Eighteen-month clinical evaluation of a filled and unfilled dentin adhesive

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Abstract

Objective: The purpose of this study was to evaluate the performance of a filled (OptiBond Solo) and an unfilled (Prime & Bond 2.1) “one-bottle” adhesive in Class V restorations after 18 months of clinical service.

Methods: Thirty-three patients with non-caries cervical lesions were enrolled in the study. A total of 101 lesions were restored using one of the adhesives and a hybrid composite resin. Enamel was not beveled, nor was any mechanical retention placed. The restorations were evaluated at baseline, and at 6 and 18 months after placement using modified USPHS criteria.

Results: Cumulative 18-month retention rates were 93.6% for OptiBond Solo and 98.0% for Prime & Bond 2.1. The difference in retention rates was not statistically significant. For OptiBond Solo, the only notable problems were interfacial staining and marginal adaptation, both of which were less than ideal in 9% of restorations. Marginal problems were slightly less frequent for Prime & Bond 2.1 restorations, but the difference was not significant.

Conclusions: Both adhesives provided Class V retention rates exceeding the 18-month, full acceptance guidelines set by the American Dental Association. Any additional benefit provided by the use of a filled adhesive was not detected in this 18-month clinical trial. © 2001 Elsevier Science Ltd. All rights reserved.

Keywords: Dentin bonding; Clinical trial; Composites

1. Introduction

Many modern dental adhesives have similar in vitro bond strengths to dentin and enamel. This represents significant progress in adhesive technology, because bonding to dentin is much more difficult than bonding to enamel. As dentin bond strengths have improved to this level, the focus of development has shifted somewhat to other aspects of adhesion. For example, most manufacturers have introduced “one-bottle” adhesives that combine priming and bonding functions into a single solution. Also, some manufacturers have introduced filled adhesives. Some in vitro evidence suggests that filled adhesives can provide a stress-relief function that compensates for stresses resulting from composite polymerization shrinkage and occlusal forces [1–5].

The ultimate test of such developments is not their performance in the laboratory, but rather in the clinical environment. Clinical trials are needed to validate laboratory observations. The purpose of this study, therefore, was to evaluate the clinical performance of filled and unfilled one-bottle dentin adhesives in Class V cavities having no macro-mechanical retention (retentive grooves or bevels). The adhesives tested were OptiBond Solo (Kerr Corporation, Orange, CA, USA) and Prime & Bond 2.1 (Dentsply Caulk, Milford, DE, USA). OptiBond Solo is an ethanol-based adhesive that is filled with barium glass and silica (approximately 25% by weight). Prime & Bond 2.1 is an unfilled acetone-based adhesive.

2. Materials and methods

2.1. Selection criteria

Thirty-three subjects ranging in age from 27 to 77 years were enrolled in the study. Patients with fewer than 20 teeth were excluded. The dental health status of the patients was considered normal in all respects. Prior to participating in the study, all patients signed a consent form. The consent form and research protocol were reviewed and approved by an institutional review board (IRB).

Teeth treated in the study had non-caries cervical lesions...
(abrasion/erosion/abfraction) with no undercuts. Class V carious lesions were excluded, although small areas of caries were removed from two teeth in one patient. In general, no more than 50% of the cavosurface margin involved enamel, and at least 75% of the surface area of the restoration was in contact with dentin. All restored teeth contacted the opposing teeth in a normal occlusal relationship and had normal periodontal health.

To minimize the chance that strong patient-related effects could distort the outcome of the study, no more than three restorations per patient were allowed for each restorative system. Nearly all patients received restorations of both types. The distribution of restorations was approximately equal between maxillary and mandibular arches, but about 70% of restorations were placed in premolars.

Patient, tooth, and lesion characteristics are summarized in Table 1. As noted therein, the characteristics examined included both evidence of occlusal stress (wear facets, fremitus) and dentinal sclerosis. The scale used for scoring dentin sclerosis is shown in Table 2. As shown in the summary in Table 3, differences in lesion size and other characteristics between the two restorative groups were very minor. Mean lesion volumes were not significantly different (Student’s t-test, \( p = 0.49 \)). Two OptiBond Solo/Prodigy restorations were placed in cervical areas from which small areas of caries were removed.

### 2.2. Restorative procedures

Operative procedures were usually performed without local anesthesia. Operating sites were isolated with cotton rolls and retraction cord. Tooth preparation did not include retentive grooves or enamel bevels; rather, dentin and enamel walls of the preparation were lightly roughened with a coarse diamond.

OptiBond Solo and Prime & Bond 2.1 were applied to randomly selected lesions according to directions supplied by the respective manufacturers. For OptiBond Solo, enamel and dentin were etched for 15 s using 37.5% phosphoric acid. The etchant was rinsed, and the tooth surface was lightly dried with compressed air, but was not desiccated. OptiBond Solo was applied with a light brushing motion for 15 s. As per the manufacturer’s instructions, the material was not dried with air, but was immediately

<table>
<thead>
<tr>
<th>Lesion or patient characteristic</th>
<th>OptiBond Solo (( n = 50 ))</th>
<th>Prime &amp; Bond 2.1 (( n = 51 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location by arch</strong></td>
<td>Maxillary 48%</td>
<td>51%</td>
</tr>
<tr>
<td></td>
<td>Mandibular 52%</td>
<td>49%</td>
</tr>
<tr>
<td><strong>Location by tooth</strong></td>
<td>Anterior 18%</td>
<td>16%</td>
</tr>
<tr>
<td></td>
<td>Premolar 72%</td>
<td>76%</td>
</tr>
<tr>
<td></td>
<td>Molar 10%</td>
<td>8%</td>
</tr>
<tr>
<td><strong>Internal angle</strong></td>
<td>0°–45° 10%</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>45°–90° 53%</td>
<td>56%</td>
</tr>
<tr>
<td></td>
<td>90°–135° 31%</td>
<td>36%</td>
</tr>
<tr>
<td></td>
<td>135°–180° 6%</td>
<td>6%</td>
</tr>
<tr>
<td><strong>Enamel margin</strong></td>
<td>0°–25% 0%</td>
<td>6%</td>
</tr>
<tr>
<td></td>
<td>25°–50% 85%</td>
<td>82%</td>
</tr>
<tr>
<td></td>
<td>50°–75% 15%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Mean height</strong></td>
<td>2.2 mm</td>
<td>2.3 mm</td>
</tr>
<tr>
<td><strong>Mean width</strong></td>
<td>3.8 mm</td>
<td>3.6 mm</td>
</tr>
<tr>
<td><strong>Mean depth</strong></td>
<td>1.5 mm</td>
<td>1.3 mm</td>
</tr>
<tr>
<td><strong>Mean volume</strong></td>
<td>6.2 mm(^3)</td>
<td>5.4 mm(^3)</td>
</tr>
<tr>
<td><strong>Sclerosis</strong></td>
<td>1 33%</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>2 29%</td>
<td>43%</td>
</tr>
<tr>
<td></td>
<td>3 32%</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>4 6%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Patient age range</strong></td>
<td>20–40 years 10%</td>
<td>6%</td>
</tr>
<tr>
<td></td>
<td>40–60 years 62%</td>
<td>72%</td>
</tr>
<tr>
<td></td>
<td>60–80 years 28%</td>
<td>22%</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Male 30%</td>
<td>16%</td>
</tr>
<tr>
<td></td>
<td>Female 70%</td>
<td>84%</td>
</tr>
<tr>
<td><strong>Traumatic occlusion</strong></td>
<td>No 73%</td>
<td>62%</td>
</tr>
<tr>
<td></td>
<td>Yes 27%</td>
<td>38%</td>
</tr>
</tbody>
</table>

\( ^* \) Frequency, %.

\( ^b \) As evidenced by wear facets or fremitus.
light-cured for 20 s. A second coat of OptiBond Solo was applied and cured in the same manner.

For Prime & Bond 2.1, enamel and dentin were etched for 15 s using 34% phosphoric acid. After rinsing, excess moisture was blotted with a moistened cotton pellet. Prime & Bond 2.1 was applied to the surface, and was replenished as needed during a 20-s period. The surface was gently air-dried for 5 s. Whenever the surface did not appear glossy, more adhesive was applied. The material was light-cured for 10 s. A second coat was applied, but following the manufacturer’s directions, was not light-cured.

Preparations were restored with a light-cured hybrid composite resin restorative material (Prodigy for OptiBond Solo; Prisma TPH Spectrum for Prime & Bond 2.1). The composite was inserted in increments of 2 mm or less. Each increment was polymerized for 40 s using an Optilux 401 visible-light-curing device. After polymerization, finishing was accomplished with tapered and/or flame-shaped 12-fluted carbide finishing burs or microfine diamonds. Polishing was accomplished with slow-speed polishing cups and points (Enhance, Dentsply Caulk).

2.3. Direct evaluation criteria and procedures

Restorations were examined at baseline, and 6 and 18 months after placement. The following characteristics were recorded using modified USPHS direct evaluation procedures (Table 3):

1. Retention,
2. Color match,
3. Marginal discoloration (interfacial staining),
4. Recurrent caries,
5. Wear, or loss of anatomical form or contour,
6. Marginal adaptation/integrity,
7. Post-operative sensitivity.

Post-operative sensitivity was recorded as present (charlie) or absent (alpha) after patient inquiry or if the tooth was sensitive to a stream of compressed air 2–3 cm from the restoration for 3 s. Retention was recorded as completely retained (alpha) or partially or completely lost (charlie).

Intraoral color photographs were taken immediately following insertion and at each recall appointment for re-evaluation by a second investigator. Clinical photographs were 35 mm transparencies taken at an original magnification of 1.5×.

Restoration retention rates were calculated using the following equation [6]:

\[
\text{Cumulative failure percentage} = \left[ \frac{\text{PF} + \text{NF}}{\text{PF} + \text{RR}} \right] \times 100% 
\]

where PF is the number of previous failures before the current recall; NF the number of new failures during the current recall; and RR the number of restorations recalled for the current recall.
3. Results

Retention rates at 6 months were 98% (one failure) for OptiBond Solo and 100% for Prime & Bond 2.1. Very few problems were noted with either material at 6 months.

Of 98 restorations present at the 6-month recall, 97 were recalled at 18 months after initial placement. In the OptiBond Solo group, one restoration could not be evaluated because the tooth had been crowned. All of the original 51 Prime & Bond 2.1 restorations were recalled. Two restorations in the OptiBond Solo group had been lost between 6 and 18 months, as had one restoration in the Prime & Bond 2.1 group.

Eighteen-month restoration evaluations are summarized in Tables 4 and 5. Using the ADA Guidelines formula [6], the 18-month retention rates were 93.6% for OptiBond Solo and 98.0% for Prime & Bond 2.1. The retention rates were not significantly different (Cramer’s V, \( p = 0.51 \)).

For OptiBond Solo, the only problems worthy of note were interfacial staining and marginal adaptation, where the percent alfa at 18 months was 91%. In contrast, the percent alfa values for Prime & Bond 2.1 were 94% for interfacial staining and 100% for marginal adaptation. Differences between the two materials were not statistically significant.

The rates of retention loss and marginal problems were so low that the analysis could not associate them with any of the pre-treatment variables such as occlusal stress or sclerosis.

Post-operative sensitivity was associated with only two restorations (Prime & Bond 2.1) at 18 months. Both restorations were in the same patient, and both teeth had been sensitive before the restorations were placed.

4. Discussion

At the 18-month recall, retention rates were 93.6% for OptiBond Solo and 98.0% for Prime & Bond 2.1. Therefore, the retention rate of each adhesive exceeded the 90% level required by ADA guidelines for full acceptance [6]. Of the retained restorations, 9% of OptiBond Solo/Prodigy restorations had less than ideal marginal adaptation, and 6% of Prime & Bond/TPH restorations had interfacial staining. ADA acceptance criteria call for “< 10% charlie microleakage” at 18 months. Although microleakage is defined as being clinically undetectable [7], the ADA guidelines clearly express the importance of marginal integrity. Both adhesives appear to fall within guidelines for evaluation criteria that reflect marginal quality.

Contemporary dentin adhesives have three distinct
functions: (1) etching or conditioning to remove or modify the dentin smear layer; (2) priming to modify the substrate’s surface energy; and (3) bonding, or resin impregnation of the conditioned and primed dentin surface [8]. The more traditional, or fourth-generation systems have separate etching, priming, and bonding steps. However, many manufacturers have attempted to simplify the bonding process by combining steps. The fifth-generation, or “one-bottle” systems combine primer and bonding functions into a single solution, but require a separate etchant. Self-etching primer systems combine the etchant and primer functions, but require a separate bonding agent. Systems that combine all three functions into a single solution are currently being introduced to the market.

Although literally hundreds of papers have been published on the bond strengths of modern dental adhesives over the last decade, the literature on clinical performance is rather sparse. In general, the fourth-generation, etch/prime/bond systems have performed well in clinical trials. For example, Scotchbond Multi-Purpose (3M Dental Products Division, St. Paul, MN, USA) has demonstrated retention rates of just under 90% up to 100% at 2- and 3-year recall evaluations [9–11]. OptiBond Dual-Cure (Kerr) had a 100% retention rate at 2 years [12], and an 86% retention rate at 2 years [13] (A.D. Wilder, personal communication) in separate studies. Interestingly, All-Bond (Bisco, Inc., Schaumburg, IL, USA) had a three-year retention rate of approximately 70% in two clinical trials. In one study, most retention failures occurred within the first 6 months [14], while in the other most failures occurred between the 2- and 3-year recalls [15].

Far less information is available regarding the performance of fifth-generation, or one-bottle, adhesives. However, one recent study of One-Step (Bisco, Inc.) reported 100% retention at 6 months and 95% retention at 1 year [16].

One purpose of the present study was to evaluate the clinical performance of a filled versus an unfilled adhesive. Based on various in vitro studies [1–5], some researchers and manufacturers believe that some low-modulus component should be included in a composite restoration, as either the restorative material itself, or as some sort of “stress-breaking liner” that can absorb stresses caused, for example, by polymerization shrinkage or occlusal forces. The effects of tooth flexure on restoration retention and marginal integrity remain a point of contention. However, in one early clinical trial [17], restorations were more likely to be lost when a high-modulus composite material was used than when low-modulus microfill was used. Evidence of occlusal stress was also reported as a co-variable in restoration failure. Other authors have speculated that restoration stiffness might contribute to failure. For example, McCoy et al. suggested that the failure of All-Bond 2/Z100 restorations following 2 years of clinical service might have resulted from the cumulative effects of occlusal stresses over time, as Z100 (3M Dental) is a very stiff restorative material [15]. However, a recent report showed almost identical two-year retention rates for Silux (3M Dental) and Z100 cervical restorations bonded with Scotchbond Multi-Purpose [11]. Silux and Z100 represent the low and high extremes of composite elastic moduli, so in that particular study, the stiffness of the restorative material had no apparent effect on restoration retention.

Several clinical trials of Clearfil Liner Bond (Kuraray, Osaka, Japan) have reported retention rates of 93–100% at 2- and 3-year recall evaluations [9,10,18]. The early version of Clearfil Liner Bond used a citric acid solution to etch enamel and dentin; later versions were self-etching primer systems. Regardless, some of the success of this system may be due to the use of Protect Liner, a low-viscosity filled resin that can be used with Clearfil as a “stress-breaking liner”.

In the present study, both the OptiBond Solo/Prodigy and the Prime & Bond 2.1/TPH adhesive systems have performed well to date, with retention rate and all other evaluation criteria rated alpha for 91–100% of restorations. The filled adhesive OptiBond Solo had neither a higher retention rate nor better marginal integrity than the unfilled adhesive Prime & Bond 2.1.

The clinical problems noted in this paper are relatively minor, and perhaps reflect the increased expectations for adhesives more than anything else. However, the real test for these materials will be their performance over longer periods of clinical service. One study reported that one- and 2-year performance did not predict performance at 3 years [15].

5. Conclusions

Filled and unfilled one-bottle adhesives provided Class V retention rates approaching 100% at 18 months of clinical service. If the use of a filled adhesive provides any additional benefits regarding retention, marginal seal or other performance criteria, such benefits were not obvious at this relatively early recall evaluation. Such benefits might become apparent at later evaluations, so the clinical performance of these materials should be monitored over longer periods of time.

Acknowledgements

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References

[2] Kemp-Scholte CM, Davidson CL. Marginal integrity related to bond


