©Operative Dentistry, 2010, **35-3**, 273-278

Two-Year Clinical Performance of Clearfil SE and Clearfil S3 in Restoration of Unabraded Non-carious Class V Lesions

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Clinical Relevance

No difference was observed between two adhesives. Instructions for self-etching resins should be more specific for restoration of non-carious Class V lesions, especially regarding air-drying to remove residual solvent.

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DOI: 10.2341/09-266-C

SUMMARY

This study was undertaken to evaluate the two-year clinical performance of a self-etching primer and a self-etching adhesive, both of which employ the same acidic monomer. Forty pairs of restorations of AP-X hybrid resin composite (Kuraray Co, Ltd, Osaka, Japan) were placed in caries-free cervical erosion/abfraction lesions. Based on insensitivity to air, the dentin in 62% of these lesions was considered to be sclerotic. The restorations were placed with no abrasion of tooth surfaces, except for cleaning with plain pumice and no use of phosphoric acid etching, which is counter to the manufacturer's instructions that call for etching of unprepared enamel. One restoration from each pair was placed using Clearfil SE Bond, an adhesive employing a self-

etching primer, and the other was placed using Clearfil S³ Bond, a self-etching adhesive. To emulate the results likely to occur in a private practice, the restorations were placed by well-educated, experienced clinicians who had no particular expertise in adhesive dentistry research and who placed the restorations according only to their interpretation of the manufacturer's instructions. The restorations were clinically evaluated at baseline and at 6, 12 and 24 months, using modified Ryge/USPHS criteria. For both products, retention of 81%-84% of the restorations was observed over two years, which is lower than has been previously observed with these products and is likely due to limitations in the manufacturer's instructions compounded by inexperience of the operators in adhesive dentistry research. One restoration placed with each adhesive demonstrated secondary caries, which was probably attributable to the study being conducted in a non-fluoridated area and which reduced the percentages of clinically successful restorations to 78%-81%. No statistically significant difference (*p*=0.50) between the two adhesives was observed in overall performance.

INTRODUCTION

The restoration of non-carious, non–retentive Class V lesions, also referred to as abrasion/abfraction lesions, has long been the primary clinical method for testing the adhesive behavior of restorative materials, since being incorporated into the former American Dental Association acceptance program for dentin and enamel adhesive materials in 1994. A systematic review,[1] including 85 clinical trials of non-retentive Class V resin composite restorations, published between 1998 and 2004, has demonstrated that resin adhesives employing a self-etching primer retain Class V resin composite restorations in non-retentive abrasion/abfraction lesions about as effectively as earlier etch-and-rinse formulations, with both showing an annual failure rate below 5%. Self-etching adhesives from that period demonstrated an annual failure rate greater than 10%,[1] although improved formulations have since been introduced.

Within this body of clinical studies of non-retentive Class V resin restorations, many investigators have mechanically prepared tooth surfaces prior to restoration. Although reasons for doing this are rarely stated, it is probably intended to remove the hypermineralized dentin characteristic of the surface of abrasion/abfraction lesions, which could inhibit dentin etching and formation of hybrid layers.[2] However, prior grinding of tooth surfaces has not been shown to be a significant factor in annual failure rates of non-retentive Class V resins placed with etch-and-rinse adhesives.[3-5]

Laboratory studies show that self-etching resins produce less change in enamel topography than phosphoric acid etching[6] and, due to the lower acid solubility of the surface of unground enamel, lower laboratory bond strengths to unground versus ground enamel.[7-8] This is attributable to the considerably higher pH (1.9-2.7) of these products, relative to that of phosphoric acid etchants (pH<1). Based on this, the prior etching of enamel, usually accompanied by prior grinding of both the enamel and dentin surfaces, has become a common protocol for clinical studies using self-etching resins to retain Class V restorations in non-retentive abrasion/abfraction lesions. Prior etching of unground enamel is also recommended by several manufacturers of self-etching resins.

Whether prior grinding or etching improves the clinical performance of self-etching resins has been investigated in multiple trials only for Clearfil SE Bond (Kuraray Co, Ltd, Osaka, Japan). This adhesive employs a self-etching primer with a pH of 1.9, has been available in the USA since 1999 and has also demonstrated favorable laboratory bond strengths to dentin and enamel.[6] Peumans and others[9] used a protocol wherein dentin surfaces were unground and enamel margins were beveled, and they observed enamel etching with phosphoric acid prior to using Clearfil SE as having no effect on the survival of non-retentive Class V resin restorations over five years, with both the etched and unetched groups demonstrating a nearly 100% survival rate. However, a higher rate of small enamel margin defects was observed in the unetched group. Similar studies between 18-36 months' duration have demonstrated 90%-100% survival of non-retentive Class V restorations placed using Clearfil SE Bond without prior etching or grinding of tooth surfaces.[10-11]

Single component self-etching adhesives have only recently demonstrated sufficient laboratory bond strengths[6] to be considered viable for clinical use, with clinical trials on their use limited. The self-etching adhesive Clearfil S³ Bond (Kuraray Co, Ltd), which was introduced in the US in 2005, is of particular interest, because it employs the same acidic monomer as Clearfil SE Bond, although at a higher pH of 2.7. Two trials of non-retentive Class V resin restorations placed with this adhesive, one with and one without prior grinding of tooth surfaces, demonstrate restoration survival of 98%-100% over one-two years, with a 10%-20% incidence of marginal discoloration noted in both. Based on the above-cited evidence, there does not appear to be a compelling reason for prior etching of enamel or prior grinding of tooth surfaces with either Clearfil SE or Clearfil S³. Despite their similar composition, no clinical comparison of these products in Class V resin composite restorations has been accomplished.

Finally, in most clinical trials, restorations are placed by an operator who has considerable expertise in adhe-

sive dentistry research. Because such clinicians are highly aware of variables such as evaporation of solvent, which can adversely influence adhesion if not done thoroughly,[12] they are better able to overcome any lack of clarity within the manufacturers' instructions, and their results are probably more favorable than would be attained by a dentist without any particular experience in adhesive dentistry research.

This study compared the two-year clinical performance of Clearfil SE Bond and Clearfil S³ Bond in the restoration of Class V abrasion/abfraction lesions with resin composite over two years. Prior etching or micromechanical removal of the tooth structure was not done; however, the restorations were placed according to the manufacturer's instructions by experienced, well-educated clinicians who had particular expertise in adhesive dentistry research.

Table 1: *Adhesives, Manufacturer's Instructions/Technique, Composition, Manufacturer*

Adhesive	Technique (Composition, pH)
Clearfil SE Bond	
Primer	*(Etch uncut enamel, 10 seconds)** Apply 20 seconds, evaporate volatile ingredients with mild air stream (10-methacryloyloxy decyl dihydrogenphosphate [MDP,] HEMA, water; pH=1.9)
Bond	Apply, thin to uniform layer with mild air stream, light cure (MDP, Bis-GMA, HEMA)
Clearfil S³ Bond	
Primer/Bond	*(Etch uncut enamel, 10 seconds)** Apply 20 seconds, air dry >5 seconds with high-pressure air stream, light cure (MDP, Bis-GMA, HEMA, water, ethanol; pH=2.7)
Kuraray Co, Ltd, Osaka, Japan	

**Etching of uncut enamel not done in this study.*

METHODS AND MATERIALS

The two adhesives chosen for the current study are manufactured by Kuraray Co, Ltd, Osaka, Japan. Clearfil SE Bond employs a self-etching primer followed by a solvent-free adhesive, while Clearfil S³ Bond is a self-etching adhesive. Both share the same acidic resin monomer, although at a differing pH—1.9 and 2.7, respectively (Table 1). Restorations for this study were placed by two experienced operators with postgraduate credentials in general dentistry. Both are faculty in a postgraduate general dentistry program but have not had extensive experience in adhesive dentistry research. These operators were instructed to follow the manufacturer's instructions, except to do no prior etching of enamel.

Forty pairs of equivalent-sized cervical erosion/abfraction lesions, primarily in premolars and anterior teeth, were identified in 14 healthy patients presenting for treatment at the student clinics of the Facultad de Estomatologia, Benémerita Universidad Autónoma de Puebla. The study was conducted in accordance with all local regulations for the ethical treatment of human subjects. The median age of these patients was 46 years, their age ranged from 31 to 58 years and all consumed unfluoridated water.

Each pair of cervical erosion/abfraction lesions received one restoration placed using each adhesive, assigned randomly. All the patients received three pairs of restorations except for one patient, who received one pair. Three of the lesions included in the study were rated as having an axial depth greater than 2 mm, while the remainder were scored 1-2 mm in axial depth. The approximate size of each lesion and any sensitivity of the lesion to air from the dental unit was recorded prior to placing the restoration (Table 2). Sixty-two percent of the lesions were insensitive to air and considered as having sclerotic dentin surfaces.

Table 2: *Distribution of Restorative Materials to Teeth Restored; Axial Depth and Preoperative Sensitivity of Erosion/Abfraction Lesions (n=40)*

Clearfil SE	**Incisors**						**Canines**						**Premolars**						**Molars**					
	n	***s***	***o***	***a***	***b***	***c***	***n***	***s***	***o***	***a***	***b***	***c***	***n***	***s***	***o***	***a***	***b***	***c***	***n***	***s***	***o***	***a***	***b***	***c***
Maxillary	3	2	1		3		5	1	4	1	4		10	3	7	1	9		7	5	2		6	1
Mandibular							1		1		1		13	2	11	1	11	1	1	1			1	
Clearfil S³																								
	Incisors						**Canines**						**Premolars**						**Molars**					
	n	***s***	***o***	***a***	***b***	***c***	***n***	***s***	***o***	***a***	***b***	***c***	***n***	***s***	***o***	***a***	***b***	***c***	***n***	***s***	***o***	***a***	***b***	***c***
Maxillary	2	1	1		2		4	2	2	2	2		11	4	7		11		5	2	3		5	
Mandibular													17	7	10	2	14	1	1		1		1	

s = sensitive to air
o = insensitive to air
a = axial depth < 1 mm
b = axial depth 1-2 mm
c = axial depth > 2 mm

The study was conducted according to the protocol for clinical studies set forth in the former American Dental Association acceptance program for dentin and enamel adhesive materials (2001). Isolation was accomplished using cotton rolls, with unimpregnated gingival retraction cord moistened with water placed to expose any subgingival margins. With the exception that no etching of uncut enamel was done, all the restorations were placed according to the manufacturers' instructions, as summarized in Table 1. Other than cleaning with plain fine pumice and water in a rubber prophylaxis cup, no mechanical preparation of the tooth surfaces was done. After using the two adhesives, restorations of the same manufacturer's hybrid resin composite, AP-X (Kuraray Co, Ltd) were placed.

Table 3: *Modified USPHS Rating System*

Category	Score	Criteria
Retention	Alfa	No loss of restorative material
	Charlie	Any loss of restorative material
Color match	Alfa	Matches tooth
	Bravo	Acceptable mismatch
	Charlie	Unacceptable mismatch
Marginal Discoloration	Alfa	No discoloration
	Bravo	Discoloration without axial penetration
	Charlie	Discoloration with axial penetration
Secondary Caries	Alfa	No caries present
	Charlie	Caries present
Anatomic Form	Alfa	Continuous
	Bravo	Slight discontinuity, clinically acceptable
	Charlie	Discontinuous, failure
Marginal Adaptation	Alfa	Closely adapted, no detectable margin
	Bravo	Detectable margin, clinically acceptable
	Charlie	Marginal crevice, clinical failure
Surface Texture	Alfa	Enamel-like surface
	Bravo	Surface rougher than enamel, clinically acceptable
	Charlie	Surface unacceptably rough

Because the lesions were of minimal axial depth, each restoration was placed in one increment and light-cured for 40 seconds. Light output from the SL3000 curing light (3M ESPE, St Paul, MN, USA) was found to exceed 450 mW/cm^2 prior to and after the study, and it was verified during placement of the restorations with the unit's built-in radiometer. For all restorations, the shade considered the closest match using a Vita Classic shade guide (Vita-Zahnfabrik, Bad Säckingen, Germany) was selected. The restorations were shaped with a plastic instrument prior to light-curing, contoured after curing with finishing burs using air/water coolant and polished with wet abrasive rubber points and cups.

At baseline and at 6, 12 and 24 months, the restorations were clinically evaluated by two calibrated investigators using the modified Ryge/USPHS criteria[13] listed in Table 3. The examiners were unaware of which adhesive had been used for any restoration, and any discrepancy between examiners was resolved before the patient was dismissed.

For purposes of statistical analysis, restorations receiving a score of "Charlie" in any category were classified as failed restorations. The incidence of failures was analyzed as a pairwise comparison using an exact binomial test at a significance level of 5%.

RESULTS

At the end of two years, 37 pairs of restored sites were available for evaluation, a recall rate of 93%. Retention of the restorations was 84% for Clearfil SE and 81% for Clearfil S^3, with lost restorations and a single incidence of secondary caries along a dentin margin for each adhesive being the only scores of "Charlie" assigned in the study. Because restorations with caries were considered failed, the percentage of clinically successful restorations for each adhesive was 81% and 78% for Clearfil SE and Clearfil S^3, respectively. There was no difference in the percentage of successful restorations between the two operators.

Of the six lost Clearfil SE-retained restorations, one was lost prior to the six-month recall and the remaining five were lost during the 12-24 month interval. Of the seven lost Clearfil S^3-retained restorations, two were lost during the 6-12 month interval, and the other five were lost during the 12-24 month interval. The axial depth and dentinal sclerosis status of the lesions from which the restorations were lost closely paralleled traits in the overall population of the restored lesions, except that six of the seven (86%) lost Clearfil S^3 restorations had been placed in insensitive/sclerosed lesions, which constituted 60% of the lesions originally restored with this adhesive.

None of the teeth with retained restorations that exhibited sensitivity to air at the beginning of the study were sensitive at any recall. Marginal discoloration was observed in 27% and 33% of the Clearfil S^3- and Clearfil SE-retained restorations, respectively, but it was considered slight and evenly distributed between the enamel and dentin margins. The secondary caries observed in two restorations occurred along the dentin

margins. The hybrid resin composite displayed good color match and surface texture over the course of the study, with scores of greater than 90% alfa and 77%-81% alfa for these categories, respectively. No statistically significant difference in the incidence of failed restorations was found between the materials (Exact binomial test; p=0.50). Complete results are presented in Table 4.

DISCUSSION

The current study offered the opportunity to clinically compare two adhesives employing the same acidic monomer, one a self-etching primer system and the other a self-etching adhesive. Both products have been previously compared in the laboratory, with the self-etching adhesive found to have significantly lower bond strengths to both enamel and dentin.[6] Although the overall clinical performance did not differ between the two adhesives, lost restorations in the self-etching adhesive group occurred primarily in teeth considered to have sclerotic dentin surfaces. This suggests that a mild pH of 2.7 does not optimally decalcify sclerotic dentin for formation of hybrid layers.

It is surprising to the authors of the current study that, based on the study's equivalent clinical performance, the self-etching adhesive of mild pH apparently decalcified enamel as effectively as the self-etching primer of pH 1.9. Most of the restoration loss over the course of the study was observed after one year of clinical service, indicating that bonds were formed initially but they were unable to withstand either mechanical fatigue or hydrolysis over time, although the exact failure mechanism is beyond the scope of this study. The occurrence of a secondary carious lesion in each group is considered to be a result of the study subjects residing in a non-fluoridated area, rather than to any material or operator influence.

In keeping with current trends toward practice-based research, clinicians with the credentials and experience of accomplished practitioners, rather than clinicians experienced in adhesive dentistry research, were selected for this study. These clinicians, similar to practicing dentists purchasing a product, were limited to the information contained in the manufacturer's instructions. Based on a comparison of these results with previous studies done with the same materials, the authors of the current study believe that the adhesive technology expertise of the operators placing the restorations is a significant variable in clinical studies.

As previously mentioned, the inadequate air drying of self-etching resins would result in too much residual solvent in adhesive and hybrid layers beneath resin composite restorations, making them susceptible to

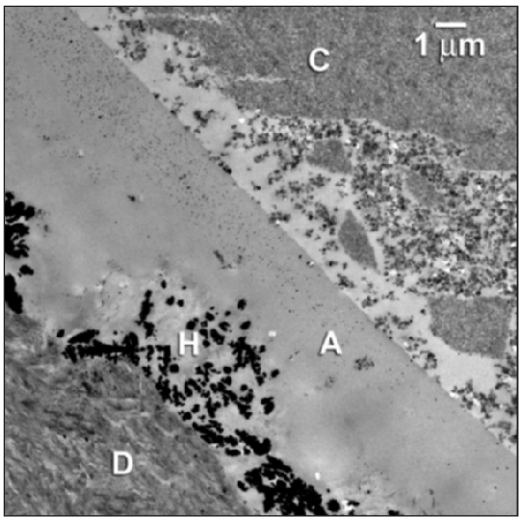

Figure 1. *TEM of unstained human coronal dentin (D) bonded with a self-etching adhesive demonstrating 2-3 µm thick hybrid (H) and adhesive (A) layers, covered with resin composite (C). Black areas are weak solvent-rich phases, which remain after insufficient drying, disclosed with metallic silver via a nanoleakage test. (Courtesy Franklin R Tay; original magnification 10,000x.)*

Table 4: *Results of Clinical Evaluation of Class V Resin Composites Placed with Self-etching Primer and Self-etching Adhesive (%)*

Clearfil SE		**Retention****		**Color Match**			**Marg Disc**		**Sec Caries**		**Anat Form**		**Marg Adapt**		**Surf Texture**	
	n*	**alfa**	**charlie**	**n***	**alfa**	**bravo**	**alfa**	**bravo**	**alfa**	**charlie**	**alfa**	**bravo**	**alfa**	**bravo**	**alfa**	**bravo**
Baseline	40	100	0	40	100	0	100	0	100	0	100	0	100	0	100	0
6 months	40	97	3	39	100	0	97	3	100	0	100	0	97	3	92	8
12 months	40	97	3	39	100	0	87	13	97	3	93	7	87	13	82	18
24 months	37	84	16	31	100	0	61	39	97	3	97	3	81	19	81	19
Clearfil S³		**Retention****		**Color Match**			**Marg Disc**		**Sec Caries**		**Anat Form**		**Marg Adapt**		**Surf Texture**	
	n*	**alfa**	**charlie**	**n***	**alfa**	**bravo**	**alfa**	**bravo**	**alfa**	**charlie**	**alfa**	**bravo**	**alfa**	**bravo**	**alfa**	**bravo**
Baseline	40	100	0	40	100	0	100	0	100	0	100	0	100	0	100	0
6 months	40	100	0	40	97	3	95	5	100	0	97	3	95	5	90	10
12 months	40	92	8	37	97	3	95	5	97	3	94	6	73	27	76	24
24 months	37	81	19	30	93	7	83	27	100	0	100	0	67	33	77	23

**sample size larger for retention than for other criteria because lost restorations unavailable for evaluation.*
***cumulative throughout the study.*

hydrolysis, which would reduce bond durability (Figure 1). However, most manufacturers' instructions suggest only a time and approximate air pressure for drying (Table 1) that does not take into account variations in the amount of fluid resin applied by different clinicians. These instructions should make mention of the desired clinical endpoint of maximal evaporation of solvent, which could be characterized as air drying at least until no movement of the resin is apparent and is well-known to clinicians with experience in adhesive dentistry research. The authors of the current study do not believe that factors, such as axial depth or dentinal sclerosis, influenced the results of this study, as these were similar to the patient populations in several previous clinical studies of non-retentive Class V restorations done at the same site.

Whether the findings of the current study support the authors' earlier assertion, that prior mechanical grinding or prior etching of tooth surfaces is not particularly indicated with the two products tested, is uncertain. The authors concede that the clinical performance of these two adhesives, as used by the operators in this study, might well have been improved by one of these, and favor the latter as the most conservative. The authors believe that the results of the current study, which show an approximate 20% reduction in clinical efficacy relative to studies employing clinicians more versed in adhesive dentistry research, will correlate very closely with results that would be expected in a private practice setting.

Whatever the reason for the reduced efficacy in clinical performance of these adhesives in abrasion/abfraction lesions, relative to other clinical studies, the authors believe that separate manufacturers' instructions for this type of restoration should be given for all resin-based adhesives and that these instructions should be detailed in describing the desired clinical endpoint. Since laboratory studies do not appear to be adequately predictive, it is suggested that these instructions be verified via clinical studies.

CONCLUSIONS

Under the protocol of restoration of Class V lesions used in this study, no significant difference between the two adhesives was observed in the overall clinical performance.

Acknowledgment

The authors gratefully acknowledge financial support for this study provided by the Facultad de Estomatologia, Benémerita Universidad Autónoma de Puebla, materials provided by Kuraray, USA, and statistical evaluation done by Dr William D Browning.

(Received 29 August 2009)

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