Bonded amalgam sealants and adhesive resin sealants: Five-year clinical results

Michal Staninec DDS, PhD[1]/Nelson Artiga, DDS, MPH, FACD[2]/Stuart A. Gansky, DrPH3/
Grayson W. Marshall, DDS, MPH, PhD[4]/W. Stephan Eakle, DDS[5]

Bonded amalgams were used as pit-and-fissure sealants without mechanical preparation. They were compared with resin-based pit-and-fissure sealants for retention over a 5-year period. Clinical examinations at 6 months, 1 year, 2 years, and 5 years revealed no difference between the two techniques. Although amalgam sealants may not be practical by themselves, they can be used to seal pits and fissures surrounding very conservative preparations, in the "preventive amalgam restoration." Conventional amalgam retentive features and 90-degree cavosurface margins may not be necessary when bonding is used with amalgam. *(Quintessence Int 2004;35:xxx–xxx)*

Key words: adhesion, clinical study, dental amalgam, dental sealants

CLINICAL RELEVANCE: Occlusal pits and fissures can be successfully sealed with bonded amalgam. This may be particularly useful around amalgam restorations, eliminating the need for extension for prevention and creating a "preventive amalgam restoration." **[Au: The previous sentence is awkward and confusing. Please rephrase]** The amalgam-resin-tooth bond appears to be clinically stable.

[Au: Are all affiliations OK?]

[1]Clinical Professor, Department of Preventive and Restorative Dental Sciences, UCSF School of Dentistry, San Francisco, California.

[2]Director, University of California at San Francisco (UCSF) Family Dental Center; Associate Clinical Professor, Department of Preventive and Restorative Dental Sciences, UCSF School of Dentistry, San Francisco, California.

[3]Assistant Professor, Department of Preventive and Restorative Dental Sciences, Center for Health and Community, Center to Address Disparities in Children's Oral Health, UCSF School of Dentistry, San Francisco, California.

[4]Professor, Department of Preventive and Restorative Dental Sciences, UCSF School of Dentistry; Chair, Biomaterials and Bioengineering Division, UCSF, San Francisco, California.

[5]Professor, Department of Department of Preventive and Restorative Dental Sciences, UCSF School of Dentistry, San Francisco, California.

Reprint requests: Dr Michal Staninec, Department of Preventive and Restorative Dental Sciences, UCSF School of Dentistry, Box 0758, San Francisco, CA 94143-0758. E-mail: stanin@itsa.ucsf.edu

*This study was presented at the 2000 AADR **[Au: Please spell out AADR]** meeting in Chicago, Illinois. **[Au: What were the dates of this meeting?]***

The use of amalgam is decreasing in developed countries as many patients and clinicians are opting for tooth-colored restorations, but amalgam is still used for a large portion **[Au: "Portion" OK?]** of direct posterior restorations.[1] Adhesive restorative techniques are popular because, among other advantages, they decrease the need to remove noncarious tooth structure for retention,[2] and, like many other restorative materials, amalgam can be bonded to tooth surfaces with resins.[3] Amalgam-bonding resins were introduced in the 1980s,[4] and since then, the use of adhesives for amalgam has become a popular but not universal procedure. The introduction of newer resin systems suggests a need for continued evaluation of adhesive-amalgam techniques to prevent caries, marginal leakage, and postoperative sensitivity.

The adhesive-amalgam technique has been studied extensively in vitro. Early studies demonstrated the possibility of bonding fresh amalgam to tooth surfaces with adhesive resins, which resulted in a decrease in leakage.[5] **[Au: You say "studies" but only give one reference. Please include other references]** Subsequent laboratory studies demonstrated several advantages, including retention of amalgams by bonding superior or equal to retention of amalgams by undercuts when exposed to simulated occlusal loads in proximal cavities[6,7]; inhibition of secondary caries in vitro[8]; and improved resistance to fracture.[9] **[Au: The previous sentence is awkward and confusing. Please rephrase]**

TABLE 1 Materials used

Purpose	Product	Batch no.	Manufacturer
Etching	Unietch (32% phosphoric acid semi-gel)	029254	Bisco
Primer	Primer A (Na NTG-GMA in acetone)	029094	Bisco
	Primer B (BPDM in acetone)	019214	Bisco
Liner	Liner F base	029154	Bisco
	Liner F catalyst	029264	Bisco
Sealant	Bisco Pit & Fissure Sealant	029034	Bisco
Amalgam	Tytin, spherical high-copper alloy		Kerr

More recently, some clinical evaluations of the bonded amalgam technique have begun to appear. Staninec et al[10] reported results from a pilot retrospective clinical study that examined bonded amalgams after several years of clinical service in primary molars. Some of the studies examined amalgam restorations in standard preparations,[11–13] and some used extensive preparations with cusp replacements.[14,15] Generally, no significant differences were reported between bonded and nonbonded amalgams placed in standard, undercut preparations. For this reason, one author questioned the wisdom of using bonding, which takes additional materials and time.[13] However, when sufficient undercut is not present, a bonded amalgam restoration can be retained in a preparation that would not retain a nonbonded amalgam restoration.[11] One of the studies used extensive preparations, many without any undercuts, and compared bonded amalgam restorations to amalgam restorations retained by pins. The adhesive was able to retain amalgam without undercuts over a 5-year period.[15]

The present study examined bonded amalgam sealants over a 5-year period. This is a follow-up of 2-year data reported previously.[16] The original hypothesis of the study was amalgam sealants will perform better over time because amalgam possesses wear resistance superior to that of unfilled or lightly filled resins, which are generally used for sealants. Another aim was to examine the stability of the amalgam-resin-tooth bond in a clinical environment, with possible implications for bonded amalgam restorations. A thin layer of amalgam bonded over unprepared pits and fissures represents a rather severe retention challenge for the material, and thus presents an opportunity to examine the stability of the bond without any mechanical retention. After 2 years, no differences between amalgam and resin sealants were found.[16] This report compares these two groups after 5 years of clinical service.

PURPOSE

The hypothesis tested was that adhesively bonded amalgam could be used instead of resin-based pit and fissure sealants, and that such amalgam sealants will be retained as well or better than resin based sealants, will be more wear resistant, and will provide longer clinical service than resin-based pit and fissure sealants. Another hypothesis was the amalgam-resin-tooth bond is stable in vivo after 5 years of clinical service.

METHOD AND MATERIALS

Patients in good health, with no contraindications to routine dental treatment, needing at least two pit-and-fissure sealants in permanent posterior teeth were screened and selected. The study received ethical approval from the University of California at San Francisco Committee on Human Research, and informed consent was obtained from the patients or their guardians prior to treatment. An attempt was made to find contra-lateral pairs of teeth in the same patient, one of which would be sealed with a conventional, resin-based sealant and the other with the adhesive amalgam technique. A total of 114 teeth in 26 patients were initially included in the study. The age of the patients ranged from 6 to 25 years at placement. Table 1 shows the materials used for this investigation.

Each tooth was photographed prior to treatment. The sealants were placed as follows: For the experimental amalgam sealants, teeth were cleaned using a prophylaxis brush with nonfluoridated pumice, isolated with rubber dam, etched with phosphoric acid for 30 seconds, rinsed for 30 seconds, and gently dried, leaving surface slightly moist. All-Bond 2 Primer A & B (Bisco) mixture was placed in several coats until the surface was glossy. The surface was then dried thoroughly, and primer was light cured 30 seconds. Liner F (Bisco) was mixed and painted in a thin layer over the set primer, then amalgam was immediately condensed over the surface and burnished into all grooves. Excess amalgam was cut away. The rubber dam was removed, and occlusion was checked and adjusted. The protocol for amalgam bonding was derived from the authors' clinical and research experience, recently reviewed.[3]

TABLE 2 United States Public Health Service criteria [Au: need reference] for success of sealants

A	Complete retention, no exposed grooves judged to be at risk for developing caries (no loss)
B	Partial retention with some grooves exposed, but not judged to be at risk for developing caries (slight loss)
C	Partial retention, exposed grooves judged to be at risk for developing caries; reapplication indicated (repair required)
D	Total loss of material

The control teeth (with resin sealant) were treated in the same way up to and including the primer step. A conventional sealant (Bisco) was placed into all grooves and light cured 30 seconds. For both groups, photographs of the sealed teeth were taken before dismissing the patient.

Recalls were scheduled at 6 months and 1, 2, 3, 4, and 5 years following placement. At each recall, a clinical examination was performed, and sealant retention was rated (Table 2). A photograph of each sealant was made, and a polyvinyl siloxane impression (Exaflex, GC America) was made of selected sealants. Epoxy casts (Stycast, Emerson & Cuming) were made from the impressions for scanning electron microscope (SEM) examination of interesting features, such as site of failure. Table 2 shows the four-point rating scale (A to D), and Table 3 summarizes the experimental and control tooth numbers at placement and the 5-year recall. Two operators placed all the resin and amalgam sealants, and two trained examiners working together, from a total of five different examiners, performed each clinical evaluation. Because of the obvious difference between amalgam and resin sealants, examiners could not be blinded during the examinations.

Statistical methods

Ninety-seven teeth were included in the 5-year analysis. Mantel-Haenszel chi-square tests stratifying on participant, as well as logistic (binary), ordinal logistic, and discrete time-to-event models accounting for clustering of teeth within patients (Generalized Estimating Equation [GEE] models), were used to compare longevity of amalgam to resin sealants and of sealants on premolar to molars. Since some people missed intermediate follow-up visits and then were rated as needing sealant replacement (eg, B at 36 months, missed 48 months, and C at 60 months), results were re-assessed assuming a uniform distribution (eg, C at 54 months above).

TABLE 3 No. of experimental and control teeth at placement and 5-year recall

	Placement	5-year recall
Total no. of patients	26	15
Total no. of teeth treated	116	97
Total no. of perfectly matched pairs	45	39
Molar amalgam sealants	37	29
Molar resin sealants	36	29
Premolar amalgam sealants	20	18
Premolar resin sealants	23	19

Au: please indicate which are control and whiare experimental.

RESULTS

Table 4 shows the summary of results at the 5-year recall. In the within-person analyses, there was no difference between the two types of sealants in the 2-year clinical scores, as the Mantel-Haenszel chi-square tests of trend score stratifying on participant were not significant for teeth in subjects in the paired-teeth study design (P = .72) or for all teeth (P = .56). This pattern also held when separate analyses by tooth type (premolars and molars) were performed. However, each material performed better in premolars than molars (Table 5). Caries were not observed on any of the sealed surfaces throughout the 5-year period of follow-up examinations. The odds ratio of failure (C or D rating) by 60 months for amalgam versus resin was 1.15 (P = .62; 95% confidence interval [CI]: 0.65–2.05) from binary GEE model, while the odds ratio of having a worse category by 60 months for amalgam versus resin was 1.16 (P = .47; 95% CI: 0.77–1.75) from the ordinal GEE model. Moreover, the hazard ratio of time to failure (C or D) rating for amalgam versus resin was 0.81 (P = .65; 95% CI: 0.33–2.02; design effect = 1.13) from cluster adjusted proportional hazards regression. Assuming uniform imputation for people who missed an intermediate visit, did not change the results appreciably. **[Au: The previous sentence is confusing. Please rephrase]** A molar tooth was 4.9 times more likely to need resealing by 60 months than a premolar (binary GEE P = .04) and 5.6 times more likely to have a worse rating than a premolar tooth by

TABLE 4 Five-year clinical ratings—amalgam vs resin sealants (no. of teeth)

Rating	Amalgam sealants	Resin sealants
A = no loss	26% (12)	30% (15)
B = slight loss	34% (16)	32% (16)
C = repair required	40% (19)	38% (19)

TABLE 5 Five-year clinical ratings—molars vs premolars (no. of teeth)

Rating	Molar	Premolars
A = no loss	14% (8)	49% (19)
B = slight loss	33% (19)	33% (13)
C = repair required	53% (31)	18% (7)

Fig 1a Two mandibular molars at the 6-month recall, one sealed with resin and the other with bonded amalgam. (both rated A).

Fig 1b The same two molars at the 5-year recall. Both were rated A, although slight loss of material is apparent at the 5-year recall.

60 months (ordinal GEE $P = .02$). Finally, a molar tooth had a hazard ratio of 6.8 compared to a premolar tooth (cluster discrete survival model $P = .004$).

Qualitative observations showed the failure mode of the resin sealants appeared to be mostly by debonding, where some of the grooves and pits lost all of the sealant, leaving a deep fissure. In the amalgam group, sometimes the amalgam appeared to debond along with the underlying resin, leaving an exposed deep fissure, and sometimes the amalgam debonded from the resin, leaving a layer of resin in the fissure.

Figure 1a shows two mandibular molars at the 6-month recall, one sealed with resin, and the other with bonded amalgam. Figure 1b shows the same two molars at the 5-year recall. Both were rated A at both recalls, although slight material losswas apparent at the 5-year recall. Figure 2a shows a maxillary molar sealed with bonded amalgam at the 6-month recall (rating A), and Fig 2b shows the same tooth at the 5-year recall (rating B). Loss of material was apparent, but the tooth was not judged to be in need of resealing. Figure 3a shows the 2-year recall image of an amalgam sealant on a maxillary second premolar, a resin sealant on a first molar, and another amalgam sealant on a second molar. All were rated A. Figure 3b shows the same teeth at 5 years. At this time, loss of material was apparent, particularly in the molars. The 5-year ratings were A for the premolar, B for the first molar, and C for the second molar, because the distal pit was completely exposed. Figure 4a shows a maxillary first molar sealed with a resin sealant at the 6-month recall (rating A). Figure 4b shows the same tooth at the 5-year recall. The rating was C because the distal and lingual grooves were completely exposed.

DISCUSSION

The original hypothesis was bonded amalgam sealants would be superior to resin sealants. An improved, longer-lasting method of sealing pits and fissures would result in a reduction of caries in the cases where there was no follow-up. For those followed-up, reapplication of sealants could be done less frequently, resulting in savings of time and money. However, at both the 2-year recall and the 5-year recall, the bonded amalgam sealants appeared to be only equal and not superior to resin sealants. It seems unlikely that any future recalls would show superiority of the bonded amalgam sealants.

Fig 2a A maxillary molar sealed with bonded amalgam at the 6-month recall (rated A)

Fig 2b The same tooth at the 5-year recall (rated B). Loss of material is apparent, but the tooth was not judged to be in need of resealing.

Fig 3a An amalgam sealant on a maxillary second premolar, a resin sealant on a first molar, and another amalgam sealant on a second molar at the 2-year recall. All were rated A.

Fig 3b The same teeth at 5-year recall. Loss of material is apparent, particularly in the molars. The 5-year ratings were A for the premolar, B for the first molar, and C for the second molar, because the distal pit was completely exposed.

Fig 4a A maxillary first molar sealed with a resin sealant at the 6-month recall (rated A).

Fig 4b The same tooth at the 5-year recall. It was rated C because the distal and lingual grooves were completely exposed.

Cost effectiveness was not examined in the present study; however, the amalgam sealants would clearly be more expensive, as more materials and steps are involved in the procedure. Therefore, the placement of amalgam sealants as a stand-alone technique does not appear to be a practical alternative to resin sealants. Resin-based pit-and-fissure sealants have been used successfully since the 1960s, and recent studies **[Au: References aside from 17?]** show their long-term effectiveness in preventing caries for periods up to 20 years.[17] Other reports **[Au: References?]** have demonstrated the effectiveness of sealants in various populations, including high-caries-risk populations.[18]

Amalgam sealants were compared to resin sealants, because resin sealants are universally accepted as an effective technique for preventing pit-and-fissure caries. In the current study, teeth sealed with amalgam sealants were not compared to unsealed teeth because the authors felt it would have been unethical to leave susceptible pits and fissures unsealed. Since resin sealants are an accepted, well-documented, and effective method of preventing caries on occlusal surfaces, any new technique should be compared to this standard.[17] No caries on the sealed surfaces were observed throughout the study, and care was taken to reseal any surfaces that obtained a C rating (needing repair because of exposed susceptible grooves).

Limitations of the study included nonrandomized assignment of sealant type to teeth and the inability to blind evaluators at follow-up. However, since no differences were found between groups, and because the hypothesis was amalgam sealants would have better retention, there did not appear to be any evaluator bias. Eleven participants (42%) with 19 teeth (16%) were lost to follow-up. Those lost to follow-up had a mean of 1.7 teeth in the study, while those retained had a mean of 6.5 teeth. Thus, other factors related to the number of study teeth might also be related to lost-to-follow-up. Due to the somewhat high loss-to-follow-up of participants, power may be low. The results of the present study may be relevant to bonded amalgam restorations. It appears from the current results that the tooth-resin-amalgam bond is as stable in the clinical environment over the 5-year observation period as the tooth-resin bond. The bonded amalgam sealant represents a challenge in terms of retention as only a thin layer of amalgam is bonded into the pits and fissures and is exposed to the forces of mastication. With any mechanical preparation of the teeth, which would increase the bulk of amalgam and provide some walls for the restoration, the performance should be improved; however, heavy occlusal forces or a bruxing habit may compromise the result.

In recent clinical studies of bonded amalgam restorations, it appears that improvement in retention is the only advantage that can be discerned. Most studies have used conventional preparations,[11–13,19] and some have used extensive preparations with cusp replacements.[14,15] None of the studies reported any significant differences in postoperative sensitivity, marginal integrity, secondary caries, or tooth fracture between bonded and nonbonded amalgam restorations. Because of this lack of differences, particularly in conventional preparations, one author questioned the wisdom of using bonding, which takes additional materials and time.[13] Three of the studies reported that some of the bonded restorations were successful in preparations without mechanical retention.[11,15,19] The study of Summitt et al[15] did compare pin retention to the adhesive; however, in such studies it is difficult to eliminate mechanical retention entirely, as some undercuts may be present after removing caries and previous restorations. Thus, so far, there is some limited evidence that bonded amalgam restorations can be successful in preparations without mechanical retention.

Consideration should be given to the resin that is used for bonding amalgam. Other published clinical studies all used different resins: One study used Amalgambond Plus **[Au: Manufacturer?]**,[15] two used Panavia EX **[Au: Manufacturer?]**,[11,13] another used All-Bond C & B **[Au: Manufacturer?]**.[19] All of these resins have demonstrated fairly high bond strengths in laboratory studies; however, other resins may not perform as well, because bond strengths can vary considerably.[20] Future research should examine various adhesives and various preparation designs, including ultraconservative preparations without undercuts.

CONCLUSION

Amalgam was bonded in a thin layer into unprepared pits and fissures as a sealant and was as well retained as resin sealant at 5 years.

Conventional retentive features and a 90-degree cavosurface angle may not be necessary for amalgam restorations when bonding is used.

ACKNOWLEDGMENT

The authors gratefully acknowledge support by a grant from Bisco, Schaumburg, Illinois, during the first year of the study and the administrative and technical help provided by Ms Esperanza Urista.

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