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Clinical Research

Clinical Evaluation of an All-in-one Adhesive in Non-Carious Cervical Lesions with Different Degrees of Dentin Sclerosis

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Clinical Relevance

Lower scores for marginal discoloration and adaptation were noted when an all-in-one self-etching adhesive was applied to non-carious cervical lesions and compared to a three-step total-etch adhesive.

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SUMMARY

This randomized clinical trial compared the performance of an all-in-one adhesive (iBond) applied in sclerotic and non-sclerotic non-carious cervical lesions with that of a three-step etch-prime-bond adhesive (Gluma Solid Bond, SB). One-hundred and five lesions were randomly assigned to four groups according to adhesive, sclerosis scale and technique: 1) SB applied to lesions with sclerosis scale 1 and 2 (n=26); 2) iBond applied to lesions with sclerosis scale 1 and 2 (n=28); 3) iBond applied to lesions with sclerosis scale 3 and 4 (n=25) and 4) iBond applied with prior acid-etching to lesions with sclerosis scale 3 and 4 (n=26). A microfilled composite (Durafill VS) was used as the restorative material. The restorations were evaluated for retention, color match, marginal adaptation, anatomic form, cavosurface margin discol-

oration, secondary caries, pre- and post-operative sensitivity, surface texture and fracture at insertion (baseline), 6, 18 months and at 3 years using modified USPHS evaluation criteria (Alfa=excellent; Bravo=clinically acceptable; Charlie=clinically unacceptable). There was a high percentage of Bravo scores for marginal adaptation (4%-32%) and marginal discoloration (18%-60%) in Groups 2, 3 and 4, but all groups had <5% Charlie scores at 6 months and <10% Charlie scores at 18 months for retention and marginal discoloration, respectively. However, it should be noted that 13% of the restorations in Group 4 were not retained at three years.

INTRODUCTION

Despite the important structural and compositional differences between these two substrates, bonding to enamel and dentin has long become an essential clinical procedure. The bonding of resin-based materials requires etching, priming and bonding. Each step has a different function in the bonding process: etching partially demineralizes enamel and dentin, priming permeates the exposed collagen fibers with amphiphilic molecules and bonding provides the link between the etched and primed enamel and dentin and the hydrophobic resin-based composite. Three-step etch-and-rinse adhesives have worked very well with consistent clinically-acceptable results in great part because this strategy allows for a distinct chemical function to be accomplished by each of the three steps.[1-2] In traditional multi-step adhesives, these three tasks are performed sequentially, requiring close attention to, among other factors, etching time, degree of moisture/dryness of dentin after rinsing and drying, amount and time of primer application, bonding resin application and more.

Simplified dental adhesives were introduced as a means of reducing the number of application steps necessary for bonding. In theory, simplified adhesives are easier to use and require a shorter application time than traditional multi-step adhesives. Simplified adhesives can combine etching and priming into one solution (self-etching primers) or they can combine etching, priming and bonding into one solution (self-etching adhesives or all-in-one adhesives).

Although they are widely used, simplified adhesives do not lack shortcomings. Due to their hydrophilicity, research has shown that simplified adhesives can be undesirably permeable, allowing water to infiltrate the adhesive layer and weaken the bond.[3-5] Monomer-solvent phase separation also has been reported with all-in-one adhesives.[6] Both *in vitro* and *in vivo* studies have shown that adhesion of simplified adhesives to dentin decrease over time.[2,7-9]

Bonding to dentin is not only affected by the type of adhesive, but also by the degree of mineralization or sclerosis of the substrate.[10-13] The dentin composition on the surface of non-carious cervical lesions (NCCL), especially sclerotic lesions, can be very different from the composition of normal dentin.[11,14] Although it has been shown that the degree of dentin mineralization or sclerosis can influence dentin bonding when etch-and-rinse multi-step adhesives are used,[15-18] little published data are available on the clinical performance of simplified adhesives used in sclerotic and non-sclerotic NCCL.[11]

This randomized clinical trial compared the performance of a simplified, all-in-one adhesive (iBond, Heraeus Kulzer, Hanau, Germany) with that of a three-step etch-prime-bond adhesive (Gluma Solid Bond, Heraeus Kulzer) when applied in sclerotic and non-sclerotic NCCL. The null hypothesis tested was that there is no difference between the clinical performance of the all-in-one adhesive and the three-step etch-prime-bond adhesive used to restore these lesions.

METHODS AND MATERIALS

The study protocol was reviewed and approved by the Biomedical Institutional Review Board of the University of North Carolina at Chapel Hill. Thirty participants who required NCCL restorations were enrolled in the study. The participant pool was randomized to exclude bias due to age, gender or other factors, such as unusual dietary, habitual or oral hygiene factors, which might affect the results. Prior to enrollment, participants read, understood and signed a consent form.

The dental health status of the participant was normal in all respects except for ongoing restorative procedures in unrelated quadrants. Any tooth included in the study contacted the opposing tooth in a normal occlusal relationship and had normal periodontal health. Teeth to be restored had NCCL (abrasion, erosion or abfraction) with no undercuts. Class V carious lesions were excluded. All lesions were preoperatively-characterized relative to height, width, depth, shape and internal angle of the lesion, percent of margin in enamel and degree of dentin sclerosis (Table 1).[10] Evidence of stressful occlusion (wear facets, fremitus) also was noted.

To minimize subject-related effects, no more than three restorations of each type of material (six total restorations) per subject were allowed. A randomized insertion schedule was prepared to minimize the effects of operator, subject and material on the results of the study.

All tooth preparations were of a modified design.[19] The preparations did not include retentive grooves or bevels. The dentin and enamel walls of the preparation

Table 1: *Sclerosis Scale (modified)*[10]

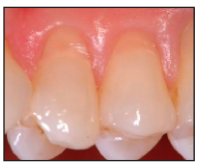
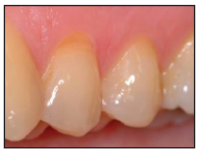
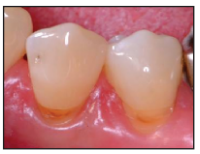
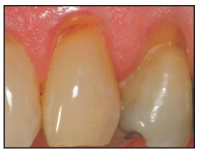
Category	Clinical Example	Description
1.		No sclerosis present. Dentin is light yellow or whitish in color with little discoloration. Dentin is opaque, with little translucency or transparency. (These lesions are typical in young individuals.)
2.		More than category 1, but less than 50% of the difference between categories 1 and 4.
3.		Less than category 4, but more than 50% of the difference between categories 1 and 4.
4.		Significant sclerosis present. Dentin is dark yellow or even discolored (brownish). Dentin appears glassy, with significant translucency or transparency evident. (These lesions are typical in older individuals.)

Table 2: *Composition and Batch Numbers of Adhesives Used in the Study*

Material	Composition	Batch #s
iBond	UDMA, 4-META, Acetone, H_2O, Glutaraldehyde	#VP050901Ge2 #010024
Gluma Etch 20 Gel	Phosphoric acid (20 wt %), Blue Dye, Pyrogenic Silica (Aerosil)	#155061
Gluma Solid Bond Primer	Maleic Acid, HEMA, Mod. Polyacrylic Acid, H_2O, Ethanol	#040028
Gluma Solid Bond Sealer	Bis-GMA, TEGDMA, HEMA, Carboxylic Acids Filler content: 25 wt % (Ba-Al-B-F-Si-glass, pyrogenic Silica)	#070039

were lightly roughened with a coarse diamond rotary instrument. Tooth preparation was limited to roughening the involved surfaces and producing a definite finish line, where indicated. Operative procedures were performed using local anesthesia as needed. The operating sites were isolated with cotton rolls and retraction cord or rubber dam, depending on access and location of the lesion.

As mentioned above, the NCCL were stratified by sclerosis scale and the adhesives were applied according to the specific directions supplied by the manufacturer (except where indicated), comprising the following four study groups:

- Group 1—Gluma Solid Bond applied to NCCL with sclerosis 1-2
- Group 2—iBond applied to NCCL with sclerosis 1-2
- Group 3—iBond applied to NCCL with sclerosis 3-4
- Group 4—iBond applied to NCCL with sclerosis 3-4 after acid-etching

The composition and batch numbers of the adhesives used are listed in Table 2. Briefly, the application technique for Gluma Solid Bond was as follows: the preparation walls were etched with Gluma Etch 20 Gel (Heraeus Kulzer) for 15 seconds, rinsed for at least 15 seconds and dried with oil-free air. The dentin was not desiccated. Gluma Solid Bond P (primer) was applied without agitation and air-dried for 5 seconds. Gluma Solid Bond S (bond) was applied, gently dried and light-cured for 40 seconds.

The application technique for iBond in Groups 2 and 3 was as follows: the preparation walls were dried, but not desiccated, and three consecutive coats of iBond were applied. After 30 seconds, the solvent was evaporated, first for a few seconds with a gentle air-blast until no movement of the adhesive film was noticeable, then with a more intensive air-blast to completely remove the acetone-water solvent. The surface appeared shiny; if not, the adhesive was reapplied. The adhesive was then light-cured for 20 seconds.

The application technique for iBond in Group 4 was identical to that in Groups 2 and 3, except that the preparation walls were etched with Gluma Etch 20 Gel (Heraeus Kulzer) for 15 seconds, rinsed for at least 15 seconds and dried (not desiccated) with oil-free air prior to application of the adhesive.

All preparations were restored with a light-cured microfilled resin-based composite (Durafill VS, Heraeus Kulzer). Shades of the composite were selected according to the requirements of the case. The composite was inserted in increments of 2 mm or less. Each increment was polymerized for 20 or 40 seconds, according to the manufacturer's recommended curing time for the specific shade, using a Translux Energy light-curing unit (Heraeus Kulzer). The power output of the light-curing unit was monitored periodically

throughout the insertion phase of the study and determined to be above 400 mW/cm^2.

After polymerization, finishing was accomplished with 12-fluted tapered and/or flame-shaped carbide finishing burs using light intermittent pressure to avoid damaging the margins. Polishing was accomplished with slow-speed polishing cups and points (Jiffy Polishers, Ultradent, South Jordan, UT, USA) and aluminum-oxide polishing discs (Sof-Lex, 3M ESPE, St Paul, MN, USA) where accessible. Finishing and polishing procedures were carried out predominantly under dry conditions.

The study was conducted with six operators, all full-time faculty with many years of experience in clinical research.

The restorations were evaluated at insertion (baseline) and 6 months and 18 months and 3 years post-insertion for retention, color match, marginal adaptation, anatomic form, cavosurface margin discoloration, secondary caries, pre- and post-operative sensitivity, surface texture and restoration fracture using modified United States Public Health Service (USPHS) criteria for clinical evaluation of dental restorative materials (Table 3).[12]

Table 3: *Modified USPHS Direct Evaluation System*[12-14]

Category	Criteria*
Retention	A = Retained C = Mobile or missing; clinically unacceptable
Color Match	A = Restoration matches adjacent tooth structure B = Perceptible mismatch; clinically acceptable C = Esthetically unacceptable
Marginal Adaptation	A = Undetectable B = Visible evidence of a crevice along the margin, dentin not exposed, clinically acceptable C = Explorer penetrates into crevice, dentin is exposed; clinically unacceptable
Anatomic Form	A = Restoration is continuous w/ existing anatomic form B = Discontinuous, but dentin is not exposed; clinically acceptable C = Material is missing, dentin is exposed; clinically unacceptable
Marginal Discoloration	A = No discoloration at margins B = Shallow discoloration (localized or generalized); clinically acceptable C = Deep discoloration (localized or generalized); clinically unacceptable
Secondary Caries	A = Absent C = Present; clinically unacceptable
Pre-/Post-operative Sensitivity	A = Absent C = Present; clinically unacceptable
Surface Texture	A = Smooth to finely granular B = Coarse, gritty; clinically acceptable C = Pitted; clinically unacceptable
Restoration Fracture	A = Absent C = Present; clinically unacceptable

**A=Alfa; B=Bravo; C=Charlie*

Intraoral color digital photographs were taken at baseline and at each evaluation visit as a permanent record for subsequent indirect evaluation and later reference. All restorations were evaluated independently by two operators. Consensus was determined by consultation and reevaluation as needed.

Data were analyzed using Fisher's Exact Test (p=0.05) for significant differences between treatment groups. Specifically, Groups 1 and 2 were compared to determine the influence of type of adhesive used to restore similar lesions (sclerosis 1 and 2); Groups 2 and 3 were compared to determine the influence of sclerosis on the performance of a single adhesive (iBond) and Groups 3 and 4 were compared to determine the effects of acid-etching for one adhesive (iBond) in similar lesions (sclerosis 3 and 4).

After data collection at the three-year evaluation visit, if any of the restorations required refinishing or repolishing because of poor marginal adaptation or marginal discoloration, they were prepared following the same finishing/polishing techniques used at the insertion visit. Although pictures and records were taken after refinishing or repolishing, these additional data were not used in the analysis of the performance of the restorations.

RESULTS

Thirty patients received a total of 105 restorations (see Table 4), all of which were evaluated at baseline and six months post-insertion. One-hundred and two restorations were evaluated at 18 months post-insertion (one participant moved out of state between the 6- and 18-month evaluation periods), resulting in a 97% restoration recall rate at 18 months. Ninety-four restorations were available for recall and evaluated at three years post-insertion, resulting in an 89% restoration recall rate at three years. Eleven restorations (11.6%) required refinishing or repolishing at the 3-year evaluation (three from Group 1, four from Group 2 and four from Group 3).

Table 5 contains data on the subjects' gender, age range and tooth-specific information, including occlusion and sclerosis scale. Table 6 shows more specific information related to the teeth and lesions, including distribution of the restored lesions' internal angle, per-

Table 4: *Number of Restorations Inserted (baseline) and Evaluated Per Group*

Group	Adhesive	Technique	Sclerosis Scale	# of Restorations Evaluated			
				BL	6 months	18 months	3 years
G1	Solid Bond	Etch+Prime+Bond	1-2	26	26	25	25
G2	iBond	Bond (self-etch)	1-2	28	28	26	26
G3	iBond	Bond (self-etch)	3-4	25	25	25	20
G4	iBond	Etch+Bond	3-4	26	26	26	23
Total # of restorations				**105**	**105**	**102**	**94**

Table 5: *Data on Subjects' Gender, Age, Teeth, Occlusion and Sclerosis Scale*

Gender (n)	Age (y-o)	Teeth (n)	Stressful Occlusion (n)	Sclerosis Scale
		Premolars: 70		#1: 32
Males: 13	Range: 36–77	Molars: 17	Yes: 55	#2: 22
Females: 17	Mean: 55	Canines: 13	No: 50	#3: 41
		Incisors: 5		#4: 10

Table 6: *Distribution of the Number of NCCLs (as total numbers) Within Each Category of Internal Angle, % of Enamel Margin, Presence of Stressful Occlusion at Baseline Per Group*

		Group 1	Group 2	Group 3	Group 4	Total
Angle	<45°	7	3	0	0	**10**
	45-90°	9	11	15	4	**39**
	90-135°	3	8	8	14	**33**
	>135°	7	6	2	8	**23**
% Enamel Margin	<25%	1	1	1	0	**3**
	25-50%	22	27	23	24	**96**
	>50%	3	0	1	2	**6**
Shape	Saucer	9	11	4	17	**41**
	Notch	17	17	21	9	**64**
Stressful Occlusion	Yes	15	12	14	14	**55**
	No	11	16	11	12	**50**

cent of enamel margin and the presence of stressful occlusion at baseline in each group.

Table 7 summarizes the evaluation data for each criterion per group at every evaluation time. At baseline, 8%, 11%, 4% and 4% of the lesions in Groups 1, 2, 3 and 4, respectively, exhibited dentinal sensitivity. None of the examined teeth had post-operative sensitivity.

No statistically significant differences were noted among the groups for retention rates, color match, secondary caries, surface texture, fracture, pre-op sensitivity and post-op sensitivity at any of the evaluation times. Additionally, the number of Alfa scores for retention, color match, secondary caries, post-operative sensitivity, surface texture and fracture remained relatively unchanged from baseline to 6 and 18 months to 3 years in all the experimental groups for all the evaluated restorations.

Although a very small number of clinically unacceptable restorations were identified during the study, the percentage of Alfa scores for marginal adaptation declined significantly ($p<0.02$) from baseline (100%) to all evaluation periods in Groups 2 (71% at 6 months, 81% at 18 months and 81% at 3 years) and 3 (68% at 6 months, 72% at 18 months and 70% at 3 years). Marginal adaptation in Groups 1 and 4 did not change significantly from baseline to any of the evaluation periods.

The number of Alfa scores for marginal discoloration significantly declined ($p<0.001$) from baseline (100%) to 18 months and 3 years in Groups 2 (69% at 18 months and 3 years), 3 (48% at 18 months and 35% at 3 years) and 4 (64% at 18 months and 75% at 3 years). (The increase in Alfa scores from 18 months to 3 years in Group 4 might be result of the two additional retention failures, which were not computed in the other criteria.) Additionally, the number of Alfa scores for marginal adaptation was significantly reduced from baseline (100%) to 6 months (56%) in Group 3 ($p<0.001$). One restoration from Group 3 received a Charlie score (clinically unacceptable) for marginal discoloration at 18 months, but no further Charlie scores (other than the two additional retention failures in Group 4) were recorded at three years. There was no marginal discoloration in Group 1 at any evaluation.

When the groups were compared, Group 3 had a significantly lower number of Alfa scores for marginal adaptation than Group 4 at 6 months ($p=0.01$) but not at 18 months ($p=0.1$) and 3 years ($p=0.09$). Group 2 had significantly more marginal discoloration (lower num-

Table 7: *Summary of Restoration Evaluations by Group (see Table 4 for group description). For Data Cell, Data Shown is N of Alfa Scores/Total N of Restorations Evaluated (% of Alfa Scores)*

	Group #s	Baseline	6 Months	18 Months	3 Years
Retention	G1	26/26 (100%)	26/26 (100%)	25/25 (100%)	25/25 (100%)
	G2	28/28 (100%)	28/28 (100%)	26/26 (100%)	26/26 (100%)
	G3	25/25 (100%)	25/25 (100%)	25/25 (100%)	20/20 (100%)
	G4	26/26 (100%)	26/26 (100%)	25/26 (96%)	20/23 (87%)
Color Match	G1	26/26 (100%)	25/26 (100%)	25/25 (100%)	25/25 (100%)
	G2	24/28 (86%)	23/28 (82%)	24/26 (92%)	26/26 (100%)
	G3	22/25 (88%)	21/25 (84%)	25/25 (100%)	20/20 (100%)
	G4	21/26 (81%)	24/26 (92%)	24/25 (96%)	18/20 (90%)
Marginal Adaptation	G1	25/26 (96%)	23/26 (88%)	25/25 (100%)	23/25 (92%)
	G2	28/28 (100%)	20/28 (71%)*	21/26 (81%)*	21/26 (81%)*
	G3	25/25 (100%)	17/25 (68%)*[a]	18/25 (72%)*	14/20 (70%)*
	G4	26/26 (100%)	25/26 (96%)[a]	23/25 (92%)	19/20 (95%)
Anatomic Form	G1	25/26 (96%)	25/26 (96%)	25/25 (100%)	25/25 (100%)
	G2	28/28 (100%)	28/28 (100%)	25/26 (96%)	26/26 (100%)
	G3	25/25 (100%)	24/25 (96%)[a]	24/25 (96%)	18/20 (90%)
	G4	26/26 (100%)	19/26 (73%)*[a]	25/25 (100%)	20/20 (100%)
Marginal Discoloration	G1	26/26 (100%)	26/26 (100%)	25/25 (100%)[a]	25/25 (100%)[a]
	G2	28/28 (100%)	23/28 (82%)	18/26 (69%)*[a]	18/26 (69%)*[ab]
	G3	25/25 (100%)	14/25 (56%)*[a]	12/25 (48%)*	7/20 (35%)*[bc]
	G4	26/26 (100%)	26/26 (100%)[a]	16/25 (64%)*	15/20 (75%)*[c]
Secondary Caries	G1	26/26 (100%)	26/26 (100%)	25/25 (100%)	25/25 (100%)
	G2	28/28 (100%)	28/28 (100%)	26/26 (100%)	26/26 (100%)
	G3	25/25 (100%)	25/25 (100%)	25/25 (100%)	20/20 (100%)
	G4	26/26 (100%)	26/26 (100%)	25/25 (100%)	20/20 (100%)
Surface Texture	G1	25/26 (96%)	26/26 (100%)	24/25 (96%)	25/25 (100%)
	G2	28/28 (100%)	27/28 (96%)	26/26 (100%)	26/26 (100%)
	G3	25/25 (100%)	24/25 (96%)	24/25 (96%)	20/20 (100%)
	G4	26/26 (100%)	26/26 (100%)	25/25 (100%)	20/20 (100%)
Fracture	G1	26/26 (100%)	26/26 (100%)	25/25 (100%)	25/25 (100%)
	G2	28/28 (100%)	28/28 (100%)	24/26 (92%)	26/26 (100%)
	G3	25/25 (100%)	25/25 (100%)	24/25 (96%)	20/20 (100%)
	G4	26/26 (100%)	26/26 (100%)	25/25 (100%)	20/20 (100%)

• Asterisk (*) indicates statistically significant difference (p<0.05) from baseline, across lines (same group and criterion).
• Cells with same superscript letter indicate statistically significant differences (p<0.05) for a given evaluation time and criterion. Only the comparisons G1-G2, G2-G3, and G3-G4 were tested for statistical significance (see text for details)
• Only retained restorations were evaluated for color match, marginal adaptation, anatomic form, marginal discoloration, secondary caries, surface texture and fracture.

ber of Alfa scores) than Group 1 at 18 months (p=0.004) and at 3 years (p=0.004). Group 3 had significantly more marginal discoloration (lower number of Alfa scores) than Group 4 at 6 months (p<0.001) and Groups 2 and 4 at 3 years (p<0.03).

DISCUSSION

There has been increased clinical interest in the past several years in the use of simplified adhesives, despite equivocal research findings. This randomized clinical trial was designed to compare the performance of a simplified, all-in-one adhesive with that of a three-step etch-prime-bond adhesive when applied to NCCL with different degrees of dentin sclerosis.

The excellent clinical performance of the restorations in Group 1 for all criteria demonstrates that the control three-step etch-prime-bond adhesive performs adequately in non-retentive NCCL. The good retention rates for Groups 2 and 3 indicate that, whenever the simplified adhesive is used as directed, retention rates remain high at least over the three year evaluation period. As noted in Table 7, marginal adaptation and marginal discoloration were the criteria with the most substantial drops in Alfa scores from baseline to the evaluation periods, particularly in Groups 2, 3 and 4. Although a Bravo score indicates that some problem was observed, the restoration remains clinically acceptable. However, in this study, six restorations received

Charlie scores, indicating that they were not clinically acceptable: one from Group 2 (marginal adaptation), two from Group 3 (both for marginal discoloration) and three from Group 4 (all for retention).

There appears to be no obvious relationship between restorations with Charlie scores for retention, marginal adaptation or marginal discoloration and participant age or gender, operator, tooth type, evidence of stressful occlusion, percent of enamel margin and/or internal angle. All three missing restorations were in saucer-shaped lesions restored in Group 4 (sclerosis =4, all-in-one adhesive, total-etch technique). No lesions with a sclerosis score of 4 were restored using the control adhesive, therefore, a comparison between the two adhesives was not appropriate here. Additionally, only 10 teeth with sclerosis scores of 4 were included in the study, from which two were in Group 3 (which were restored with the all-in-one adhesive, self-etch technique), and eight were in Group 4 (which were restored with the all-in-one adhesive, total-etch technique). Although the sample size for these groups was very small, it is interesting to note that all failures occurred in teeth with a sclerosis scale equal to 4 in the total-etch iBond group. However, whether the retention failures are directly related to the lesion shape, sclerotic scale or adhesive technique, cannot be determined conclusively with this study due to the small number of failures.

Based on the study design, it was not appropriate to compare the performance of Group 1 versus Group 3, because Group 1 included almost exclusively restorations placed in lesions with dentin sclerosis scale 1 and 2, while Group 3 included only restorations placed in lesions with sclerosis scale 3 and 4 (see Table 4). However, Group 1 can be compared with Group 2 based on similar lesion characteristics but different adhesive techniques. A Group 1 versus Group 2 comparison provides data on the performance of the experimental adhesive versus that of the control adhesive in lesions with sclerosis scale 1 and 2. Table 7 shows that the number of Alfa scores for marginal adaptation and marginal discoloration was noticeably lower for Group 2 than for the control Group 1. Alfa scores for marginal discoloration in Group 2 decreased from 82% at 6 months to 69% at 18 months and remained unchanged at three years, while 100% Alfa scores were noted for Group 1 at both 6 and 18 months and 3 years. A similar (although less obvious) tendency was observed for marginal adaptation. These results are in line with those of a recent report also comparing the clinical performance of a self-etching adhesive with that of a total-etch adhesive in NCCL.[9] The authors report that, although significantly more marginal discoloration was observed with the self-etching adhesive than with the total-etch adhesive, both adhesives showed retention rates that were not statistically different after 36 months. The authors, however, did not characterize the degree of sclerosis on the lesions restored. Another report, including a large sample of unprepared sclerotic NCCL, compared the clinical performance of a self-etching primer with that of a total-etch adhesive, showing poor retention, marginal discoloration and marginal adaptation rates at 18 months for both adhesives.[15]

A comparison of the clinical performance of Group 2 versus Group 3 yields isolation of the primary variable of differences in dentin sclerosis scale, as both Groups were restored with the same adhesive (iBond) and technique (self-etch). Table 7 shows similar scores for marginal adaptation when Groups 2 and 3 are compared at 6 months (71% versus 68% Alfa, respectively), but at 18 months (81% versus 72% Alfa, respectively) and at 3 years (Group 2=81% Alfa vs Group 3=70% Alfa), there appears to be a slight advantage for Group 2, although these differences were not statistically significant.

An additional analysis can be made by comparing the clinical performance of specimens in Group 3 versus specimens in Group 4, both sets with restorations placed in lesions with sclerosis scale 3-4. The number of Alfa scores for marginal adaptation and marginal discoloration was noticeably lower for Group 3 when compared to Group 4 both at 6 and 18 months and 3 years post-insertion. These differences were statistically significant at 6 months (marginal adaptation and marginal discoloration) and 3 years (marginal discoloration), which suggest that an additional acid-etch step might improve performance of the simplified adhesive when used for the restoration of highly sclerotic NCCL. However, albeit statistically insignificant, it should be noted that Group 4 had the lowest number of Alfa scores for retention. A recent study on the clinical effectiveness of a two-step self-etching adhesive with or without acid etching of the enamel margins reported similar results after five years; that is, etching resulted in improved marginal adaptation but was not critical for the overall clinical performance (retention) of the restorations.[16]

It has been reported that the aggressiveness of the acidic resin monomers used in simplified or self-etching adhesive systems, characterized by their pH, is directly related to their capacity to bond to enamel margins.[17] Simplified adhesives with a pH<1 are considered "strong," while those with a pH>1.5 are considered "mild."[18] The relatively high pH of the simplified adhesive used in this study (1.77 ± 0.02),[19] therefore, may have contributed to the high incidence of discolored margins noted in Groups 2 and 3. These results are consistent with those of another study, where a self-etching primer with pH similar to that of the simplified adhesive used in this study, was used.[16] This variable (pH) has been shown to be not only critical for enamel bonding,[20] but also for dentin bonding,[18-19] although pH alone did not directly correspond to bond strengths and/or interface morphology.[19] Another possible explanation for

the poor marginal adaptation and marginal discoloration noted can be the hydrophilic nature of the simplified adhesive used, which can lead to monomer-solvent phase separation, as reported previously.[3-6]

Because the most substantial findings in the current study relate to a perceived progressive reduction in marginal adaptation and marginal discoloration Alfa scores over time, the authors will briefly expand the discussion of the findings related to these specific criteria. The modified USPHS direct evaluation system for tooth-colored restorations was used in this study, because it is widely known and used, enabling the results reported here to be compared with other research findings published over the past several years. Additionally, this system was suggested by the American Dental Association (ADA) Acceptance Program Guidelines for Dentin and Enamel Adhesive Materials at the time this study was initiated. However, one important limitation of this evaluation system is that the observations, despite being relatively objective, are not site-specific for each specimen. More specifically, if a given specimen (restoration) has "visible evidence of a crevice along the margin," regardless of the defect being present on only a portion of the restoration's periphery, that specimen will receive a Bravo score for marginal adaptation at that evaluation time. Likewise, if a given specimen presents with "shallow discoloration," it will receive a Bravo score for marginal discoloration, regardless of whether the discoloration is localized or generalized.

This lack of specificity hinders the interpretation of the results to some extent, as it is not possible to determine, for example, if the high incidence of marginal discoloration or marginal adaptation Bravo/Charlie scores for any given specimen (or group) is more pronounced at the occlusal (enamel) versus the gingival (cementum) margin of the restorations, based solely on the objective direct and indirect evaluations conducted.

As noted previously, of the 11 restorations that required refinishing or repolishing at the three-year evaluation, three were from Group 1, four from Group 2 and four from Group 3. The repolishing procedures resulted in different (improved) scores for most of the criteria and restorations, but not for all of them. Only one of the 11 refinished or repolished restorations had received a Charlie score for marginal discoloration, which was reversed to a Bravo score after refinishing/repolishing (data not shown). All other repolished restorations had received a Bravo score for marginal adaptation, anatomic form or marginal discoloration.

Regardless of the limitations inherent to the evaluation system used, the combined, independent direct and indirect observations collected at three year post-insertion suggest inadequate performance of the all-in-one adhesive in restoring non-beveled, non-carious cervical lesions, especially those with a sclerosis scale of 3 and 4 when no acid-etch is used. Although the retention rate of the adhesive, when used as directed (no acid-etch), was 100%, marginal discoloration was very common.

CONCLUSIONS

Despite the high incidence of Bravo scores for the criteria marginal discoloration and marginal adaptation in Groups 2, 3 and 4, all groups satisfied the clinical requirements (performance criteria) for acceptance under the ADA Guidelines, that is, they demonstrated <5% Charlie scores at 6 months and <10% Charlie scores at 18 months for the criteria retention and marginal discoloration, respectively. However, it should be noted that the three-year evaluation revealed Charlie retention scores of 13% for the restorations placed in Group 4. Therefore, the null hypothesis tested was rejected, that is, there were differences between the clinical performance of the all-in-one adhesive and that of the three-step etch-prime-bond adhesive when applied to NCCL with different degrees of dentin sclerosis.

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