixed by hand for 10 s as per the manufacturer's instructions was applied sparingly with a Microbrush to the cavity walls and floor.

All amalgams, irrespective of whether bonded or not, were formed from Tytin Slow set amalgam alloy (Kerr, Romulus, MI, USA) in encapsulated form. This was placed by the use of a hand amalgam condenser (Dentsply Ash) using axial and lateral force to pack the amalgam into the cavity. When the cavity had been overfilled, the matrix band (if used) was removed and the amalgam carved to the anatomical form, removing the surface mercury-rich layer with a Ward's carver (Dentsply Ash). The occlusion was checked using 12 μm articulating paper (Coltène Whaledent) held in Miller's forceps (Kent Dental, Gillingham, UK) and any adjustment made if necessary. Appropriate post-operative advice was given to the patient and the patient dismissed. Contemporaneous clinical notes were then entered into the patient's paper record card or, if after June 2003 when the practice computerised the

clinical notes, into the computer using Exact™ Dental (Version 6) (Software of Excellence UK Ltd, Marden, England).

Data extraction and analysis

Prior to the entry of patient details into the study records, a trial database, capable of being flexibly interrogated, was constructed using Microsoft Office Access 2003 (Microsoft Corporation, Redmond, WA, USA) and thoroughly tested. This permitted data under the following headings to be entered:

- Patient's forename
- Patient's surname
- Patient's date of birth
- Tooth (recorded using the FDI system) restored
- Surfaces of tooth restored
- Date of restoration placement
- The names of any bonding agents used in the restoration of the tooth
- If the patient was seen following restoration, a note of either restoration failure or survival was made
- If the restoration had failed, the clinical reason for this and the date that restoration failure was detected was made
- If the restoration was sound the date that the patient was last seen by a dentist was noted.

Various possible parameters were included in drop-down boxes to facilitate data entry in terms of accuracy, speed and convenience. After the database had been designed, fictitious data was fed into it and this was robustly interrogated to ensure that when the real data was entered, the information that was required could be easily retrieved and analysed. This process allowed the design of the database to be modified to further enhance efficient and accurate data entry, before the study data was inputted into the database.

A restoration was classified as failed if it needed replacement or patching. Restorations that were electively modified, for example, by the placement of a crown, were considered not to have failed. In such a case the date of survival entered was the date of crown preparation.

When the database was complete, it was checked for typographical errors.

A number of trial queries whose answer was known were also run to further verify the data. The database was then interrogated to yield survival data on:

- Conventionally placed amalgams
- Amalgams bonded using Panavia Ex
- Amalgams bonded using Rely X ARC.

This was exported into Prism (Version 4.0, Graphpad Software Inc., San Diego, CA, USA) and survival curves were generated by the Kaplan Meier method. Restorations that had survived were treated as censored data, whereas failures were classified as uncensored. Where the data permitted, survival curves were compared using the Log Rank test and the Hazard Ratios computed. The Hazard Ratio was computed to give a measure of how rapidly the restorations were failing and it must be borne in mind that the Hazard Ratio compares two treatments. If the Hazard Ratio is 3.0, the rate of restoration failure is three times the rate in the other group. If survival exceeds 50% at the longest observation interval however, it is not possible to compute a median survival curve[36] and this was indeed the case in the present study. In addition, to enable comparison, the survival rates at one and five years were calculated. Further interrogation of the database yielded the clinical reasons for failure of the restorations and these were compared, for the various restoration groups, using a k × n Chi square test.

RESULTS

In the period covered by the study, a total of 6,331 restorations were initially placed. Of these, the records for 5,702 were suitable for analysis. These encompassed 3,854 conventional amalgams, 1,797 amalgams bonded with Rely X ARC (3M ESPE, Seefeld, Germany) and 51 amalgams bonded with Panavia Ex (Kuraray, Okayama, Japan). The discrepancy between total restorations placed and total analysed arose because restorations that were not clinically reviewed at an appointment subsequent to placement were excluded. These comprised 353 conventionally placed amalgams, 270 restorations bonded with Rely X ARC and three that had been bonded with Panavia Ex.
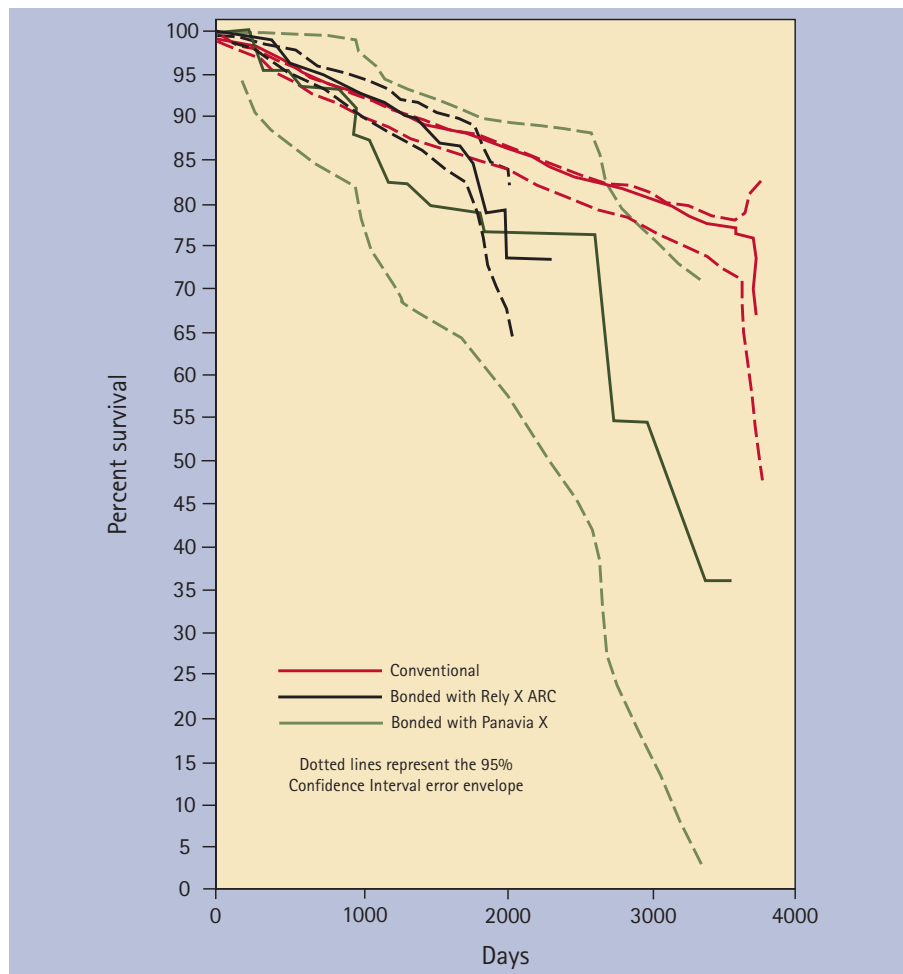
Fig. 1 Survival curves, with 95% confidence interval error envelopes, for the amalgam restoration groups

Table 1 Hazard ratio values for the log rank comparison of survival curves shown in Figure 1		
	Bonded with Rely X ARC	Bonded with Panavia Ex
Conventional amalgam	1.03 (0.82-1.29)	0.57 (0.22-1.00)
Bonded with Rely X ARC	-	0.92 (0.42-1.85)
Parenthesised values are the 95% confidence intervals		

Kaplan Meier survival analyses of the data were undertaken to determine restoration survival according to the type of restoration. Figure 1 presents the survival curves for the three types of amalgam restorations, namely conventionally placed amalgams, those amalgams bonded using Rely X ARC and those using Panavia Ex. This plot also gives the 95% confidence interval error envelope of these curves. When compared using the Log Rank test, there was no statistically significant difference (p >0.05) between them. As reported in Table 1 however, the hazard ratios for (a) conventional amalgams *versus* those

bonded with Rely X ARC and (b) amalgams bonded with Rely X ARC *versus* those bonded with Panavia Ex were similar. Amalgams bonded with Panavia Ex compared to those placed conventionally displayed a lower hazard ratio.

Table 2 gives the number of restorations for each of the three amalgam restoration groups and indicates the proportion surviving at one and five years, together with the 95% confidence intervals of these estimates. It shows that 3.71% and 13.79% of conventional amalgams failed at the one and five year marks respectively. 2.42% of those amalgams bonded using Rely X ARC had failed at one year and 17.41%

were deemed to have failed at the five year period. Of the amalgams bonded with Panavia Ex, 4.35% had failed at twelve months. This level of failure increased to 23.65% at five years. In addition, this table indicates the number of restorations available for scrutiny on starting years one to five and gives the cumulative number of restoration failures that had occurred on entering years two to six.

Notwithstanding the lack of statistical difference between the survival curves, it is interesting to note that around the 1,700 day mark there is a marked separation of the survival curve for those restorations bonded with Rely X ARC away from that for conventionally placed amalgam restorations (Fig. 1). Likewise, at around the 1,000 day mark, the same can be seen for those amalgams bonded using Panavia Ex. The conventional amalgam group thus displayed a more gradual decline in restoration survival compared to the bonded restorations, where this was more rapid. Although at five years conventionally placed amalgam restorations demonstrated a greater longevity than amalgam restorations bonded either with Rely X ARC or Panavia Ex, there was no statistically significant difference for survival between any of the groups.

In order to ascertain if the overall survival curves (Fig. 1) may have been influenced by a significantly different allocation of the methods of restoration (conventional, bonded with Rely X ARC or Panavia Ex) to restored tooth type (premolar/molar) or cavity preparation (Class I or II) K × n Chi square analyses were undertaken of the number of restorations at outset in each category. This demonstrated no significant allocation difference in respect of tooth type (π = 4.55, d.f. = 2, p <0.05) but revealed a significant difference in the case of cavity type (π = 63.39, d.f. = 2, P <0.01). As a consequence, a Kaplan Meier survival analysis of the data according to cavity preparation with subgroupings of method of restoration placement (conventional, bonded with Rely X ARC or Panavia Ex) was undertaken. The subsequent Log Rank test showed highly significant (p <0.0001) differences between the Class I and II cavity survival curves. When however, the survival curves for the Class I cavities alone were compared,

Table 2 The number of restorations for the three amalgam restoration groups with the proportions surviving at one and five years with 95% confidence intervals. The number of restorations at the start of years 1–5 and also the number of cumulative restoration failures that had occurred at the start of years 2–6 are given

	Number of restorations at start of year					Cumulative number of restorations failed at start of year					% survival at 1 year (+/-)	% survival at 5 years (+/-)
	1*	2	3	4	5	2	3	4	5	6		
Conventional amalgam	3,854	2,957	2,498	2,146	1,807	143	274	378	470	540	96.29 (0.64)	86.21 (1.33)
Bonded with Rely X ARC	1,797	1,004	632	382	209	44	96	157	214	313	97.68 (0.83)	82.59 (4.97)
Bonded with Panavia Ex	51	44	38	32	28	2	3	8	10	12	95.65 (4.35, 5.91)	76.35 (13.76)

*Of these, 3,159 (conventional), 1,619 (Rely X ARC) and 46 (Panavia Ex) restorations were in Class II cavities and the remainder in Class I. In relation to tooth type, 1,162 (conventional), 572 (Rely X ARC) and 10 (Panavia Ex) restorations were in premolars and the remainder in molars.
Where the percentage survival at 1 and 5 years are quoted, the values in parentheses are the upper and lower 95% confidence intervals. Where only one value is parenthesised, this represents both upper and lower confidence intervals.

according to method of restoration, they did not differ statistically significantly (p = 0.2634). This was also the case for the Class II cavities (p = 0.2260).

Table 3 summarises, for each placement technique, the reason for classification of restoration failure and both the number and proportion of restorations so affected for the entire duration of the study. The small number of failures, particularly in the case of the Panavia Ex group, makes meaningful statistical comparison problematical. It is clear however, by a Chi square test that excludes the Panavia Ex group, that the distribution of failure types is statistically significantly (p <0.01, X^2 = 36.53) influenced by the method of restoration placement. In this regard, restorations bonded with Rely X ARC suffered proportionally less failures due to pulpal episodes, recurrent caries and fractures of either tooth or restoration. Despite these apparent advantages, proportionally more amalgams bonded with Rely X ARC were lost compared to those that were placed conventionally.

DISCUSSION

In the study reported here, the number of restorations reported as failed, due to the wide ranging definition of failure, is perhaps an overestimate. It is therefore pleasing to see such low overall restoration failure rates. The data giving a breakdown of reasons for restoration failure (Table 3) suggests that restorations bonded with Rely X ARC, compared to conventionally placed amalgams, offer reduced microleakage and incidence of

Table 3 Reason for amalgam failure – the actual number and proportion of failed restorations of each type of amalgam

	Pulpal episode	Tooth fracture	Restoration fracture	Recurrent caries	Loss of restoration	other
Conventional amalgam	179 (4.64%)	186 (4.83%)	22 (0.57%)	75 (1.95%)	23 (0.60%)	14 (0.10%)
Bonded using Rely X ARC	36 (2.00%)	37 (2.06%)	7 (0.39%)	7 (0.39%)	22 (1.22%)	1 (0.05%)
Bonded using Panavia Ex	3 (5.88%)	8 (15.69%)	0 (0.00%)	1 (1.96%)	1 (1.96%)	0 (0.00%)

Numbers of restorations refer to the number of failures throughout the study

tooth fracture. Such findings appear to an extent to match the expectations of other workers[16-21] for such restorations. In contrast, in the present study, there was a higher proportional incidence of lost restorations in the Rely X ARC bonded group compared to those in the conventionally placed amalgam group (Table 3). For the longer term however, it is of potential concern to note that although no statistically significant difference in the performance of conventionally placed amalgam restorations in terms of longevity compared to those amalgam restorations that were bonded was detected, an accelerated decline in survival of the bonded amalgams at around 1,000 days was noted (Fig. 1). This suggests strongly that there may be a different mode of failure occurring in the bonded restoration groups compared to the conventional amalgam group. The phenomenon so observed is suggestive of some form of time dependent degeneration. In the case of the Rely X ARC bonded restorations, these were placed following acid etching and application of a dentine bonding agent. Such a wet bonding technique is both operator

sensitive[37] and said to risk nanoleakage[38] at the tooth/bonding agent interface (hybrid layer). Nanoleakage arises where the dentine has been demineralised to a greater depth in the bonding process than the bonding resin can penetrate. The collagen in these deeper layers is susceptible, with time, to degradation or degeneration,[38] with catastrophic disruption of dentine microstructure and consequential loss of attachment of the bonding resin. This, or suboptimal clinical technique, may account for the failure of the restorations bonded with this agent.

In the case of Panavia Ex bonded amalgams, it has been reported that the phosphonated ester, a part of the adhesive component of the material, is prone to hydrolytic degradation.[39,40] This may, in clinical function, have brought about the failures seen. The phosphonated ester is less stable than other chemicals present in other bonding systems as a consequence of its greater chemical reactivity.[41] This fact may account for the earlier decline in survival of the Panavia Ex bonded amalgams compared to those bonded with Rely X ARC, which

has no phosphonated ester present. It is, however, acknowledged that the survival results in the present study compare less favourably than in other published work using Panavia Ex as the bonding agent.[35] Panavia Ex bonds fairly poorly to dentine but reasonably well to fresh amalgam.[35] As a result, failure at the bond to dentine is risked. Although, in order to optimise the anaerobic polymerisation of the cement, application of Oxyguard (Kuraray Dental Company, Osaka, Japan) to the restoration margins is advocated by some,[3] this was not carried out at placement for it was believed that the presence of the amalgam restoration would in part seal the cavity and so produce such environmental conditions. Such a difference in placement protocol may account for the lower durability of the Panavia Ex bonded restorations compared to that reported by others.[35]

The decision to place either a conventional or adhesively bonded amalgam restoration was based purely upon the prevailing standard operating procedure of the operator at the time the restoration was required. Although, to certain recollection, cavity design was not radically different between the groups, it is acknowledged that, as the operator's experience with the bonding technique developed, it could have decreased the level of emphasis placed upon mechanical cavity preparation features. Although the use of rubber dam has been advocated to improve the longevity of dental restorations,[42,43] it was not applied for any restorations placed in this study. It is acknowledged that, had scrupulous cotton wool roll isolation and the use of high volume aspiration not been in place, this could have affected longevity. With this point in mind it is of interest to note that a recent consensus summary on the teaching of posterior composite restorations in undergraduate dental schools in the UK and Ireland subscribes to this technique of isolation without rubber dam when placing this moisture sensitive material.[44]

In light of these results, the clinician must consider if the additional time and monetary cost of routinely placing a bonded restoration is of benefit to the patient. In the study reported here,

no statistically significant increase in longevity was observed and there was a suggestion of a time dependent failure mechanism at around 1,000 days for such restorations. Under the conditions of this study, the routine use of such amalgams cannot therefore be justified.

CONCLUSIONS

From this work and within the limitations of the study, it is concluded that:

- Bonding amlagam restorations has no significant effect upon the longevity of the restoration compared to conventionally placed amalgam restorations
- The conventional amalgams over the period of the study displayed a more gradual decline in survival than those that were bonded. This emerging separation in survival curve, at 1,000-1,700 days, is of potential concern for the future survival prospects of the bonded restorations
- The lack of any obvious long-term benefits of bonded amalgams, with their associated increased cost of placement, questions the validity of routinely bonding amalgams.

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