Clinical evaluation and marginal leakage of Amalgambond Plus: Three-year results

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Abstract Amalgambond Plus with a high-performance additive was evaluated for its ability to bond a resin composite or an amalgam alloy to deep dentin in primary teeth with nonretentive cavity preparations. The clinical performance of amalgam and resin composite mesio-occlusodistal restorations bonded with Amalgambond Plus was evaluated at 15 months and 2 and 3 years. There was no statistically significant difference in the retention, marginal adaptation, secondary caries, and post-operative sensitivity over the times of the evaluation or between amalgam and resin composite restorations. After 3 years, most of the teeth were extracted because it was their exfoliation time, and 29 restorations limited within buccal and lingual cusps were evaluated for marginal leakage. There were no significant differences in microleakage between amalgam and resin composite restorations lined with Amalgambond Plus. Amalgambond Plus has the potential for serving successfully as a cavity liner with either amalgam or resin composite restorations. (Quintessence Int 1997;28:651-656.)

Clinical relevance
The long-term in vivo performance of resin-lined amalgam restorations was as clinically acceptable as that of bonded resin composite restorations. Microleakage was absent in both types of restoration.

Introduction
Resin composite restorations should adapt perfectly to tooth structure because they have no clinically verified bacteriostatic or bactericidal properties, and mechanisms that close marginal gaps, such as the formation of corrosion products, are missing.

During the polymerization of resin composites, shrinkage of 3% to 5% takes place. The forces of the polymerization contraction generally exceed the adhesive forces to the cavity walls. This results in marginal gaps. 1 Open margins lead to marginal discoloration, bacterial penetration, hypersensitivity, and secondary caries. 2-4 An increased amount of filler in the resin composite material 5 and the use of incremental techniques 6 contribute to the reduction of polymerization shrinkage.

Marginal microleakage has also long been a problem in amalgam restorations. Because the adherence of amalgam to enamel and dentin is not strong, microleakage is an inevitable consequence. Cavity varnishes have, to some extent, proven useful in decreasing microleakage. However, they too adhere poorly to amalgam and tooth tissues, so they have not solved the problem. 7

Another technique for sealing amalgam margins, reported by Fukuda, 8 consists of placing a resin based on diethylene glycol dimethacrylate o-methacryloxyethyl phthalate on the margins of the restoration after carving. This method is effective in inhibiting recurrent caries around amalgam; however, it is not able to seal enamel fissures not directly bordered by amalgam.
Recently, marginal microleakage associated with amalgam and resin composite restorations can be greatly reduced by bonding agents. Although introduced primarily to bond amalgam to tooth surfaces, Amalgambond (4-methylacryloxyethyl trimellitate anhydride-methyl methacrylate-tri-N-butylborane [4-META/MMA-TBB]) dentin bonding agent (Parkell) achieves a bond between resin composite and dentin at least as strong as today's best dentin bonding systems, and its effectiveness in deep dentin provides an advantage over the other dentin bonding agents for resin composites. Amalgambond Plus, with high-performance additive (HPA) powder, allows amalgam restoration of virtually flat teeth and is indicated when the restoration offers severely limited retention and resistance form, although it is not always required for resin composites. In spite of the advantages of the product, few long-term in vivo studies have been published on the adhesive amalgam technique.

The purpose of this in vivo study was to evaluate the clinical performance and marginal microleakage of Amalgambond Plus in deep dentin in primary teeth, comparing its effectiveness when used as a bonding agent with a resin composite and amalgam alloy.

**Method and materials**

**Clinical evaluation**

In a previously published article, symmetric primary molars with large mesio-occlusodistal or bucco-occlusolingual cavities had been selected in 25 children, 6 to 9 years of age. Following radiographic and clinical examinations, the cavities were prepared by removal of only carious tissues. If the dentin was pink, a calcium hydroxide layer was used. If not, Amalgambond Plus was applied. If there was a pulp exposure, it was capped with calcium hydroxide and restored with a provisional restorative material to allow healing and formation of a dentinal bridge. At the end of 21 days, the provisional restoration was removed and formation of the reparative dentin was confirmed.

Amalgambond Plus dentin bonding agent was applied according to the manufacturer's instructions before amalgam (Alloyx) and Superlux resin composite (Dental Material) restorations were placed in symmetric cavities in the same patient. Resin composite (Dental Material) was light cured with a Visilux 2 curing light (3M Dental) for 40 seconds. After the restorations were polished, postoperative radiographs were taken and restorations were observed at baseline and every 3 months for up to 15 months. Restorations were examined for marginal adaptation, secondary caries, postoperative hypersensitivity, and retention, using the US Public Health Service criteria described by Cvar and Ryge.

This study is a continuation of the previous one. The same patients were evaluated clinically between 15 months and 3 years by using the same parameters. Postoperative periapical and bitewing radiographs were taken and restorations were observed at 2 and 3 years.

**Dye penetration**

At the end of 3 years, most of the teeth were extracted because it was their exfoliation time. Twenty-nine restorations limited within buccal and lingual cusps were selected for buccolingual sections. The teeth were kept in a humid environment until the time of sectioning. The surfaces of the teeth, apart from the restoration and 1 mm of the surrounding enamel, were coated with a layer of nail varnish and a layer of boxing wax. The coated teeth were then immersed in a solution of 1.25% methylene blue in absolute ethanol for 24 hours. The coatings were stripped from the teeth by peeling, and the teeth were embedded in acrylic resin. Buccolingual sections were obtained by grinding off the embedded teeth parallel to their axes.

The sections were polished under running water and examined under binocular microscope. The examiners evaluated the specimens two times. The degree of dye penetration was evaluated according to the following numerical criteria: 0 = no leakage; 1 = penetration of dye along the occlusal wall limited to the enamel; 2 = penetration of dye along the complete length of the occlusal wall but not along the pulpal wall; 3 = penetration of dye along the pulpal wall; 4 = diffusion of dye into the dentin under the pulpal wall; and 5 = penetration of dye through the dentin to the pulp chamber.

**Results**

**Clinical evaluation**

Of the 50 restorations performed in this study, 45 restorations were available for clinical evaluation after 15 months. At the end of 2 years, 38 restorations could be included for the study. After 3 years, 34 restorations were available for this study. Results of the clinical evaluation at 15 months, 2 years, and 3 years are summarized in Table 1. The chi-square test was used, and there was no statistically significant difference in
Table 1 Evaluation results according to the US Public Health Service system

<table>
<thead>
<tr>
<th>Marginal adaptation</th>
<th>15 mo</th>
<th>2 y</th>
<th>3 y</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Amalgam</td>
<td>23 Alfa</td>
<td>100</td>
<td>19 Alfa</td>
</tr>
<tr>
<td>Composite</td>
<td>22 Alfa</td>
<td>100</td>
<td>19 Alfa</td>
</tr>
<tr>
<td>Secondary caries</td>
<td>22 Alfa</td>
<td>100</td>
<td>19 Alfa</td>
</tr>
<tr>
<td>Retention</td>
<td>22 Alfa</td>
<td>100</td>
<td>19 Alfa</td>
</tr>
<tr>
<td>Postoperative hypersensitivity</td>
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<tr>
<td>Amalgam</td>
<td>23 Alfa</td>
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Dye penetration

The results of the dye penetration test are summarized in Table 2. Six of 14 teeth in the amalgam group and 3 of 15 teeth in the resin composite group presented no dye penetration (Figs 3a and 3b). Seven amalgam and eight resin composite restorations presented degree 1 dye penetration. One amalgam restoration and three resin composite restorations had degree 2 dye penetration. Only one amalgam restoration presented severe leakage. A chi-square test revealed that there was no significant difference between amalgam and resin composite restorations lined with Amalgambond Plus.

Discussion

A lack of adhesion to tooth structure is the shortcoming that has limited the effectiveness of amalgam restorations in certain situations. The concept of bonded amalgam diminishes the requirement for mechanical retention of the restoration and permits greater conservation of the tooth structure in the same fashion as resin composite restorations that are placed in conservative, nontraditional cavity preparations and secured by the acid-etch technique.

Another major problem associated with amalgam restorations is microleakage, which leads to pulpal irritation and secondary caries. Ben-Amar et al evaluated the sealing effect of a new adhesive material (Amalgambond) comparing it to a conventional varnish (Copalite) and a silver-containing varnish (Amalgamliner), and reported that Amalgambond was significantly a better sealing agent than the others. This result was supported by other investigations.

Charlton et al evaluated the ability of three commercially available adhesive resins to reduce microleakage and to provide retention between amalgam restorations and tooth structure and found that Amalgambond reduced leakage significantly more than Panavia EX, Prisma Universal Bond 2, and Copalite. Coli and Brännström evaluated the marginal adaptation of Tokuso Light Bond, C&B Superbond, All-Bond, and Amalgambond in Class II cavities and reported that Amalgambond was a more effective agent than the others. Chigira et al examined the bonding efficacy of nine commercially available intermediate resins by measuring the maximum contraction gap of a light-activated composite in a cylindrical specimen of human dentin and reported a considerably wide gap in nearly all of the tested specimens with the exception of 4-META.
Turner et al.\textsuperscript{26} evaluated in vitro the microleakage of Amalgambond Plus, Tenure, Syntac, and All-Bond 2. A significant reduction in microleakage was found at the enamel and dentin margins in all systems when compared to unlined and Copalite-lined alloys.

Edgren and Denehy\textsuperscript{27} compared the effect of Amalgambond and Copalite as cavity liners in reduction of microleakage in both retentive and nonretentive cavity preparations and reported that microleakage was significantly greater with the nontraditional cavity designs and with cavity margins located in dentin. However, the results of the present in vivo study indicate that Amalgambond Plus is effective in sealing the interface of cavities in resin composite and amalgam restorations, even though nontraditional cavity preparations were included. Only restorations limited within the buccal and the lingual cusps were accepted in this leakage study for standardization.

The literature includes no investigation of in vivo long-term marginal leakage of amalgam and resin composite restorations lined with Amalgambond. Therefore, it was difficult to compare the present results with those of other studies. Ben-Amar et al.\textsuperscript{28} compared the degree of microleakage in vitro at 14 days, 6 months, and 1 year in Class V amalgam restorations lined with Copalite or Amalgambond. They reported that Amalgambond showed significantly less microleakage than unlined restorations at all time periods and significantly less short-term (14-day) microleakage than did the Copalite-lined group. This finding supports the present results, although this study included long-term in vivo conditions and cavity preparations were in nontraditional designs.

Torii and others\textsuperscript{29} reported that, compared to bonded resin composite restorations, bonded amalgam
Fig 2a Periapical radiograph of a primary right second molar before treatment.

Fig 2b Periapical radiograph of the same tooth after 15 months.

Fig 2c Bitewing radiograph of the same tooth after 3 years.

Fig 2d Periapical radiograph of the same tooth after 3 years.

Fig 3a Buccolingual section of a resin composite restoration that had been in the mouth for 3 years. Penetration of dye along the occlusal wall is limited to the enamel (degree 1).

Fig 3b Buccolingual section of an amalgam restoration that had been in the mouth for 3 years. There is no leakage (degree 0).
restorations exhibit less leakage above the cemento-enamel junction, presumably because shrinkage on setting is much less than the polymerization shrinkage of resin composites. However, the leakage results of the present study of bonded composite and amalgam restorations were similar even though the cemento-enamel junction was not included.

Early research and the known properties of the materials involved offer promise for long-term performance of bonded amalgam restorations. Ueno et al. reported no postoperative hypersensitivity and good retention after a 1-year clinical trial of 129 restorations in which Amalgambond was used to bond amalgam to dentin in deep, nonretentive preparations. Masaka reported no pulpal necrosis in 103 bonded amalgam restorations lined with 4-META/MMA-TBB. In a previous study, tensile bond strength and clinical performance of amalgam and resin composite restorations bonded with Amalgambond Plus were evaluated over 15 months, and results were perfect for both types. Clinical evaluation during the present study, which included the same parameters of marginal adaptation, secondary caries, postoperative hypersensitivity, and retention, supports the previous one and others.

Conclusion
This 3-year follow-up study including evaluation of clinical parameters and marginal leakage showed that Amalgambond Plus is a desirable bonding agent for nontraditional and wide cavity preparations restored with amalgam or resin composite.

References