

# A New Universal Simplified Adhesive: 18-Month Clinical Evaluation

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## Clinical Relevance

At 18 months, the new multimode adhesive, Scotchbond Universal Adhesive, fulfilled the American Dental Association criteria required for full approval. Its clinical behavior is reliable when used in noncarious cervical lesions and may not depend on the bonding strategy.

## SUMMARY

**Purpose:** To evaluate the 18-month clinical performance of a multimode adhesive (Scotch-

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bond Universal Adhesive, SU, 3M ESPE, St Paul, MN, USA) in noncarious cervical lesions (NCCLs) using two evaluation criteria.

**Materials and Methods:** Thirty-nine patients participated in this study. Two-hundred restorations were assigned to four groups: *ERm*, etch-and-rinse + moist dentin; *ERd*, etch-and-rinse + dry dentin; *Set*, selective enamel etching; and *SE*, self-etch. The composite resin, Filtek Supreme Ultra (3M ESPE), was placed incrementally. The restorations were evaluated at baseline, and at 18 months, using both the World Dental Federation (FDI) and the United States Public Health Service (USPHS) criteria. Statistical analyses were performed using Friedman repeated-measures analysis of variance by rank and McNemar test for significance in each pair ( $\alpha=0.05$ ).

**Results:** Five restorations (*SE*: 3; *Set*: 1; and *ERm*: 1) were lost after 18 months ( $p>0.05$  for either criteria). Marginal staining occurred in four and 10% of the restorations evaluated ( $p>0.05$ ), respectively, for USPHS and FDI criteria. Nine restorations were scored as

**bravo** for marginal adaptation using the USPHS criteria and 38%, 40%, 36%, and 44% for groups ERm, ERd, Set, and SE, respectively, when the FDI criteria were applied ( $p > 0.05$ ). However, when semiquantitative scores (or SQUACE) for marginal adaptation were used, SE resulted in a significantly greater number of restorations, with more than 30% of the total length of the interface showing marginal discrepancy (28%) in comparison with the other groups (8%, 6%, and 8%, respectively, for ERm, ERd, and Set).

**Conclusions:** The clinical retention of the multimode adhesive at 18 months does not depend on the bonding strategy. The only differences between strategies were found for the parameter marginal adaptation, for which the FDI criteria were more sensitive than the USPHS criteria.

## INTRODUCTION

The constant development of dental adhesive materials over the past decades has resulted in the launching of adhesives without reliable clinical validation. Often, a new version of a dental adhesive is introduced to the dental market when clinical studies with the previous version are still being carried out. This is increasingly common, especially with one-step self-etch adhesives. Ideally, once an adhesive is tested *in vitro*, a clinical trial must follow immediately to evaluate the clinical effectiveness of the tested adhesive.

Bonding to enamel is based primarily on micro-mechanical interlocking of resin monomers into the enamel microporosities created by chemical dissolution of hydroxyapatite crystallites using phosphoric acid.<sup>1,2</sup> For most dental adhesives, the depth of the etching pattern plays a significant role in the magnitude of the enamel bond strengths.<sup>3</sup> Phosphoric acid etching significantly increases the bond strength of one-step self-etch adhesives to enamel.<sup>4,5</sup> However, when enamel is ground or beveled, self-etch adhesives tend to result in enamel bond strengths comparable with those of etch-and-rinse adhesives.<sup>6,7</sup> In class I and class II composite restorations, phosphoric acid-etched margins resulted in tighter marginal integrity and a lower degree of discoloration.<sup>8</sup>

Because self-etch adhesives do not etch enamel to the same depth that phosphoric acid does, selective etching of enamel margins has been recommended by some authors prior to the application of self-etch

adhesives.<sup>9,10</sup> Manufacturers have also suggested selective enamel etching in the instructions for use of their self-etch adhesives. In noncarious cervical lesions (NCCLs), selective enamel etching did not increase the retention rate in clinical studies when a two-step self-etch adhesive with the ability for chemical bonding was used.<sup>11,12</sup> However, when compared with the self-etch mode, selective enamel etching resulted in an improvement in the enamel marginal integrity at 8 years.<sup>12</sup> The potential drawback of selective enamel etching is that the clinician may inadvertently etch dentin. In fact, bond strengths may decrease when self-etch adhesives are applied on acid-etched dentin when compared with the same adhesive applied in the self-etch mode.<sup>13,14</sup>

Despite unreliable *in vitro* studies and clinical longevity results associated with one-step adhesives when compared with that of adhesives that rely on several steps,<sup>15-17</sup> multimode one-bottle universal adhesives have been developed recently to make the clinical procedure more user-friendly. These new adhesives can be used as self-etch or as etch-and-rinse adhesives. The concept behind these adhesives is novel; hence, only short-term clinical and immediate ultramorphological and bond strength studies have been reported.<sup>18-20</sup>

The aims of this randomized double-blind clinical trial were to study the influence of different application strategies on the clinical behavior of a new universal multimode adhesive (Scotchbond Universal Adhesive, SU, 3M ESPE, St Paul, MN, USA) placed in NCCLs, over the course of 18 months, using two evaluation criteria: World Dental Federation (FDI) and United States Public Health Service (USPHS) criteria. The null hypotheses tested were: 1) bonding to NCCLs using the self-etch strategy, associated or not with selective enamel etching or using the etch-and-rinse strategy, applied on dry or moist dentin, would result in similar retention rates over 18 months of clinical service, and 2) different evaluation criteria (FDI or USPHS criteria) would not result in different outcomes for the same data.

## MATERIALS AND METHODS

### Study Design

The experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement.<sup>21</sup> This was a randomized, double-blind clinical trial. The study was carried out in the clinic of the State University of Ponta Grossa (UEPG) School of Dentistry from January 2011 to November 2011. All

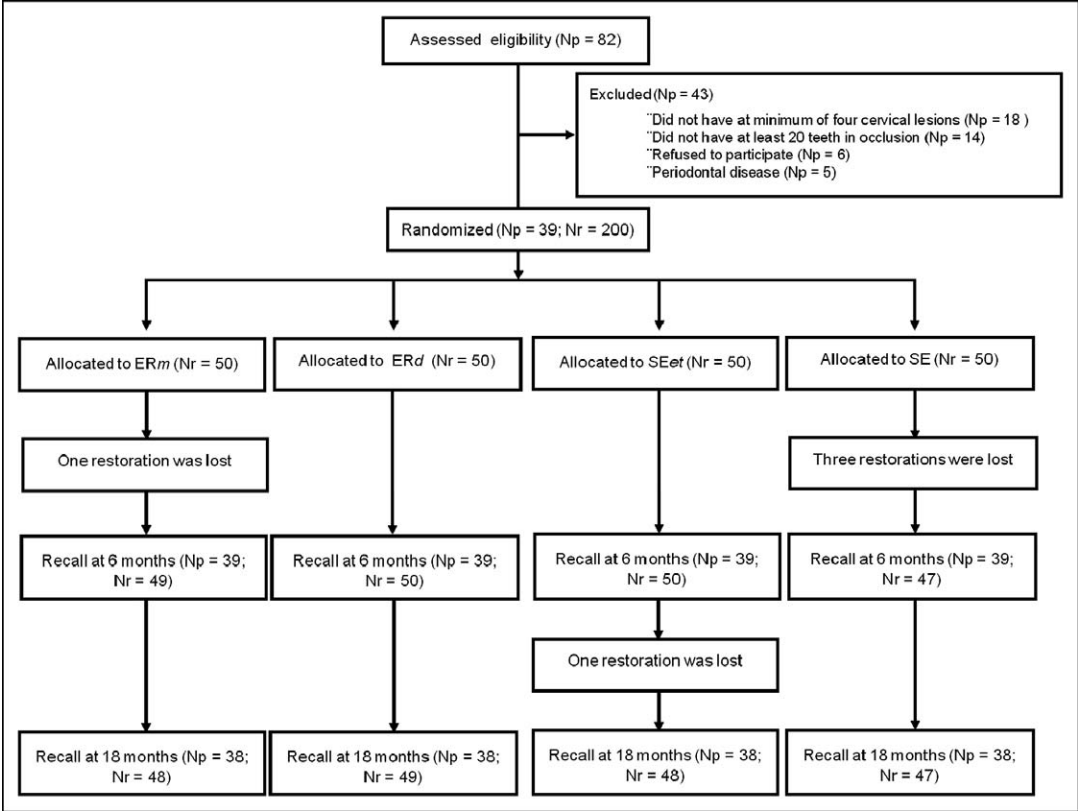


Figure 1. Flow diagram. ERd, total-etch, dry dentin; ERm, total-etch, moist dentin; Np, number of patients; Nr, number of restorations; SE, self-etch; Set, selective enamel etching.

participants were informed about the nature and objectives of the study, but they were not aware of what tooth received the specific treatments under evaluation.

Participant Selection

The local Ethics Committee on Investigations Involving Human Subjects reviewed and approved the protocol and consent form for this study (protocol 05909/11). Written informed consent was obtained from all participants prior to starting the treatment. Based on preestablished criteria, 39 volunteers were selected for this study (Figure 1).

Inclusion and Exclusion Criteria

A total of 82 participants were examined by two precalibrated operative dentistry residents to check if they met the inclusion and exclusion criteria (Figure 1). The qualified patients were recruited in the order in which they reported for the screening appointment, thus forming a convenience sample.

The evaluations were performed using a mouth mirror, an explorer, and a periodontal probe. Participants had to be in good general health, be at least 18 years old, have an acceptable oral hygiene level, and present at least 20 teeth under occlusion.

Table 1: Dentin Sclerosis Scale<sup>a</sup>

Category	Criteria
1	No sclerosis present; dentin is light yellowish or whitish, with little discoloration; dentin is opaque, with little translucency or transparency
2	More sclerosis than in category 1 but less than halfway between categories 1 and 4
3	Less sclerosis than in category 4 but more than halfway between categories 1 and 4
4	Significant sclerosis present; dentin is dark yellow or even discolored (brownish); glassy appearance, with significant translucency or transparency evident

<sup>a</sup> Adapted from Swift and others.<sup>23</sup>

Table 2: Adhesive System: Composition and Application Mode

Adhesive Systems	Composition/Batch Number	Application Mode <sup>a</sup>			
Scotchbond Universal Adhesive (3M ESPE, St Paul, MN, USA)	1. Scotchbond Universal Etchant: 34% phosphoric acid (UXT-02/Etch-01) 2. Adhesive (UXT-02/Adh-02): methacryloyloxydecyl dihydrogen phosphate, phosphate monomer, dimethacrylate resins, hydroxyethyl methacrylate, methacrylate-modified polyalkenoic acid copolymer, filler, ethanol, water, initiators, silane	Etch-and-rinse (ER)	Apply etchant for 15 s Rinse for 10 s Air dry to remove excess water	Keep dentin moist  Keep dentin dry, do not overdry	Apply the adhesive for 20 s with vigorous agitation Gently air thin for 5 s Light cure for 10 s
		Selective etching (Set)	Apply etchant only on enamel for 15 s Rinse for 10 s Air dry to remove excess water	Keep dentin dry, do not overdry	
		Self-etch (SE)	Do not use etchant	Keep dentin dry, do not overdry	

<sup>a</sup> According to the manufacturer's instructions.

Participants were required to have at least four NCCLs in four different teeth that needed to be restored. These lesions had to be noncarious, non-retentive, deeper than 1 mm, and involve both the enamel and dentin of vital teeth without mobility. The cavo-surface margin could not involve more than 50% of enamel.<sup>22</sup>

All patients were given oral hygiene instructions before the operative treatment was performed. Patients with extremely poor oral hygiene, severe or chronic periodontitis, or heavy bruxism habits were excluded from the study.

### Interventions: Restorative Procedure

All of the volunteer participants received dental prophylaxis with a suspension of pumice and water in a rubber cup and signed an informed consent form two weeks before the restorative procedures.

The features of the NCCLs were evaluated prior to the placement of the restorations. The degree of sclerotic dentin was measured according to the criteria described by Swift and others<sup>23</sup> (Table 1). The cavity dimensions in millimeters (height, width, and depth) and the geometry of the cavity (evaluated by profile photograph and labeled at <45°, 45°-90°, 90°-135°, and >135°) were recorded.

Table 3: World Dental Federation (FDI) Criteria Used for Clinical Evaluation<sup>33,34</sup>

Esthetic Property		Functional Properties	
1. Staining Margin		2. Fractures and Retention	3. Marginal Adaptation
1. Clinically very good	1.1 No marginal staining	2.1 Restoration retained, no fractures/cracks	3.1 Harmonious outline, no gaps, no discoloration
2. Clinically good (after correction, very good)	1.2 Minor marginal staining, easily removable by polishing	2.2 Small hairline crack	3.2.1 Marginal gap (50 µm) 3.2.2 Small marginal fracture removable by polishing
3. Clinically sufficient/satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	1.3 Moderate marginal staining, not esthetically unacceptable	2.3 Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity)	3.3.1 Gap <150 µm not removable 3.3.2. Several small enamel or dentin fractures
4. Clinically unsatisfactory (repair for prophylactic reasons)	1.4 Pronounced marginal staining; major intervention necessary for improvement	2.4 Chipping fractures, which damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration)	3.4.1 Gap >250 µm or dentin/base exposed 3.4.2. Chip fracture damaging margins 3.4.3 Notable enamel or dentin wall fracture
5. Clinically poor (replacement necessary)	1.5 Deep marginal staining not accessible for intervention	2.5 (Partial or complete) loss of restoration	3.5 Filling is loose but <i>in situ</i>

90°-135°, >135°) were also recorded. Other features, such as the presence of attrition facets, were also observed and recorded. Preoperative sensitivity was evaluated by applying air for 10 seconds from a dental syringe placed 2 cm from the tooth surface. For the calibration procedure step, the study director placed one restoration of each group in order to identify all steps involved in the application technique. Then, all four operators, who were resident dentists with more than five years of clinical experience in operative dentistry, placed four restorations of each group under the supervision of the study director in a clinical setting. The restoration deficiencies were shown to the operators prior to starting the study. At this point, the operators were considered calibrated to perform the restorative procedures.

The same calibrated operators restored all teeth under the supervision of the study director. All subjects received a minimum of four restorations, one of each experimental group, in different lesions previously selected according to the inclusion criteria.

The randomization process within patients was performed using computer-generated tables by a staff member not involved in the research protocol. Details of the allocated group were recorded on cards contained in sequentially numbered, opaque, sealed envelopes. These were prepared by a staff member not involved in any of the phases of the clinical trial. The allocation assignment was revealed by opening

the envelope on the day of the restorative procedure. The operator was not blinded to group assignment when administering interventions; however, participants were blinded to the group assignment.

Before placing the rubber dam, the operators anesthetized the teeth with a 3% mepivacaine solution (Mepisv, Nova DFL, Rio de Janeiro, RJ, Brazil) and cleaned all lesions with pumice and water in a rubber cup, followed by rinsing and drying. Using a shade guide, the proper shade of the composite was determined. Following the guidelines of the American Dental Association (ADA),<sup>24</sup> the operators did not prepare any additional retention or bevel.

The NCCLs received the SU adhesive system applied in different modes: an etch-and-rinse approach, keeping the dentin moist (ER<sub>m</sub>) or dry (ER<sub>d</sub>), and a self-etch approach with (Set) or without (SE) selective enamel etching. The compositions, application modes, and batch numbers are described in Table 2.

In the ER<sub>m</sub> group, dentin was kept visibly moist, while in the ER<sub>d</sub> group, dentin was air dried for five seconds but not overdried. In the Set group, the lesion was air dried after rinsing the etchant from the enamel. Dentin was kept dry in both the Set and SE groups. The adhesive was vigorously agitated on the entire dentin surface in all groups for approximately 20 seconds, according to the manufacturer's recommendations (Table 2). The brush was scrubbed

Table 3: Extended.

Biological Properties		
	4. Postoperative (Hyper-) Sensitivity	5. Recurrence of Caries
1. Clinically very good	4.1 No hypersensitivity	5.1 No secondary or primary caries
2. Clinically good (after correction, very good)	4.2 Low hypersensitivity for a limited period of time	5.2 Very small and localized demineralization No operative treatment required
3. Clinically sufficient/satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	4.3.1 Premature/slightly more intense 4.3.2 Delayed/weak sensitivity; no subjective complaints, no treatment needed	5.3 Larger areas of demineralization, but only preventive measures necessary (dentin not exposed)
4. Clinically unsatisfactory (repair for prophylactic reasons)	4.4.1 Premature/very intense 4.4.2 Extremely delayed/weak with subjective complaints 4.4.3 Negative Sensitivity Intervention necessary but not replacement	5.4 Caries with cavitation (localized and accessible and can be repaired)
5. Clinically poor (replacement necessary)	4.5 Very intense, acute pulpitis or nonvital; endodontic treatment is necessary and restoration has to be replaced	5.5 Deep secondary caries or exposed dentin that is not accessible for repair of restoration



Table 4: Modified United States Public Health Service (USPHS) Criteria According to Bittencourt and Others<sup>35</sup> and Perdigão and Others<sup>30</sup>

	Marginal Staining	Retention	Fracture
<i>Alfa</i>	No discoloration along the margin	Retained	None
<i>Bravo</i>	Slight and superficial staining (removable, usually localized)	Partially retained	Small chip, but clinically acceptable
<i>Charlie</i>	Deep staining cannot be polished away	Missing	Failure due to bulk restorative fracture

on the dentin surface under manual pressure (equivalent to approximately 45 g or more) followed by gentle air thinning for five seconds and finally light curing (Radii Cal, SDI, Victoria, Australia) for 10 seconds (1000 mW/cm<sup>2</sup>).

Filtek Supreme Ultra (3M ESPE, St. Paul, MN, USA) resin composite was used in up to three increments, each one being light cured (Radii Cal, SDI, Victoria, Australia) for 30 seconds. The restorations were finished immediately with fine diamond burs (KG Sorensen, Barueri, SP, Brazil). Polishing was performed with rubber points (Astropol, Ivoclar Vivadent, Liechtenstein) one week after placement of the restorations.

Sample Size Calculation

The sample size calculation was based on the retention rate of the simplified etch-and-rinse Adper Single Bond (3M ESPE), the predecessor of this multimode adhesive from the same manufacturer. The retention rate was reported to be 94% at 18- to 24-month follow-ups.<sup>25-30</sup> Using an  $\alpha$  of 0.05, a power of 80%, and a two-sided test, the minimal sample size was 50 restorations in each group in order to detect a difference of 20% among the tested groups.<sup>31</sup>

Clinical Evaluation

Two experienced and calibrated dentists, not involved with the placement of the restorations and therefore blinded to the group assignment, performed the evaluation. For training purposes, the examiners observed 10 photographs that were representative of each score for each criterion. They evaluated 10 to 15 patients each on two consecutive days. These subjects had cervical restorations, and they did not participate in this project. An intraexaminer and interexaminer agreement of at least 85% was necessary before beginning the evaluation.<sup>32</sup>

All parameters during evaluation were recorded using a standardized paper case report form. The evaluation paper was sent to the research staff after

each observation, so that the evaluators were blinded to group assignment during follow-up recalls.

The restorations were evaluated by two criteria: the FDI criteria<sup>33,34</sup> and the classical USPHS criteria adapted by Bittencourt and others<sup>35</sup> and Perdigão and others<sup>30</sup> at baseline and after 6 and 18 months of clinical service.

For either of the two criteria, only the clinically relevant measures of performance for adhesives were evaluated. Therefore, wear and color match were not evaluated (Tables 3 and 4). The primary clinical endpoint was restoration retention/fractures, but the following secondary endpoints were also evaluated: marginal staining, marginal adaptation, postoperative sensitivity, and recurrence of caries. The evaluation of the postoperative sensitivity was performed one week after the restorative procedure by applying air for 10 seconds from a dental syringe placed 2 cm from the tooth surface.

These variables were ranked according to the criteria in the following scores: 1) FDI criteria (clinically very good, clinically good, clinically sufficient/satisfactory, clinically unsatisfactory and clinically poor) and USPHS criteria (*alfa*, *bravo*, and *charlie*). In the case of marginal staining and marginal adaptation, the semiquantitative criteria (SQUACE) proposed by Hickel and others was used.<sup>33,34</sup> Each evaluator outlined the extent of the observed event on a sketch of each restoration using a pen and according to defined criteria (marginal staining and marginal adaptation); after that, each margin was assessed quantitatively as a proportion of the total length of the margin.

Both examiners evaluated all the restorations once and independently. When disagreements occurred during the evaluations, they had to reach a consensus before the participant was dismissed.

The restoration retention rates were calculated according to the ADA guidelines.<sup>24</sup> Cumulative failure percentage = [(PF + NF)/(PF + RR)] × 100%, where PF is the number of previous failures

Table 4: Extended.

	Marginal Adaptation	Postoperative Sensitivity	Recurrence of Caries
<i>Alfa</i>	Restoration is continuous with existing anatomic form	No postoperative sensitivity directly after the restorative process and during the study period	No evidence of caries contiguous with the margin
<i>Bravo</i>	Detectable V-shaped defect in enamel only; catches explorer going both ways	—	—
<i>Charlie</i>	Detectable V-shaped defect to dentin-enamel junction	Sensitivity present at any time during the study period	Evidence of presence of caries

before the current recall, NF is the number of new failures during the current recall, and RR is the number of currently recalled restorations.

### Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to CONSORT suggestion.<sup>21</sup> This protocol includes all participants in their originally randomized groups, even those who were not able to keep their scheduled recall visits. This approach is more conservative and less open to bias.

Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis for each individual item was performed, as well as for each overall parameter (FDI criteria). The differences in the ratings of the four groups after 18 months were tested with the Friedman repeated-measures analysis of variance by rank ( $\alpha=0.05$ ), and differences in the ratings of each group at baseline and after 18 months were evaluated using the McNemar test ( $\alpha=0.05$ ). Data from SQUACE was categorized into three scores: 1) marginal discrepancies involving less than 10% of the total length of the restoration, 2) between 10% and 30%, and 3) more than 30%, and the groups were compared with Kruskal-Wallis and Mann-Whitney nonparametric tests ( $\alpha=0.05$ ). Cohen's kappa statistic was used to test interexaminer agreement.

## RESULTS

Forty-three of 82 patients were not enrolled in the study because they did not fulfill the inclusion criteria. Thus, 39 subjects (28 patients with four restorations and 11 patients with eight restorations) were selected. All baseline details relative to the research subjects and characteristics of the restored lesions are displayed in Table 5. The overall Cohen's Kappa statistics showed excellent agreement between the examiners at the 6-month (0.94) and 18-month (0.92) follow-up. All research subjects were evaluated at baseline and at six months, and only

one patient did not attend the 18-month recall (moved to another city; Figure 1).

### Retention

Four restorations were lost at six months (one for ER<sub>m</sub> and three for SE). One restoration was lost between the six- and the 18-month recall (one for SE). According to FDI and USPHS criteria, the 18-month retention rates (95% confidence interval) were 98% (90%-100%) for ER<sub>m</sub>, 100% (93%-100%) for ER<sub>d</sub>, 98% (90%-100%) for SE, and 94% (84%-98%) for SE. There was no statistical difference between any pair of groups at 18-month recall and for each group when baseline and 18-month times was compared ( $p>0.05$ ; Tables 6 and 7).

### Postoperative Sensitivity

Eight restorations had postoperative sensitivity at the 18-month recall using both the FDI and USPHS criteria (three for ER<sub>m</sub>, three for ER<sub>d</sub>, and two for SE) with no statistically significant difference when comparing different pairs of groups and for each group when baseline and 18-month times were compared ( $p>0.05$ ; Tables 6 and 7).

### Marginal Adaptation

Seventy-nine restorations were considered to have minor discrepancies in marginal adaptation at the 18-month recall using the FDI criteria (19 for ER<sub>m</sub>, 20 for ER<sub>d</sub>, 18 for SE, and 22 for SE). No significant difference was detected between any pair of groups at the 18-month recall for either criteria ( $p>0.05$ ). However, a significant difference was detected when baseline and 18-month data were compared within each group ( $p<0.05$ ). Despite these minor discrepancies, only nine restorations were considered to have clinically relevant discrepancies in marginal adaptation (one for ER<sub>m</sub>, five for ER<sub>d</sub>, and three for SE,  $p>0.05$ ; Table 6). When the USPHS criteria were used, nine restorations were scored as *bravo* for marginal adaptation (one for ER<sub>m</sub>, five for ER<sub>d</sub>, and

Table 5: *Distribution of Noncarious Cervical Lesions According to Research Subject (Gender and Age) and Characteristics of Class V Lesions (Shape, Cervicoincisal Size of the Lesion, Degree of Sclerotic Dentin, Presence of Antagonist, Presence of Attrition Facets, Presence of Preoperative Sensitivity, and Tooth and Arch Distribution)*

Characteristics of Research Subjects	Number of Lesions/ Subjects			
Gender distribution				
Male	24			
Female	15			
Age distribution, y				
20-29	05			
30-39	12			
40-49	12			
>49	10			
Characteristics of Class V lesions	ERm	ERd	Set	SE
Shape, ° of angle				
<45				
45-90	14	14	12	12
90-135	34	34	38	38
>135	02	02	00	00
Cervico-incisal height, mm				
<1.5	06	03	05	07
1.5-2.5	29	36	29	30
2.5-4.0	12	10	14	12
>4.0	03	01	02	01
Degree of sclerotic dentin				
1	20	18	17	19
2	12	14	13	10
3	12	12	09	09
4	06	06	11	12
Presence of antagonist				
Yes	50	50	50	50
No	00	00	00	00
Attrition facet				
Yes	24	22	18	26
No	26	28	32	24
Preoperative sensitivity (spontaneous)				
Yes	50	50	50	50
No	00	00	00	00
Preoperative sensitivity (air dry)				
Yes	24	26	30	28
No	26	24	20	22
Tooth distribution				
Anterior				
Incisor	02	02	02	02
Canines	04	08	06	08
Posterior				
Premolar	32	26	34	28

Table 5: Continued.

Characteristics of Research Subjects	Number of Lesions			
Molar	12	14	08	12
Arch distribution				
Maxillary	25	26	30	28
Mandibular	25	24	20	22

three for SE,  $p>0.05$ ). No significant difference was detected between any pair of groups at the 18-month recall for either criteria and for each group when baseline and 18-month times were compared for both criteria ( $p>0.05$ ).

When SQUACE<sup>33,34</sup> was used, there was a statistical difference among groups at the 18-month evaluation ( $p<0.007$ ; Table 8). SE resulted in a significantly greater number of restorations, with more than 30% of the total length of the interface showing marginal discrepancy (14 restorations) in comparison with the other groups (four for ERm, three for ERd, and four for Set). Also, when baseline vs 18-month results were compared, SE was the only group for which a significantly greater percentage of the interface showed marginal discrepancy at 18 months ( $p<0.05$ ).

For the USPHS modified criteria, nine restorations were classified as *bravo* for marginal adaptation (one for ERm, five for ERd, and three for SE). No significant difference was found between any pair of groups at the 18-month recall. Likewise, no significant difference was found for each group when baseline and 18-month marginal adaptation data were compared ( $p>0.05$ ; Table 7).

Marginal Staining

Marginal staining was observed in 15 restorations (four for ERm, five for ERd, two for Set, and four for SE) according to FDI criteria. No significant difference was found between groups at 18 months and within each group when baseline and 18-month data were compared ( $p>0.05$ ). For the USPHS-modified criteria, 11 restorations were classified as *bravo* for marginal staining (three for ERm, three for ERd, two for Set, and three for SE), and no significant difference was found between any pair of groups at the 18-month recall. No statistical difference was measured when the baseline and 18-month results were compared within each group ( $p>0.05$ ; Table 7).

Other Parameters

No restoration had clinical problems related to fracture and recurrence of caries at 18 months for



Table 6: Number of Evaluated Restorations for Each Experimental Group According to the Adhesive (ERm [Etch-and-Rinse, Moist Dentin]; ERd [Etch-and-Rinse, Dry Dentin]; Set [Self-Etch, Selective Enamel Etching]; SE [Self-Etch, No Etching]) Classified According to the World Dental Federation (FDI) Criteria<sup>33,34</sup>

FDI Criteria	Time	Baseline				6 mo				18 mo			
		ERm	ERd	Set	SE	ERm	ERd	Set	SE	ERm	ERd	Set	SE
Marginal staining	VG	50	50	50	50	50	50	50	49	45	44	46	45
	GO	—	—	—	—	—	—	—	1	1	2	—	1
	SS	—	—	—	—	—	—	—	—	3	3	2	3
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—
Fractures and retention	VG	50	50	50	50	49	50	50	47	48	49	48	46
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	1	—	—	3	1	—	1	3
Marginal adaptation	VG	50	50	50	50	34	32	29	27	29	29	30	24
	GO	—	—	—	—	16	18	21	23	18	15	18	19
	SS	—	—	—	—	—	—	—	—	1	5	—	3
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—
Postoperative (hyper-) sensitivity	VG	49	46	47	49	50	50	50	50	45	46	46	46
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	1	4	3	1	—	—	—	—	3	3	2	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—
Recurrence of caries	VG	50	50	50	50	50	50	50	50	48	49	48	46
	GO	—	—	—	—	—	—	—	—	—	—	—	—
	SS	—	—	—	—	—	—	—	—	—	—	—	—
	UN	—	—	—	—	—	—	—	—	—	—	—	—
	PO	—	—	—	—	—	—	—	—	—	—	—	—

Abbreviations: VG, clinically very good; GO, clinically good; SS, clinically sufficient/satisfactory; UN, clinically unsatisfactory; PO, clinically poor.

either the FDI or the USPHS criteria. When the FDI criteria for “acceptable” vs “not acceptable” restorations were applied, only the five lost restorations were ranked as “not acceptable” (Table 9).

## DISCUSSION

New criteria for evaluating dental restorations were published in 2007 and named the “FDI criteria,” as a result of the efforts of the FDI to organize them.<sup>33,34</sup> Nonetheless, only a few publications have used the FDI criteria since then.<sup>20,36-38</sup> Most clinical studies reporting clinical evaluation of NCCL restorations still use the USPHS criteria.<sup>23,25-30,39-42</sup> One study,<sup>36</sup> published as an abstract, concluded that the FDI criteria were more sensitive for identifying differences in the restorations than the USPHS criteria. A more recent publication<sup>20</sup> compared the six-month clinical behavior of several adhesion strategies using both FDI and USPHS-modified criteria. The findings

suggested that the FDI criteria are more sensitive than the USPHS-modified criteria to small variations in the clinical outcomes when evaluating restorations of NCCLs. This finding was corroborated in the present study, as the marginal discrepancies were more frequently measured in the FDI criteria in relation to USPHS criteria.

Under the USPHS criteria, only nine restorations were scored as *bravo* after 18 months of clinical service, and no significant difference was detected among groups. This percentage is very similar to what was previously reported in clinical trials that used the USPHS-modified criteria after 18 months of evaluation.<sup>23,25,35,43,44</sup> On the other hand, marginal integrity was statistically worse for SE when assessed with the FDI criteria, specifically when SQUACE was used.

SU is considered an ultra-mild self-etch adhesive because its pH is relatively high (3.0; data not

Table 7: Number of Evaluated Restorations for Each Experimental Group According to the Adhesive (ERm [Etch-and-Rinse, Moist Dentin]; ERd [Etch-and-Rinse, Dry Dentin]; Set [Self-Etch, Selective Enamel Etching]; SE [Self-Etch, No Etching]) Classified According to the Adapted United States Public Health Service (USPHS) Criteria<sup>30,35</sup>

USPHS Criteria	Time	Baseline				6 mo				18 mo			
		ERm	ERd	Set	SE	ERm	ERd	Set	SE	ERm	ERd	Set	SE
Marginal staining	Alfa	50	50	50	50	50	50	50	49	45	46	46	43
	Bravo	—	—	—	—	—	—	—	1	3	3	2	3
	Charlie	—	—	—	—	—	—	—	—	—	—	—	—
Retention	Alfa	50	50	50	50	49	50	50	47	48	49	48	46
	Charlie	—	—	—	—	1	—	—	3	1	—	1	3
Fracture	Alfa	50	50	50	50	50	50	50	50	48	49	48	46
	Bravo	—	—	—	—	—	—	—	—	—	—	—	—
	Charlie	—	—	—	—	—	—	—	—	—	—	—	—
Marginal adaptation	Alfa	50	50	50	50	50	50	50	48	47	44	48	43
	Bravo	—	—	—	—	—	—	—	2	1	5	—	3
	Charlie	—	—	—	—	—	—	—	—	—	—	—	—
Postoperative sensitivity	Alfa	49	46	47	49	50	50	50	50	45	46	46	46
	Bravo	1	4	3	1	—	—	—	—	—	—	—	—
	Charlie	—	—	—	—	—	—	—	—	3	3	2	—
Recurrence of caries	Alfa	50	50	50	50	50	50	50	50	48	49	48	46
	Charlie	—	—	—	—	—	—	—	—	—	—	—	—

shown). This high pH may explain the significant deterioration of marginal adaptation from baseline to 18 months for SE, especially when compared with Set. The less pronounced etching pattern of SE when compared with the results of previous studies in which phosphoric acid was applied prior to self-etch application<sup>45-47</sup> may explain these findings. It is worth mentioning that the marginal discrepancies were typically observed in the enamel margins, and this occurrence was not deemed as a clinical failure as it can usually be solved by repolishing the restoration.<sup>48,49</sup>

Despite the use of two clinical evaluation criteria, the most important parameter for the evaluation of NCCL restorations has been retention rate. If the restorations are lost, all of the other criteria cannot be evaluated. In general, the clinical behavior of SU at 18 months in this study, regardless of the bonding strategy, was very good and comparable to that of the three-step etch-and-rinse adhesive Adper Scotch-bond Multi-Purpose (3M ESPE) and that of the two-step etch-and-rinse adhesive Adper Single Bond Plus (3M ESPE).<sup>30</sup>

SU differs from Adper Single Bond Plus adhesive primarily by the incorporation of the 10-MDP monomer in the former, to provide acidity for its self-etching capability. Chemical bonding between 10-MDP and enamel/dentin may have resulted in stable interfaces even without micromechanical

retention from etching in the SE group.<sup>50,51</sup> The success of 10-MDP has been reported in the literature. Its intrinsic chemical bonding, combined with the good mechanical properties and high conversion rate of a filled hydrophobic resin,<sup>52,53</sup> resulted in very good clinical behavior of Clearfil SE Bond (CSE, Kuraray, Osaka, Japan) at eight years.<sup>12</sup>

The clinical behavior of SU in our study was also similar to that of Adper Easy Bond (AEB, 3M ESPE), a one-step self-etch adhesive, in a recent 18-month clinical study,<sup>43</sup> regardless of the application of a hydrophobic resin layer over AEB. This similarity in clinical behavior between these two adhesives from the same manufacturer may have to do with the comparable concentration of the polyalkenoic acid copolymer in both materials (1%-5%).<sup>54,55</sup> This copolymer may also provide chemical bonding derived from its spontaneous bonding to hydroxyapatite.<sup>56</sup> The polyalkenoic acid copolymer was first used in the composition of Vitrebond (3M ESPE) and therefore is also known as Vitrebond copolymer, or VCP. For self-etch adhesives, chemical bonding between polycarboxylic monomers (such as VCP) and hydroxyapatite plays a crucial role in their bonding mechanism.<sup>57,58</sup> More than 50% of the carboxyl groups in the polyalkenoic acid copolymer are capable of bonding to hydroxyapatite.<sup>57</sup> Carboxylic groups replace phosphate ions on the substrate and make ionic bonds with calcium.<sup>57</sup>

Table 8: Number of Evaluated Restorations for Each Experimental Group According to the Adhesive Classified for Semiquantitative Score (SQUACE)<sup>33,34</sup>

FDI Criteria	Statistical Analysis <sup>a</sup>	ERm	ERd	Set	SE
SQUACE	Less than 10%	0	0	1	0
	Between 10% and 30%	12	13	14	14
	Between 31% and 50%	4	3	4	14
		A	A	A	B

Abbreviations: ERd, etch-and-rinse, dry dentin; ERm, etch-and-rinse, moist dentin; SE, self-etch, no etching; Set, self-etch, selective enamel etching.

<sup>a</sup> Different letters indicate significant differences between groups (Kruskal-Wallis,  $p=0.007$ ).

Taking into account that SU contains two molecules with a potential for chemical bonding (10-MDP and VCP), the clinical behavior of SE and Set in our study may have been a result of: 1) the formation of a submicron micromechanical interlocking at the dentin surface by SU,<sup>51</sup> 2) the chemical bonding of both the 10-MDP monomer and VCP to hydroxyapatite, or 3) the protective effect of the Ca-MDP salt, which is a very hydrolytically stable salt.<sup>59</sup> However, it is worth mentioning that, although CSE resulted in nano layering within the hybrid layer and into the adhesive layer, SU resulted in nano layering only at the tubule orifices, where the adhesive infiltrated the residual smear layer.<sup>51</sup> The difference between these two adhesives may rely not only on the higher concentration of 10-MDP in CSE, but also on the presence of hydroxyethyl methacrylate (HEMA) in SU, which may prevent interfacial self-assembled nanolayering.<sup>60</sup> Therefore, further data from subsequent clinical recalls should be compared with those of CSE<sup>12</sup> to validate this compositional difference between SU and CSE. In fact, nano layering of two 10-MDP molecules may result in an adhesive interface more resistant to degradation.<sup>60</sup>

At 18 months, there were no differences in postoperative sensitivity between any pair of groups in the present study. Nevertheless, it is noteworthy that SE did not result in any restoration with postoperative sensitivity. Other clinical studies in NCCLs have shown no difference in postoperative

sensitivity between self-etch and etch-and-rinse adhesives.<sup>30,61,62</sup> Self-etch adhesives use part of the smear layer as the bonding substrate; therefore, the monomer-impregnated smear plugs serve as a barrier to prevent the fluid shift inside the tubules. It has been reported that self-etch adhesives result in a simultaneous demineralization and infiltration of the dentin substrate.<sup>12</sup> Nevertheless, incomplete infiltration of dentin by mild self-etch adhesives has been reported,<sup>63</sup> because these adhesives have a reduced etching potential toward the base of hybrid layers.<sup>63</sup> On the other hand, etching dentin with phosphoric acid has been associated with reduced bond strengths with self-etch adhesives.<sup>13,14</sup> However, more recent studies have demonstrated that the effects of intentional dentin etching with phosphoric acid prior to the application of self-etch adhesives are material dependent.<sup>64,65</sup>

One-step self-etch adhesives are highly hydrophilic; therefore, they attract water and may increase the potential for degradation,<sup>66,67</sup> as water sorption of adhesive resins is proportional to their hydrophilic characteristics.<sup>68</sup> The self-etching ability of self-etching primers is achieved by incorporating sufficient water in the solution for adequate ionization of the acidic monomers without lowering the monomer concentration to a threshold that would compromise the bonding efficacy. Water is an important ingredient because it ionizes the acidic groups, allowing the formation of hydronium ions ( $H_3O^+$ ), which etch

Table 9: Restorations Acceptable or Not Acceptable According to the Federation Dental International (FDI) Criteria After 6 Months<sup>33,34</sup>

Properties	Esthetic				Functional								Biological							
	Staining Margin				Fractures and Retention				Marginal Adaptation				Postoperative (Hyper-) Sensitivity				Recurrence of Caries			
	ERm	ERd	Set	SE	ERm	ERd	Set	SE	ERm	ERd	Set	SE	ERm	ERd	Set	SE	ERm	ERd	Set	SE
Acceptable	46	48	44	43	45	48	43	40	46	48	44	43	46	48	44	43	46	48	44	43
Not acceptable	00	00	00	00	01	00	01	03	00	00	00	00	00	00	00	00	00	00	00	00
Reasons	Total loss of restoration																			

Abbreviations: ERd, etch-and-rinse, dry dentin; ERm, etch-and-rinse, moist dentin; SE, self-etch, no etching; Set, self-etch, selective enamel etching.

hydroxyapatite.<sup>69</sup> Water also facilitates solubilization of the reaction products resulting from the etching process. Increasing the water concentration dilutes the concentration of the acidic monomer and may decrease its bonding effectiveness. The presence of such hydrophilic moieties may induce increased water sorption and water uptake,<sup>70</sup> in turn jeopardizing the stability of the polymer network with time.

With this in mind, further studies should include the use of SU as a two-step self-etch adhesive by adding a hydrophobic resin layer as a second step in the bonding sequence. The laboratory and clinical success of mild two-step self-etch adhesives might also be a result of the presence of a hydrophobic bonding layer.<sup>44,71</sup> Nonetheless, adding a hydrophobic layer to one-step self-etch adhesives may not result in improved clinical performance for all simplified adhesives. A recent 18-month clinical trial reported that the clinical behavior of AEB did not change with the application of an extra layer of a bonding resin.<sup>43</sup> Therefore, the effect of the hydrophobic layer may depend on the specific composition of the one-step self-etch adhesive.

In addition to further recall evaluations already planned for this same project, bond strengths of aged dentin-resin interfaces with the same experimental groups are needed, as they may shed some light on the clinical behavior of SU over five years. While laboratory studies cannot always predict the clinical durability of bonded restorations, the dentin bond strengths of aged specimens seem to correlate with five-year clinical data.<sup>17,72</sup>

This clinical study has limitations, as 18 months is still a short period for evaluating the long-term clinical behavior of any dental adhesive. Nevertheless, SU belongs to a novel generation of simplified adhesives that are indicated for use under different application strategies, although they lack clinical data. Another limitation of the present study is that more than four restorations were placed in several patients, which may have caused a clustering effect. Despite being a common situation in the dental literature,<sup>35,73</sup> the influence of clustering on the data was not computed.

SU fulfilled the ADA guidelines<sup>23</sup> on the basis of the 18-month recall data, as this clinical study demonstrated no greater incidence of clinical failures than 10%, regardless of the bonding strategy used. We failed to reject the first null hypothesis, as there were no statistical differences in the clinical retention rates at 18 months for the different bonding

strategies tested in this study. We have to partially reject the second null hypothesis, as significant differences were measured for marginal integrity when using the FDI criteria.

## CONCLUSIONS

Within the limitations of this study, the 18-month clinical behavior of Scotchbond Universal Adhesive (3M ESPE) does not depend on the bonding strategy used. The new multimode adhesive fulfilled the ADA criteria for full approval when using all of the bonding strategies suggested by the manufacturer. The FDI evaluation criteria are more sensitive to small variations in the clinical outcomes than the USPHS criteria are, when evaluating restorations of NCCLs.

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## Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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