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A 12-year clinical evaluation of a three-step dentin adhesive in noncarious cervical lesions

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Resin-based dentin adhesives have been widely available since the early 1980s.¹ At that time, successful bonding of resin to enamel had been routine in dental practice for more than a decade. Because enamel is essentially inorganic and dry, it presents a relatively homogeneous substrate with which to bond. Dentin is different. It is inherently wet because of outward flow of fluid through the dentinal tubules. It contains far more organic material and fluid than does enamel, and, by volume, is less than one-half inorganic hydroxylapatite. The heterogeneity of dentin can affect the quality and durability of the resin-dentin bond.² In vitro and in vivo evidence suggests that resin-based adhesives are less durable than once thought.³

A poor marginal seal, manifested clinically as poor marginal adaptation and interfacial staining, is the most common reason for failure of adhesive resin-based restorations, and it predisposes the restorations to retention failure⁴ and recurrent caries.⁵ Study results have demon-

ABSTRACT

Background. The authors conducted a study to evaluate the clinical performance of a dual-cured, three-step dentin adhesive (OptiBond Dual Cure, Kerr, a subsidiary of Sybron Dental Specialties, Orange, Calif.; no longer on the market) at 12 years.

Methods. The authors restored 100 noncarious cervical lesions without use of macromechanical retention or enamel bevels. In one-half of the lesions (group A), the authors etched only the enamel; in the other half (group B), they etched both enamel and dentin. After etching, they applied a light-cured primer and dual-cured adhesive to enamel and dentin in both groups. They restored the preparations with a resin-based composite. They performed direct evaluations by using modified U.S. Public Health Service criteria at insertion (baseline) and at one year and 12 years after insertion.

Results. The 12-year retention rates were 93 percent in group A and 84 percent in group B, for an overall retention rate of 89 percent. Except for marginal discoloration in both groups and retention in group B, the restorations in both groups had Alfa ratings of 88 percent or greater in all of the direct clinical evaluation categories.

Conclusions. The 12-year clinical performance, including retention rate, of a dual-cured dental adhesive was excellent and was not affected by dentin acid-etching.

Clinical Implications. This clinical study provides additional evidence for the long-term durability of a three-step etch-and-rinse adhesive in noncarious cervical lesions.

Key Words. Adhesives; clinical research; resin-based composites. *JADA* 2009;140(5):526-535.



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strated a significant reduction in dentin adhesion over time.⁶⁻⁸ Researchers have reported the longevity of adhesive restorations in general to be three to eight years.^{5,9-11}

Hybridization is the primary mechanism of retention for adhesive restorations in the absence of mechanical features such as retention grooves. Among current adhesives, three-step etch-and-rinse adhesives (also referred to as “total-etch adhesives”) are considered the gold standard for durability.¹² In these systems, the dentist applies an acidic conditioner (typically 32-40 percent phosphoric acid) to both enamel and dentin. In addition to removing the smear layer, the etchant demineralizes the superficial surface of inter-tubular dentin, exposing a porous network of collagen fibrils. Etching also dissolves peritubular dentin at the orifice of the dentinal tubules, leaving the tubule orifices somewhat funnel-shaped. Next, the dentist applies a primer to promote wetting between the hydrophilic demineralized dentin surface and the hydrophobic adhesive resin to be applied in the next step. The primer contains amphiphilic monomers, which contain hydrophilic and hydrophobic groups at opposite ends of their molecules. The monomers usually are dissolved in an organic solvent such as acetone or ethanol, which serves to displace moisture from the conditioned dentin surface. This action allows intermingling of the monomers with the collagen network and formation of resin tags in the demineralized dentin surface. In some systems, the primer component is light-activated, which results in a layer of resin-reinforced dentin called “the hybrid layer.”¹³ However, in most systems, the hybrid layer develops only after the third step (etching and priming), during which the dentist applies and light-activates the bonding agent.

Clinical trials are necessary to assess the clinical effectiveness of adhesive systems.^{12,14} As prescribed by the American Dental Association (ADA) acceptance guidelines for dentin and enamel adhesives,¹⁵ the studies should include only noncarious Class V lesions for the following reasons.¹⁴

- The lesions provide no inherent macromechanical retention, so the restoration will be lost if the adhesive system fails. Retention is an obvious and objective measure of restoration success or failure.
- Class V restorations typically include both enamel and dentin margins.

■ Preparation and restoration of Class V lesions are relatively simple, thus minimizing the effect of operator variability.¹²

We conducted a MEDLINE search, which revealed that from 1998 to 2007, investigators published 95 clinical trials of adhesives, of which 16 involved three-step etch-and-rinse adhesives. Investigators in these 16 trials evaluated 13 different adhesives for as long as five years.¹⁶⁻²¹ In only a few published clinical trials did evaluation extend beyond five years. One group of researchers evaluated a three-step etch-and-rinse adhesive at seven years.²² Other investigators evaluated seven other three-step etch-and-rinse adhesives at 13 years.^{23,24} Additional long-term clinical trials are needed to provide supporting evidence of adhesive longevity.

OptiBond Dual Cure (Kerr, a subsidiary of Sybron Dental Specialties, Orange, Calif.) was one of the first three-step etch-and-rinse adhesives available, and it performed well in early clinical trials.^{14,25-27} In one of these clinical trials, our research group evaluated the effect of dentin acid-etching on the clinical performance of OptiBond Dual Cure.²⁶ Because of favorable early results and the likely availability of subjects from the original study, we planned and conducted a 12-year evaluation. The purpose of this article is to report the effect of dentin acid-etching on the clinical performance of OptiBond Dual Cure adhesive restorations in noncarious cervical lesions 12 years after insertion of the restorations. (**Authors’ note:** As of 2008, OptiBond Dual Cure is no longer marketed. Often, the results of long-term clinical research studies are not known until after products are reformulated or “improved.” However, long-term studies such as this one reveal important information about three-step etch-and-rinse adhesive systems and the techniques involved in their use as they relate to restoration longevity.)

SUBJECTS, MATERIALS AND METHODS

Subject selection. We selected 53 subjects on the basis of their need for restoration of noncarious cervical lesions. We randomly assigned them to two groups on the basis of the etching method used; this led to the placement of 26 subjects in

ABBREVIATION KEY. **ADA:** American Dental Association. **DEJ:** Dentinoenamel junction. **HEMA:** 2-hydroxyethyl methacrylate. **USPHS:** U.S. Public Health Service.

BOX

Composition of OptiBond Dual Cure adhesive system.*

ETCHANT

- 37 percent phosphoric acid gel

LIGHT-CURED HYDROPHILIC SURFACE PRIMER:

OPTIBOND PRIME

- 2-Hydroxyethyl methacrylate (HEMA)
- Glycerol phosphate dimethacrylate
- Mono (2-methacryloxyethyl) phthalate
- Ethanol
- Water

BONDING AGENT: OPTIBOND DUAL CURE A/B

Catalyst resin liquid

- Bisphenol A glycidyl dimethacrylate
- HEMA
- Chemical and light-cure catalyst

Accelerator paste: 48 percent filled by weight

- Barium aluminum borosilicate glass
- Fumed silica
- Disodium hexafluorosilicate
- Barium borosilicate glass
- HEMA
- Glycerol dimethacrylate

* OptiBond Dual Cure was manufactured by Kerr, a subsidiary of Sybron Dental Specialties, Orange, Calif., but is no longer on the market. The manufacturer numbered the components as follows: OptiBond Prime, "1"; OptiBond Dual Cure catalyst resin liquid, "3A"; OptiBond Dual Cure accelerator paste, "3B."

group A (etching of enamel only) and of 27 subjects in group B (etching of both enamel and dentin). We excluded subjects who had fewer than 20 teeth. We randomized the sample to exclude possible bias caused by factors of age, sex, race or national origin.

We recruited patients from the health affairs campus of the University of North Carolina at Chapel Hill. Before participating in the study, each subject signed a consent form. The Committee on Investigations Involving Human Subjects at the University of North Carolina School of Dentistry at Chapel Hill reviewed and approved both the form and the research protocol.

Tooth selection. To minimize the chance that subject-related effects could distort the outcome of the study, we included no more than six lesions per subject. We selected a total of 100 teeth with facial noncarious cervical lesions (50 in each group). Some have described these cervical defects as areas of stress corrosion, or "abfraction," resulting from tooth flexure,^{28,29} and they often are associated with occlusal wear facets.³⁰ However, we refer to them as "noncarious cervical lesions."

Preoperatively, we measured the dimensions of each lesion to the nearest 0.5 millimeter for height, width and depth with the aid of a perio-

dontal probe. We categorized each lesion for angulation and percentage of enamel margin.³¹ Every tooth had occlusal contacts with the opposing dentition, as well as normal periodontal health.

The lesion distribution involved 35 percent anterior teeth and 65 percent posterior teeth. To minimize possible subject-operator effects, we randomized the assignment of subjects to operators. No one operator placed more than three restorations per group in any one subject.

Tooth preparation procedures. Six operators (among them H.O.H., J.R.S. and A.D.W.) performed the operative procedures. All tooth preparations were of the modified design described by Sturdevant³² and were limited to producing a definite finish line. Cotton rolls and retraction cord provided moisture control. The operators lightly roughened the dentin and enamel surfaces of each lesion with a diamond. They placed no retentive grooves, did not bevel the enamel cavosurface margins and applied no liners or bases.

Restoration procedures. We divided the lesions into two groups for acid-etching. In group A, operators etched only the enamel with 37 percent phosphoric acid gel, applied for 30 seconds. In group B, operators etched both the enamel and dentin. The operators applied the etchant to the enamel for 15 seconds and then to the dentin for 15 seconds; the total time of contact with the enamel was 30 seconds. After acid-etching, rinsing and drying, the operators applied OptiBond primer (Kerr; no longer marketed) to enamel and dentin by using a microbrush with a continuous scrubbing motion for 30 seconds. The operators evaporated solvent from the primed surface with compressed air for 10 to 15 seconds and light-activated the primer for 20 seconds. They did not rinse the surface. They mixed the fluoride-releasing dual-cured two-component OptiBond bonding agent and applied it to the primed dentin and enamel surfaces. They blew gross excess from the cavity preparation lightly to prevent pooling, but they did not intentionally air-thin the bonding agent. Also, they did not light-activate the adhesive separately. The box lists the composition of the adhesive system (primer and bonding agent). The operators placed a total of 50 restorations in each group.

The operators restored the preparations incrementally by using a light-activated hybrid resin-based composite restorative material (Herculite XRV, Kerr). They activated the resin for 40 seconds per increment by using a quartz-tungsten-

halogen curing light (Optilux 400, Kerr/Demetron, a subsidiary of Sybron Dental Specialties, Orange, Calif.). The operators monitored the intensity of the curing light regularly to ensure that it equaled or exceeded 500 milliwatts per square centimeter.

After completing the polymerization, the operators finished the restorations by using 12-fluted and 30-fluted carbide finishing burs (tapered, flame-shaped or both) and fine finishing diamonds. Polishing was accomplished with slow-speed polishing disks and points (Enhance, Dentsply Caulk, Milford, Del.) and aluminum oxide polishing pastes (Micro 1, Kerr, and Luster Paste, Kerr).

Evaluation procedures. Preoperatively, the evaluators (among whom were H.O.H., A.V.R., E.J.S., J.R.S. and A.D.W.) rated each noncarious cervical lesion for dentin sclerosis by using the following scale: category 1, no sclerosis of dentin in cervical lesion; category 2, more sclerosis than category 1 but sclerosis more like that in category 1 than that in category 4; category 3, less sclerosis than category 4 but sclerosis more like that in category 4 than that in category 1; category 4, significant sclerosis of dentin in cervical lesion.^{33,34} (Figure 1 shows examples of sclerosis in categories 1 and 4.) Postoperatively, the evaluators assessed each restoration at insertion (baseline) and at one year and 12 years after insertion for the following characteristics:

- retention;
- color match;
- marginal discoloration;
- recurrent caries;
- loss of anatomical form (wear);
- marginal adaptation (marginal integrity);
- surface texture;
- postoperative sensitivity;
- other failure.

The operators evaluated these characteristics by using modified U.S. Public Health Service (USPHS) direct evaluation criteria (Table 1).³¹ They recorded postoperative sensitivity as present (yes) or absent (no) after patient inquiry. In addition, they recorded sensitivity to a dry air blast 1 inch from the restoration for three

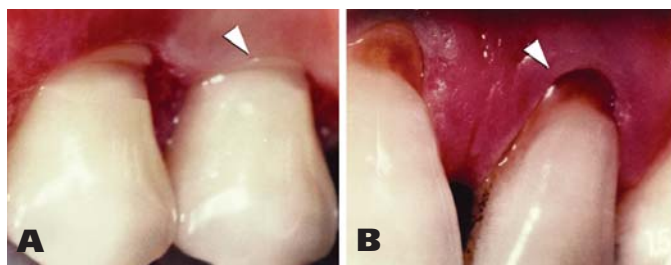


Figure 1. Clinical examples of category 1 and category 4 ratings on the dentin sclerosis scale. **A.** An example of category 1 (no sclerosis of dentin in cervical lesion). **B.** An example of category 4 (significant sclerosis of dentin in cervical lesion).

seconds. They recorded retention as completely retained (Alfa) or partially or completely lost (Charlie). They noted evidence of stressful occlusion preoperatively and at each recall evaluation.

TABLE 1

Criteria for modified U.S. Public Health Service and other direct evaluations.*	
CRITERION	SCORE
Retention	Alfa: Yes (completely retained) Charlie: No (partially or completely lost)
Color Match	Alfa: No mismatch in room light in 3 to 4 seconds (margins should be exempted from grading; interfacial staining should not affect grading) Bravo: Perceptible mismatch (clinically acceptable) Charlie: Esthetically unacceptable (clinically unacceptable)
Marginal Discoloration	Alfa: No Bravo: Superficial staining (removable, usually localized) Charlie: Deep staining (not removable, generalized)
Recurrent Caries	Alfa: No Charlie: Yes
Loss of Anatomical Form (Wear)	Alfa: No perceptible wear (or only localized wear) Bravo: Generalized wear (clinically acceptable; 50 percent of margins are detectable; explorer catches going from material to tooth) Charlie: Wear beyond dentinoenamel junction (DEJ) (clinically unacceptable)
Marginal Adaptation (Marginal Integrity)	Alfa: Undetectable Bravo: Detectable (V-shaped defect in enamel only; explorer catches going both ways) Charlie: Detectable (V-shaped defect to DEJ)
Surface Texture	Alfa: Smooth (better than or equal to microfilled composite) Bravo: Rougher than microfilled composite Charlie: Pitted
Postoperative Sensitivity	Alfa: None Charlie: Some
Other Failure	Alfa: No Charlie: Yes

* Source: Heymann and colleagues.³¹

TABLE 2

Summary of direct evaluation results.			
GROUP*	RESTORATIONS WITH ALFA SCORE/ RECALLED RESTORATIONS (% WITH ALFA SCORE), ACCORDING TO EVALUATION PERIOD		
	Baseline	1 Year	12 Years
A			
Recall rate	50/50 (100)	48/50 (96)	27/50 (54)
Retention	50/50 (100)	48/48 (100)	25/27 (93)
Color match	50/50 (100)	46/48 (96)	23/25 (92)
Marginal discoloration	50/50 (100)	48/48 (100)	17/25 (68)
Recurrent caries	50/50 (100)	48/48 (100)	25/25 (100)
Loss of anatomical form (wear)	50/50 (100)	48/48 (100)	24/25 (96)
Marginal adaptation (marginal integrity)	50/50 (100)	48/48 (100)	22/25 (88)
Surface texture	50/50 (100)	48/48 (100)	25/25 (100)
Postoperative sensitivity	50/50 (100)	47/48 (98)	25/25 (100)
B			
Recall rate	50/50 (100)	47/50 (94)	19/50 (38)
Retention	50/50 (100)	45/47 (96)	16/19 (84)
Color match	50/50 (100)	44/45 (98)	15/16 (94)
Marginal discoloration	50/50 (100)	44/45 (98)	13/16 (81)
Recurrent caries	50/50 (100)	45/45 (100)	16/16 (100)
Loss of anatomical form (wear)	50/50 (100)	45/45 (100)	16/16 (100)
Marginal adaptation (marginal integrity)	50/50 (100)	45/45 (100)	15/16 (94)
Surface texture	50/50 (100)	45/45 (100)	16/16 (100)
Postoperative sensitivity	50/50 (100)	45/45 (100)	16/16 (100)
A and B			
Recall rate	100/100 (100)	95/100 (95)	46/100 (46)
Retention	100/100 (100)	93/95 (98)	41/46 (89)
Color match	100/100 (100)	90/95 (95)	38/41 (93)
Marginal discoloration	100/100 (100)	92/95 (97)	30/41 (73)
Recurrent caries	100/100 (100)	93/95 (98)	41/41 (100)
Loss of anatomical form (wear)	100/100 (100)	93/95 (98)	40/41 (98)
Marginal adaptation (marginal integrity)	100/100 (100)	93/95 (98)	37/41 (90)
Surface texture	100/100 (100)	93/95 (98)	41/41 (100)
Postoperative sensitivity	100/100 (100)	92/95 (97)	41/41 (100)

* In group A, the enamel only was etched; in group B, both enamel and dentin were etched.

For documentation, the evaluators took intra-oral color photographs at each evaluation appointment. Clinical photographs consisted of color slides taken at an original magnification of $\times 1.5$ that the operators used primarily for reference to document the direct evaluations.

Statistical analysis. We analyzed subjects' age and sex, lesion characteristics and operator differences between groups A and B at baseline to determine if any were statistically significant. Lesion characteristics included internal angle, percentage of enamel margin, sclerosis scale value, presence or absence of occlusal stress, and lesion size and volume. We compared modified USPHS criteria scores of restorations in group A and group B at each evaluation time to identify

any statistically significant differences. We analyzed data by means of *t* tests, one-way analysis of variance and the Pearson χ^2 ($P = .05$).

RESULTS

We noted no statistically significant differences between groups A and B in terms of subjects' age and sex, overall lesion characteristics and operators ($P = .05$). As stated earlier, operators placed the 50 restorations in group A in 26 subjects and the 50 restorations in group B in 27 subjects. They placed 35 percent of the baseline restorations in anterior teeth and 65 percent in posterior teeth. Male and female subjects received approximately equal numbers of restorations. Although operators made every effort to place the restorations in subjects representing all age groups, we noted that the prevalence of these lesions in young adults was low in the study sample (4 percent of the total restorations in subjects aged 20-39 years).

The operators placed approximately equal numbers of restorations in middle-aged adults (50 percent in subjects aged 40-59 years) and older adults (46 percent in subjects aged 60-79 years).

The lesions' average dimensions \pm standard deviation (SD) were height = 3.3 mm \pm 1.2 mm, width = 4.4 mm \pm 1.3 mm and depth = 1.4 mm \pm 0.5 mm. Most of the cervical lesions had an internal angle of 45 to 135°, and most of the lesions had 25 to 50 percent of their margins in enamel. The dentin sclerosis ratings indicate that relatively few lesions had no sclerosis (6 percent), as most had ratings of 2, 3 or 4 on the dentin sclerosis scale (Figure 1).

The recall rates at 12 years were 54 percent for group A and 38 percent for group B; the overall

recall rate was 46 percent. Twenty percent of the recalled restorations were in anterior teeth; 80 percent were in posterior teeth. Table 2 summarizes the results of the direct evaluations of the OptiBond/Herculite XRV restorations at baseline and each recall period. The distribution of restorations evaluated in 12 years was similar to that of restorations at insertion. We detected no statistically significant differences between the two treatment groups in terms of retention or any of the other evaluation criteria. At 12 years, subjects retained 93 percent of the restorations in group A and 84 percent of the restorations in group B. The retention of groups A and B combined was 89 percent. In most direct evaluation categories, we noted few changes from baseline to the 12-year evaluation visit. At 12 years, the color match was good, with 92 percent Alfa ratings in group A and 94 percent Alfa ratings in group B (Figure 2). Only one restoration (group A) exhibited loss of anatomical form (wear). Alfa scores for marginal adaptation (marginal integrity) were 88 percent for group A and 94 percent for group B, and the Alfa scores for marginal discoloration were 68 percent for group A and 81 percent for group B (Figure 3).

DISCUSSION

Investigators have published a review of the five-year clinical performance of 11 three-step etch-and-rinse adhesive systems in noncarious cervical lesions.¹⁶ At five years, the three-step etch-and-rinse adhesives (including OptiBond Dual Cure) and the two-step self-etch adhesives exhibited the highest retention rates (76 percent and 77 percent, respectively). The retention rate at five years was lower among the two-step etch-and-rinse adhesives (69 percent) and lowest among the one-step self-etching adhesives (60 percent). At five years, 81 percent of the three-step etch-and-rinse adhesives fulfilled the ADA guidelines for acceptance of dentin and enamel adhesive materials.¹⁵ Seventy-one percent of the two-step self-etch adhesives fulfilled the ADA guidelines for acceptance.¹⁶

Recently, investigators reported results of two 13-year clinical trials of three-step etch-and-rinse adhesive systems in noncarious cervical lesions.^{24,35} Both of these trials included OptiBond Dual Cure. Boghosian and colleagues³⁵ evaluated clinical variables paralleling those used in our study. van Dijken and Pallesen²⁴ found that the retention rate of OptiBond Dual Cure at 13 years



Figure 2. Typical color match of Class V composite restorations.



Figure 3. Marginal discoloration at distoincisor corner of Class V composite restoration.

was 60 percent. Boghosian and colleagues³⁵ found the 13-year retention rate for OptiBond Dual Cure to be 97 percent.

The relative clinical success of OptiBond Dual Cure in our study—89 percent in the combined groups—could be related to several of the product's characteristics. The product uses an intermediary layer of filled adhesive that might serve as a shock absorber during the stress associated with polymerization shrinkage and occlusal loading, thus reducing its risk of debonding.³⁶ Researchers have suggested that three-step etch-and-rinse adhesive systems are less sensitive to technique than are simplified adhesive systems.¹⁶ Systems in which the smear layer is removed, such as the three-step etch-and-rinse adhesive systems, tend to exhibit better clinical performance than that of systems that

involve modification of the smear layer.¹⁴ Three-step etch-and-rinse adhesive systems involving ethanol/water-based solvents, such as OptiBond Dual Cure, generally are regarded as the gold standard for bond durability.¹²

OptiBond Dual Cure performed well at 12 years, irrespective of the use of dentin etching. We did not expect the number of successfully retained restorations we found. Of 46 recalled restorations (46 percent recall rate), only five demonstrated retention failure (two in group A and three in group B). The rate of restoration retention was 93 percent in group A and 84 percent in group B, or 89 percent for the combined groups. Except for marginal discoloration in both groups and retention in group B, 88 percent or more of the restorations in both groups received Alfa scores in all of the direct clinical evaluation categories. At 12 years, 100 percent of the restorations in both groups received Alfa ratings in three categories: recurrent caries, surface texture and postoperative sensitivity. Although the number of failed restorations in both groups was low, it is possible to speculate about the influence (or lack of influence) of recall rate, restoration distribution, lesion characteristics, clinical characteristics and operators on the results of the 12-year recall.

Fifty-four percent of the restorations (27 restorations) in group A were in patients who were recalled, compared with 38 percent of the restorations in group B. Seven percent of the restorations in group A exhibited retention failure compared with 16 percent in group B. It is possible that a higher recall rate in group B (similar to that of group A) would have yielded a similar retention rate for group B. The recall rates of the two groups are too different to consider them evenly paired. However, considering the lack of statistically significant differences, comparisons of the data from the two groups is worthy of brief discussion.

Eighty-nine percent of the recalled restorations in group B, compared with 74 percent in group A, were in posterior teeth. It is possible that the higher number of posterior restorations in group B contributed to its lower retention rate. It is well-accepted that the occlusal load is heavier on the posterior teeth than on the anterior teeth. If we had intentionally selected more abfraction lesions in posterior teeth for group B, it follows that these lesions may have been subjected to a more stressful environment, which would explain their lower retention rate.

Overall, restoration distribution and lesion characteristics were similar in the two groups and seemed to have had little effect on the retention of these restorations. However, three factors differed between the two groups of retention failures. The two failed restorations in group A were in women, and the three in group B were in men. Although we judged only one of the five restorations to be in stressful occlusion and that one was in group A, group B had a higher percentage of retention failures. This could suggest that sex differences may be a factor in predicting retention of these restorations; alternatively, the difference in this study might have been coincidental.

The internal angle of the lesions is thought to contribute to the success of adhesive restorations. Investigators have shown that lesions with greater internal angles provide less inherent retention than do lesions with smaller internal angles.³¹ In our study, most of the lesions with larger internal angles occurred in group B; 79 percent of the restorations in group B, compared with 59 percent of those in group A, had an internal angle of 90° or greater. We expected this factor to contribute to a lower retention rate in group B. However, only one of the three restorations with retention failures in that group had an internal angle greater than 90°. The other two restorations with retention failures had an internal angle less than 90°, and the internal angle of one was less than 45°.

Researchers consider older dentin to be more sclerotic and less amenable to adhesion than is younger dentin.^{33,34} The results of our study offer some conflicting evidence regarding this issue. The two failures in group A had sclerosis levels of 1 or 2, but both failures were in the oldest age cohort. One of the group B failures had a sclerosis level of 3, but none of the subjects with the three failures in this group was in the older age cohorts, and one subject with a failure was in the youngest cohort. Consistent with these results, researchers have reported that the clinical performance of newer etch-and-rinse systems may be less sensitive to substrate variables.^{14,37,38}

The operators involved in our study have participated in clinical trials for many years. Involving experienced operators is important in reducing interoperator variability.²³ The operator effect in our study apparently was minimal. Three of six operators placed the failed restorations.

The operators discovered one of the failed res-

torations seen at the 12-year recall visit first at the one-year recall visit. One other restoration discovered at the one-year recall visit was not seen at the 12-year recall visit because we could not locate the patient. The missing patient had one restoration to be evaluated at recall other than the previously failed restoration. Both of the restorations were in group B.

We should discuss two clinical characteristics of the restorations. The USPHS criteria state that any evidence of marginal discoloration should be given a Bravo score. This overrepresents the marginal discoloration exhibited at 12 years (68 percent for group A; 81 percent for group B). Each incidence of marginal discoloration was localized. In most cases it was associated with flash at the margin, which had stained at its interface (Figure 3). There were instances of interfacial staining below the margin of the restoration, but the staining was shallow in each case. Also, there were two restorations rated Bravo for color match. In both cases, the tooth had darkened over the 12-year period but the restoration had not. The result was that the restoration was lighter than the tooth (Figure 3).

Marginal discoloration is associated with microleakage at the composite-tooth interface. No method of handling an adhesive restoration can ensure that it is "leak proof."³⁹ Microleakage, not retention, is the primary cause of clinical failure in noncarious cervical restorations.¹⁴ Microleakage is defined as an ingress of water at the interface⁴⁰ that can slowly hydrolyze collagen fibrils,^{8,41,42} degrade demineralized dentin⁴³ and leach out resin components,⁴⁴ resulting in bond degradation. Bond degradation is progressive, as suggested by increasing loss rates across time in the previously mentioned 13-year clinical trial of noncarious cervical restorations.²³ In our study, the relatively low incidence of marginal discoloration (27 percent receiving Bravo ratings) in the combined groups at 12 years may be related to the high incidence of retention (89 percent receiving Alfa ratings) in the combined groups. The high 12-year retention rate of OptiBond Dual Cure, a three-step etch-and-rinse adhesive, suggests that it was less vulnerable to microleakage than are other categories of adhesives. In fact, *in vitro* test results have shown that the bonding effectiveness of OptiBond Dual Cure is affected significantly

less by water storage⁴⁵⁻⁴⁸ than is its two-step counterpart, OptiBond Solo (Kerr).^{7,49}

We considered other clinical features as well. As in other similar clinical trials, the operators roughened the surfaces to be bonded with a diamond stone to increase the surface area available for bonding. However, evidence suggests that a roughened surface does not increase retention significantly over that provided by a nonroughened surface.³⁸ The operators did not bevel the enamel margins of the lesions because bonding to beveled enamel could produce false-negative retention results and because beveling has been shown not to affect retention significantly.⁵⁰ Consistent with the manufacturer's directions, *in vitro* study results have shown that vigorously rubbing adhesive onto the dentin surface, whether air dried or rewetted, helps ensure long-term bond strength.¹⁹ Depending on the axial depth, the operators restored some lesions incrementally and some by means of bulk filling. Evidence suggests both techniques can produce similar clinical results.^{51,52}

When we initiated this study, we presumed that retention for group B would be better, as those participants had undergone the total-etch treatment. However, at 12 years after placement, we found that the failure rates of the two groups were not significantly different. The results of this study did not isolate a single determining factor in the success of adhesively retained Class V restorations. Although the total-etch group had the greater number of failures, the failed restorations did not have the expected characteristics. This group included a greater number of restorations with an internal angle of 90° or greater, higher sclerosis scale values and stressful occlusion. However, the failed restorations in both groups had similar lesion characteristics. The presence of these lesion characteristics is not necessarily predictive of clinical performance.

As previously described, the operators used different etching techniques for groups A and B. In group A, the operators etched only the enamel for 30 seconds. In group B, the operators etched the enamel similarly and etched the dentin walls for 15 seconds. However, when they applied the etchant in group A, it was difficult to restrict the etchant to the enamel only; in group B, they found it difficult to restrict the etchant to the enamel for only 15 seconds. Also, when they

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The results of this study did not isolate a single determining factor in the success of adhesively retained Class V restorations.

rinsed the etchant from the teeth, the etchant flowed over the dentin, if only briefly, and inadvertently etched the dentin during rinsing. To some extent, the operators probably etched the dentin in both groups more than intended. As a result, the two treatments might not have been as different as they appear. Group A, the enamel-etch-only group, had the highest retention rates, suggesting that the less aggressive etching resulting from the acid wash actually conditioned the dentin more optimally than in group B, the total-etch group. The mild etching effect of the acid wash actually may have been beneficial, although differences between the two groups were not statistically significant.

The primary outcome of this study is that OptiBond Dual Cure/Herculite XRV was a successful restorative system for adhesively bonded restorations. At 12 years, the 93 percent retention rate in group A and 84 percent retention rate in group B, or the 89 percent rate in the combined groups, are virtually unmatched in clinical research studies to date. This outcome is particularly remarkable given the variables inherent in a 12-year clinical study.

CONCLUSIONS

At 12 years, the retention rate of Class V composite restorations bonded by using the three-step adhesive system OptiBond Dual Cure was nearly 90 percent and not affected by dentin acid-etching. Marginal discoloration was fairly common in both groups, but we generally rated other restoration characteristics as Alfa, the highest rating possible under the evaluation system used. ■

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