Clinical evaluation of a dentinal adhesive system: three-year results

E. Steven Duke* / J. William Robbins** / David S. Snyder**

The dentinal adhesive Scotchbond 2 was evaluated with the microfilled composite resin Silux in cervical and root caries lesions for up to 3 years. Clinical criteria evaluated included retention, marginal integrity, marginal discoloration, color match, anatomic form, recurrent caries, gingival response, and postoperative sensitivity. Overall, the adhesive demonstrated improved performance over earlier dentinal adhesive systems.

Retention was greatest at 3 years when available enamel margins had been etched (93%) and when root caries lesions (97%) had been restored. Other criteria were reported as generally favorable. Early findings suggest that the level of development of sclerotic dentin may influence behavior of the adhesive. The greatest difficulty was noted in lesions presenting with heavy sclerotic dentin.


Introduction

Research aimed at developing durable adhesion between resin restorative materials and tooth surfaces has been progressing for more than 30 years. Intimate adaptation of the material to cavity interfaces would resist microleakage and the influx of oral irritants, which may lead to postoperative sensitivity, interfacial staining, and recurrent caries.

The treatment of enamel surfaces with acidic solutions, such as phosphoric acid, is a well established clinical practice and has been shown in laboratory studies to reduce microleakage. However, clinically, enamel is often absent and cavity margins are contained partially or totally in cementum or dentin. The use of phosphoric acid as a pretreatment on dentin has been suggested and has also been the subject of much controversy. Unfortunately most reports advocating the use of phosphoric acid have been anecdotal and lacking in controlled clinical validation. Hence, efforts have been directed towards developing a chemically adhesive mechanism for dentinal substrates.

As early as 1956, Buonocore et al described the use of glycerophosphoric acid dimethacrylate as a bonding agent for direct restorative resins. While initial laboratory reports were promising for this agent, clinical trials met with poor success, and speculation was made relative to the inadequate hydrolytic behavior of this system in the oral environment.

A second generation of dentinal bonding agents became available with the use of halophosphorus esters of BIS-GMA and hydroxyethyl methacrylate (HEMA), a phosphorus ester of BIS-GMA, and a urethane prepolymer of toluene-diisocyanate and trimethylolpropane in methylene chloride. Such representative agents again demonstrated encouraging laboratory behavior with improved bond strengths and microleakage resistance. Unfortunately, clinical data once again dampened enthusiasm with reports of poor rates of retention and high incidence of microleakage.

Recent modifications to dentinal adhesive systems have given rise to a third generation of agents. Unique to these systems is the incorporation of a dentinal conditioning or dentinal priming step and the use of...
Dental Research

resin formulas with increased hydrophilicity. One such system, Scotchbond 2 (3M Dental Products Div), employs a weak solution of maleic acid containing HEMA as a hydrophilic primer for dentinal surfaces. The use of the hydrophilic primer solution is reported to solubilize the outer dentinal surface, or smear layer, if present, thereby affording an improved wetting by the subsequently applied adhesive agent. An in vitro examination by Erickson of the mechanism of adhesion of this particular system has shown that a micromechanical retention develops, with the adhesive resin forming a complex, continuous, intertubular-penetrating network.

An improvement in laboratory properties has been reported for several of the third-generation adhesives. Long-term clinical trials to validate these properties have yet to be reported.

The purpose of this study was to clinically evaluate a representative third-generation adhesive system when used to restore cervical abrasion/erosion and root caries lesions.

Method and materials

The dentinal adhesive system, Scotchbond 2 was evaluated with the light-curing composite resin Silux (3M Dental Products Div) in patients presenting with cervical abrasion/erosion and root caries lesions. All patients were required to provide informed consent after being thoroughly informed of all aspects of the study. A total of 38 patients, ranging in age from 44 to 70 years, took part in the study. Patients were in need of restorative procedures for at least two cervical abrasion/erosion or two root caries lesions. Patients were without severe medical complications, demonstrated normal oral hygiene practice, did not present with periodontitis or rampant caries, and showed no evidence of severe bruxism.

Restorative procedures

Three experimental groups were evaluated in this study:

1. Group A: Cervical restorations placed in dentin without etching of enamel
2. Group B: Cervical restorations placed in dentin with etching of adjacent enamel margins
3. Group C: Root caries restorations placed totally in dentin

All restorative procedures were carried out using the rubber dam, and a No. 212 retainer was used to ensure isolation. A total of 100 restoration, 34 each in groups A and B, and 32 in group C, were placed with two to four restorations per patient.

Group A. Following isolation, the cervical lesion was cleaned using a flour of pumice slurry in a rubber cup with light pressure. The primer solution, Scotchprep (3M Dental Products Div), was then applied with a cotton pellet; the dentinal surface was kept wet for 60 seconds. A gentle stream of air was then applied to the area for 30 seconds to dry the treated surface. The adhesive agent was next applied to the surface with a brush to a uniform thickness. The adhesive agent was then exposed to light curing for 20 seconds with a curing unit (Teledyne Getz).

The Silux composite resin material was then used to restore the cervical lesion to natural tooth contour. An initial increment of material, no greater than 1 mm thick, was placed in the cervical region and polymerized with light for 20 seconds. Additional increments were added as necessary and polymerized. Final finishing of the restorations was performed using the Sof-Lex finishing system (3M Dental Products Div) with a slow-speed handpiece and water.

Group B. The technique for this group was the same as for group A, with the additional step of etching enamel margins prior to priming the dentin. The etching gel (3M Dental Products Div) was applied to the enamel margins for 30 seconds and rinsed with water for 30 seconds and air dried.

Group C. Following adequate isolation, the root caries lesion was excavated using slow speed and a round carbide bur or spoon excavator. No attempt was made to create undercuts or mechanical retention; a “dish-shaped” preparation resulted. In areas where it was suspected that less than 1 mm of dentin remained between the pulp and pulpal floor, a calcium hydroxide liner was placed (Dycal, LD Caulk Co) on the floor only. The primer solution, adhesive, and composite resin were then applied as previously described for groups A and B.

Evaluation procedures

Restorations were evaluated at baseline (2 weeks after placement), 6 months, 1 year, 2 years, and 3 years after placement using the Cvar and Ryge method for the following criteria: retention, color match, marginal integrity, marginal discoloration, anatomic form, secondary caries, postoperative sensitivity, and
Results presented as percentage of Alfa ratings for the various clinical criteria, can be found in Table 1. A 100% subject recall resulted at 6 months and 1 year. One subject was lost from the study at 2 years, resulting in a recall rate of 97%. Two additional subjects were lost at 3 years, resulting in a final recall rate of 92%.

Retention
In group A, the nonetched enamel group, three of the original 34 restorations were lost at 6 months, for a retention rate of 91%. One additional restoration was lost at 1 year, 2 years, and 3 years. This resulted in retention rates of 88%, 86%, and 80%, respectively. The 80% at 3 years represented 24 retained restorations of a possible 30 restorations. This excluded the restorations in the absent subjects, who were not evaluated. In group B, the etched enamel group, a 100% retention rate resulted at both 6 months and 1 year. Two restorations were lost at 2 years for a retention rate of 94%. Twenty-eight of 30 possible restorations were retained at 3 years, for a retention rate of 93%. A 100% retention rate resulted up to 2 years in group C. One restoration was lost at the 3-year recall, for a final retention rate of 97%.

Marginal integrity and discoloration
A 97% Alfa rating resulted at 6 months for both marginal integrity and marginal discoloration in group A. At 1 year, a 94% Alfa rating was observed for these same criteria. Marginal integrity was 86% Alfa and marginal discoloration was 89% Alfa at 2 years for this group. These criteria changed to 75% and 83%, respectively, at 3 years. Group B resulted in 94% and 97% Alfa ratings for marginal integrity and marginal discoloration at both 6 months and 1 year. At 2 years, these criteria were 90% and 94% Alfa, respectively. At 3 years, they were 79% and 82% Alfa, respectively. In group C, marginal integrity was 100% Alfa up to 1 year, 91% Alfa at 2 years, and 86% Alfa at 3 years. Marginal discoloration was rated at 97% at 6 months, 94% at 1 year, 88% at 2 years, and 79% at 3 years.
Recurrence caries

There was no evidence of any secondary caries associated with any group up to 2 years. At 3 years, two restorations in group B (7%) and one restoration in group C (3%) presented with recurrent caries.

Color match, anatomic form, and gingival response

There were no apparent color changes noted up to 3 years for groups A and B. At 3 years, two restorations in group C (7%) exhibited moderate bulk discoloration. Both of these restorations were located in the same subject. Changes in anatomic form were observed in groups A and B at the 3-year recall. Three restorations in group A (13%) and four restorations in group B (14%) demonstrated significant loss in contour. Gingival response for all groups was 100% Alpha at 6 months, 1 year, 2 years, and 3 years.

Postoperative sensitivity

An improvement in sensitivity resulted in all experimental groups following placement of the restorations. A 71% Alpha rating for group A prior to treatment improved to 94% at 6 months, 97% at 1 year, and 100% at 2 and 3 years. Group B went from 74% to 97% at 6 months, 1 year, and 2 years, and to 100% Alpha at 3 years. In group C, a 69% Alpha rating prior to treatment improved to 97% at 6 months and 100% at 1, 2, and 3 years.
Discussion

Previous studies with second-generation dentinal adhesives have reported failure rates from as low as 24%\textsuperscript{15} at 2 years to as high as 96%\textsuperscript{30} at 1 year. The retention rates observed in this study of a third-generation dentinal adhesive show marked improvement over those of earlier systems. In addition, Ziemiecki et al\textsuperscript{10} noted significant marginal discoloration in retained restorations (acid-etched enamel) utilizing a second-generation adhesive. The retained restorations in the present study have not demonstrated such adverse behavior up to 3 years. Representative retained restorations from groups A and B are shown in Figs 1 and 2. An examination of the cervical lesions for the three lost restorations in group A at 6 months revealed that all were extremely small lesions (occlusogingival) compared to the total population of lesions. Furthermore, two additional small restorations became dislodged during initial finishing procedures and were not included in the study. This may indicate that a minimum “threshold” of surface area may be necessary to ensure adequate clinical bonding with this system when enamel margins are not available.

The additional three restorations lost from group A up to 3 years were from lesions presenting with moderate-to-heavy sclerotic (transparent) dentin. The ability to bond adhesively to aged sclerotic dentin has been previously questioned.\textsuperscript{27-29} A recent study has found that the primer solution with Scotchbond 2 is much less effective on dentin that has undergone sclerotic changes.\textsuperscript{30} Figure 3 shows an example of a restoration...
in group A lost at 3 years from a moderately sclerotic lesion. Figure 4 is an example of a retained restoration in group B on sclerotic dentin presenting with advanced marginal discoloration.

The initial Bravo ratings in gingival response at baseline for groups A and B is felt to have resulted from trauma during the restorative procedures. At 6 months, and up to 3 years, all areas had resolved, with no evidence of irritation.

The increase in Bravo ratings for marginal integrity in all groups during this study was associated with a loss in anatomic form. Over the 3-year period, the microfilled composite resin (Silux) demonstrated deterioration from what appeared to be continued toothbrush abrasion. This was most notable in marginal areas, where the composite resin became ditched.

The significant improvement in postoperative sensitivity following the placement of the restorations in all experimental groups would suggest that an adhesive bond has been established to protect the sensitive dentinal surfaces. These restorations were challenged with thermal shock during the evaluations. The sensitivity was of short duration, and only occurred as a result of cold stimulation. The complete elimination of sensitivity at the 3-year recall further suggests that the remaining restorations were adhesively sealed to the dentinal surfaces.

As stated earlier, the mechanism of adhesion for Scotchbond 2 is reported to be principally one of micromechanical retention. It is therefore not surprising that the greatest difficulty was observed in the more aged dentinal lesions. With increased age and sclerotic changes, changes in dentinal microstructure and chemistry may be responsible for less-effective priming. For example, the increase in peritubular dentin and obturation of dentinal tubules with calcified deposits may preclude the development of intratubular resin retention. In addition, changes in aged dentinal chemistry, such as the increased mineral content of sclerotic dentin, may influence the action of primer solutions and subsequent intertubular microretention.

Further research into not only the microstructure, but also chemical changes that are unique to these aged dentinal surfaces is warranted. Additionally, long-term clinical trials on various dentinal substrates will be required to validate these early findings. Such data would assist in the development of new adhesive strategies and provide valuable clinical direction for the use of current and future adhesive agents.

Conclusions

1. The clinical performance of Scotchbond 2 dentinal adhesive shows improvement over earlier dentinal adhesives when used to restore cervical lesions and root caries.
2. The performance of Scotchbond 2 dentinal adhesive is enhanced when etched enamel margins are available on cervical lesions.
3. Early clinical results suggest that the performance of Scotchbond 2 dentinal adhesive may be influenced by changes in dentinal microstructure and chemistry that occur with age.

References


